



# Improving Health Care: A Dose of Competition



**A Report by the  
Federal Trade Commission  
and the Department of Justice**

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## EXECUTIVE SUMMARY

Health care is a vital service that daily touches the lives of millions of Americans at significant and vulnerable times: birth, illness, and death. In recent decades, technology, pharmaceuticals, and know-how have substantially improved how care is delivered and the prospects for recovery. American markets for innovation in pharmaceuticals and medical devices are second to none. The miracles of modern medicine have become almost commonplace. At its best, American health care is *the* best in the world.

Notwithstanding these extraordinary achievements, the cost, quality, and accessibility of American health care have become major legislative and policy issues. Substantial increases in the cost of health care have placed considerable stress on federal, state, and household budgets, as well as the employment-based health insurance system. Health care quality varies widely, even after controlling for cost, source of payment, and patient preferences. Many Americans lack health insurance coverage at some point during any given year. The costs of providing uncompensated care are a substantial burden for many health care providers, other consumers, and tax payers.

This Report examines the role of competition in addressing these challenges. The proper role of competition in health care markets has long been debated. For much of our history, federal and state regulators, judges, and academic commentators saw health care as a “special” good to which normal economic forces did not apply. Skepticism about the role of competition in health care continues.

This Report by the Federal Trade Commission (Commission) and the Antitrust Division of the Department of Justice (Division) (together, the Agencies) represents our response to such skepticism. In the past few decades, competition has profoundly altered the institutional and structural arrangements through which health care is financed and delivered. Competition law and policy have played an important and beneficial role in this transformation. Imperfections in the health care system have impeded competition from reaching its full potential. These imperfections are discussed in this Report.

The Agencies based this Report on 27 days of Joint Hearings from February through October, 2003; a Commission-sponsored workshop in September, 2002; and independent research. The Hearings broadly examined the state of the health care marketplace and the role of competition, antitrust, and consumer protection in satisfying the preferences of Americans for high-quality, cost-effective health care. The Hearings gathered testimony from approximately 250 panelists, including representatives of various provider groups, insurers, employers, lawyers, patient advocates, and leading scholars on subjects ranging from antitrust and economics to health care quality and informed consent. The Hearings and Workshop elicited 62 written submissions from interested parties. Almost 6,000 pages of transcripts of the Hearings and Workshop and all written submissions are available on the Commission website.

The Report addresses two basic questions. First, what is the current role of competition in health care, and how can it be

enhanced to increase consumer welfare? Second, how has, and how should, antitrust enforcement work to protect existing and potential competition in health care?

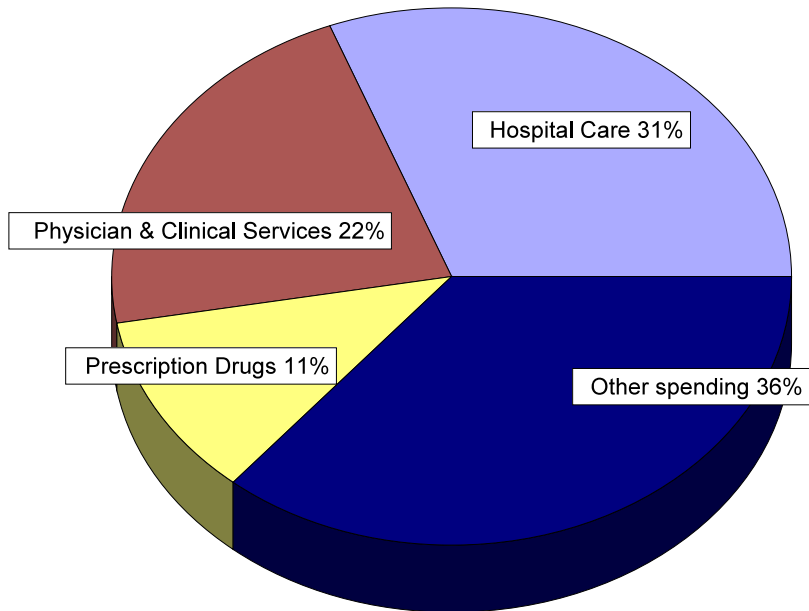
This Executive Summary outlines the Agencies' research, findings, conclusions, recommendations, and observations. Subsequent chapters provide in-depth discussion and analyses. Chapter 1 provides an overview and introduction. Chapter 2 focuses on physicians. Chapters 3 and 4 address hospitals. Chapters 5 and 6 consider insurance. Chapter 7 focuses on pharmaceuticals. Chapter 8 addresses a range of issues, including certificate of need, state action, long-term care, international perspectives, and remedies. We begin with a review of why health care issues are so important.

## I. CURRENT HEALTH CARE CHALLENGES

### A. *Health Care Expenditures Are Once Again Rising Dramatically*

Health care spending in the United States far exceeds that of other countries. Approximately 14% of gross domestic product, or \$1.6 trillion in 2002, is spent on health care services in the United States. Federal, state, and local governments pay for approximately 45 percent of total U.S. expenditures on health care; private insurance and other private spending account for 40 percent; and consumer out-of-

**Figure 1: Total Health Care Spending**



pocket spending accounts for the remaining 15 percent.

As Figure 1 reflects, in 2002, 31 percent of the \$1.6 trillion spent by Americans on health care went to inpatient hospital care; that percentage has declined substantially over the past twenty years, as hospitalization rates and lengths of stay have declined. Physician and clinical services account for 22 percent, but physicians' decisions and recommendations affect a far larger percentage of total expenditures on health care. Prescription drugs account for about 11 percent; that percentage has increased substantially over the past decade. The remaining 36 percent is split among long-term care, administrative, and other expenditures.

The percentage of gross domestic product spent on health care rose substantially during the 1970s and 1980s,

but stabilized during most of the 1990s at around 13.5 percent. In the last few years, however, dramatic cost increases have returned, attributable to both increased use of and increased prices for health care services. Inpatient hospital care and pharmaceuticals are the key drivers of recent increases in expenditures. These trends are likely to continue – and even accelerate – as new technologies are developed and the percentage of the population that is elderly increases.

### **B. *Health Care Quality Varies***

Quality has multiple attributes. Many health services researchers and providers focus on whether the care that is provided is based on empirical evidence of efficacy. The Institute of Medicine defines quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” The Agency for Healthcare Research and Quality defines quality health care as “doing the right thing at the right time in the right way for the right person and having the best results possible.” Some consumers may focus on how long they must wait for an appointment, and how they are treated at the provider’s office. Many health care providers and health services researchers treat the cost of care (and the resources of consumers) as immaterial; for them, you either provide high quality care to a particular patient or disease set, or you do not.

From a consumer perspective, health care quality encompasses several distinct

factors, and the delivery system must perform well on each if it is to provide high quality care. These factors include whether the diagnosis is correct, whether the “right” treatment is selected (with the “right” treatment varying, depending on the underlying diagnosis and patient preferences), whether the treatment is performed in a technically competent manner, whether service quality is adequate, and whether consumers can access the care they desire. Information is necessary for consumers to make decisions regarding their care, and determine how well the health care system is meeting their needs.

If we focus strictly on technical measures, what is known about the quality of health care in the United States? Commentators and panelists agree that the vast majority of patients receive the care they need, but there is still significant room for improvement. Commentators and panelists note that treatment patterns vary significantly; procedures of known value are omitted, and treatments that are unnecessary and inefficacious are performed and tens of billions of dollars are spent annually on services whose value is questionable or non-existent. As one commentator stated, “quality problems . . . abound in American medicine. The majority of these problems are not rare, unpredictable, or inevitable concomitants of the delivery of complex, modern health care. Rather, they are frighteningly common, often predictable, and frequently preventable.”<sup>1</sup>

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<sup>1</sup> Mark R. Chassin, *Is Health Care Ready for Six Sigma Quality?*, 76 MILBANK Q. 565, 566 (1998).

**C. *The U.S. Economy Typically Relies on Market Competition***

In the overwhelming majority of markets, the government does not decide the prices and quality at which sellers offer goods and services. Rather, rivals compete to satisfy consumer demand, and consumers make decisions about the price and quality of goods or services they will purchase. A well-functioning market maximizes consumer welfare when consumers make their own consumption decisions based on good information, clear preferences, and appropriate incentives.

Vigorous competition, both price and non-price, can have important benefits in health care as well. Price competition generally results in lower prices and, thus, broader access to health care products and services. Non-price competition can promote higher quality and encourage innovation. More concretely, competition can result in new and improved drugs, cheaper generic alternatives to branded drugs, treatments with less pain and fewer side effects, and treatments offered in a manner and location consumers desire. Vigorous competition can be quite unpleasant for competitors, however. Indeed, competition can be ruthless – a circumstance that can create cognitive dissonance for providers who prefer to focus on the necessity for trust and the importance of compassion in the delivery of health care services. Yet, the fact that competition creates winners and losers can inspire health care providers to do a better job for consumers. Vigorous competition promotes the delivery of high quality, cost-effective health care, and vigorous antitrust enforcement helps protect competition.

At the same time, competition is not a panacea for all of the problems with American health care. Competition cannot provide its full benefits to consumers without good information and properly aligned incentives. Moreover, competition cannot eliminate the inherent uncertainties in health care, or the informational asymmetries among consumers, providers, and payors. Competition also will not shift resources to those who do not have them. The next section identifies some of the features of health care markets that can limit the effectiveness of competition.

**II. FEATURES OF HEALTH CARE MARKETS THAT CAN LIMIT COMPETITION**

**A. *The Health Care Marketplace is Extensively Regulated***

An extensive regulatory framework, developed over decades, at both the federal and state levels of government affects where and how competition takes place in health care markets. Much of the regulatory framework arose haphazardly, with little consideration of how the pieces fit together, or how the pieces could exacerbate anticompetitive tendencies of the overall structure. Proposals for new regulatory interventions have often focused solely on their claimed benefits, instead of considering their likely costs, where proposals fit into the larger regulatory framework, and whether proposals frustrate competition unnecessarily. Failure to consider such matters can reinforce existing regulatory imperfections and reward incumbent interests. Indeed, in health care, some commentators see competition as a problem to be tamed with top-down prescriptive



regulations, instead of an opportunity to improve quality, efficiency, and enhance consumer welfare.

As a significant purchaser in most health care markets, the government uses regulations to influence the price and quality of the services for which it pays. The government's actions as both purchaser and regulator have profound effects on the rest of the health care financing and delivery markets as well. Price regulation, even if indirect, can distort provider responses to consumer demand and restrict consumer access to health care services. Regulatory rules also can reduce the rewards from innovation and sometimes create perverse incentives, rewarding inefficient conduct and poor results. Restrictions on entry and extensive regulation of other aspects of provider behavior and organizational form can bar new entrants and hinder the development of new forms of competition. The scope and depth of regulation is also not universal; providers offering competing services are routinely subject to widely varying regulatory regimes and payment schedules.

***B. Third-Party Payment Can Distort Incentives***

Health insurance shifts and pools the risks associated with ill health. By providing greater predictability, health insurance protects the ill and their families from financial catastrophe. Nonetheless, third-party payment of health-related expenses can distort incentives and have unintended consequences.

*Consumer Incentives.* Insured consumers are insulated from most of the costs of their decisions on health care treatments. The result is that insured consumers have limited incentive to balance costs and benefits and search for lower cost health care with the level of quality that they prefer. A lack of good information also hampers consumers' ability to evaluate the quality of the health care they receive.

*Provider Incentives.* Panelists and commentators agreed that providers have a strong ethical obligation to deliver high quality care. The health care financing system, however, generally does not directly reward or punish health care providers based on their performance. When this fact is coupled with the consumer incentives outlined above, the result is that providers who deliver higher quality care are generally not directly rewarded for their superior performance; providers who deliver lower quality care are generally not directly punished for their poorer performance and, worse still, may even be rewarded with higher payments than providers who deliver higher quality care.

*Payor Incentives.* Insurers generally offer coverage terms tied to professionally dictated standards of care, restricting the range of choices and trade-offs that consumers may desire. Insurers aggregate consumer preferences, but there can be incentive mismatches because insurers generally bear the costs but do not capture the full benefits of coverage decisions and because insurance contracts have a defined term (usually annually) that is generally shorter than the period of interest to the consumer.

**C. *Information Problems Can Limit the Effectiveness of Competition***

*The Lack of Reliable and Accurate Information about Price and Quality.* The public has access to better information about the price and quality of automobiles than it does about most health care services. It is difficult to get good information about the price and quality of health care goods and services, although numerous states and private entities are experimenting with a range of “report cards” and other strategies for disseminating information to consumers. Without good information, consumers have more difficulty identifying and obtaining the goods and services they desire.

*The Asymmetry of Information between Providers and Consumers.* Most consumers have limited information about their illness and their treatment options. Consumers with chronic illnesses have more opportunity and incentive to gather such information, but there is still a fundamental informational asymmetry between providers and patients. There is also considerable uncertainty about the optimal course of treatment for many illnesses, given diverse patient preferences and the state of scientific knowledge.

*Consumer Uncertainty about Reliability of Health Care Information.* Uncertainty increases transaction costs, fraud, and deception dramatically. Although the Internet can provide access to information about health care, it also enhances the risks of fraud and deception regarding “snake oil” and miracle cures.

*Information Technology.* Health care does not employ information technology

extensively or effectively. Prescriptions and physician orders are frequently hand-written. Records are often maintained in hard copy and scattered among multiple locations. Few providers use e-mail to communicate with consumers. Public and private entities have worked to develop and introduce electronic medical records and computerized physician order entry, but commentators and panelists agreed that much remains to be done.

**D. *Cost, Quality, and Access: The Iron Triangle of Trade-offs***

Health policy analysts commonly refer to an “iron triangle” of health care.<sup>2</sup> The three vertices of the triangle are the cost, quality, and accessibility of care. The “iron triangle” means that, in equilibrium, increasing the performance of the health care system along any one of these dimensions can compromise one or both of the other dimensions, regardless of the amount that is spent on health care.

Such tradeoffs are not always required, of course. For example, tying payments to health care providers to the quality of services provided could improve providers’ incentives to contain costs and improve quality. Better quality also could be achieved at less cost by reducing unnecessary services and managing consumers with chronic conditions more cost-effectively. Competition has an important role to play in accomplishing these objectives.

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<sup>2</sup> WILLIAM L. KISSICK, MEDICINE’S DILEMMAS: INFINITE NEEDS VERSUS FINITE RESOURCES (1994).

Nonetheless, trade-offs among cost, quality, and access can be necessary. Those trade-offs must be made at multiple levels by multiple parties. Some consumers may prefer a “nothing but the best” package of medical care, but others are willing to trade-off certain attributes of quality for lower cost, or trade-off one attribute of quality for another. For example, some consumers will be more willing than others to travel in exchange for lower prices, while others may be more willing to travel in exchange for higher quality care. Good information about the costs and consequences of each of these choices is important for competition to be effective.

***E. Societal Attitudes Regarding Medical Care***

For most products, consumers’ resources constrain their demand. Consumers and the general public do not generally expect vendors to provide services to those who cannot pay for them. Few would require grocery stores to provide free food to the hungry or landlords to provide free shelter to the homeless. By contrast, many members of the public and many health care providers view health care as a “special” good, not subject to normal market forces, with significant obligational norms to provide necessary care without regard to ability to pay. Similarly, many perceive risk-based premiums for health insurance to be inconsistent with obligational norms and fundamental fairness, because those with the highest anticipated medical bills will pay the highest premiums. A range of regulatory interventions reflect these norms.

***F. Agency Relationships***

A large majority of consumers purchase health care through multiple agents – their employers, the plans or insurers chosen by their employers, and providers who guide patient choice through referrals and selection of treatments. This multiplicity of agents is a major source of problems in the market for health care services. Agents often do not have adequate information about the preferences of those they represent or sufficient incentive to serve those interests.

**III. HOW THE HEALTH CARE MARKETPLACE CURRENTLY OPERATES**

Competitive pressures for cost containment have spurred the development of new forms of health care financing and delivery. Government payors have adopted new forms of payments for health care providers to slow health care inflation. Private payors have adopted systems, such as managed care and preferred provider organizations, to encourage or require consumers to choose relatively lower-cost health care. Physicians have tried new types of joint ventures and consolidation, and hospitals have consolidated through merger and the creation of multi-hospital networks. These new organizational forms offer the potential for reducing costs and increasing provider bargaining power. More recently, strategies for improving the quality of health care have gained attention. Health care markets remain in flux.

## **A. *How Consumers Pay for Health Care***

Most Americans pay for health care through health insurance. Most Americans under the age of 65 obtain health insurance through their employer or the employer of a family member. Some Americans under the age of 65 obtain coverage through a government program or purchase an individual insurance policy. Americans aged 65 and over are almost always covered by Medicare. In 2002, the Census Bureau estimated that approximately 85 percent of the total U.S. population had health insurance coverage.

### **1. Publicly Funded Programs**

*Medicare.* Medicare provides coverage for approximately 40 million elderly and disabled Americans. Medicare Part A covers most Americans over 65, and provides hospital insurance coverage. Although Medicare Part B is optional, almost all eligible parties enroll, given substantial federal subsidies to the program. Medicare Part B provides supplementary medical coverage for, among other things, doctors' visits and diagnostic tests. Many Medicare beneficiaries also purchase Medicare Supplemental Insurance (Medigap) policies or have coverage from a former employer. Medigap policies are federally regulated and must include specified core benefits.

In 1997, Congress enacted Medicare + Choice (M+C). M+C encouraged Medicare beneficiaries to join privately operated managed care plans, which often offer greater benefits (*e.g.*, prescription drug coverage) in exchange for accepting limits

on choice of providers. In 2003, Congress renamed M+C Medicare Advantage, and enacted prescription drug benefits for Medicare beneficiaries.

*Medicaid.* Medicaid provides coverage for approximately 50 million Americans. Although the federal government sets eligibility and service parameters for the Medicaid program, the states specify the services they will offer and the eligibility requirements for enrollees. Medicaid programs generally cover young children and pregnant women whose family income is at or below 133 percent of the federal poverty level, as well as many low-income adults. Most states have most of their Medicaid population in some form of managed care. Medicaid pays for a majority of long term care in the United States.

*Payments to Health Care Providers: Past and Present.* Prior to 1983, Medicare, as well as most other insurers, reimbursed providers under a "fee-for-service" (FFS) system based on the costs of the number and type of services performed. Despite some restraints on how much a provider could claim as its costs, the result was to reward volume and discourage efficiency. Commentators argued that the combination of FFS payment, health insurance, and consumers' imperfect information about health care created incentives for providers to provide, and consumers to consume, greater health care resources than would be the case in competitive markets. In addition, FFS payment dampened the potential for effective price competition, because FFS guaranteed reimbursement for claimed charges. Thus, providers lacked incentives to lower prices.

*Hospitals and Ancillary Services.* In response to increasing health care expenditures, Congress directed the Center for Medicare and Medicaid Services (CMS) to adopt the inpatient prospective payment system (IPPS) as a means to create a more competitive, market-like environment for hospital reimbursement by Medicare. The IPPS took effect in 1983. The diagnosis-related group (DRG) for the diagnosis at discharge determines the amount that the hospital is paid. Each DRG has a payment weight assigned to it, which reflects the average cost of treating patients in that DRG. Hospitals receive this predetermined amount regardless of the actual cost of care, although adjustments are made for extraordinarily high-cost cases (“outlier payments”), teaching hospitals, and hospitals that serve a disproportionate number of low-income patients.

Similarly, Congress directed CMS to change its payment system for hospital-based outpatient care provided to Medicare beneficiaries. On August 1, 2000, the payment system changed from a cost-based system to the outpatient prospective payment system (OPPS), under which CMS reimburses hospitals based on one of about 750 ambulatory payment classifications (APCs) in which an episode of care falls. Each APC has a general weight based on the median cost of providing the service.

Congress also directed CMS to adopt prospective payment systems for skilled nursing facilities and home health care services, and those systems are currently in effect. As of 2007, Medicare is scheduled to begin a competitive bidding system to determine which providers will offer durable medical equipment to Medicare

beneficiaries.

Both the IPPS and the OPPS have constrained expenditures more effectively than the cost-based systems they replaced. With the introduction of IPPS, the increase in hospital expenditures slowed, and average length of hospital stay declined. The adoption of prospective payment for home health care services also had an immediate impact on the number of beneficiaries that received services and the average number of visits.

Any administered pricing system inevitably has difficulty in replicating the price that would prevail in a competitive market. Not surprisingly, one unintended consequence of the CMS administered pricing systems has been to make some hospital services extraordinarily lucrative and others unprofitable. As a result, some services are more available (and others less available) than they would be in a competitive market.

*Physicians.* Medicare pays for physician services using the resource-based relative value scale (RBRVS), a system for calculating a physician fee schedule. CMS calculates the fee schedule on the basis of the cost of physician labor, practice overheads and materials, and liability insurance, as adjusted for geographic and yearly differences.

## **2. Employment-Based Insurance**

Employers offer insurance to their employees and retirees through various sources, including commercial insurance companies, employers’ self-funded plans, or various combinations of the two. Employers

that offer health insurance through commercial insurers usually negotiate on behalf of their employees for a package of benefits at a specified monthly premium per person or per family. Some employers choose to self-fund (self-insure) by assuming 100 percent of the risk of expenses from their employees' health care coverage. Some employers create self-insured plans, but contract with commercial insurance companies to act as a third-party administrator for claims processing, for access to a provider network, or to obtain stop-loss coverage. The applicability of federal and state laws and regulations varies, depending on the source of health care coverage an employer makes available to employees and retirees.

Not all employers offer health coverage, and some employers offer coverage only to full-time employees. In some sectors of the economy, employment-based health insurance is less common. The larger the employer, the more likely it is to offer health insurance. Premiums and coverage vary widely. The number of people with employment-based insurance fluctuated throughout the 1990s but has currently stabilized at approximately 61 percent of the U.S. population.

The federal government subsidizes employment-based health insurance through the tax code. Employer contributions for health insurance coverage are deductible to employers, but are not considered taxable income to employees and retirees. The result is that employees can obtain health care coverage through their employer with pre-tax dollars. Although it is common parlance to speak of "employer contributions" to the cost of health care

coverage, employees and retirees ultimately bear these costs in the form of lower salaries and benefits.

*Payments to Providers.* In some instances, private payors have copied the payment strategies of the Medicare program or have used Medicare payments as a reference price for negotiation with providers. For example, some payors negotiate either a specified discount or a specified premium relative to the payment the Medicare program would make for a specific episode of hospitalization or service. To be sure, many payors do not rely on these strategies, and instead structure their own payment arrangements with providers, including discounted per diem payments to hospitals and negotiated discounts off charges for other providers.

### **3. Individual Insurance**

In 1999, approximately 16 million working-age adults and children – almost 7 percent of the population under 65 – obtained health insurance coverage through individually issued, non-group policies. Commentators suggest that this small market share is due, in part, to the tax subsidies provided for employment-based coverage. Individual insurance policies are generally more expensive and less comprehensive than group policies.

### **4. The Uninsured**

Approximately 15 percent of the population, or 44 millions Americans, lacked health insurance at some point during 2002. A study by the Congressional Budget Office found that 45 percent of the uninsured were without coverage for four

months or less, and that only 16 percent of the uninsured (or approximately 6.9 million Americans) remained so for more than two years. The uninsured are more likely to be younger and less likely to have a regular source of care, less likely to use preventive services, and more likely to delay seeking treatment. Studies indicate a variety of adverse health consequences are associated with being uninsured.

Medical treatment for the uninsured is often more expensive than care of the insured, because the uninsured are more likely to delay treatment and receive care in an emergency room. Hospitals typically bill the uninsured full price for the services they received, instead of the discounted prices that hospitals offer insured patients pursuant to negotiated contracts with their insurers. The uninsured bear some of the costs of treatments themselves and often cannot fully pay for the care they receive. The burden of providing this uncompensated care varies significantly among providers and regions. For example, the burden of uncompensated care is greater in the South and West, where a higher percentage of the population is uninsured, than in the rest of the United States. The costs of uncompensated treatments for the uninsured are either paid by taxpayers, absorbed by providers, or passed on to the insured.

***B. How Consumers Receive Health Care: The Rise and Decline of Managed Care***

Burgeoning health care expenditures in the 1960s and 1970s led to numerous proposals to provide better incentives to contain costs. Some commentators argued that organizations that agreed to meet the

health care needs of a consumer at a set price for a set period of time offered a solution to this problem. Such prepaid group practices existed in some parts of the United States beginning in the early part of the 20<sup>th</sup> century, but Congress took a significant step in this direction with passage of the Health Maintenance Organizations Act of 1973 (HMO Act). The HMO Act provided start-up funds to encourage the development of HMOs, overrode State anti-HMO laws, and required large firms to offer an HMO choice to their employees. These forces set the stage for the development of managed care organizations (MCOs). Managed care means different things to different people, and it has meant different things at different times. There is general agreement, however, that MCOs integrate the financing and delivery of health care services, albeit to varying degrees. In global terms, managed care offers a more restricted choice of (and access to) providers and treatments in exchange for lower premiums, deductibles, and co-payments than traditional indemnity insurance.

MCOs historically relied on three strategies to control costs and enhance quality of care. One is selective contracting with providers that must meet certain criteria to be included in the MCO's provider network. Selective contracting can intensify price competition and allow MCOs to negotiate volume discounts and choose providers based on a range of discounts. When MCOs and other insurers have a credible threat to exclude providers from their networks and send patients elsewhere, providers have a powerful incentive to bid aggressively to be included in the network. Without such credible threats, providers have less incentive to bid aggressively, and

even MCOs with large market shares may have less ability to obtain lower prices.

Another strategy is to use incentives that shift some of the financial risk to providers. Capitation, for example, pays providers a fixed amount for each of the patients for whom they agree to provide care, regardless of whether those patients seek care or the costs of their care exceeds the fixed amount. Some physician groups participating in capitation arrangements underestimated these risks and went bankrupt, and providers have become increasingly reluctant to accept the risks of capitation in recent years. Direct financial incentives for providers in the form of bonuses (or withholding a percentage of payment) based on meeting clinical or financial targets remain fairly prevalent, with considerable variation in their details.

A third strategy is utilization review of proposed treatments and hospitalizations. This strategy involves an appraisal of the appropriateness and medical necessity of the proposed treatment. Many MCOs and other insurers use utilization review in a variety of forms.

In recent years, many MCOs have adopted a fourth strategy: increased cost-sharing. Cost sharing creates direct financial incentives for consumers – through varying co-payments and deductibles – to receive care from particular providers or in particular locations.

By the late 1990s, managed care had grown so unpopular that commentators began to refer to a “managed care backlash.” Providers complained that their clinical judgments were second-guessed; consumers

complained that managed care was restricting choices, limiting access to necessary medical care, and lowering quality. These concerns resulted in a number of federal and state legislative and regulatory initiatives, as well as private litigation against MCOs.

Commentators report a substantial gap between consumer and provider perceptions, on the one hand, and managed care’s actual impact, on the other. They point to surveys and studies showing that consumers are generally satisfied with their own MCOs, that MCOs do not provide poorer quality care than FFS medicine, and that “managed care horror stories” are often exaggerated or highly unrepresentative.

In recent years, more restrictive forms of managed care have been eclipsed by offerings with more choice and flexibility. These offerings include point-of-service (POS) plans, which allow patients to select a primary care gatekeeper, yet use out-of-plan physicians for some services. Preferred provider organizations (PPOs) are similar to POS programs, but generally do not require a coordinating primary care physician. Instead, PPOs have a panel of “preferred providers” who agree to accept discounted fees. Some physicians who wish to avoid managed care entirely have begun “concierge practices,” where they provide personalized care, including house calls, to patients willing and able to pay out of pocket for health care costs.

Public and private payors are also experimenting with payment for performance (P4P) initiatives. Commentators and panelists generally agreed that P4P should be more widely



employed in health care. Many payors have yet to adopt P4P programs, and some providers have resisted such programs. The development of P4P programs will require better measurement of, and information about, health care quality.

#### **IV. HEALTH CARE PROVIDERS: NEW DELIVERY SYSTEMS, NEW FORMS OF ORGANIZATION, AND COMPETITIVE PRESSURES**

##### **A. Physicians**

Spending on physician services accounts for approximately 22 percent of the \$1.6 trillion spent annually on health care services. Total spending on physician services increased at an average annual rate of 12 percent from 1970-1993, and at 4 to 7 percent a year since then. In response to increased competitive pressures from MCOs and other payors to lower their prices, some physicians have attempted to respond procompetitively, while others have engaged in anticompetitive conduct.

*Multiprovider Network Joint Ventures.* Historically, physicians were predominantly solo practitioners, but many physicians implemented network joint ventures in response to managed care. The 1980s saw the emergence of two types of joint ventures with physician members (Independent Practice Associations (IPAs) and Physician Hospital Organizations (PHOs)). In general, IPAs are networks of independent physicians that, among other things, may contract with MCOs and employers. PHOs are joint ventures between a hospital (or more than one hospital) and physicians who generally have

admitting privileges there; hospital and physician members sometimes contract jointly through the PHO with MCOs to provide care to a population of patients.

IPAs and PHOs are often integrated to varying degrees financially (sharing financial risk) or clinically (using various strategies to improve the quality of care they provide) or both. Such joint ventures may provide various cost savings, such as reduced contracting costs, and clinical efficiencies, such as better monitoring and management of patients with chronic illnesses. IPAs and PHOs can also represent attempts by providers to increase their bargaining leverage with insurers. Some contend that the primary advantage for physicians and hospitals in forming a PHO is that the member hospital(s) and physicians present a united front for bargaining with payors. In recent years, the use of IPAs and PHOs has decreased, as MCOs and providers have abandoned capitation arrangements.

One antitrust issue that physician joint ventures confront with respect to their contracting practices is how to avoid summary condemnation under the antitrust laws. The *Health Care Statements* outline the key factors the Agencies will consider in determining whether to apply the per se rule or more elaborate rule of reason analysis to particular conduct.<sup>3</sup> These factors include the degree of integration that the venture achieves to obtain efficiencies and the extent to which joint pricing is reasonably

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<sup>3</sup> DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996), available at <http://www.ftc.gov/reports/hlth3s.pdf>.

necessary to achieve those efficiencies.

*The “Messenger Model.”*

Arrangements to allow networks of providers to contract with payors, while avoiding any agreement on price among the providers, sometimes use a “messenger” to facilitate contracting. The payor usually submits a proposed fee schedule to an agent or third party, who transmits this offer to the network physicians. Each physician decides unilaterally whether to accept the fee schedule, and the agent transmits those decisions to the payor. Providers may also individually give the messenger information about the prices or other contract terms that the provider will accept, and the messenger aggregates this information and markets it to payors. *Health Care Statement 9* describes how to avoid antitrust problems when using a messenger model, and provider networks have used the model successfully. Nonetheless, physician networks using so-called “messengers” to orchestrate or participate in price-fixing agreements have resulted in considerable antitrust enforcement activity in recent years.

*Physician Collective Bargaining.*

Some physicians have lobbied heavily for an antitrust exemption to allow independent physicians to bargain collectively. They argue that payors have market power, and that collective bargaining will enable physicians to exercise countervailing market power. The Agencies have consistently opposed these exemptions, because they are likely to harm consumers by increasing costs without improving quality of care. The Congressional Budget Office estimated that proposed federal legislation to exempt physicians from antitrust scrutiny would increase expenditures on private health

insurance by 2.6 percent and increase direct federal spending on health care programs such as Medicaid by \$11.3 billion.

*Licensing Regulation and Market Entry.* State licensing boards composed primarily of physicians determine, apply, and enforce the requirements for physicians to practice within a particular state. Various state licensing boards have taken steps to restrict allied health professionals and telemedicine. Some states have limited or no reciprocity for licensing physicians and allied health professionals already licensed by another state. The Report discusses the anticompetitive potential of such restrictions, as well as their rationales.

**B. Hospitals**

As with physicians, some hospitals have responded to competitive pressures by finding ways to lower costs, improve quality, and compete more efficiently. Some commentators contend, however, that a number of hospital networks are exercising market power to demand price increases from payors, and seeking to forestall entry by new competitors, such as single-specialty hospitals.

*Hospital Networks.* Over the past 20 years, many hospitals have merged or consolidated into multi-hospital networks or systems. Although the Agencies had considerable early success in challenging certain hospital mergers, the Agencies and state enforcers have lost all seven hospital merger cases they have litigated since 1994. Courts in these cases typically disagreed with the Agencies on how to measure relevant antitrust markets, how to assess the prospects for entry to remedy any

anticompetitive effects, how to determine the magnitude of any likely efficiencies, and the relevance of the hospital's nonprofit status. The Commission has undertaken a retrospective study to evaluate the market results in several consummated mergers, and one case is currently pending in administrative litigation.

Initially, national systems acquired hospitals throughout the United States, but recent acquisitions have been more localized. Some believe that hospital consolidation generally has promoted the development of efficiencies and instilled life back into failing hospitals. They point to the savings from consolidated operations that hospital networks may make possible. Others believe that a primary result of consolidation has been to create hospital market power, thus allowing hospitals to increase their prices. Hospitals claim that rising prices result not from market power, but from a multitude of pressures they confront, such as shortages of nurses and other personnel, rising liability premiums, the costs of improved technology, and the obligations of indigent care.

Most studies of the relationship between competition and hospital prices have found that high hospital concentration is associated with increased prices, regardless of whether the hospitals are for-profit or nonprofit. Some studies have found that merged hospitals experienced smaller price and cost increases than those that have not merged, except in highly concentrated markets, where the pattern was reversed. Another study found that some systems' acquisition of hospitals did not produce efficiencies, because of a failure to combine operations. Some have pointed out

that studies typically do not differentiate among transactions that occur within local markets and those that occur across markets, such as national system acquisitions; different types of consolidations might reflect very different hospital strategies and could have different efficiency effects.

*Entry: Specialty Hospitals.*

Specialty hospitals provide care for a specific specialty (*e.g.*, cardiac) or type of patient (*e.g.*, children). Newer single-specialty hospitals (SSHs) tend to specialize in cardiac or orthopedic surgery, and participating physicians often have an ownership interest in the facility, for reasons described *infra*. Some contend that SSHs have achieved better outcomes through increased volume, better disease management, and better clinical standards.

Others disagree, suggesting that physician-investors send healthier, lower risk patients to their SSH and sicker patients to a general hospital to enable the SSH to produce service less expensively yet still be reimbursed at the same rates as the general hospital. These commentators fear that SSHs will siphon off the most profitable procedures and patients, leaving general hospitals with less money to cross subsidize socially valuable, but less profitable care.

Some general hospitals facing competition from SSHs have removed the admitting privileges of physicians involved with the SSH or otherwise acted to limit physician access to the general hospital; other general hospitals have established their own single-specialty wing to prevent physicians from shifting their patients to a new entrant. Some commentators state that general hospitals have used certificate of

need (CON) laws to restrict entry by SSHs. There are relatively few SSHs, and the vast majority are in states without CON programs. Debate about SSHs continues. A recently imposed Congressional moratorium on physician referrals to SSHs in which they have an ownership interest and two Congressionally mandated studies on SSHs and general hospitals will likely affect the future of SSHs.

*Entry: Ambulatory Surgery Centers.* Ambulatory surgery centers (ASCs) perform surgical procedures on patients who do not require an overnight stay in the hospital. Technological advances in surgery and anesthetic agents have made it possible for ASCs to perform a wide range of surgical procedures. Medicare reimbursement has had a profound effect on the number of ASCs and the amount and types of surgery performed in them.

Commentators express divergent views on ASCs, with some focusing on likely benefits to consumers including greater convenience, and others expressing concerns about ASCs similar to those regarding SSHs. Hospital reactions to deter ASC entry and restrict competition have been similar to those for SSHs.

*Government Purchasing of Hospital Services.* Government-administered pricing by CMS inadvertently can distort market competition. For example, CMS never decided as a matter of policy to provide greater profits for cardiac surgery than many other types of service, but the IPPS tends to do so. This pricing distortion creates a direct economic incentive for specialized cardiac hospitals to enter the market; such entry reflects areas that government pricing

makes most profitable, which may or may not reflect consumers' needs and preferences. When the government is the sole or primary payor for a service, such as kidney dialysis or vaccines, paying too much wastes resources, while paying too little reduces output and capacity, lowers quality, and diminishes incentives for innovation.

Although CMS can set prices, its ability directly to encourage price and non-price competition is limited. With few exceptions, CMS cannot force providers to compete for CMS's business or reward suppliers that reduce costs or enhance quality with substantially increased volume or higher payments. CMS has limited ability to contract selectively with providers or use competitive bidding. Even straightforward purchasing initiatives, such as competitive bidding for durable medical equipment (DME), have generated considerable resistance, despite the success of a pilot project for DME competitive bidding that resulted in savings of 17 to 22 percent with no significant adverse effects on beneficiaries. Worse still, CMS's payment systems do not reward providers who deliver higher quality care or punish providers who deliver lower quality care. As the Medicare Payment Advisory Commission reported, the Medicare payment system is "largely neutral or negative towards quality . . . . At times providers are paid even more when quality is worse, such as when complications occur as the result of error."<sup>4</sup>

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<sup>4</sup> MEDICARE PAYMENT ADVISORY COMMITTEE, REPORT TO CONGRESS: VARIATION AND INNOVATION IN MEDICARE 108 (2003), available at [http://www.medpac.gov/publications/congressional\\_reports/June03\\_Entire\\_Report.pdf](http://www.medpac.gov/publications/congressional_reports/June03_Entire_Report.pdf).

CMS has worked to enhance quality through public reporting initiatives. For example, since CMS began public reporting of quality information on dialysis care in 1996, the number of patients receiving inadequate dialysis or experiencing anemia has declined substantially. Since 2002, CMS publicly reports on the quality of care provided in nursing homes and by home health agencies. Recently, CMS joined with hospitals and the Quality Improvement Organizations in Maryland, New York, and Arizona to design pilot tests for publicly reporting hospital performance measures. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 creates modest financial incentives for hospitals to report such information.

Examples of other government initiatives include New York State, which began to publicize provider-specific outcomes for cardiac surgery in 1989. By 1992, one study found risk-adjusted mortality had dropped 41 percent statewide, giving New York the lowest risk-adjusted mortality rate for cardiac surgery in the nation. Studies show the mortality rate has continued to fall. Pennsylvania reportedly experienced similar improvements when it began collecting and publishing risk-adjusted report cards.

Some have criticized these findings on methodological and policy grounds. For example, critics suggest that some of the improvement in mortality rates in New York resulted from the migration of high-risk patients to other states for surgery, and that data collection and risk adjustment methods were flawed. A general criticism of such “report cards” is that they discourage providers from treating higher risk patients.

More research is required to determine the best methods for measuring and reporting on hospital quality.

*Private Purchasing of Hospital Services.* In recent years, contracting between hospitals and private payors has sometimes been controversial and contentious. Some contend that many hospital systems include at least one “must-have” hospital in each of the geographic markets in which they compete. A “must-have” hospital is one that health care plans believe they must offer to their beneficiaries to attract employers to the plan. Payors complain that hospital systems insist on including all or none of the hospitals in a system in the payor’s coverage plan. Consumer pressure for open networks has made it more difficult for payors to exclude an entire hospital system, and the presence of a “must-have” hospital in the network also increases a hospital’s bargaining power. Although some commentators believe that particular hospitals and hospital systems have the upper hand in bargaining in some markets, bargaining advantage varies substantially within and among different markets.

In a few markets, certain payors have experimented with “tiering” hospitals, which results in different consumer co-payments depending on the hospital. Hospital tiers may be established based on a variety of criteria. Tiering usually does not apply to emergency care and may depend on where routine and specialty services are offered. Tiering allows a payor to maintain a broad network and include a “must-have” hospital, yet still create incentives for consumers to use lower cost hospitals. Hospitals usually resist tiering, in some cases negotiating

contracts that prohibit tiering. Hospitals express concern that low-cost facilities will be mislabeled as low quality and high-cost facilities as inefficient, and that tiering might force poorer consumers to use only low-cost hospitals.

Private-sector efforts are underway to provide more information about quality. A number of private initiatives seek to make quality-related information available to employers, health plans, and consumers. The Health Plan Employer Data and Information Set (HEDIS), developed by the National Committee for Quality Assurance to assess health plans, uses more than 50 measures of provider and plan performance in areas such as patient satisfaction, childhood immunization, and mammography screening rates.

*Hospital Purchasing.* Some hospitals have joined group purchasing organizations (GPOs) to consolidate their purchases and achieve volume and other discounts. GPOs have the potential to assist hospitals in lowering costs. There have been complaints about certain GPO practices. The Agencies investigate GPO practices that appear to merit antitrust scrutiny. The market-share safety zones contained in *Health Care Statement 7* do not constrain Agency enforcement in cases involving anticompetitive contracting practices.

*Consumer Price and Quality Sensitivity: The Need for Better Information.* Tiering represents an attempt to force consumers to bear some of the increased price associated with receiving care at a more expensive hospital. Medical savings accounts, which combine a high-deductible insurance policy with a tax

advantaged fund for paying a portion of uncovered costs, are intended to accomplish the same goal for most health care purchasing decisions. For such strategies to work, however, consumers will need reliable and understandable information about the prices and quality of the services among which they must choose.

At present, most insured consumers are “rationally ignorant” of the price of medical services they receive, because insurance largely insulates them from the financial implications of their treatment. Even if consumers were interested in the price of their care, they would find it very difficult to obtain the information. The pricing of health care services is complicated and frequently obscure. Thus, proposals to increase consumer price sensitivity must develop strategies to increase the transparency of pricing.

An analogous finding emerges for quality measures. Although consumers typically express interest in report cards, they often do not use such information to select health plans and providers. If the information is usable, consumers will select treatments that accord with their preferences. Publicly available report cards can motivate providers to address quality deficiencies, even when it does not appear that many consumers rely on that information. Not all consumers must be well-informed for the market to deliver an efficient level of quality.

*Pricing: Bulk Purchasing, Price Discrimination, Cost-Shifting, and Cross-Subsidies.* Understanding health care pricing requires an understanding of four terms: bulk purchasing, price

discrimination, cost shifting, and cross subsidies. The terms have distinct meanings, although there is some overlap between cost shifting and cross subsidies. Bulk purchasing occurs when large organizations receive purchasing discounts because of the volume of their purchases. Price discrimination involves charging different consumers different prices for the same services, based on differential demand. Cost shifting refers to raising the price charged to one group of consumers as a result of lowering the price to other consumers. Cross subsidizing is the practice of charging profit maximizing prices above marginal costs to some payors or for some services and using the surpluses to subsidize other payors or other clinical services.

Some panelists stated that cost-shifting is common in the medical marketplace, but most commentators and panelists disagreed, and stated that bulk purchasing discounts and price discrimination explain observable pricing patterns. Panelists and commentators agreed, however, that there are a range of subsidies and cross-subsidies in the medical marketplace. For example, providers lose money by treating the uninsured, but make money by treating the well insured. Any administered pricing system has difficulty replicating competitive prices. Thus, not surprisingly, under Medicare's administered pricing system, some services are much more profitable than others.

Congress has also created direct subsidies for certain hospitals. CMS pays more to teaching hospitals (approximately \$5.9 billion in 1999) and to hospitals that provide a disproportionate share of care to the poor (approximately \$5 billion per year).

The existence of subsidies and cross-subsidies complicates any plan to give consumers better price information and increase their price sensitivity. Cross-subsidies can distort relative prices and makes access to care contingent on matters such as the number of uninsured that seek care, the wealth of the community, and the degree of competitiveness of the market for medical services.

### **C. *Pharmaceuticals***

*Competition between Brand-Name and Generic Drug Manufacturers.* The availability of patent protection creates innovation incentives for brand-name pharmaceutical companies by excluding others from making, using, or selling a claimed invention for a specified period of time. This protection helps ensure revenues to pharmaceutical firms that they can use for more research. Patent law also requires the disclosure of information about the patented invention that otherwise would remain a trade secret and thus encourages competition to design around brand-name patents.

In 1984, Congress passed the Hatch-Waxman Act, which has encouraged competition from lower-priced generic drugs. Hatch-Waxman has shaped substantially the legal environment governing Food and Drug Administration approval of generic drug products, and established a framework to balance incentives for continued innovation by brand-name firms with entry by generic drug firms.

The Commission has pursued several enforcement actions to remedy actions by particular firms to game certain Hatch-

Waxman provisions and deny consumers the benefits of generic competition that Congress intended. The Commission also issued a study in July, 2002 that addresses strategies among drug companies to affect the timing of generic drug entry prior to patent expiration. Congress has adopted the two major recommendations proposed in this study to preclude certain abuses of Hatch-Waxman.

*Current Policy Debates.* Concern about pharmaceutical prices in the United States has received much attention, and discussion continues about how best to address this issue. Certain policy choices currently under debate might lead to problems similar to those that this Report identifies in other health care sectors. For example, price regulation to lower prescription drug prices could lead to problems with administered pricing similar to those described above. Government purchasing that reflects monopsony power would likely reduce output and innovation.

*PBMs.* The use of pharmacy benefit managers (PBMs) as intermediaries between pharmaceutical managers and payors has raised questions whether PBMs increase the costs of pharmacy benefits. Pursuant to Congressional direction, the Commission is examining one aspect of these concerns: whether costs are higher if a payor uses a mail-order pharmacy integrated with a PBM rather than retail pharmacies or non-integrated mail-order pharmacies. This study is due in June, 2005. To date, empirical evidence suggests that PBMs have saved costs for payors.

*Direct-to-Consumer Advertising.* Some suggest that direct-to-consumer

advertising has increased prices for consumers or caused them to consume inappropriate prescription drugs. The available evidence does not support these allegations. Indeed, competition can help address these information problems by giving market participants an incentive to deliver truthful and accurate information to consumers. Nobel Laureate George Stigler once observed that advertising is “an immensely powerful instrument for the elimination of ignorance.”<sup>5</sup> Studies by the FTC’s Bureau of Economics have confirmed that advertising provides a powerful tool to communicate information about health and wellness to consumers – and the information can change people’s behavior. Thus, good information is a necessary building block both for consumer empowerment and enhanced health.

## V. RECOMMENDATIONS TO IMPROVE COMPETITION IN HEALTH CARE MARKETS

Competition has affected health care markets substantially over the past three decades. New forms of organization have developed in response to pressures for lower costs, and new strategies for lowering costs and enhancing quality have emerged. Nonetheless, competition remains less effective than possible in most health care markets, because the prerequisites for fully competitive markets are not fully satisfied. This list of recommendations focuses on how to encourage the development of prerequisites to competition such as good information about price and quality. The Agencies recognize that the work remaining

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<sup>5</sup> George J. Stigler, *The Economics of Information*, 69 J. POL. ECON. 213, 220 (1961).



to be done is complex and difficult and will take time. A renewed focus on the prerequisites for effective competition, however, may assist policymakers in identifying and prioritizing tasks for the near future.

#### **Recommendation 1:**

**Private payors, governments, and providers should continue experiments to improve incentives for providers to lower costs and enhance quality and for consumers to seek lower prices and better quality.**

***a) Private payors, governments, and providers should improve measures of price and quality.***

As noted above, health care pricing can be obscure and complex. Increased transparency in pricing is needed to implement strategies that encourage providers to lower costs and consumers to evaluate prices. Achievement of this goal will likely require addressing the issue of cross-subsidization, which encourages providers to use pricing that does not reveal the degree to which the well-insured may be subsidizing the indigent, and more profitable services may be subsidizing less well-compensated care.

A great deal of work already has been done on measuring quality. Quality measures exist for a considerable number of conditions and treatments. The Agencies encourage further work in this area. The Agencies suggest that particular attention be paid to the criticism that report cards and other performance measures discourage

providers from treating sicker patients. If it is not addressed, this criticism could undermine the perceived validity and reliability of information about quality.

***b) Private payors, governments, and providers should furnish more information on prices and quality to consumers in ways that they find useful and relevant, and continue to experiment with financing structures that will give consumers greater incentives to use such information.***

Information must be reliable and understandable if consumers are to use it in selecting health plans and providers. Research to date indicates that many consumers have not used the price and quality information they have received to make decisions about health plans and providers. Additional research into the types of price and quality information that consumers would use for those decisions appears to be necessary. Further experiments with varying co-payments and deductibles based on price- and quality-related factors such as the “tier” of service that consumers choose can help give consumers greater responsibility for their choices. Such responsibility will also likely increase consumer incentives to use available information on price and quality.

***c) Private payors, governments, and providers should experiment further with payment methods for aligning providers’ incentives with consumers’ interests in lower prices, quality improvements, and innovation.***

Payment methods that give incentives for providers to lower costs, improve quality, and innovate could be powerful forces for improving competition in health care markets. Although payors have experimented with some payment methods that provide incentives to lower costs, no payment method has yet emerged that more fully aligns providers' incentives with the interests of consumers in lower prices, quality improvements, and innovation. At present, for example, most payments to providers have no connection with the quality of care provided.

A focus on the degree to which providers' incentives are compatible with consumers' interests is important. Compatible incentives and interests are more likely to yield better results; incompatible incentives and interests are more likely to have unintended consequences that can lead to worse results. Initiatives that address the use of payment methods to align providers' incentives with consumers' interests are necessary. These experiments should be carefully analyzed to evaluate their consequences, both intended and unintended.

## **Recommendation 2:**

**States should decrease barriers to entry into provider markets.**

*a) States with Certificate of Need programs should reconsider whether these programs best serve their citizens' health care needs.*

The Agencies believe that, on balance, CON programs are not successful in containing health care costs, and that they

pose serious anticompetitive risks that usually outweigh their purported economic benefits. Market incumbents can too easily use CON procedures to forestall competitors from entering an incumbent's market. As noted earlier, the vast majority of single-specialty hospitals – a new form of competition that may benefit consumers – have opened in states that do not have CON programs. Indeed, there is considerable evidence that CON programs can actually increase prices by fostering anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns.

*b) States should consider adopting the recommendation of the Institute of Medicine to broaden the membership of state licensure boards.*

State licensing boards are disproportionately composed of licensed providers, although some states require broader representation. Many state licensing boards have taken steps, such as restricting allied health professionals (AHPs) from independent practice and direct access to consumers, that significantly reduce certain forms of competition. State licensure boards with broader membership, including representatives of the general public, and individuals with expertise in health administration, economics, consumer affairs, education, and health services research, could be less likely to limit competition by AHPs and new business forms for the delivery of health care, and are less likely to engage in conduct that unreasonably increases prices or lowers access to health care.

*c) States should consider implementing uniform licensing standards or reciprocity compacts to reduce barriers to telemedicine and competition from out-of-state providers who wish to move in-state.*

When used properly, telemedicine has considerable promise as a mechanism to broaden access, lower costs, and improve health care quality. When used improperly, telemedicine has the potential to lower health care quality and to increase the incidence of consumer fraud. To foster telemedicine's likely pro-competitive benefits and to deter its potential to harm consumers, states should consider implementing uniform licensure standards or reciprocity compacts. Uniform licensure standards and reciprocity compacts could operate both to protect consumers and to reduce barriers to telemedicine. State regulators and legislators should explicitly consider the pro-competitive benefits of telemedicine before restricting it. Similar considerations apply to the potential for licensure to restrict competition from out-of-state providers who wish to move in-state.

**Recommendation 3:**

**Governments should reexamine the role of subsidies in health care markets in light of their inefficiencies and potential to distort competition.**

Health care markets have numerous cross-subsidies and indirect subsidies. Competitive markets compete away the higher prices and supra-competitive profits necessary to sustain such subsidies. Such competition holds both the promise of consumer benefits and the threat of

undermining an implicit policy of subsidizing certain consumers and types of care.

Competition cannot provide resources to those who lack them; it does not work well when certain facilities are expected to use higher profits in certain areas to cross-subsidize uncompensated care. In general, it is more efficient to provide subsidies directly to those who should receive them, rather than to obscure cross subsidies and indirect subsidies in transactions that are not transparent. Governments should consider whether current subsidies best serve their citizens' health care needs.

**Recommendation 4:**

**Governments should not enact legislation to permit independent physicians to bargain collectively.**

Physician collective bargaining will harm consumers financially and is unlikely to result in quality improvements. There are numerous ways in which independent physicians can work together to improve quality without violating the antitrust laws.

**Recommendation 5:**

**States should consider the potential costs and benefits of regulating pharmacy benefit manager transparency.**

In general, vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms. Just as competitive forces encourage PBMs to offer

their best price and service combination to health plan sponsors to gain access to subscribers, competition should also encourage disclosure of the information health plan sponsors require to decide with which PBM to contract. To the extent the Commission’s Congressionally mandated study of PBMs provides relevant information to the issue of PBM transparency, it will be discussed in the Commission’s study report.

#### **Recommendation 6:**

**Governments should reconsider whether current mandates best serve their citizens’ health care needs. When deciding whether to mandate particular benefits, governments should consider that such mandates are likely to reduce competition, restrict consumer choice, raise the cost of health insurance, and increase the number of uninsured Americans.**

State and federal governments mandate numerous health insurance benefits. Proponents argue that mandates can correct insurance market failures, and that the required inclusion of some benefits in all health insurance plans can be welfare enhancing. Opponents argue that the case for many mandates is anecdotal, and that mandates raise premium costs, leading employers to opt out of providing health insurance and insured individuals to drop their coverage. Opponents also note that providers of the mandated benefit are usually the most vigorous proponents of such legislation, making it more likely that the mandated benefits may constitute

“provider protection” and not “consumer protection.” The Commission has submitted numerous competition advocacy letters on this issue in the last fifteen years, focusing on any willing provider and freedom of choice provisions.

For mandates to improve the efficiency of the health insurance market, state and federal legislators must be able to identify services the insurance market is not currently covering for which consumers are willing to pay the marginal costs. This task is challenging under the best of circumstances – and benefits are not mandated under the best of circumstances. In practice, mandates are likely to limit consumer choice, eliminate product diversity, raise the cost of health insurance, and increase the number of uninsured Americans.

State and federal policy makers should consider ways of evaluating these risks in their decision making processes and reconsider whether current mandates best serve their citizens’ health care needs.

#### **VI. AGENCY PERSPECTIVES ON ISSUES IN ANTITRUST ENFORCEMENT IN HEALTH CARE**

The Agencies have been active for nearly 30 years in health care markets, challenging anticompetitive conduct and providing guidance to consumers and industry participants. This section outlines the Agencies’ perspective on several issues in antitrust enforcement in health care markets.

## A. Perspective on Physician-Related Issues

*Physician Joint Ventures and Multi-provider Networks.* *Health Care Statement 8* provides that “physician network joint ventures . . . will not be viewed as per se illegal, if the physicians’ integration through the network is likely to produce significant efficiencies that benefit consumers, and any price agreements (or other agreements that would otherwise be per se illegal) by the network physicians are reasonably necessary to achieve those efficiencies.” *Health Care Statement 8* further notes that financial risk-sharing and clinical integration may involve sufficient integration to demonstrate that the venture is likely to produce significant efficiencies.

### 1<sup>st</sup> Observation:

**Payment for performance arrangements among a group of physicians may constitute a form of financial risk-sharing.**

In determining whether a physician network joint venture is sufficiently financially integrated to avoid *per se* condemnation, the Agencies will consider the extent to which a particular payment for performance (P4P) arrangement constitutes the sharing of substantial financial risk among a group of physicians, and the relationship between the physicians’ pricing agreement and the P4P program.

### 2<sup>nd</sup> Observation:

**The Agencies do not suggest particular structures with which to**

**achieve clinical integration that justifies a rule of reason analysis of joint pricing, but the analysis of whether a physician network joint venture is clinically integrated may be aided in some circumstances by asking questions like those outlined in Chapter 2.**

Attempts to achieve clinical integration were discussed at length at the Hearings. Panelists described a wide variety of factors as possibly relevant to evaluating clinical integration. Panelists and commentators asked the Agencies to define the criteria that the Agencies will consider sufficient to demonstrate that a particular venture is clinically integrated. The Agencies do not suggest particular structures with which to achieve clinical integration that justifies a rule of reason analysis of joint pricing, because of the risk that it would channel market behavior, instead of encouraging market participants to develop structures responsive to their particular goals and the market conditions they face. As an aid to analysis, Chapter 2 of the Report includes a broad outline of some of the kinds of questions that the Agencies are likely to ask when analyzing whether a physician network joint venture is clinically integrated.

## B. Perspective on Hospital-Related Issues

*Hospital Mergers.* The Agencies will continue carefully to evaluate proposed hospital mergers and to challenge those with likely anticompetitive effects. Certain issues addressed in hospital merger cases are discussed below.

### 3<sup>rd</sup> Observation:

#### **Research on hospital product markets is encouraged.**

In most cases, the Agencies have analyzed hospital product markets as a broad group of acute, inpatient medical conditions where the patient must remain in a health care facility for at least 24 hours for treatment, recovery or observation. The Agencies continue to examine whether smaller markets exist within the traditional cluster product market definition or other product market adjustments might be warranted, and encourage research on these matters. For example:

- The percentage of total health care spending devoted to outpatient care is growing. The Agencies encourage research on whether services provided in outpatient settings may constitute additional relevant product markets, and if so, whether those services might be adversely affected by a hospital merger.
- In recent years, single-specialty hospitals have emerged in numerous locations. The Agencies encourage further research into the competitive significance of SSHs, including whether payors can discipline general acute care hospitals by shifting a larger percentage of patients to SSHs.
- The Agencies encourage additional research to validate or refute the analytical techniques for defining product markets suggested by various commentators and panelists.

### 4<sup>th</sup> Observation:

#### **Hospital geographic markets should be defined properly.**

The definition of hospital geographic markets has proven controversial. In connection with this Report, the Agencies undertook a substantial analysis of how best to determine the contours of the relevant geographic market in which hospitals operate, consistent with the process described in the *1992 Horizontal Merger Guidelines (Merger Guidelines)*. The Agencies' conclusions are:

- a) The “hypothetical monopolist” test of the *Merger Guidelines* should be used to define geographic markets in hospital merger cases. To date, the Agencies' experience and research indicate that the Elzinga-Hogarty test is not valid or reliable in defining geographic markets in hospital merger cases. The limitations and difficulties of conducting a proper critical loss analysis should be fully considered if this method is used to define a hospital geographic market.
- b) The types of evidence used in *all* merger cases – such as strategic planning documents of the merging parties and customer testimony and documents – should be used by Courts to help delineate relevant geographic markets in hospital merger cases. Evidence regarding the willingness of consumers to travel and physicians to steer consumers to less expensive alternatives should also be considered by Courts.

- c) The Agencies encourage additional research to validate or refute the analytical techniques for defining geographic markets suggested by various commentators and Hearings participants.

**5<sup>th</sup> Observation:**

**Hospital merger analysis should not be affected by institutional status.**

The best available evidence shows that the pricing behavior of nonprofits when they achieve market power does not systematically differ from that of for-profits. The nonprofit status of a hospital should not be considered in determining whether a proposed hospital merger violates the antitrust laws.

**6<sup>th</sup> Observation:**

**The resolution of hospital merger challenges through community commitments should be generally disfavored.**

The Agencies do not accept community commitments as a resolution to likely anticompetitive effects from a hospital (or any other) merger. The Agencies believe community commitments are an ineffective, short-term regulatory approach to what is ultimately a problem of competition. Nevertheless, the Agencies realize that in some circumstances, State Attorneys General may agree to community commitments in light of the resource and other constraints they face.

**C. General Issues**

**7<sup>th</sup> Observation:**

**The safety zone provision of *Health Care Statement 7* does not protect anticompetitive contracting practices of group purchasing organizations.**

*Health Care Statement 7* and its safety zone aim to address monopsony and oligopoly concerns with the formation of a GPO. This statement does not address all potential issues that GPOs may raise. The Agencies believe amending the statement to address some, but not all potential issues, is likely to be counterproductive. *Health Care Statement 7* does not preclude Agency action challenging anticompetitive contracting practices that may occur in connection with GPOs. The Agencies will examine, on a case-by-case basis, the facts of any alleged anticompetitive contracting practice to determine whether it violates the antitrust laws.

**8<sup>th</sup> Observation:**

**Countervailing power should not be considered an effective response to disparities in bargaining power between payors and providers.**

Although there appear to be disparities in bargaining power between some payors and some providers, the available evidence does not indicate that there is a monopsony power problem in most health care markets. Even if it were assumed that providers confront monopsony health plans, the Agencies do not believe that allowing providers to exercise

countervailing power is likely to serve consumers' interests.

**9<sup>th</sup> Observation:**

**Private parties should not engage in anticompetitive conduct in responding to marketplace developments.**

The permissibility of unilateral and collective provider conduct in response to marketplace developments (including P4P, tiering, SSHs, and ASCs) is raised in several different settings in the Report. Generally speaking, antitrust law permits unilateral responses to competition. If there is specific evidence of anticompetitive conduct by individual providers or provider collusion in response to marketplace developments, the Agencies will aggressively pursue those activities.

**10<sup>th</sup> Observation:**

**The state action and Noerr-Pennington doctrines should be interpreted in light of the principles that justified those doctrines in the first place.**

The state action and Noerr Pennington doctrines curb competition law to promote important values such as federalism and the right to petition the government for redress. Inappropriately broad interpretations of these doctrines can chill or limit competition in health care markets. It is important to recognize both the genuine interests these doctrines serve as well as the anticompetitive consequences that result from an overly expansive interpretation of their scope.

**11<sup>th</sup> Observation:**

**Remedies must resolve the anticompetitive harm, restore competition, and prevent future anticompetitive conduct.**

Remedies are a critical issue in implementing an effective competition policy. Optimal enforcement must steer between over-deterrence and under-deterrence. Over-deterrence may occur if conduct that is not, in fact, anticompetitive is challenged, or if excessive sanctions are imposed on anticompetitive conduct. Under-deterrence may occur if anticompetitive conduct is not identified and addressed, or if inadequate remedies are imposed in response to such conduct. The Agencies must avoid both of these extremes to effect optimal deterrence, while recognizing that bringing cases helps create a "compliance norm."

The Agencies view all anticompetitive conduct as serious, and will seek appropriate sanctions. In general, much more stringent measures are necessary against those who violate the antitrust laws repeatedly or flagrantly and those who facilitate anticompetitive conduct by multiple parties. The Division will also pursue criminal sanctions in appropriate cases. Disgorgement and/or dissolution will be sought in appropriate cases.

**VIII. CONCLUSION**

The fundamental premise of the American free-market system is that consumer welfare is maximized by open competition and consumer sovereignty – even when complex products and services



such as health care are involved. The Agencies play an important role in safeguarding the free-market system from anticompetitive conduct, by bringing enforcement actions against parties who violate the antitrust and consumer protection laws. To be sure, in some instances compelling state interests may trump or limit free-market competition. The Agencies play an important role here as well, by making policy makers aware of the costs of impediments to competition, and by advocating for competitive market solutions.

The Agencies do not have a pre-existing preference for any particular model for the financing and delivery of health care. Such matters are best left to the impersonal workings of the marketplace. What the Agencies do have is a commitment to vigorous competition on both price and non-price parameters, in health care and in the rest of the economy. Much remains to be accomplished to ensure that the market for health care goods and services operates to serve the interests of consumers. This Report identifies concrete steps to improve competition in the health care marketplace, and improve the application of competition law to health care.

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## CHAPTER 1: OVERVIEW/BACKGROUND

### I. DEVELOPMENTS IN HEALTH CARE FINANCING AND DELIVERY

Health care financing and delivery arrangements have undergone dramatic changes in the past several decades. This section provides a brief overview of some of these developments, including changes in provider payment, the rise of managed care, and the integration (and then partial dis-integration) of health care delivery.<sup>1</sup>

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<sup>1</sup> There are numerous books on the issues covered in this section. See DAVID DRANOVE, *THE ECONOMIC EVOLUTION OF AMERICAN HEALTH CARE: FROM MARCUS WELBY TO MANAGED CARE* (2000); JAMES C. ROBINSON, *THE CORPORATE PRACTICE OF MEDICINE* (1999); MICHAEL MILLENSON, *DEMANDING MEDICAL EXCELLENCE* (1999); SHERRY GLIED, *CHRONIC CONDITION: WHY HEALTH REFORM FAILS* (1997); CHARLES E. ROSENBERG, *THE CARE OF STRANGERS: THE RISE OF AMERICA'S HOSPITAL SYSTEM* (1995); ROSEMARY STEVENS, *IN SICKNESS AND IN WEALTH: THE RISE OF AMERICAN HOSPITALS* (1990); JOSEPH A. CALIFANO, JR., *AMERICA'S HEALTH CARE REVOLUTION: WHO LIVES? WHO DIES? WHO PAYS?* (1986); PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1983); ROSEMARY STEVENS, *AMERICAN MEDICINE AND THE PUBLIC INTEREST* (1976); HERMAN M. SOMERS & ANNE R. SOMERS, *DOCTORS, PATIENTS, AND HEALTH INSURANCE* (1961). See also *Special Issue: Kenneth Arrow and the Changing Economics of Health Care*, 26 J. HEALTH, POL., POL'Y & L. 823-1203 (Issue 5, Oct. 2001); Paul B. Ginsburg, Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy (Feb. 26, 2003), at page 58 (noting that "history matters in health care markets") [hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)]. Transcripts of the Hearings are available at <http://www.ftc.gov/ogc/healthcarehearings/index.htm#Materials>.

This chapter does not address a number of important issues, including the rise of medical technology. See generally COUNCIL OF ECONOMIC ADVISORS, *ECONOMIC REPORT OF THE PRESIDENT,*

### A. *Fee For Service Reimbursement and the Rise of Managed Care*

For most of the twentieth century, most consumers relied on independent physicians to provide care. Pricing was fee-for-service (FFS).<sup>2</sup> FFS payment was based on the number and type of services performed. Insurers imposed few constraints on consumer choice of providers and limited oversight of the type and extent of care provided.<sup>3</sup> FFS payment provided little incentive for physicians and other health care providers to coordinate and integrate the care they rendered. FFS arrangements conformed with public sentiment that more care was better care, and

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HEALTH CARE AND INSURANCE 190-93 (2004); PENNY E. MOHR ET AL., PROJECT HOPE CTR. FOR HEALTH AFFAIRS, *PAYING FOR NEW MEDICAL TECHNOLOGIES: LESSONS FOR THE MEDICARE PROGRAM FROM OTHER LARGE HEALTH CARE PURCHASERS* (2003) (submitted to Medicare Payment Advisory Committee), available at [http://www.medpac.gov/publications/contractor\\_reports/Jun03\\_MedTechPay\\_PurchSrv\(cont\)Rpt2.pdf](http://www.medpac.gov/publications/contractor_reports/Jun03_MedTechPay_PurchSrv(cont)Rpt2.pdf); David M. Cutler & Mark McClellan, *Is Technological Change in Medicare Worth It?*, 20 HEALTH AFFAIRS 11 (Sept./Oct. 2002); Barbara J. McNeil, *Hidden Barriers to Improvement in the Quality of Care*, 345 NEW ENG. J. MED. 1612 (2001); DAVID J. ROTHMAN, *BEGINNINGS COUNT: THE TECHNOLOGICAL IMPERATIVE IN AMERICAN HEALTH CARE* (1997); CALIFANO, *supra*; STARR, *supra*.

<sup>2</sup> Gail B. Agrawal & Howard R. Veit, *Back to the Future: The Managed Care Revolution*, 65 LAW & CONTEMP. PROB. 11, 13 (2003).

<sup>3</sup> The principal limitation was that charges had to be "usual, customary and reasonable." Agrawal & Veit, *supra* note 2, at 13; GENERAL ACCOUNTING OFFICE (GAO), *MANAGED HEALTH CARE: EFFECT ON EMPLOYERS' COSTS DIFFICULT TO MEASURE 1* (1993), available at <http://archive.gao.gov/t2pbat5/150139.pdf>.

the treating physician was best positioned to judge the most appropriate care for any given case.<sup>4</sup>

Policymakers began seriously questioning the consequences of these institutional arrangements in the late-1960s.<sup>5</sup> Commentators argued that the combination of FFS payment, health insurance, and consumers' imperfect information about health care limited the possibility of effective price competition and created an incentive for physicians to over-provide (and consumers to over-consume) healthcare resources.<sup>6</sup> Some commentators argued that organizations that agreed to meet the health care needs of a consumer for a set time

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<sup>4</sup> ROBINSON, *supra* note 1, at 22, 24.

<sup>5</sup> Tufts Managed Care Institute, *A Brief History of Managed Care 2* (1998), at <http://www.tmci.org/downloads/BriefHist.pdf> ("In the late 1960s and early 1970s, politicians and interest groups of all stripes promoted various proposals for reforming the nation's healthcare system . . . . In 1971, the Nixon Administration announced a new national health strategy: the development of health maintenance organizations (HMOs) . . . . In adopting this policy, the Administration was influenced by Paul Ellwood, MD of Minneapolis, who argued that the structural incentives of traditional fee-for-service medicine had to be reversed in order to achieve positive reform.").

<sup>6</sup> Burns 4/9 at 87; Carol J. Simon et al., *The Effect of Managed Care on the Incomes of Primary Care and Speciality Physicians*, 33 HEALTH SERVICES RES. 2 (1998); Lawrence Casalino, *Markets and Medicine: Barriers to Creating a 'Business Case for Quality*, 46 PERSP. BIO. MED. 38, 39-42 (2002); John G. Day, *Managed Care and the Medical Profession: Old Issues and New Tensions the Building Blocks of Tomorrow's Health Care Delivery and Financing System*, 3 CONN. INS. L.J. 1, 21 (1996); Sherry Glied, *Managed Care*, in 1A HANDBOOK OF HEALTH ECONOMICS (Anthony J. Culyer & Joseph P. Newhouse, eds. 2000).

period at a set price could solve these problems.<sup>7</sup> More generally, many commentators argued that consumers should be given greater control over health care spending and treatment decisions.<sup>8</sup> Over the past three decades, state and federal policy has encouraged the emergence of a range of financing and delivery options, and embraced, to varying degrees, price and non-price competition in health care.

Managed care existed for most of the 20<sup>th</sup> century, but it did not spread widely until the 1980s and early 1990s.<sup>9</sup> In 1980, the overwhelming majority of the population was enrolled in an indemnity insurance plan and managed care organizations (MCOs) accounted for a small percentage of the market. Fifteen years later, these patterns had reversed, and various managed care offerings accounted for an overwhelming majority of the insured population.<sup>10</sup> To be sure, managed care means different things to

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<sup>7</sup> Congress took a significant step in this direction with the Health Maintenance Organization Act of 1973 (HMO Act). The HMO Act provided start-up funds to encourage the development of HMOs, overrode State anti-HMO laws, and required large firms to offer an HMO choice to their employees. Glied, *supra* note 6, at 13.

<sup>8</sup> Agrawal & Veit, *supra* note 2, at 21-22.

<sup>9</sup> Staff and group-model HMOs existed throughout this period, but for much of the 20<sup>th</sup> century had only a modest enrollment and were found primarily in geographically limited areas – principally California and the Pacific Northwest. Agrawal & Veit, *supra* note 2, at 21-22; Thomas Mayer & Gloria Gilbert Mayer, *HMOs: Origins and Development*, 312 NEW ENG. J. MED. 590 (1985).

<sup>10</sup> Glied, *supra* note 6, at 710 ("Beginning in the mid-1980s, enrollment in managed care plans in the US grew very rapidly, more than 10% per year.").

different people, and it has meant different things at different times.<sup>11</sup> Commentators generally agree, however, that MCOs integrate, to varying degrees, the financing and delivery of health care services.<sup>12</sup>

Managed care encompasses a wide array of institutional arrangements for the financing and delivery of health care services.<sup>13</sup> Usually when one speaks of a

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<sup>11</sup> Cara S. Lesser et al., *The End of An Era: What Became of the 'Managed Care Revolution' in 2001?*, 38 HEALTH SERVICES RES. 337 (2003); James C. Robinson, *The End of Managed Care*, 285 JAMA 2622 (2001).

<sup>12</sup> Glied, *supra* note 6, at 708 (“The term managed care encompasses a diverse array of institutional arrangements, which combine various sets of mechanisms, that, in turn, have changed over time.”); Jacob S. Hacker & Theodore R. Marmor, *How Not to Think About “Managed Care,”* 32 U. MICH. J.L. REF. 661, 667-68 (“What exactly constitutes “managed care,” however, has never been clear, even by its strongest proponents. Perhaps the most defensible interpretation of ‘managed care’ is that it represents a fusion of two functions that once were regarded as largely separate: the financing of medical care and the delivery of medical services.”).

*See also* COUNCIL ON MEDICAL SERVICE, AMERICAN MEDICAL ASS’N, PRINCIPLES OF MANAGED CARE 3 (4th ed.1999), available at <http://www.ama-assn.org/ama/upload/mm/363/principles.pdf> (defining “managed care” as “processes or techniques used by any entity that delivers, administers and/or assumes risk for health services in order to control or influence the quality, accessibility, utilization, costs and prices, or outcomes of such services provided to a defined population.”); Academy for Health Mgmt, *A Glossary of Managed Care Terms*, at <http://www.aahp.org/glossary/index.html> (last visited July 13, 2004); Mark A. Kadzielski et al., *Managed Care Contracting: Pitfalls and Promises*, 20 WHITTIER L. REV. 385, 387 (1998).

<sup>13</sup> Health Maintenance Organizations (HMO) are licensed health plans that agree to cover all or most of an enrollees health needs for a

managed care organization, one is speaking of the entity that manages risk, contracts with providers, is paid by employers or patient groups, or handles claims processing. The “tools” of managed care include the creation of networks of preferred providers or the hiring of a staff of employed physicians to provide care, selective contracting based on price, required pre-authorization, restricted access to specialists, restricted panels of providers, higher copayments (and sometimes denial of coverage) for out-of-network care, capitation, bonuses, practice guidelines, retrospective denials of coverage, “real-time” utilization review, restricted coverage of prescription drugs, disease management for chronic illnesses, limitations on benefits, and an emphasis on prevention.

In global terms, managed care offers a more restricted choice of (and access to) providers and treatments in exchange for lower premiums, deductibles, and co-payments than traditional indemnity insurance. Stated differently, managed care inverts, to varying degrees, the incentives of a piece-work based fee-for-service system, and employs a variety of supply- and demand-side strategies to do so.

MCOs typically use three strategies to control costs and enhance quality of care: (i) selective contracting; (ii) direct financial

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predetermined monthly fee, with a designated physician acting as a gatekeeper. Point-of-Service (POS) plans allow patients to select a primary care gatekeeper, yet use out-of-plan physicians for some services. Preferred Provider Organizations (PPOs) are similar to POSs, but generally do not require a coordinating primary care physician.

incentives; and (iii) utilization review.<sup>14</sup> Selective contracting is used to create a restricted networks of providers.<sup>15</sup> Selective contracting intensifies price competition and allows payors to negotiate volume discounts and choose providers based on a range of criteria.<sup>16</sup> The intensity of competition increases with the number of providers and covered lives in the relevant market, and

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<sup>14</sup> GAO, *supra* note 3, at 8 (“Despite the variety of managed care plans, most include the following common cost control features: (1) provider networks, with explicit criteria for selection; (2) alternative payment methods and rates that often shift some financial risk to providers; and (3) utilization controls over hospitals and specialist physicians services.”); SHERMAN FOLLAND ET AL., *THE ECONOMICS OF HEALTH AND HEALTH CARE* 252 (4th ed. 2003); Simon et al., *supra* note 6, at 2 (“Managed care includes a variety of cost-containment strategies used by employers and insurers, such as utilization review (UR), selective contracting, and financial incentives.”).

<sup>15</sup> FOLLAND ET AL., *supra* note 14, at 252; Day, *supra* note 6, at 8-10. On selective contracting more generally, see Simon et al., *supra* note 6, at 2 (stating physicians can be selected on the “basis of their prices, quality history, treatment styles, their willingness to abide by [utilization review], and their willingness to accept financial risk”).

<sup>16</sup> See Michael Morrissey, *Competition in Hospital and Health Insurance Markets: A Review and Research Agenda*, 36 *HEALTH SERVICES RES.* 191 (2001); Gabel 4/23 at 160; Jon Gabel, *Competition Among Health Plan* 3 (4/23) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030423jongabel.pdf>. HMOs also relied on capitation, preauthorization review, and primary care gatekeepers. Gabel 4/23 at 160-61. Plans that engage in selective contracting can also “deselect” a provider who does not meet their needs and requirements. TIMOTHY LAKE ET AL., *MEDICARE PAYMENT ADVISORY COMM’N*, MPR No. 8568-700, *HEALTH PLANS’ SELECTION AND PAYMENT OF HEALTH CARE PROVIDERS*, 1999, at 72-73 (2000) (final report).

with the restrictiveness of the insurance contracts found in the market (*i.e.*, HMOs, which have more limited panels than PPOs, induce more intense price competition among providers than would PPOs of equivalent size).<sup>17</sup>

When insurers have a credible threat to exclude providers from their networks and channel patients elsewhere, providers have a powerful incentive to bid aggressively. Inclusion in a restricted panel offers the provider the prospect of substantially increased revenue. Without such credible threats, however, providers have less incentive to bid aggressively, and even managed care organizations with large market shares may have less ability to obtain low prices.<sup>18</sup>

Direct financial incentives can take a

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<sup>17</sup> Gabel 4/23 at 160. Another panelist stated that provider margins do not begin to fall until at least three HMOs are competing, and that more than 4 or 5 HMOs in a local market have no additional effect on margins. Mazzeo 4/23 at 137-138. Another panelist focused on competition in the Medicare managed care market. Pizer 4/23 at 144.

See also Alan T. Sorensen, *Insurer-Hospital Bargaining: Negotiated Discounts in Post-Deregulation Connecticut*, 51 *J. INDUSTRIAL ECON.* 469 (2003) (noting the “ability of insurers to obtain discounts [is] determined primarily by [the] ability of insurer to channel patients to hospitals with which favorable discounts have been negotiated”); Michael Staten et al., *Market Share and the Illusion of Power: Can Blue Cross Force Hospitals to Discount?*, 6 *J. HEALTH ECON.* 43 (1987) (“Blue Cross obtained substantial discounts only when it had numerous hospitals with which to potentially contract”).

<sup>18</sup> Gabel 4/23 at 160; Douglas R. Wholey et al., *The Effect of Market Structure on HMO Premiums*, 14 *J. HEALTH ECON.* 81 (1995) (“[M]ore competition, measured by the number of HMOs in the market area, reduces HMO premiums”).

variety of forms, including capitation, putting the physician on salary, and paying a bonus (or withholding a percentage of payment) based on meeting clinical and/or financial targets.<sup>19</sup> Capitation pays the provider a fixed amount for each of the patients for whom he agrees to provide care, regardless of whether those patients seek care. Payment is typically based on a set number of dollars “per member-per month.” In the mid-1990s, many commentators believed that capitation would become the basis for compensating most providers. Capitation lost some of its allure when some physician groups that had received capitation payments underestimated the associated costs, and were forced to file bankruptcy.<sup>20</sup> Payors also grew less interested in capitation in the late-1990s, as providers became increasingly reluctant to accept the associated risks. Financial incentives can also be employed to encourage consumers to receive care from particular providers or in particular locations. Co-payments and deductibles are well-recognized forms of demand

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<sup>19</sup> David Orentlicher, *Paying Physicians More To Do Less: Financial Incentives To Limit Care*, 30 U. RICH. L. REV. 155, 158-159 (1996); GAO, *supra* note 3, at 10 (“Managed care plans also use provider payment methods to control costs.”); AMERICAN MEDICAL ASS’N, MODEL MANAGED CARE CONTRACT: WITH ANNOTATIONS AND SUPPLEMENTAL DISCUSSION PIECES 46 (3rd ed. 2002), available at <http://www.ama-assn.org/ama1/pub/upload/mm/368/mmcc-02-public.pdf>; Glied, *supra* note 6, at 714-716; Stephen Latham, *Regulation of Managed Care Incentive Payments to Physicians*, 22 AM. J.L. & MED. 399 (1996).

<sup>20</sup> Peter R. Kongstvedt, *Compensation of Primary Care Physicians in Managed Health Care Plans*, in ESSENTIALS OF MANAGED HEALTH CARE 85, 106 (Peter R. Kongstvedt ed., 4th ed. 2003).

management.<sup>21</sup>

Utilization review appraises the appropriateness and medical necessity of the proposed treatment.<sup>22</sup> Utilization review can be conducted on a retrospective, concurrent, or prospective basis. Although many payors use utilization review, the variety of forms it takes limit the ability to draw general conclusions about its effectiveness.<sup>23</sup>

These strategies can have an effect beyond the consumers covered by the MCO if providers tend to adopt a unitary standard of practice. Providers who must comply with certain quality protocols or report their performance for their MCO patients may (whether consciously or unconsciously)

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<sup>21</sup> See Haiden A. Huskamp et al., *The Effect of Incentive-Based Formularies on Prescription Drug Utilization and Spending*, 349 NEW ENG. J. MED. 2224 (2003) (copayments can affect pharmaceutical spending and usage); Dana P. Goldman et al., *Pharmacy Benefits and the Use of Drugs by the Chronically Ill*, 291 JAMA 2344 (2004) (documenting substantial price responsiveness in pharmaceutical use by the chronically ill); JOSEPH P. NEWHOUSE, FREE FOR ALL? LESSONS FROM THE RAND HEALTH INSURANCE EXPERIMENT (1993); Willard G. Manning et al., *Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment*, 77 AM. ECON. REV. 251 (1987).

<sup>22</sup> See generally GAO, *supra* note 3, at 20 (“By reviewing physicians’ clinical decisions and requiring authorization for some specialist and hospital services, UR attempts to lower costs by avoiding services that do not meet the reviewers’ standards for necessity of care.”).

<sup>23</sup> DRANOVE, *supra* note 1, at 83 (“The bottom line is that there are no studies to date that provide a definitive answer about how UR affects costs, nor are there any studies of whether UR systematically affects quality.”).



adopt those protocols for all their patients.<sup>24</sup>

## **B. The Managed Care Backlash**

Managed care grew so unpopular by the late-1990s that most commentators began referring to a “managed care backlash.”<sup>25</sup> Providers complained about the second-guessing of their clinical judgment, and argued that managed care undermined the doctor-patient relationship and quality of care.<sup>26</sup> Consumers expressed concern that

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<sup>24</sup> Alex D. Federman & Albert L. Siu, *The Challenge of Studying Managed Care as Managed Care Evolves*, 39 HEALTH SERVICES RES. 7 (2004); Lawrence C. Baker, *Managed Care Spillover Effects*, 24 ANN. REV. PUB. HEALTH 435 (2003); Kate M. Bundorf et al., *Impact of Managed Care on the Treatment, Costs, and Outcomes of Fee-for-Service Medicare Patients with Acute Myocardial Infarction*, 39 HEALTH SERVICES RES. 131 (2004).

<sup>25</sup> Bloche 6/10 at 181; Lesser 9/9/02 at 76; Peter Jacobson, *Who Killed Managed Care: A Policy Whodunit?*, 47 ST. LOUIS L.J. 365, 371 (2003) (noting that physicians “provided some of the most vociferous opposition to managed care that contributed to the public backlash beginning in the mid-1990s”); David Mechanic, *The Managed Care Backlash: Perceptions and Rhetoric in Health Care Policy and the Potential for Health Care Reform*, 79 MILBANK Q. 35, 40 (2001) (observing that “[u]nhappy physicians contribute[d] to the managed care backlash . . . .”); David A. Hyman, *Regulating Managed Care: What’s Wrong With A Patient Bill of Rights*, 73 S. CAL. L. REV. 221 (2000). See also *Special Issue The Managed Care Backlash*, 24 J. HEALTH, POL., POL’Y & L. 873-1218 (Issue 5, Oct. 1999).

<sup>26</sup> Mechanic, *supra* note 25, at 41 (“Doctors complain increasingly about not having sufficient time for their patients, and our understanding of managed care leads us to suspect . . . that time is ‘being squeezed out’ of the physician-patient relationship.”); Jacobson, *supra* note 25, at 370 (observing that “[i]n a relatively short period of time,

managed care was restricting choices, limiting access to necessary medical care, and lowering quality.”<sup>27</sup> Consumers were also exceedingly skeptical about the use of direct financial incentives and utilization review.<sup>28</sup> These concerns resulted in a substantial number of state and federal legislative and regulatory initiatives targeting more restrictive forms of managed care, along with private litigation. These

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managed care challenged and undermined . . . core doctrines” such as the physician-patient relationship). See also American Chiropractic Ass’n, *Comments Regarding Health Care and Competition Law and Policy* (Sept. 9, 2003) [Submitted by Daryl D. Wills & James D. Edwards] 1-3 (Public Comment) [hereinafter links to FTC/DOJ Health Care Hearings Public Comments are available at <http://www.ftc.gov/os/comments/healthcarecomments2/index.htm>].

<sup>27</sup> Agrawal & Veit, *supra* note 2, at 41 (noting a survey that reported 58% of Americans thought managed care hurt care quality); Robert J. Blendon et al., *Understanding the Managed Care Backlash*, 17 HEALTH AFFAIRS 83 (July/Aug. 1998) (citing surveys that found 45 percent of American believed that managed care had decreased the quality of health care for patients and that 54 percent of Americans believed that managed care will reduce quality of medical care in the future); Eleanor D. Kinney, *Tapping and Resolving Consumer Concerns About Health Care*, 26 AM. J.L. MED. 335, 339 (2000) (“Consumer concerns about health care vary greatly but pertain primarily to three issues: quality, cost and access.”); Mechanic, *supra* note 25, at 37 (“But a more fundamental reason for the public perception is that most Americans are discomfited by mechanism for doing so.”).

<sup>28</sup> Mark A. Hall, *The Theory and Practice of Disclosing HMO Physician Incentives*, 65 LAW & CONTEMP. PROBS. 207, 214 (2002); Henry T. Greely, *Direct Financial Incentives in Managed Care: Unanswered Questions*, 6 HEALTH MATRIX 53, 70 (1996) (discussing consumers’ concerns that managed care’s use of direct financial incentives will lead to different treatments, at some risk to patients’ health); Robinson, *supra* note 11, at 2623.

initiatives have affected the forms of managed care available in the marketplace, although some commentators believe that competitive responses to the backlash had a bigger impact.<sup>29</sup>

Several commentators have argued that there is a substantial gap between consumer and provider perceptions and the actual impact of managed care.<sup>30</sup> These commentators point to surveys and studies which show that consumers are generally satisfied with their own MCOs, that MCOs do not provide worse quality care than FFS medicine, and that managed care “horror stories” are often exaggerated or highly unrepresentative.<sup>31</sup> Regardless, as Part C

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<sup>29</sup> See Ginsburg 2/26 at 60-61; M. Gregg Bloche & David Studdert, *Law as an Agent of Health System Change*, 23 HEALTH AFFAIRS 29 (Mar./Apr. 2004).

<sup>30</sup> See Richard I. Smith et al., *Examining Common Assertions about Managed Care*, in ESSENTIALS OF MANAGED HEALTH CARE, *supra* note 20, at 71 (examining common assertions about managed care and concluding “[the] claims made by opponents of managed care are often simply wrong”); Mechanic, *supra* note 25, at 36 (arguing that many have “a distorted understanding of the relation between financial constraints and the provision of accessible and competent health care,” and these “factual misconceptions about managed care feed on themselves, make the public anxious, and . . . contribute to an atmosphere of distrust”); Hyman, *supra* note 25, at 241-242.

<sup>31</sup> Smith et al., *supra* note 30, at 72 (noting national surveys that “have reported high levels of consumer satisfaction with managed care plans”); Blendon et al., *supra* note 27, at 82 (“[M]ost insured Americans, regardless of whether they have managed care or traditional coverage, are satisfied with their own health insurance plan.”); Robert H. Miller & Harold S. Luft, *HMO Plan Performance Update: An Analysis Of The Literature, 1997-2001*, 21 HEALTH AFFAIRS 63 (July/Aug. 2002) (“Results from

reflects, less restrictive forms of managed care have become extremely popular in recent years.<sup>32</sup>

### C. *Recent Developments*

#### 1. **The Return of Open Networks and the Rise of Tiering**

New forms of health care delivery have emerged, including preferred provider organizations (PPOs), point-of-service (POS) plans, and “concierge care.” PPOs involve a broad network of providers, who

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seventy-nine studies suggest that both types of plans provide roughly comparable quality of care . . . . Quality-of-care results in particular are heterogeneous, which suggests that quality is not uniform – that it varies widely among providers, plans (HMO and non-HMO), and geographic areas.”); Joseph M. Gottfried & Frank A. Sloan, *The Quality of Managed Care: Evidence from the Medical Literature*, 65 LAW & CONTEMP. PROBS. 103 (2002); R. Adams Dudley et al., *The Impact of Financial Incentives on Quality of Care*, 76 MILBANK Q. 649 (1998).

Negative consumer perceptions were frequently fueled by negative media coverage and political debate. Hyman, *supra* note 25, at 237-241; Jacobson, *supra* note 25, at 381-385; Mechanic, *supra* note 25, at 37 (“The chorus of opposition from physicians and other professionals, negative media coverage, repeated atrocity-type anecdotes, and bashing by politicians all contribute to the public’s discomfort with new arrangements.”).

<sup>32</sup> See Robert E. Hurley et al., *The Puzzling Popularity of the PPO*, 23 HEALTH AFFAIRS 59-60 (2004) (“Consumer backlash, intensified regulatory pressures, provider disenchantment with risk, and the unsustainable pricing practices of plans seeking to buy entry into new markets all conspired to produce a rapid reversal of fortune for the HMO product and stimulate a massive migration in to PPO arrangements.”); William M. Sage & Peter J. Hammer, *A Copernican View of Health Care Antitrust*, 65 LAW & CONTEMP. PROBS. 241 (2002).

agree to accept discounted FFS payments in exchange for participating in the network.<sup>33</sup> POS programs generally require consumers to select a primary care gatekeeper, yet allow them to use out-of-plan providers for services in exchange for a higher co-payment. Some physicians who seek to avoid managed care entirely have begun concierge practices, where they provide personalized care, including house calls to patients willing and able to pay out of pocket for health care costs.<sup>34</sup> The price of these options vary, with consumers facing greater out-of-pocket costs if they select less restrictive options.

Health care financing has also moved toward a tiered system of payment. As the prior paragraph states, and Chapter 5 outlines in greater detail, consumers pay less if they select a restricted managed care plan, or use an in-network provider than if they opt for a less restrictive plan or use an out-of-network provider. As Chapters 3 and 6 explain, tiering is also being used for hospitals and pharmaceuticals. Such strategies expose consumers to an increased share of the economic costs of their decisions.<sup>35</sup>

## 2. Payment for Performance

In health care, payment has generally

not been directly tied to the quality of the services that are provided. Numerous commentators have argued that payment for performance (P4P) should be more widely used. The Institute of Medicine (IOM) recently recommended that financing and delivery systems should “[a]lign financial incentives with the implementation of care processes based on best practices and the achievement of better patient outcomes.<sup>36</sup> A prominent trade association of health plans similarly advocates using “payment incentives that reward quality care.”<sup>37</sup> An open letter in a prominent health policy journal similarly argued that strong financial incentives were necessary to motivate providers to improve quality.<sup>38</sup> Other commentators suggest that “quality-

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<sup>36</sup> INSTITUTE OF MEDICINE (IOM), CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21<sup>ST</sup> CENTURY 184 (2001) (recommending that financing and delivery systems “[a]lign financial incentives with the implementation of care processes based on best practices and the achievement of better patient outcomes. Substantial improvements in quality are most likely to be obtained when providers are highly motivated and rewarded for carefully designing and fine-tuning care processes to achieve increasingly higher levels of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.”).

<sup>37</sup> AMERICA’S HEALTH INSURANCE PLAN, BOARD OF DIRECTORS STATEMENT: A COMMITMENT TO IMPROVE HEALTH CARE QUALITY, ACCESS, AND AFFORDABILITY (Mar. 2004), at <http://www.ahip.org/content/default.aspx?docid=428>. See also Ignagni 5/27 at 59 (“We need to pay for quality and effectiveness, not for overuse, misuse, and underuse.”).

<sup>38</sup> Donald M. Berwick et al., *Pay for Performance: Medicare Should Lead*, 22 HEALTH AFFAIRS 8 (Nov./Dec. 2003). See also Casalino 5/28 at 134 (“[P]hysicians for the most part don’t have an incentive to improve quality . . .”).

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<sup>33</sup> See Hurley et al., *supra* note 32, at 56-58.

<sup>34</sup> Carl F. Ameringer, *Devolution and Distrust: Managed Care and the Resurgence of Physician Power and Authority*, 5 DEPAUL J. HEALTH CARE L. 187, 203 (2002). Some concierge practices charge consumers on a FFS basis for the services they provide, while others impose a flat fee on top of their FFS charges.

<sup>35</sup> See Brewbaker 9/9/02 at 22-26.

incentive programs should be viewed as part of a broader strategy of promoting health care quality through measuring and reporting performance, providing technical assistance and evidence-based guidelines, and, increasingly, giving consumers incentives to select higher-quality providers and manage their own health.”<sup>39</sup> Public and private payors are experimenting with P4P.<sup>40</sup>

Panelists noted that some providers have resisted P4P and tiering programs, and refused to provide information regarding the quality of care they provide.<sup>41</sup> Other

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<sup>39</sup> Meredith B. Rosenthal et al., *Paying for Quality: Providers’ Incentives for Quality Improvement*, 23 HEALTH AFFAIRS 127 (Mar./Apr. 2004).

<sup>40</sup> See David A. Hyman & Charles Silver, *You Get What You Pay For: Result-Based Compensation for Health Care*, 58 WASH. & LEE L. REV. 1427 (2001); Arnold M. Epstein et al., *Paying Physicians For High Quality Care*, 350 NEW ENG. J. MED. 406 (2004); NAT’L HEALTH CARE PURCHASING INSTITUTE, ENSURING QUALITY PROVIDERS: A PURCHASER’S TOOLKIT FOR USING INCENTIVES (The Robert Wood Johnson Foundation) (May 2002); NAT’L COMMITTEE FOR QUALITY ASSURANCE, INTEGRATED HEALTHCARE ASS’N PAY FOR PERFORMANCE PROGRAM: 2004 CLINICAL MEASURE SPECIFICATIONS AND AUDIT REVIEW GUIDELINES (Dec. 2003); The Leapfrog Group, *Leapfrog Compendium*, <http://www.leapfroggroup.org/ir/compendium.htm> (last visited July 13, 2004).

In Britain, the National Health Service is experimenting with a similar P4P strategy. Peter C. Smith & Nick York, *Quality Incentives: The Case of U.K. General Practitioners*, 23 HEALTH AFFAIRS 112 (Mar./Apr. 2004).

<sup>41</sup> Milstein 5/30 at 32; Milstein 5/28 at 179; Tuckson 5/30 at 113 (“There is no question that we have experienced dominant players in the marketplace who basically can say to us, and who say to employers as well on whose behalf we operate, ‘we don’t have to play this quality game because (A) we

panelists noted that providers are concerned about the reliability and validity of P4P measures, and the fact that payors are requiring them to invest in expensive equipment without providing additional funds or evidence that such investments are cost-justified.”<sup>42</sup>

### 3. The Road Forward

As Chapters 2, 3, and 5 reflect, there has been considerable ferment in the health care financing and delivery markets in the last three decades. Such “creative destruction” is one of the benefits of a competitive market.<sup>43</sup> Because no single arrangement is likely to satisfy everyone, diversity of financing and delivery options helps ensure that consumer welfare is maximized. Finally, competition is a process; as one commentator noted, “the superiority of open markets ... lies in the fact

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have got the market; or (B) we are the only game in town. And either way we can thumb our nose at this thing and we will continue to do what we are doing and provide lip service to the people who come here saying we are going to give you some information about quality.”); Probst 5/29 at 90; Romano 5/28 at 95.

<sup>42</sup> Kumpuris 5/30 at 47; KELLY J. DEVERS & GIGI Y. LIU, LEAPFROG PATIENT-SAFETY STANDARDS ARE A STRETCH FOR MOST HOSPITALS 5 (Ctr. for Studying Health Sys. Change, Issue Brief No. 77, 2004), available at <http://www.hschange.org/CONTENT/647/647.pdf>; The Leapfrog Group, *Leapfrog’s Regional Roll-Outs Fact Sheet* (June 2004), at [http://www.leapfroggroup.org/FactSheets/RRO\\_FactSheet.pdf](http://www.leapfroggroup.org/FactSheets/RRO_FactSheet.pdf); Hyman & Silver, *supra* note 40, at 1462-1471.

<sup>43</sup> See JOSEPH SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY 83 (1945) (“This process of Creative Destruction is the essential fact about capitalism. It is what capitalism consists in and what every capitalist concern has got to live in.”).

that the optimum outcome cannot be predicted.”<sup>44</sup>

## II. QUALITY

Quality is an extremely important multi-dimensional attribute of health care.<sup>45</sup> Many health services researchers and providers focus on whether the care that is provided is evidence-based.<sup>46</sup> Economists typically view quality as a component of non-price competition.<sup>47</sup> The IOM defines quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”<sup>48</sup> The Agency for Healthcare Research and Quality (AHRQ) defines quality health care as “doing the right thing at the right time in the right way for the right person and having the best

result possible.”<sup>49</sup> Regulators and most academic commentators have historically employed a three-part framework (structure, process, and outcome) to assess quality of care.<sup>50</sup> Some consumers may focus on how long they must wait for an appointment, and how they are treated when they arrive at the provider’s office.<sup>51</sup> Depending on which of these attributes is emphasized and the particular condition being evaluated, it is possible for the same care to be simultaneously deemed high quality and low quality.<sup>52</sup>

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<sup>49</sup> AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEP’T OF HEALTH & HUMAN SERVICES, NATIONAL HEALTHCARE QUALITY REPORT 10 (2003), at [http://qualitytools.ahrq.gov/qualityreport/download\\_report.aspx](http://qualitytools.ahrq.gov/qualityreport/download_report.aspx).

<sup>50</sup> See Clancy 5/27 at 6-9; Kumpuris 5/30 at 43; Romano 5/28 at 50-61. Structural measures of quality focus on whether particular organizational structures are in place, such as a mechanism for credentialing physicians who seek admission to a medical staff. Process measures of quality focus on whether particular inputs are in place, such as the vaccination rate among a pediatric practice and the number of nurses per patient in an ICU. Outcome measures of quality focus on the results of medical treatment, such as the five year mortality rate following treatment for lung cancer.

<sup>51</sup> Darby 5/30 at 8-9 (“For example, patients value having communication with their provider, being able to have things explained to them in a way that they can understand, and that the provider will listen to them and answer the questions that they have.”); John Kenagy, *Service Quality in Health Care*, 281 JAMA 661 (1999).

<sup>52</sup> See Myers 5/29 at 218, 220. Even if one uses the same definition, it is possible for an institution to provide high quality care for some conditions and low quality care for other conditions. See Clancy 5/27 at 12. An additional complication is that “the proportion of healthcare . . . where there’s clearly one right answer is clearly a minority of what’s provided in healthcare.” *Id.* at 139.

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<sup>44</sup> MARTHA DERTHICK & PAUL J. QUIRK, *THE POLITICS OF DEREGULATION* 124 (1985) (quoting Alfred Kahn, former Administrator of the Civil Aeronautics Board). See also Blumstein 2/27 at 18.

<sup>45</sup> Gaynor 5/28 at 70; Muris 2/26 at 7; Kanwit 9/9/02 at 182.

<sup>46</sup> Thomas Bodenheimer, *The American Health Care System - The Movement for Improved Quality in Health Care*, 340 NEW ENG. J. MED. 488 (1999).

<sup>47</sup> See Pauly 5/28 at 31 (defining quality as “whatever matters that isn’t quantity”); Rosenthal 5/28 at 163; William M. Sage & Peter J. Hammer, *Competing on Quality of Care: The Need to Develop a Competition Policy for Health Care Markets*, 32 U. MICH. J.L. REFORM 1069, 1072-73 (1999). But see Gaynor 5/27 at 77 (“I don’t view . . . price and quality competition as separate issues.”).

<sup>48</sup> IOM, *supra* note 36, at 46.

Several commentators and panelists suggested that many health care providers and health services researchers view quality as effectively binary: a provider is either delivering high quality care to a particular patient or he is not doing so.<sup>53</sup> This paradigm treats the resources of the individual consumer as immaterial to the determination of whether the care is of acceptable quality.<sup>54</sup> Conversely,

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<sup>53</sup> See Hammer 5/28 at 144 (“[F]rom a professional paradigm or health services research paradigm, there’s an absolutist or objective nature of what quality is.”); Hammer 2/27 at 63; Hyman 5/28 at 276. See also William M. Sage et al., *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31 (Mar./Apr. 2003); James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459, 1465-66 (1994).

<sup>54</sup> See, e.g., Blumstein 2/27 at 22-26; James 5/28 at 104-105 (“[V]ery often patients and physicians define quality as spare no expense . . . . The reason that you’d engage in price competition was a hope to increase your patient volume or your treatment volume . . . [physicians] work on a completely different set of incentives, price largely being immaterial.”); Iezzoni 5/28 at 117 (“‘Throw everything that you can possibly do for me, Doctor,’ is how some patients do define quality, although this is going to vary from patient to patient.”); Lomazow 6/10 at 250 (“[D]o you want to run the system on high octane or regular? Do you want to use factory parts or do you want to use knock-offs or rebuilt? The American public deserves the best. They pay for the best.”).

This paradigm similarly treats quality as a purely technical matter that must be handled by providers. See Sfikas 2/27 at 187 (“[W]hen it comes to quality, the dental profession believes that it is the dentists who understand quality”); Opelka 2/27 at 178 (“I am a physician and it is my mission to deliver, what I believe is the highest quality of care to every patient.”). See also Michael L. Millenson, “*Miracle and Wonder*”: *The AMA Embraces Quality Measurement*, 16 HEALTH AFFAIRS 183, 183

economists and legal scholars sometimes treat quality as an attribute that can be traded-off against price and other attributes of health care.<sup>55</sup> Controversy can result from these differing conceptions of quality; in one Hearing session, panelists hotly disagreed over the appropriateness of conducting a cost-benefit analysis of improvements in quality.<sup>56</sup>

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(May/June 1997) (describing an advertisement in the *New York Times* in which a physician has her arm around a patient; the headline reads “She’s my patient. There’s no way I’ll let anyone put a price tag on her life.”); Blumstein 2/27 at 25 (professional paradigm “vested enormous authority in professionals to make fundamental decisions about medical care”).

<sup>55</sup> See Sage 5/29 at 144 (“Competition law treats quality as one attribute of a good or service which must be traded off against price and other attributes, while the medical profession has historically regarding quality as an irreducible minimum to be determined by physicians without reference to cost.”); Hammer 5/28 at 143-144 (“[T]here’s an underlying conflict in the way that economists and antitrust lawyers approach questions of quality than health services research.”). See also Sage et al., *supra* note 53, at 39.

<sup>56</sup> Compare Modell 6/10 at 257 (“If . . . the economist can put to me on paper what one in 400 excess mortality is worth, then I can address that question. As a physician and as someone who has spent hundreds of thousands of our own dollars trying to make anesthesia safer, I can tell you, that number is unacceptable to me”), with Bloche 6/10 at 257-58 (“You need to put a number on that one and 400. Ultimately, what is involved here is the need to come up with a valuation of a life saved. What is this particular method, this particular policy costing in terms of, well, the cost of each life saved? . . . [W]hen we lose those resources because we’re taking the more expensive method of doing this, then we don’t have those resources for other health care needs.”).

See also Guterman 5/29 at 268 (“One thing that occurs to me is deciding sort of in whose eyes quality is to be evaluated. We’ve got a number of payers here and some providers and – you know, and

Commentators and panelists agreed that health care quality actually encompasses many distinct factors, and the delivery system must perform well on each factor if it is to provide high quality care.<sup>57</sup> These factors include whether the medical diagnosis is correct, whether the “right” treatment is selected (with the “right” treatment varying, depending on the underlying diagnosis and patient preferences and resources), whether the treatment is performed in a technically competent manner, whether service quality is adequate, and whether patients are able to access the care they desire without undue travel and inconvenience. Whether cutting edge technology and treatments are available is a component of health care quality, but it is not the only consideration. Information is necessary for consumers to make decisions about the care they will receive, and determine whether they are receiving the type of care they prefer and can afford.

Competition has an important role to play in ensuring that consumers receive high quality care, and informing consumers of the costs and benefits of selecting a particular provider or treatment. Competition law promotes quality by encouraging consumer empowerment through information disclosure, and preventing market

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the title of the session is consumer information, but I think there’s a real difference between what consumers may want and what payers may want.”); Delbanco 5/29 at 269-270 (noting importance of deciding “who is the customer” in health care); McGinnis 5/30 at 53-54 (“The lack of information, and to some degree a lack of agreement on what constitutes high-quality surgical care from both the clinical and patient perspectives creates confusion.”).

<sup>57</sup> See Clancy 5/27 at 18-19; Myers 5/29 at 218-219, 264.

participants from engaging in anticompetitive conduct. At the same time, competition law provides considerable flexibility to market participants to act collectively to improve quality of care.

#### **A. *What Is Known About Health Care Quality?***

In recent decades, technology, pharmaceuticals, and know-how have substantially improved how care is delivered and the prospects for recovery. American markets for innovation in pharmaceuticals and medical devices are second to none. The miracle of modern medicine has become almost commonplace. Americans reap the benefits of new and improved drugs, cheaper generic drugs, treatments with less pain and fewer side effects, and treatments offered in a manner and location consumers desire. At its best, American health care is *the* best in the world.

Commentators and panelists agree that providers are committed to delivering high quality care, that the vast majority of consumers are getting the care they need, and that there have been recent improvements in quality of care.<sup>58</sup> There is,

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<sup>58</sup> AHRQ, *supra* note 49, at 2. See also Carolyn Clancy, *IPA Overview* 28 (5/27) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030527clancy.pdf>; Fisher 5/27 at 42 (“I think physicians are doing their best in settings of real complexity to deliver care that they know should be delivered.”); Ignagni 5/27 at 64; Kumpuris 5/30 at 49 (“The vast majority of physicians are good doctors, motivated to provide quality of care using evidence-based clinical pathways. However, good doctors and bad systems will still result in adverse and undesirable outcomes.”); McGinnis 5/30 at 50-51; Tuckson 5/30 at 82-83 (“Physicians want to do the right thing.”); Nielsen 5/30 at 225 (“We are all partners in this

however, still significant room for further improvement. A 1998 literature review noted that

there are large gaps between the care people should receive and the care they do receive. This is true for all three types of care – preventive, acute, and chronic – whether one goes for a check-up, a sore throat, or diabetic care. It is true whether one looks at overuse or underuse. It is true in different types of health care facilities and for different types of health insurance. It is true for all age groups, from children to the elderly. And it is true whether one is looking at the whole country or a single city . . . A simple average of the findings of the preventive care studies shows that about 50 percent of people received recommended care. An average of 70 percent . . . received recommended acute care, and 30 percent received contraindicated acute care. For chronic conditions, 60 percent received recommended care and 20 percent received contraindicated

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morass, and we all have a vested interest in doing it right.”); Gebhart 6/12 at 227; Kizer 6/11 at 71 (“There’s lots of good things that we do in health care here in the U.S. as far as training of our practitioners; having lots of diagnostic and treatment technology diffused throughout our community; our biomedical research program is the envy of the world and the engine that’s driving development throughout the world; and lots of technology.”); Greenberg 9/9/02 at 180.

care.<sup>59</sup>

Commentators and panelists stated that more recent studies have reached similar conclusions.<sup>60</sup> In particular,

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<sup>59</sup> Mark A. Schuster et al., *How Good Is the Quality of Health Care in the United States?*, 76 MILBANK Q. 517, 520-21 (1998). See also Mark R. Chassin & Robert W. Galvin, *The Urgent Need to Improve Health Care Quality*, 280 JAMA 1000 (1998).

<sup>60</sup> See Berenson 5/30 at 239-40 (noting there are “a couple of JAMA articles documenting quality problems for the Medicare population on . . . 23 measures of [] well accepted process and some outcome measures on quality . . . .”); Fisher 5/27 at 28 (“Errors result in the deaths of thousands. [Leape’s] estimate is that it’s the equivalent of three jumbo jet crashes every two days, dying from a consequence of errors”); Ignagni 5/27 at 133; Gaynor 5/28 at 73 (“It’s been very, very extensively documented. There’s a lot of variation in quality.”); Milstein 5/28 at 178-179 (“[Q]uality failure is severe and invisible.”); Milstein 2/27 at 100-101 (“Large employers and consumer organizations agree with the Institute of Medicine’s reports over the last four years that there’s a very wide gap between the health care that Americans are getting and what health care could and should be . . . . We think the optimality gap with respect to American spending on health care could be as large as 40 percent of the dollars that we’re spending.”); Darling 2/27 at 114; Kanwit 6/25 at 29; Kizer 6/11 at 72; Brewbaker 9/9/02 at 26-31.

See also AHRQ, *supra* note 49, at 2-3; Eve A. Kerr et al., *Profiling the Quality of Care in Twelve Communities: Results From the CQI Study*, 23 HEALTH AFFAIRS 247 (May/June 2004) (“Health care quality falls far short of its potential nationally . . . . We find room for improvement in quality overall and in dimensions of preventive, acute, and chronic care in all of these communities; no community was consistently best or worst on the various dimensions”); Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635 (2003) (“Quality varied substantially according to the particular medical condition, ranging from 78.7 percent of recommended care . . . for senile cataract



commentators and panelists noted that treatment patterns vary significantly; procedures of known value are omitted; and treatments that are unnecessary and inefficacious are performed. Moreover, commentators and panelists noted that considerable sums are spent annually on services whose value is questionable or non-existent.<sup>61</sup> As one commentator stated,

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to 10.5 percent of recommended care . . . for alcohol dependence,” with overall average of half of recommended care provided); Donald M. Berwick, *Errors Today and Errors Tomorrow*, 348 NEW ENG. J. MED. 2570 (2003); Earl P. Steinberg, *Improving the Quality of Care - Can We Practice What We Preach?*, 348 NEW ENG. J. MED. 2681 (2003); John P. Burke, *Infection Control - A Problem for Patient Safety*, 348 NEW ENG. J. MED. 651 (2003); Tejal K. Gandhi et al., *Adverse Drug Events in Ambulatory Care*, 348 NEW ENG. J. MED. 1556 (2003); Chunliu Zhan & Marlene R. Miller, *Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization*, 290 JAMA 1868 (2003) (concluding that failures in care processes for 18 medical complications resulted in more than 32,000 deaths, 2.4 million extra days in the hospital, and more than \$9 billion annually); Stephen F. Jencks et al., *Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998-1999 to 2000-2001*, 289 JAMA 305 (2003); McNeil, *supra* note 1, at 1612 (“The public has just begun to recognize that despite the enormous achievements of American medicine and the American health care system, the quality of care in this country needs to be and can be improved.”).

<sup>61</sup> See Foster 5/29 at 198 (“[W]e all know that mistakes do occur, and there is both overuse and under-use of some diagnostic and treatment procedures, as described in the Institute of Medicine’s landmark reports, *To Err is Human* and *Crossing the Quality Chasm*.”); Myers 5/29 at 217-218 (“We cannot, of course, ignore the Institute of Medicine studies that have been referenced earlier and the studies that are in the hopper both within the Institute of Medicine and by other agencies . . . .”); Kumpuris 5/30 at 41 (“[E]fforts to improve health care quality are not only needed, but long overdue. In

“quality problems . . . abound in American medicine. The majority of these problems are not rare, unpredictable, or inevitable concomitants of the delivery of complex, modern health care. Rather, they are frighteningly common, often predictable, and frequently preventable.”<sup>62</sup>

Commentators and panelists noted

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2001, the Institute of Medicine published ‘Crossing the Quality Chasm’ which found that the United States health care system does not uniformly and consistently deliver high quality care to all patients. A diverse literature addresses this variation in health quality and the difficulties in measuring those differences. Although the conclusions of this landmark IOM report are seldom disputed, the reasons are far from agreed upon.”); O’Kane 5/30 at 67-70; Milstein 5/28 at 183-184 (“[T]he probability of there being a great hospital that warrants a great brand name, based on the current evidence, is close to zero.”); Gebhart 6/12 at 222-223.

See also Schuster et al., *supra* note 59, at 518 (differentiating between too much care, too little care, and the wrong care); Mark R. Chassin, *Is Health Care Ready for Six Sigma Quality?*, 76 MILBANK Q. 565, 570-78 (1998) (differentiating between overuse, underuse, and misuse); David P. Phillips et al., *Increase in U.S. Medication-Error Deaths between 1983 and 1993*, 351 LANCET 255 (1999); David W. Bates et al., *Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention*, 274 JAMA 29 (1995).

<sup>62</sup> Chassin, *supra* note 61, at 566. See also Bodenheimer, *supra* note 46, at 488; Medicare Payment Advisory Committee (MedPAC), *Quality of Care in the Medicare Program*, in REPORT TO THE CONGRESS: VARIATION AND INNOVATION IN MEDICARE § 2, at 17 chart 2-1 (June 2003) (finding between 2000 and 2001, when a patient was admitted with a heart attack, 31 percent of patients did not receive beta blockers within 24 hours of admission, 21 percent did not receive beta blockers upon discharge, and 43 percent of smokers were not advised to stop), at [http://w3.votenet.com/newmedpac/publications%5Ccongressional\\_reports%5CJun03DataBookSec2.pdf](http://w3.votenet.com/newmedpac/publications%5Ccongressional_reports%5CJun03DataBookSec2.pdf).

that medical treatments can injure consumers. The IOM estimated that medical errors during inpatient hospitalization caused between 44,000 and 98,000 deaths per year – making medical errors the eighth leading cause of death in the United States.<sup>63</sup> According to the IOM, every year medical errors in the hospital kill more people than motor vehicle accidents, breast cancer, and AIDS – without even counting the consequences of medical errors and low quality care in the outpatient setting.<sup>64</sup> To be sure, these problems are not unique to American health care.<sup>65</sup>

Commentators and panelists agreed that “in American health care, geography is destiny. Both the amounts and kinds of care provided to residents of the United States are highly dependent on two factors: the capacity of the local health care system

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<sup>63</sup> See INSTITUTE OF MEDICINE (IOM), TO ERR IS HUMAN 22 (1999). These figures have been disputed. Compare Rodney A. Hayward & Timothy P. Hofer, *Estimating Hospital Deaths Due to Medical Errors: Preventability is in the Eye of the Reviewer*, 286 JAMA 415 (2001), and Christopher M. Hughes et al., *Deaths Due to Medical Errors are Exaggerated in Institute of Medicine Report*, 284 JAMA 93 (2000), with Lucian L. Leape, *Institute of Medicine Medical Error Figures Are Not Exaggerated*, 284 JAMA 95 (2000). See also Lucian Leape, *Error in Medicine*, 272 JAMA 1851 (1994) (estimating that injuries caused by physicians during inpatient hospitalization accounted for 180,000 deaths per year).

<sup>64</sup> IOM, *supra* note 63, at 1. One panelist noted that despite extensive publicity, Americans dramatically underestimate the number of preventable in-hospital deaths attributable to medical errors. Milstein 5/29 at 244.

<sup>65</sup> See Kanwit 2/27 at 117; Elizabeth A. McGlynn, *There is No Perfect Health System*, 23 HEALTH AFFAIRS 100 (May/June 2004).

(which influences how much care is provided) and the practice style of local physicians (which determines what kind of care is provided).”<sup>66</sup> The cost of care varies

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<sup>66</sup> Faculty of the Ctr. for the Evaluative Clinical Sciences, Dartmouth Medical School, *The Dartmouth Atlas of Medical Care* (1999), [http://www.dartmouthatlas.org/99US/chap\\_0\\_sec\\_1.php](http://www.dartmouthatlas.org/99US/chap_0_sec_1.php). See also Fischer 5/27 at 34-35; 40-41, 43; Milstein 2/27 at 122 (“[M]ost of the big dollar variation from region to region in how much it costs . . . is not driven by differences in consumer demand. It’s driven by . . . supply-sensitive services . . .”); Antos 9/30 at 119-120 (“[T]here are large variations in practice patterns across the United States that clearly indicate that medical care is practiced in peculiar and often inefficient ways”); Fisher 5/27 at 30-32; Bloche 6/10 at 169; Milstein 2/27 at 122-123 (“[M]ost of the big dollar variation from region to region . . . is not driven by differences in consumer demand. Its driven by what Dartmouth would refer to as supply sensitive services . . . only about 7 to 8 percent of health care cost differences are rooted in what’s called preference sensitive services . . .”); Greaney 2/27 at 222; Elliot S. Fisher et al., *The Implications of Regional Variations in Medicare Spending, Part 1*, 138 ANNALS INTERNAL MED. 273 (2003); John E. Wennberg et al., *Geography And The Debate Over Medicare Reform*, 2002 HEALTH AFFAIRS (Web Exclusive) W96, 96-97, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.96v1>.

Such variation may not correspond to consumer preferences. See generally Foundation for Informed Medical Decision Making (“The decision that will best serve a particular patient often depends critically on the patient’s own preferences and values. The treatment that is best for one patient may not be what is best for another who is in exactly the same situation . . . a growing body of research shows that when patients are well informed and play a significant role in deciding how they are going to treat or manage their health conditions, things work out better. Informed patients feel better about the decision process. Their decisions are more likely to match up with their preferences, values and concerns. These patients are more likely to stick with the regimens the treatment requires, and they often end up rating their health after treatment as better.”), at [http://www.fimdm.org/shared\\_decision\\_making.php](http://www.fimdm.org/shared_decision_making.php) (last visited July 14, 2004). See also Richard A.

as well: in the lowest quintile of regional spending, it costs an average of \$3,922 per Medicare enrollee per year to provide care, while in the highest quintile of regional spending it costs \$6,304 to provide care.<sup>67</sup> One panelist noted that providers deliver more services in high-cost areas, but the additional services generally do not correspond to higher use of evidence-based protocols or better outcomes.<sup>68</sup> For example, one study found 56 percent of the patients in the lowest spending region and 50 percent of patients in the highest spending region received optimal treatment for a heart attack.<sup>69</sup> Similar patterns were observed for the provision of preventative care.<sup>70</sup> One study indicates that there is an inverse relationship between Medicare spending per beneficiary and quality of care,

and higher spending actually purchases lower quality care.<sup>71</sup>

To summarize, health care quality could be improved. The next section considers the beneficial role of competition in accomplishing this objective.

## **B. Competition and Quality**

The relationship between competition and health care quality has not been studied as extensively as the relationship between competition and health care cost. One panelist reviewed the available studies and concluded that “the best evidence thus far is that quality is higher where we would think markets would be more competitive.”<sup>72</sup>

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Deyo et al., *Involving Patients in Clinical Decisions: Impact of an Interactive Video Program on Use of Back Surgery*, 38 MED. CARE 959 (2000); Joseph F. Kasper et al., *Developing Shared Decision-Making Programs to Improve the Quality of Health Care*, 18 QUALITY REV. BULL. 183 (1992); Michael J. Barry et al., *Watchful Waiting Versus Immediate Transurethral Resection for Symptomatic Prostatism: The Importance of Patients' Preferences*, 259 JAMA 3010 (1988).

<sup>67</sup> Fisher 5/27 at 31; Elliot Fisher, *What are the Underlying Causes of Poor Quality and High Costs?* 6 (5/27) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030527fisher.pdf>. These figures are adjusted for age, race, morbidity, and a substantial number of other factors.

<sup>68</sup> Fisher 5/27 at 31-40.

<sup>69</sup> *Id.* at 35-36. Elliot Fisher et al., *The Implications of Regional Variations in Medicare Spending, Part 2: Health Outcomes and Satisfaction with Care*, 138 ANNALS OF INTERNAL MED. 288 (2003).

<sup>70</sup> Fisher 5/27 at 35.

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<sup>71</sup> Katherine Baicker & Amitabh Chandra, *Medicare Spending, The Physician Workforce, and Beneficiaries' Quality of Care*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-184, 187-88, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.184v1>. See also Fisher 5/27 at 39 (discussing his study that showed “as you moved up to the highest spending regions there’s a two and half percent higher risk of death in the highest spending regions compared to the lowest spending regions”); Brewbaker 9/9/02 at 30.

<sup>72</sup> See Gaynor 5/27 at 78-79, 81-84; Wong 5/28 at 187-199; Town 5/28 at 199-209; Kessler 5/28 at 210-226; Gaynor 2/26 at 125. See also Gautam Gowrisankaran & Robert Town, *Competition, Payer, and Hospital Quality*, 38 HEALTH SERVICES RES. 1403 (2003) (“[E]stimates indicate that increasing competition for HMO patients appears to reduce prices and save lives and hence appears to improve welfare. However, increases in competition for Medicare appear to reduce quality and may reduce welfare. Increasing competition has little net effect on hospital quality for our sample.”); Daniel P. Kessler & Mark B. McClellan, *Is Hospital Competition Socially Wasteful?*, 115 Q.J. ECON. 577 (2000) (finding that welfare effects of competition in

More studies have been done regarding the impact of consumer information on quality. Information regarding quality allows consumers to make their own determinations of how best to balance those attributes that are important to them, obtain value for their money, and drive improvements throughout the system. If consumers are poorly informed about quality, providers may offer an inefficiently low level of quality.<sup>73</sup> Not all consumers must be well-informed for the market to deliver an efficient level of quality. All that is required is that a sufficient number of consumers be well-informed about prices and quality levels of different sellers.<sup>74</sup>

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the 1980s were ambiguous, but in the 1990s, competition unambiguously improves social welfare, in Medicare patients who suffered a heart attack). *But see* Kevin G. M. Volpp et al., *Market Reform in New Jersey and the Effect on Mortality From Acute Myocardial Infarction*, 38 HEALTH SERVICES RES. 515 (2003) (finding an increase in post-heart attack mortality in New Jersey after competition increased (as a result of repeal of rate-setting statute) and subsidies for inpatient care for the uninsured decreased).

<sup>73</sup> See COUNCIL OF ECONOMIC ADVISORS, ECONOMIC REPORT OF THE PRESIDENT, PROMOTING HEALTH CARE QUALITY AND ACCESS 147 (2002) (“In most market settings, consumers’ purchase decisions are based on good information on the value of the products they buy. But in healthcare the lack of good information on the success of different treatments – in terms of the best outcomes per dollar – means that individuals and families have difficulty making informed decisions, and insurance companies are not rewarded for altering their coverage to encourage high-value care.”).

<sup>74</sup> See Gaynor 5/27 at 81 (“[I]f you have enough that are well informed and sellers can’t readily discriminate between well-informed and less-well-informed individuals, the well-informed individuals can help drive the market.”); Herzlinger 5/27 at 94; Rosenthal 5/28 at 166.

These informed consumers can help drive the market to a competitive outcome.

Consumers will use such information to select health plans, providers, and treatments that accord with their preferences if the information is presented in a usable fashion.<sup>75</sup> Publicly available “report cards” can motivate providers to address quality deficiencies, even when it unclear whether consumers are relying on such information.<sup>76</sup>

Although competition can play an important role in enhancing quality of care, there are informational and payment barriers to effective competition. The next section turns to these matters.

## C. *Barriers to Improving Quality*

### 1. **Informational Barriers to Improving Quality**

In many markets, consumers have ready access to reliable information with

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<sup>75</sup> See James 5/28 at 122-23; Fraser 5/28 at 329-330; JUDITH H. HIBBARD ET AL., AARP PUBLIC POL’Y INSTITUTE, #2000-14, OLDER CONSUMERS’ SKILL IN USING COMPARATIVE DATA TO INFORM HEALTH PLAN CHOICE: A PRELIMINARY ASSESSMENT (2000) (finding consumers more likely to use information that is presented in a usable fashion), at [http://research.aarp.org/health/2000\\_14\\_choice.pdf](http://research.aarp.org/health/2000_14_choice.pdf).

<sup>76</sup> Judith H. Hibbard et al., *Does Making Hospital Performance Public Increase Quality Improvement Efforts?*, 22 HEALTH AFFAIRS 84 (Mar./Apr. 2003); Mark R. Chassin, *Achieving and Sustaining Improved Quality: Lessons From New York State and Cardiac Surgery*, 21 HEALTH AFFAIRS 48 (July/Aug. 2002); Eric C. Schneider & Arnold M. Epstein, *Influence of Cardiac-Surgery Performance Reports on Referral Practices and Access to Care: A Survey of Cardiovascular Specialists*, 335 NEW ENG. J. MED. 251 (1996).

which to assess the quality of the goods and services they intend to purchase. Such information allows consumers to define and exercise their preferences along the dimensions of health care quality that are important to them.<sup>77</sup> Information regarding quality is useful to consumers, providers, payors, and state and federal agencies. Unfortunately, in health care, such information is often difficult to obtain and is not necessarily reliable.<sup>78</sup> Panelists

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<sup>77</sup> See Ignagni 5/27 at 48 (“[F]or our competitive markets to work, information, access is key.”); Romano 5/29 at 46-47 (“[M]arket-oriented goals really focus on providing information that addresses the asymmetry of information [in] the marketplace and empowering consumers to demand better health care, giving them the information, the tools that they need to make better-informed choices that theoretically maximize their utility.”); Stoddard 5/29 at 249 (“In theory, [if] patients are given accurate information about the quality and price of hospital and physician services[, t]hey will choose the providers that offer the best value for them.”). See also William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999).

<sup>78</sup> Fisher 5/27 at 123 (“I think it’s remarkable to the degree to which we agreed on the need for better information in health care.”); Probst 5/29 at 89-91 (noting difficulty in obtaining information from hospitals about process measures of quality); Millenson 5/27 at 104-113; Darling 2/27 at 78; Matthews 9/24 at 141-42 (noting difficulty in obtaining information regarding price and value of services); Knettel 6/25 at 114 (number one priority should be “to put in place the infrastructure that’s needed to provide for . . . much more transparent health care purchasing decision-making.”); Meghrihan 9/24 at 84 (“[M]any consumers are very knowledgeable and able to tell who are and who are not good physicians, but . . . many consumers still don’t have an idea in terms of who is a good clinical physician . . .”). As one panelist noted, “historically, decisions on which hospital to use have not been based on information but have been based almost exclusively on what the patient’s doctor has

discussed a variety of public and private sector initiatives for increasing the availability of information regarding quality.<sup>79</sup>

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recommended or where that patient’s doctor actually practices.” Tirone 5/29 at 233. See also Frances H. Miller, *Illuminating Patient Choice: Releasing Physician-Specific Data to the Public*, 8 LOY. CONSUMER L. REV. 125 (1995-1996).

A related set of issues is raised in teaching hospitals, where there have been complaints about the nature of disclosure regarding the level of professional training of those rendering services and the services that will be provided. Compare Wilson 6/10 at 8-31, with Bondurant 5/30 at 34-37. See also Michael Greger, *Comments Regarding Hearings on Health Care and Competition Law and Policy* (Public Comment); Noreen Farrell Nickolas, *Comments Regarding Health Care and Competition Law and Policy (July 17, 2003)* (Public Comment). More broadly, information communication between providers and consumers has a substantial impact on consumer satisfaction and the risk of a malpractice claim. See Levinson 5/30 at 161-174.

Finally, some of the information that is available is unreliable because it is false or deceptive. The Commission has played an important role in addressing such conduct in health care, while simultaneously encouraging truthful non-deceptive advertising. See Timothy J. Muris, *Everything Old is New Again: Health Care and Competition in the 21st Century*, Prepared Remarks for the 7th Annual Competition in Health Care Forum (Nov. 7, 2002), at <http://www.ftc.gov/speeches/muris/murishealthcaresp/eech0211.pdf>. See also Carabello 6/12 at 161-178; Lee 6/12 at 179-189; Koch 6/12 at 190-199.

<sup>79</sup> Foster 5/29 at 199-200; Tuckson 5/30 at 82 (“So CMS is about to come out with their physician performance measures. The Bridges to Excellence we just heard about. The IOM has its guidance. NCQA has been leading this for years now. NQF has its performance measures that it is moving forward with. The Leapfrog Group is moving from hospitals to performance measurement. And at the base of all of this for us is the essential organization, the AMA’s Physician Consortium for Performance Improvement. Lots of people are in the drama.”); Milstein 5/30 at 33 (“[S]ignificant efforts by the Leapfrog Group, the Consumer Purchaser Disclosure

CMS has joined with hospitals and the Quality Improvement Organizations (QIOs) in Maryland, New York, and Arizona to design a group of pilot tests for publicly reporting hospital performance measures.<sup>80</sup> There is also a voluntary public-private program for reporting the same measures involving hospitals in every state.<sup>81</sup> In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides that hospitals that report the requested data of quality will receive a full market basket update in hospital payments during 2005-2007, and hospitals that do not will have their payments reduced by 0.4

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Project, and other progressive market forces, such as those catalyzed by NCQA, are already promoting such transparency-based market solutions.”); Dana 6/12 at 159 (“AHCA has developed a model to encourage its state affiliates to begin developing a satisfaction-based consumer guide. The model focuses on reporting a nursing home’s three-year trend of family satisfaction, family willingness to recommend, and staff willingness to recommend, as well as the inspection data, but presented as a percentage of the 495 standards that each nursing home must meet.”); Ignagni 5/27 at 53-54; Millenson 5/27 at 120; Kessler 5/29 at 68-73 (differentiating between survey, process, and outcome report cards).

<sup>80</sup> CMS is using ten measures relating to three medical conditions – acute myocardial infarction (heart attack), congestive heart failure, and pneumonia. See Foster 5/29 at 208-10; Guterman 5/29 at 178-79; Centers for Medicare & Medicaid Services, *CMS Hospital Three-State Pilot: Centers for Medicare & Medicaid Services Fact Sheet* (Feb. 18, 2004), at <http://www.cms.hhs.gov/quality/hospital/3StateFactSheet.pdf>. One panelist noted these measure are a subset of data already collected by the Joint Commission of Accreditation of Health Care Organizations. Tirone 5/29 at 236.

<sup>81</sup> See Kahn 5/29 at 126-128; Foster 5/29 at 209; Centers for Medicare & Medicaid Services, *Hospital Quality Initiatives (HQI)*, <http://www.cms.hhs.gov/quality/hospital> (last modified May 7, 2004).

percent.<sup>82</sup>

CMS has successfully used public reporting of quality information to improve dialysis care. Since public reporting began in 1996, the number of patients receiving inadequate dialysis or experiencing anemia declined substantially.<sup>83</sup> CMS is currently using similar strategies for disseminating quality information regarding home health care and long term care providers.<sup>84</sup>

Similarly, in 1989, New York state began making provider-specific outcomes for cardiac surgery (including coronary artery bypass grafts (CABG)) publicly available. By 1992, one study found risk-adjusted mortality had dropped 41 percent statewide, giving New York the lowest risk-

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<sup>82</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 501, 117 Stat. 2066 (2003).

<sup>83</sup> In 1994, the government began collecting clinical information annually on four key care indicators of quality for patients with end stage renal disease. Centers for Medicaid & Medicare Services, *End Stage Renal Disease Program: Core Indicators Project*, at <http://www.cms.hhs.gov/esrd/4.asp> (last modified May 16, 2002). In 1996, 26 percent of patients received inadequate dialysis. By 2001, these figures had declined to 11 percent. MedPAC, *supra* note 62, at 19 chart 2-3.

<sup>84</sup> Guterman 5/29 at 176-77; Centers for Medicare & Medicaid Services, *Nursing Home Quality Initiative*, at <http://www.cms.hhs.gov/quality/nhqi> (last visited July 13, 2004); Centers for Medicare & Medicaid Services, *Home Health Quality Initiative*, at <http://www.cms.hhs.gov/quality/hhqi> (last visited July 13, 2004). A number of demonstration projects involving physicians are also underway. Centers for Medicare & Medicaid Services, *Physician Focused Quality Initiative*, at <http://www.cms.hhs.gov/quality/pfqi.asp> (last visited July 13, 2004).

adjusted mortality.<sup>85</sup> Studies show the mortality rate has continued to fall.<sup>86</sup> Pennsylvania experienced similar improvements when it began collecting and publishing risk-adjusted report cards.<sup>87</sup> Several other states provide either volume information for specific conditions or quality ratings based on clinical quality measures.<sup>88</sup>

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<sup>85</sup> See E.L. Hannan et al., *The Decline in Coronary Artery Bypass Graft Surgery Mortality in NY State*, 273 JAMA 209 (1995).

<sup>86</sup> See E.D. Peterson et al., *The Effects of New York's Bypass Surgery Provider Profiling on Access to Care and Patient Outcomes in the Elderly*, 32 J. AM. C. OF CARDIOLGY 993 (1998) (finding a 33 percent decrease in risk-adjusted mortality in New York for CABG and a 19 percent decrease in risk-adjusted mortality rates across the nation).

<sup>87</sup> See Arnold M. Epstein, *Public Release of Performance Data: A Progress Report From the Front*, 283 JAMA 1884, 1885 (2000); Martin N. Marshall et al., *The Public Release of Performance Data: What Do We Expect to Gain?*, 283 JAMA 1866 (2000).

<sup>88</sup> See, e.g., Illinois Health Care Cost Containment Council, *2000 Hospital Care Buyer's Guides*, at <http://www.state.il.us/agency/hcccc/consumerreports.htm#hcbg> (last visited July 13, 2004); Virginia Health Information, *Cardiac Care: Introduction*, at [http://www.vhi.org/info\\_cardiac.asp](http://www.vhi.org/info_cardiac.asp) (last visited July 13, 2004); Texas Health Information Council, *Indicators of Inpatient Care in Texas Hospitals, 2002*, <http://www.thcic.state.tx.us/IQIReport2002/IQIReport2002.htm> (last visited July 13, 2004); Office of Statewide Health Planning & Development, *California Report on Coronary Artery Bypass Graft (CABG) Surgery 1999 Hospital Data (2003)*, at <http://www.oshpd.cahwnet.gov/HQAD/HIRC/hospital/Outcomes/CABG/> (revision date Apr. 1, 2004); Pennsylvania Health Care Cost Containment Council, *Hospital Performance Reports*, <http://www.phc4.org> (last visited July 13, 2004); Quality Counts (WI), at <http://www.qualitycounts.org> (last visited July 13, 2004).

The National Committee for Quality Assurance (NCQA) also developed the Health Plan Employer Data and Information Set (HEDIS) to help assess health plans. HEDIS uses more than 50 measures of provider and plan performance in areas such as patient satisfaction, childhood immunization, and mammography screening rates. HEDIS scores have been shown to affect employee plan choice.<sup>89</sup> A number of other private initiatives seek to make similar quality-related information available to employers, health plans, and the general public.<sup>90</sup> Additionally, AHRQ issues a national report on the state of the quality of care being provided.<sup>91</sup>

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<sup>89</sup> Nancy D. Beaulieu, *Quality Information and Consumer Health Plan Choices*, 21 J. HEALTH ECON. 43 (2002); G. J. Wedig & M. Tai-Seale, *The Effect of Report Cards on Consumer Choice in the Health Insurance Market*, 21 J. HEALTH ECON. 1031 (2002).

HEDIS scores may have a more limited impact when consumers do not have a choice among competing health plans, and when low-scoring plans elect to withhold their scores. Bodenheimer, *supra* note 46, at 490 (noting that 47 percent of employees in large companies and 80 percent of employees in small firms have no choice among health plans). If employers rely on HEDIS scores in selecting the plans to offer their employees, this would not be a problem, but there is some evidence that employers do not use HEDIS scores in this fashion. See *infra* note 92, and accompanying text.

<sup>90</sup> See, e.g., Bridges to Excellence, <http://www.bridgestoexcellence.com/bte> (last visited July 13, 2004). The National Quality Forum develops consensus standards and identifies best practices. See Kizer 6/11 at 72-74, 79-84; National Quality Forum, <http://www.qualityforum.org> (last visited July 13, 2004).

<sup>91</sup> Fraser 5/29 at 156. Congress mandated annual reports by AHRQ. Irene Fraser, *The Nexus of Cost and Quality: Four AHRQ Initiatives* 10-17 (5/29) (slides), at <http://www.ftc.gov/ogc/healthcare>

Although information on quality is becoming more available, the benefits and costs of information-driven strategies are disputed. Panelists stated that consumers will use report cards if they are designed appropriately and the quality measures are sufficiently salient.<sup>92</sup> One panelist noted

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hearings/docs/030529fraser.pdf.

<sup>92</sup> See Romano 5/29 at 50-60; Patrick S. Romano, *Public Reporting on Provider Quality: What We Know, What We Need to Know* 3 (5/29) (slides) (describing studies), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030529romano.pdf>; O’Kane 5/30 at 73 (“We don’t want to hear about these HEDIS measures. We didn’t get a Ph.D. but we are interested in hearing how this plan helps me stay healthy, how well they take care of people with chronic illness and so forth.”); Sofaer 5/30 at 214; Dana 6/12 at 157-159 (“Most consumers don’t want confusing clinical statistics or deficiency information. They simply want to know which facilities have the most satisfied residents and families.”); Paul 6/11 at 247-248 (“What I hear from consumers a lot is that outcome measures just resonate better for people. You know, it’s easier to understand infection rates or death rates, mortality rates or whatever, than it is to understand . . . the measures that we have on hospitals . . . [and measures] that have to do with left ventricular systolic dysfunction.”).

See also Jon Christianson et al., *Early Experience with a New Model of Employer Group Purchasing in Minnesota*, 18 HEALTH AFFAIRS 100, 112 (Nov./Dec. 1999); Robert Galvin & Arnold Milstein, *Large Employers’ New Strategies in Health Care*, 347 NEW ENG. J. MED. 939, 940-41 (2002).

Panelists and commentators identified a number of reasons why consumers have not embraced available quality information. See Foster 5/29 at 202-04; Crofton 5/30 at 17 (“The first lesson that we learned is that people want information about health care quality but they won’t use that information unless it is easy to understand and to apply”); Hibbard 5/29 at 32-33; Delbanco 5/29 at 193; Milstein 5/29 at 29-30; Ateev Mehrotra et al., *Employers’ Efforts to Measure and Improve Hospital Quality: Determinants of Success*, 22 HEALTH AFFAIRS 60 (Mar./Apr. 2003) (identifying six factors that limit usability of report cards, including

report cards have not had the desired effects because “consumers are not aware of the quality problems that have been observed in health care,” and that performance reports “have not really been designed to help people make choices.”<sup>93</sup> On the other hand, one study found that employers did not use data on quality to determine which health plans they should offer to their employees,<sup>94</sup>

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ambiguity of goals, conflicts over the measurements employed; questions of the benefits from public release; lack of economic incentives; lack of employer bargaining power; and failure to ask hospitals to collaborate on the measurements); Arnold Milstein & Nancy E. Adler, *Out Of Sight, Out Of Mind: Why Doesn’t Widespread Clinical Quality Failure Command Our Attention?*, 22 HEALTH AFFAIRS 119 (Mar./Apr. 2003) (identifying several behavioral economic reasons why consumers tolerate low quality, including optimistic bias, bias in favor of the individual, desire to trust providers, bias toward authority, and cognitive dissonance); Judith H. Hibbard et al., *Making Health Care Report Cards Easier to Use*, 27 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 591 (2001); Judith H. Hibbard et al., *Increasing the Impact of Health Plan Report Cards by Addressing Consumer Concerns*, 19 HEALTH AFFAIRS 138 (Sept./Oct. 2000) (noting importance of making quality information readily accessible to consumers).

One panelist identified several steps to make report cards more useful to consumers, and stated that the redesigned report card had a “viral effect” with people talking about it and making recommendations to one another. Hibbard 5/29 at 34-40.

<sup>93</sup> Hibbard 5/29 at 29-33 (“If you step back and you look, the quality problem is not visible to people. They don’t really think that there are differences. And then we give them these reports that are really hard to use and that require a lot of hard work. So, is it really any wonder that people aren’t using them?”); Foster 5/29 at 202-204.

<sup>94</sup> JON R. GABEL ET AL., WHEN EMPLOYERS CHOOSE HEALTH PLANS DO NCQA ACCREDITATION AND HEDIS DATA COUNT? (1998), at [http://www.cmwf.org/programs/health\\_care/gabel\\_ncqa\\_hedis\\_2](http://www.cmwf.org/programs/health_care/gabel_ncqa_hedis_2)



and another noted that the use of performance measures for evaluating PPOs, which account for a growing share of the delivery market, is controversial.<sup>95</sup>

Several panelists noted that the usefulness of information disclosure depends on the target audience and the desired objectives. Different information and disclosure strategies may be preferable, depending on whether the goal is to “inform policy makers,” “monitor progress over time,” “provide some benchmarks for the future, identify some areas for improvement . . . [or] serve as a catalyst for action, both in improving quality and improving the quality of the measures and the data themselves.”<sup>96</sup> Panelists also noted that the disclosure of information to the public can “encourage professionals to recognize and fix deficiencies in health-care quality through a kind of self-regulatory behavior.”<sup>97</sup>

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<sup>95</sup> See Dennis P. Scanlon et al., *Options for Assessing PPO Quality: Accreditation and Profiling as Accountability Strategies*, 58 MED. CARE RES. REV. S70 (2001); Lawrence C. Kleinman, *Conceptual and Technical Issues Regarding the Use of HEDIS and HEDIS-like Measures in Preferred Provider Organizations*, 58 MED. CARE RES. REV. S37 (2001).

<sup>96</sup> Fraser 5/29 at 158. See also Fisher 5/27 at 29 (causes of poor quality and high cost are “a flawed understanding of medical care . . . inadequate information to support wise decisions and flawed incentives.”).

<sup>97</sup> Romano 5/29 at 47. See also Clancy 5/27 at 24 (“The literature to date suggest modest, although a growing impact on consumer decisions and a slightly more impressive impact on individual providers.”); Romano 5/29 at 65 (“[T]he observed effects of report cards on consumer choice are small, transient, and hard to demonstrate in practice.”); Guterman 5/29 at 173; Scully 2/26 at 36-37 (“It has a

A variety of other concerns were also expressed about report cards and information disclosure strategies.<sup>98</sup> One panelist stated that providers believe payors intend to use the results to lower payments to providers instead of improve quality.<sup>99</sup> Commentators and panelists identified concerns about the clinical validity and generalizability of particular measures, the time-lag between treatment and the generation of the report card, the way in which results are risk-adjusted, and how

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big impact if you start putting patient quality information out there because the boards of the nursing homes start asking their employees, how come we have the number one number of bed sores in the community.”); Ginsburg 2/26 at 76-77 (“[H]ospitals pay a lot of attention to [report cards] and they actually have a beneficial effect from hospitals seeing where they’re weak and looking into why they’re weak and trying to do something about it. We often don’t see much use of report cards by employers or consumers and hospitals have been resistant to them and have closed down some efforts”). Whether the conduct is described as “self-regulatory” or as a predictable response to doing poorly in a competitive market, the more important point is that improvement follows from information disclosure.

<sup>98</sup> See Berenson 5/30 at 238; Nielsen 5/30 at 228; Nancy Nielsen, *Health Care Competition Law and Policy – Quality and Consumer Information: Physicians* 4 (5/30) (“[I]t remains statistically difficult to assess individual physician competence or distinguish among physicians on outcomes”), at <http://www.ftc.gov/os/comments/healthcarecomments/2/030530nielsen.pdf>; Probst 5/29 at 95. See also Stephen F. Jencks, *Clinical Performance Measurement: A Hard Sell*, 283 JAMA 2015 (2000).

<sup>99</sup> Sofaer 5/30 at 205 (noting that physicians were convinced the dissemination of information “was being done to reduce their income further”).

consumers will react to the information.<sup>100</sup> Commentators and panelists also stated that information disclosure may discourage providers from treating high-risk patients, and result in “gaming” of the system.<sup>101</sup>

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<sup>100</sup> See Foster 5/29 at 261; Gaynor 5/27 at 138 (“We do have to be careful. And we have to understand the ways that patients make choices and what matters to them because we don’t want to do something like provide information about one part of care that’s important and neglect another part of care and find out that we’re actually worse off than we were previously or worse off than we had intended”); Sofaer 5/30 at 205, 206; Romano 5/29 at 61-62, 66; Conlon 5/29 at 108, 111; Kahn 5/29 at 124; Kumpuris 5/30 at 47. See also Mehrotra et al., *supra* note 92, at 60; Thomas H. Lee et al., *A Middle Ground on Public Accountability*, 350 NEW ENG. J. MED. 2409 (2004); Lawrence P. Casalino, *The Unintended Consequences of Measuring Quality on the Quality of Medical Care*, 341 NEW ENG. J. MED. 1147 (1999).

<sup>101</sup> Kessler 5/29 at 68, 78-83 (report cards “provide an incentive for doctors and hospitals to select healthy patients in order to game the report card”); Guterman 5/29 at 262-63 (“[D]epending on how you structure the measure, you can . . . comply with better outcomes by reducing your risk at the outset”); McGinnis 5/30 at 56-57 (“Bonuses based on measures that are proxies for surgical quality at best are likely to cause system gaming.”); Mays 5/30 at 142 (same); Nielsen 5/30 at 227; Foster 5/29 at 213 (noting study that found that publishing data on in-hospital mortality resulted in a decline in in-hospital mortality, but an increase in deaths in the 30-day period post-discharge).

See also David Dranove et al., *Is More Information Better? The Effects of ‘Report Cards’ on Health Care Providers*, 111 J. POL. ECON. 555 (2003); Joshua H. Burack et al., *Public Reporting of Surgical Mortality: A Survey of New York State Cardiothoracic Surgeons*, 68 ANNALS THORACIC SURGERY 1195, 1198 (1999) (documenting concern of cardiothoracic surgeons about “gaming” of reporting requirements); Nowamagbe A. Omoigui et al., *Outmigration For Coronary Bypass Surgery in an Era of Public Dissemination of Clinical Outcomes*, 93 CIRCULATION 27 (1996); James G.

One panelist suggested that providers would be more willing to collect information if that information was not made available to the public.<sup>102</sup> Several panelists indicated that providers believe information disclosure will confuse consumers and cause malpractice litigation.<sup>103</sup> In general, the Agencies encourage information dissemination, because it allows consumers to make better informed decisions.<sup>104</sup> In addition, commentators and panelists agreed

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Jollis & Patrick S. Romano, *Pennsylvania’s Focus on Heart Attack – Grading the Scorecard*, 338 NEW ENG. J. MED. 983 (1998); John D. Clough, *Lack of Relationship Between the Cleveland Health Quality Choice Project and Decreased Inpatient Mortality in Cleveland*, 17 AM. J. MED. QUALITY 47 (2002).

<sup>102</sup> Conlon 5/29 at 97-99.

<sup>103</sup> See *id.*; Clancy 5/29 at 140 (“If you punish people now or sue them or sanction them because of making errors, there’s a really easy way to fix that problem . . . that is, don’t report it.”); Millenson 5/27 at 112 (“The hospital, backed by the local medical society and the state hospital association, argued persuasively that releasing infection data would cause doctors to stop reporting it.”); Ignagni 5/27 at 52 (“It is unreasonable to expect healthcare providers to report errors and then have that be grist for suits by plaintiffs’ attorneys.”); Fisher 5/27 at 56 (“[M]edical errors . . . is interrelated to the liability system and I think creates an innate reluctance in healthcare to report bad outcomes.”); Tuckson 5/30 at 125.

<sup>104</sup> See J. Howard Beales, Remarks Before the Food & Drug Law Institute Conference on Qualified Health Claims (Jan. 4, 2004), at <http://www.ftc.gov/speeches/beales/040114foodanddruglawinstitute.pdf>; Howard Beales et al., *Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 492 (1981) (information “allows buyers to make the best use of their budget by finding the product whose mix of price and quality they most prefer”); see also O’Kane 5/30 at 66 (“[W]e want to be sure that consumers are focusing on: How much health am I getting for my health care dollar?”).

that providers are less likely to modify their behavior if information is not publicly available.<sup>105</sup>

Public reporting of quality measures can be a powerful incentive for providers to improve.<sup>106</sup> It is important, however, to keep the costs, limitations, and potential adverse consequences of information disclosure strategies in mind. To be useful, an information disclosure strategy must balance cost-effectiveness, clinical validity, and

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<sup>105</sup> Hibbard 5/29 at 44-46 (noting importance of public release, and the dilemma that “what helps consumers the most there seems to be the most resistance from providers on. So evaluable reports that are explicit about high performers and low performers and any kind of negative framing is also strongly resisted.”); O’Kane 5/30 at 68.

See also Hibbard, *supra* note 76, at 84 (finding “public report hospitals” reported a significantly higher number of quality improvement activities in obstetrics (an average of 3.4 activities out of 7), while “private report hospitals” reported an average of 2.5 activities, and the “no measurement hospitals”, 2.0 activities; for four cardiac quality improvement activities, “public report hospitals” reported an average of 2.5 improvement activities; private-report hospitals, 1.5 activities; and no measurement hospitals, 1.4 activities).

<sup>106</sup> Millenson 5/27 at 113 (noting that some providers have a “continuing lack of conviction . . . that improvement is needed” and suggesting that public reporting could help remedy this belief); Guterman 5/29 at 173 (noting that once the State of Pennsylvania published quality information on hospitals the information was put to use “because no hospital wanted to be at the bottom of the list when it came to quality.”); Casalino 5/28 at 137 (“Getting publicly recognized for quality actually was one of the most potent predictors of whether groups would use care management processes.”); Lee 6/12 at 255 (“[I]f solid quality measures get put out there, it produces the desired effect, which is it makes consumers like . . . [me] sweat bullets and try to create systems that make it better.”). See also *supra* note 97.

consumer saliency.

Finally, information technology (IT) is an important part of making information available to consumers, providers, and other interested parties. Panelists and commentators agreed that the health care marketplace does not employ information technology extensively or effectively.<sup>107</sup> Prescriptions and physician orders are frequently hand-written.<sup>108</sup> Records are often maintained in hard copy and scattered among multiple locations. Few providers use e-mail to communicate with consumers.<sup>109</sup> Public and private entities have worked to develop and introduce electronic medical records and computerized physician order entry, but commentators and

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<sup>107</sup> See, e.g., Gingrich 6/12 at 11-12; Gaynor 5/27 at 82; Asner 9/25 at 34. See also Robert H. Miller & Ida Sim, *Physicians’ Use of Electronic Medical Records: Barriers and Solutions*, 23 HEALTH AFFAIRS 116 (Mar./Apr. 2004); David W. Bates & Atul Gawande, *Improving Safety with Information Technology*, 248 NEW ENG. J. MED. 2526 (2003); Steinberg, *supra* note 60, at 2682 (“[W]e must make greater use of information technology.”); NEWT GINGRICH ET AL., *SAVING LIVES AND SAVING MONEY* (2003); STEPHEN M. SHORTELL ET AL., *REMAKING HEALTHCARE IN AMERICA: BUILDING ORGANIZED DELIVERY SYSTEMS* 40-41 (1996) (“It is not possible to create clinically integrated care . . . without certain functions such as information systems and quality management in places.”).

<sup>108</sup> See Gingrich 6/12 at 11.

<sup>109</sup> See Thomas Bodenheimer & Kevin Grumbach, *Electronic Technology: A Spark to Revitalize Primary Care?*, 290 JAMA 259 (2003); Lawrence Baker et al., *Use of the Internet and e-mail for Health Care Information: Results From a National Survey*, 289 JAMA 2400 (2003); Alissa R. Spielberg, *On Call and Online: Sociohistorical, Legal, and Ethical Implications of e-mail for the Patient-Physician Relationship*, 280 JAMA 1353 (1998).

panelists agreed that much remains to be done.<sup>110</sup>

## 2. Payment Barriers to Improving Quality

Commentators and panelists agreed that there is not a “business case for quality” in health care because payment arrangements are rarely tied to the quality of the services that are provided.<sup>111</sup> The IOM

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<sup>110</sup> Tuckson 5/30 at 77; O’Kane 5/30 at 100.

<sup>111</sup> See Scully 2/26 at 34; Millenson 5/27 at 105; Millenson 5/28 at 179; Tirone 5/29 at 241 (“[T]here is no business case for quality. The fact is that those that we ask to invest resources to improve the quality and safety of care are not those that benefit in terms of the return on investment. Simply put, the hospital that spends the money on its CPOE [computerized physician order entry] and so forth, if they are – the more safe they are, the higher quality they give, in our current system, the less reimbursement, the less income they will have. The illogical extension of all this is that a really high quality institution can, in effect, put itself out of business.”); Stoddard 5/29 at 256 (“We think that Medicare and other hospitals should begin to reward hospitals financially if they improve staffing levels and patient outcomes. We note that other respected health care experts such as the Institute of Medicine also reviewed and recommended new reimbursement approaches that pay hospitals for demonstrated higher-quality outcomes.”); Delbanco 5/29 at 259-260.

See also Steinberg, *supra* note 60, at 2682 (“The challenge, therefore, is not to demonstrate that there already is a ‘business case’ for quality improvement in health care; rather, it is to establish new incentives that will create such a case.”); Uwe E. Reinhardt, *The Medicare World From Both Sides: A Conversation with Tom Scully*, 22 HEALTH AFFAIRS 167, 168 (Nov./Dec. 2003) (“Everyone with an M.D. or D.O. degree gets the same rate, whether they are the best or worst doc in town? Every hospital gets the same payment for a hip replacement, regardless of quality? We are very good at fixing prices and

observed that “current [compensation] methods provide little financial reward for improvements in the quality of health care delivery, and may even inadvertently pose barriers to innovation.”<sup>112</sup> The Medicare Payment Advisory Commission more bluntly noted that “at times providers are paid even more when quality is worse, such as when the complications occur as the result of error.”<sup>113</sup>

These problems are not theoretical. After Duke University Hospital created an integrated program to treat congestive heart failure, consumers were healthier – but the hospital lost money because of the resulting decline in admissions and the absence of complications.<sup>114</sup> In Utah, ten hospitals had a similar experience after implementing practice guidelines for pneumonia

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paying quickly. But we have zero ability to monitor utilization or differentiate payment based on quality . . . Having federal price fixing, no consumer information or pricing sensitivity, and no measurement of quality has led to predictable results: artificially high prices and uneven quality.”); Sheila Leatherman et al., *The Business Case for Quality: Case Studies and an Analysis*, 22 HEALTH AFFAIRS 23 (Mar./Apr. 2003).

<sup>112</sup> IOM, *supra* note 36, at 19. See also Hyman & Silver, *supra* note 40, at 1427-1485.

<sup>113</sup> MEDICARE PAYMENT ADVISORY COMMITTEE (MEDPAC), REPORT TO CONGRESS: VARIATION AND INNOVATION IN MEDICARE Ch. 7, at 108 (June 2003).

<sup>114</sup> Herzlinger 5/27 at 89. See also Regina Herzlinger, *A Better Way to Pay*, MOD. HEALTHCARE, Dec. 11, 2000, at 32; Lynn 5/30 at 197 (“There are now six randomized control trials showing better ways of taking care of patients with advanced heart failure. Every single one of those programs has folded at the end of the grant funding because it is not sustainable under Medicare.”).

treatment.<sup>115</sup> One panelist noted that current payment systems for end of life care create an economic disincentive for providers who deliver “key elements of chronic care.”<sup>116</sup>

Commentators noted that existing payment arrangements may paradoxically make providers financially worse off if they are better at delivering health care than their competitors.<sup>117</sup> Such payment arrangements are economically perverse: no rational system of compensation rewards an agent (the provider) for making a principal (the

consumer) worse off.<sup>118</sup>

At any given level of payment, commentators and panelists agreed that providers are less likely to improve quality of care if they suffer financially when doing so.<sup>119</sup> Commentators and panelists also agreed that investments in quality improvement are similarly likely to be inadequate when costs are front-loaded, and benefits are deferred – particularly if the providers and payors incurring these costs will not capture the benefits.<sup>120</sup>

Public and private payors and providers are seeking to address these problems by creating direct economic incentives for the delivery of high-quality care (pay for performance or P4P).<sup>121</sup> CMS

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<sup>115</sup> See James 5/28 at 232-233 (stating protocol to reduce variation in care for hospitalized patients with community acquired pneumonia decreased complications, mortality, and net operating revenues of hospital). See also IOM, *supra* note 36, at 191-193 (proportion of patients suffering significant complications declined from 15.3 to 11.6 percent, inpatient mortality rates fell from 7.2 to 5.3 percent, and costs fell by 12.3 percent primarily as a result of expenses avoided through the lower complication rate; “the cost savings in those ten small rural hospitals totaled more than \$500,000 per year, but an analysis of net operating income showed a loss to the facilities of over \$200,000 per year”). See also MedPAC, *supra* note 113.

<sup>116</sup> Lynn 5/30 at 197. See also Joanne Lynn et al., *Financing of Care for Fatal Chronic Illness: Opportunities for Medicare Reform*, 175 W.J. MED 299 (2001).

<sup>117</sup> IOM, *supra* note 36, at 94 (“Even when care delivery groups want to improve the quality of the clinical processes . . . they can be severely limited in their ability to pursue such strategies if providers lose revenues from many quality improvement activities because of the expenses of implementing the improvements and the revenues lost as a result of reduced care delivery.”); Steinberg, *supra* note 60, at 2682 (“The fourth and biggest problem that must be addressed is the fact that current financial incentives often discourage quality improvement . . . Physicians and hospitals often face an outright economic disincentive to invest in infrastructure that will improve compliance with best practices.”).

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<sup>118</sup> Tirone 5/29 at 241 (“What this all really means is that we have a system that pays the same for high-quality care as it pays for less than high quality care, must be revised if we’re going to change the paradigm”); Edelman 6/11 at 227 (“[I]f we give incentives, we shouldn’t be giving incentives to things that we are saying are not good care practices”); Hyman & Silver, *supra* note 40, at 1480.

<sup>119</sup> See *supra* notes 117-118, and accompanying text.

<sup>120</sup> Leatherman et al., *supra* note 111, at 27-28 (noting problems that result from temporal disconnect of costs and benefits of improvements). See also *supra* notes 117-118, and accompanying text.

<sup>121</sup> See Myers 5/29 at 223-24 (describing an experimental incentive program connected to clinical performance indicators for physicians); O’Kane 5/30 at 71-73; Mays 5/30 at 139-153; Paul 6/11 at 201 (“[W]e should be paying more for superior care.”).

See also Epstein et al., *supra* note 40; BRADLEY C. STRUNK & ROBERT HURLEY, PAYING FOR QUALITY: HEALTH PLANS TRY CARROTS INSTEAD OF STICKS (Ctr. for Studying Health Sys.

recently introduced a demonstration project that pays modest financial incentives for hospitals that score in the top 20 percent and modest financial disincentives for hospitals that score in the bottom 20 percent on specified measures of quality for five conditions.<sup>122</sup> There are significant statutory impediments to broader use of such incentives by CMS in the Medicare

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Change, Issue Brief No. 82, 2004), available at <http://www.hschange.org/CONTENT/675/675.pdf>. Robert A. Berenson, *Paying for Quality and Doing It Right*, 60 WASH. & LEE L. REV. 1315 (2003).

The United Kingdom is implementing a P4P initiative for general practitioners in which about 18 percent of practice earnings will be at risk. See Peter C. Smith & Nick York, *Quality Incentives: The Case of U.K. General Practitioners*, 23 HEALTH AFFAIRS 112 (May/June 2004).

<sup>122</sup> See Centers for Medicare & Medicaid Services, *The Premier Hospital Quality Incentive Demonstration: Rewarding Superior Quality Care: Centers for Medicare & Medicaid Services Fact Sheet* (Feb. 18, 2004), at <http://www.cms.hhs.gov/quality/hospital/PremierFactSheet.pdf>. For the first three years, hospitals in the top 10 percent receive a 2 percent bonus of Medicare payments for the measured conditions; hospitals in the second 10 percent are paid a 1 percent bonus. In the third year, hospitals that fall below the bottom two deciles (as set in the first year) will receive DRG payments that are 1 percent or 2 percent lower than would otherwise be the case.

CMS has a similar bonus program for managed care plans that contract with Medicare regarding the treatment received by individuals with congestive heart failure. Paul 6/11 at 221. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 also established a Care Management Performance pilot that will pay bonuses to physicians that adopt and use IT to improve quality and reduce avoidable hospitalizations for chronically ill patients. Medicaid News, Centers for Medicare & Medicaid Services, CMS Urges States to Adopt Disease Management Programs, Agency Will Match State Costs (Feb. 26, 2004), at <http://www.cms.hhs.gov/media/press/release.asp?Counter=967>.

program.<sup>123</sup>

Employers and private plans are also experimenting pay for performance and other strategies to reward providers that adopt processes that are believed to improve quality. The Pacific Business Group on Health has been using incentive-based performance targets for eight years in its contracts with HMOs.<sup>124</sup> HMOs that fail to meet targets for patient satisfaction and various clinical benchmarks (including prenatal care, mammography, pap smears, childhood immunizations, and cesarean section) forfeit two percent of their fees. The Leapfrog Group, a coalition of 145 private and public organizations, is using its purchasing power to encourage hospitals to adopt computerized physician order entry (CPOE), referrals to high volume hospitals for certain procedures, and staffing intensive care units (ICUs) with intensivists.<sup>125</sup>

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<sup>123</sup> David A. Hyman, *Does Quality of Care Matter to Medicare?*, 46 PERSP. BIO. MED. 55 (2003); Robert A. Berenson & Dean M. Harris, *Using Managed Care Tools in Traditional Medicare – Should We? Could We?*, 65 LAW & CONTEMP PROBS. 139, 144-145 (2002).

<sup>124</sup> Helen Halpin Schaffler et al., *Raising the Bar: The Use of Performance Guarantees by the Pacific Business Group on Health*, 20 HEALTH AFFAIRS 134 (Mar./Apr. 1999).

<sup>125</sup> Leapfrog members have agreed to reward those hospitals that meet these three standards with public recognition and by steering patients to those hospitals. Delbanco 5/29 at 186-87; David Shaller et al., *Consumers and Quality-Drive Health Care: A Call to Action*, 22 HEALTH AFFAIRS 97 (Mar./Apr. 2003).

The Leapfrog initiative may have the unintended effect of setting a standard of care for malpractice litigation. See Michelle M. Mello et al., *The Leapfrog Standards: Ready to Jump from Marketplace to Courtroom?*, 22 HEALTH AFFAIRS 47

Although more than a thousand hospitals are participating in Leapfrog, one survey showed that only six percent of hospitals had fully implemented CPOE, 57 percent had fully implemented ICU physician staffing, and most hospitals were meeting one to two of the six targets for referrals to high volume hospitals for selected procedures.<sup>126</sup> A number of large health plans and hospital networks are also experimenting with such arrangements.<sup>127</sup> Tiering can also be employed to link financial incentives to quality of care.<sup>128</sup> Commentators and panelists agreed that, to date, P4P has had limited impact on the health care marketplace.<sup>129</sup>

#### **D. Quality, Competition and Competition Law**

“Enhancing quality” has long been the invariant excuse of providers who

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(Mar./Apr. 2003).

<sup>126</sup> Devers & Liu, *supra* note 42.

<sup>127</sup> Tuckson 5/30 at 82 (listing many of the incentive experiments, but noting there may be a need to develop an industry standard so that providers do not get “whipsawed” by competing measures); Myers 5/29 at 221-222.

<sup>128</sup> See *infra* Chapter 3.

<sup>129</sup> Devers & Liu, *supra* note 42, at 3. See also MedPAC, *supra* note 113, Ch. 7, at 123. One panelist noted that even if the incentives are significant for any given health plan, that health plan may not account for a sufficient share of a provider’s practice to have a significant impact. Berenson 5/30 at 234. Another difficulty with P4P programs is that although “it is nice to have marginal incentives to do good . . . it is the base incentives that drive the market.” Berenson 5/30 at 235.

engage in anticompetitive conduct.<sup>130</sup> As Chairman Robert Pitofsky noted when testifying before Congress on behalf of the Commission, quality-of-care arguments “have been advanced to support, among other things, broad restraints on almost any form of price competition, policies that inhibited the development of managed care organizations, and concerted refusals to deal with providers or organizations that represented a competitive threat to physicians.”<sup>131</sup> There are almost always more narrowly tailored means of achieving the same quality improvements without employing the anticompetitive means selected by self-interested providers.

Some commentators and panelists stated that antitrust law impedes providers’ efforts to improve quality.<sup>132</sup> Providers

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<sup>130</sup> See Sage et al., *supra* note 53, at 35; Blumstein, *supra* note 53, at 1466-67 (“The threat to quality is perceived as the physicians’ silver bullet in the debate about health care policy.”); Apold 6/10 at 131-132 (“[T]he battle cry for anticompetitive behavior is always one of quality.”); Sage 5/29 at 136 (“Before the mid-1970s, physicians invoked quality with impunity to excuse anticompetitive conduct”); Thomas L. Greaney, *Quality of Care and Market Failure Defenses in Antitrust Health Care Litigation*, 21 CONN. L. REV. 605, 605 (1989) (noting complaints that quality will be undermined “as ethical and professional norms give way to financial incentives”).

<sup>131</sup> *Prepared Statement Concerning the “Quality Health-Care Coalition Act of 1998”*: Hearing on H.R. 4277 Before the House Comm. on the Judiciary, 105th Cong. (1998) (Statement of Robert Pitofsky, Chairman, Federal Trade Commission), at <http://www.ftc.gov/os/1998/07/campstest.htm>.

<sup>132</sup> See Opelka 2/27 at 183; Sfikas 2/27 at 185-187. See also Sage et al., *supra* note 53, at 39-43; David A. Hyman, *Five Reasons Why Health Care*

actually have considerable flexibility to act collectively to improve quality of care. Through their professional societies and other groups, health care professionals can jointly provide information and express opinions to health plans and the general public.<sup>133</sup> Physicians, for example, may collectively explain to a health plan and the general public why they think a particular policy or practice is medically unsound and may present medical or scientific data to support their views.<sup>134</sup> Finally, the Agencies have *never* brought a case based solely on providers' collective advocacy with a health plan on an issue involving patient care.<sup>135</sup>

Competition law also enhances quality in ways that are not widely

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*Quality Research Hasn't Affected Competition Law and Policy*, 4 INT'L J. HEALTH CARE FIN. & ECON. 159 (2004).

<sup>133</sup> See, e.g., *Schachar v. Am. Acad. of Ophthalmology*, 870 F.2d 397 (7th Cir. 1989); DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE §§ 4-5 [hereinafter HEALTH CARE STATEMENTS], available at <http://www.ftc.gov/reports/hlth3s.pdf>.

<sup>134</sup> *Prepared Statement Concerning the "Quality Health-Care Coalition Act of 1999": Hearing on H.R. 1304 Before the House Comm. on the Judiciary*, 106th Cong. 5 (1999) (Statement of Robert Pitofsky, Chairman, Federal Trade Commission), at <http://www.ftc.gov/os/1999/06/healthcaretestimony.htm>.

<sup>135</sup> In fact, Commission staff recently issued an advisory opinion addressing the formation and operation of a physician "healthcare advocacy group." See Letter from Jeffrey W. Brennan, Assistant Director, Federal Trade Commission, to Gregory G. Binford, Benesch Friedlander Coplan & Aronoff LLP (Feb. 6, 2003), at <http://www.ftc.gov/bc/adops/030206dayton.htm>.

appreciated. When providers engage in anticompetitive conduct they can undermine the quality of care actually received by the population as a whole. Lower prices can actually contribute to higher quality; as several commentators noted, "when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions."<sup>136</sup>

Stated differently, when anticompetitive conduct increases prices, it makes it more difficult for many Americans to obtain needed care. Estimates of the price elasticity of health insurance vary, but many small employers do not offer health insurance at all because it is too expensive.<sup>137</sup> When employers offer health

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<sup>136</sup> Sage et al., *supra* note 53, at 35-36, 41. See also *supra* note 21; Kumpuris 5/30 at 42 (noting the "interrelationship between health care quality and the access to care. To address one and ignore the other is not only mis-directed, but it represents a lack of appreciation of the day-to-day realities of delivering health care."); O'Kane 5/30 ("[A]ccess and cost-effectiveness of the system are very related concepts. If the system is out of control, there will be less access because people will have less insurance").

More generally, setting a supra-competitive level of health care quality as the mandatory minimum ignores both the short-term consequences for price and access and the long-term consequences of increased price and decreased access on the quality of care that consumers actually receive.

<sup>137</sup> See Roger Feldman et al., *The Effect of Premiums on the Small Firm's Decision to Offer Health Insurance*, 32 J. HUMAN RESOURCES 635 (1997) (estimating a fairly high firm-level demand elasticity for health insurance (-3.91 for single coverage, -5.82 for family coverage), and calculating that if monthly premiums to firms increased by \$1,



insurance, price increases can result in limitations on coverage, employees refusing to sign up for insurance, and employers dropping coverage.<sup>138</sup> Numerous studies establish that the lack of health insurance is associated with deleterious consequences, including increased mortality.<sup>139</sup>

Thus, anticompetitive conduct that raises prices, even if it is done in the name of improving “quality,” is likely to have a systemic adverse effect on the quality of care actually provided to the population as a whole.<sup>140</sup> In a competitive market, consumers consider various dimensions of quality and price. Competition law exists to promote and enhance consumer choice along all of these dimensions.

#### Provider complaints about the antitrust laws miss the point of those laws.

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the proportion of firms offering health insurance to employees would decline by almost 2 percentage points.). See also THE KAISER FAMILY FOUND. & HEALTH RESEARCH & EDUCATIONAL TRUST, EMPLOYER HEALTH BENEFITS 2003 ANNUAL SURVEY, at chart 12 (2003), at <http://www.kff.org/insurance/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=21185> [hereinafter Kaiser/HRET]; David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 YALE J. HEALTH POL’Y, L. & ETHICS 23, 26 (2001).

<sup>138</sup> See Kaiser/HRET, *supra* note 137, at Chart 27-28.

<sup>139</sup> See *infra* Chapter 5.

<sup>140</sup> The Agencies’ historical approach to health care enforcement reflects this reality. The Agencies have aggressively targeted providers who blocked the development of cheaper forms of health care delivery, even though the providers insisted they were trying to ensure that all care was of the highest possible quality. See Sage et al., *supra* note 53, at 35, 37.

As one commentator noted:

[T]he antitrust laws are concerned with maximizing the long-term welfare of consumers, but this is not inconsistent with the interests of efficient providers. The providers who are most efficient and offer the best-quality service at reasonable prices will attract patients in a competitive environment protected by the antitrust laws. The providers whose methods fall behind the times and who rely on the protection of concerted action to maintain their position may lose ground. But that is precisely what one should expect in our free enterprise system.<sup>141</sup>

In an efficient market, consumer preferences specify the targets at which providers aim. When providers engage in anticompetitive conduct, they frustrate this process. By ensuring a competitive marketplace and transparency of information, competition law and policy allows such demands to be satisfied, and prevents self-interested provider groups from preempting “the working of the market by deciding for itself that customers do not need that which they demand.”<sup>142</sup>

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<sup>141</sup> L. Barry Costilo, *Antitrust Enforcement in Health Care: Ten Years After the AMA Suit*, 313 NEW ENG. J. MED. 901, 904 (1985).

<sup>142</sup> *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447, 462 (1986). As a matter of substantive antitrust law, *Professional Engineers* made it clear that the desire of providers to ensure that only high quality services were available was, in itself, an insufficient basis to override the clear prohibitions of the antitrust laws. *Nat’l Soc’y of Prof. Engineers v. United States*, 435 U.S. 679, 695 (1978) (rejecting

### III. INTRODUCTION TO COMPETITION LAW AND HEALTH LAW

As background to the succeeding chapters, this chapter summarizes the basics of competition law and offers a brief history of the application of competition law to health care markets. This chapter also provides an abbreviated overview of several specific forms of regulation that affect the structure and performance of the health care marketplace.

#### A. *Basics of Competition Law*

Federal competition law stems from a series of federal statutes, principally the Sherman Act,<sup>143</sup> the Clayton Act,<sup>144</sup> and the Federal Trade

Commission Act.<sup>145</sup>

The Sherman Act prohibits unilateral and collective conduct that poses unacceptable dangers to competition. Section 1 of the Sherman Act declares unlawful “every contract, combination . . . or conspiracy, in restraint of trade,”<sup>146</sup> while Section 2 of the Sherman Act prohibits “monopolization” and “attempted monopolization.”<sup>147</sup> Courts reviewing Section 1 cases generally focus on whether the allegedly conspiring parties reach agreement, and whether that agreement was unreasonably restrictive. By contrast, courts reviewing Section 2 cases generally examine whether the defendant created or maintained a monopoly through wrongful or exclusionary means.

#### The Clayton Act prohibits

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the claim that markets could not adequately provide for public health and safety as “nothing less than a frontal assault on the basic policy of the Sherman Act”).

*See also* Blumstein 2/27 at 28 (“[A]ntitrust law is the engine of the market paradigm.”); Frank H. Easterbrook, *Cyberspace Versus Property Law?*, 4 TEX. REV. L. & POL. 103, 111 (1999). (“It is ironic that just as a global network and automation are reducing the costs of contracting, and moving us closer to the world in which the Coase Theorem prevails, people promote more and more contract-defeating schemes. One is tempted to think that they are concerned not about market failures but about market successes - about the prospect that the sort of world people prefer when they vote their own pocketbooks will depart from the proposers’ ideas of what people ought to prefer.”).

<sup>143</sup> 15 U.S.C. §§ 1-7.

<sup>144</sup> *Id.* §§ 12-27.

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<sup>145</sup> *Id.* §§ 41-61. In addition, state attorneys general may enforce federal antitrust statutes. *See generally* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE § 15.4, at 590-91 (2d ed. 1999) (discussing role of state attorneys general in antitrust enforcement).

<sup>146</sup> 15 U.S.C. § 1 (1994) (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal [and is a felony punishable by fine and/or imprisonment] . . .”).

<sup>147</sup> *Id.* § 2 (“Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony [and is similarly punishable] . . .”).

mergers and acquisitions where the effect “may be substantially to lessen competition, or to tend to create a monopoly.”<sup>148</sup> The Clayton Act thus reaches incipient threats to competition that might escape the Sherman Act’s reach. Under related legislation, parties to proposed mergers that exceed statutory thresholds are required to notify the federal antitrust agencies of their plans and afford the government a limited opportunity to investigate before the transaction is executed.<sup>149</sup>

Finally, Section 5 of the Federal Trade Commission Act provides that “unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce are ... unlawful.”<sup>150</sup> The Supreme Court found this provision provides the FTC with the authority to attack conduct constituting a Sherman Act violation.<sup>151</sup> The FTC Act provides no criminal penalties and is limited to equitable remedies. Depending upon the specifics of a case, the Commission enforces the FTC Act either administratively or through the courts. Advisory opinions are available for parties interested in prospective guidance as to the strictures of the FTC Act.<sup>152</sup> The Division offers business

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<sup>148</sup> *Id.* § 13(a).

<sup>149</sup> Hart-Scott-Rodino Antitrust Improvements Act, 15 U.S.C. § 18a (1976).

<sup>150</sup> 15 U.S.C. § 45.

<sup>151</sup> *FTC v. Cement Institute*, 333 U.S. 683 (1948).

<sup>152</sup> 16 C.F.R. § 1.1.

review letters that perform much the same function for the statutes that the Department of Justice enforces.<sup>153</sup>

The Agencies are the primary antitrust enforcement authorities, although state attorneys general and private parties can also bring suit. For example, both the Division and private parties may sue to enforce the civil provisions of the Sherman Act, which authorize treble damages and broad equitable relief. By contrast, only the Division may enforce the criminal provisions of the Sherman Act. Moreover, the federal laws assign each Agency responsibility to enforce various antitrust laws. Thus, both Agencies can pursue violations of the Clayton Act, but only the Commission may enforce the FTC Act.

Because most of the antitrust challenges to health care practices focus on allegedly anticompetitive agreements, an abbreviated analysis of the standards for assessing such claims is warranted. In reviewing such claims, “the development of horizontal restraints jurisprudence suggests an analytic framework that proceeds by several identifiable analytical steps.”<sup>154</sup> Some conduct – such as naked agreements among competitors to fix prices or allocate markets – is viewed as “inherently suspect owing to its likely

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<sup>153</sup> 28 C.F.R. § 50.6.

<sup>154</sup> *In re Polygram Holding, Inc.*, No. 9298, at 29 (2003) (opinion of the Commission), at <http://www.ftc.gov/os/2003/07/polygramopinion.pdf>.

tendency to suppress competition.”<sup>155</sup> Such arrangements “always or almost always tend to raise prices or reduce outputs.”<sup>156</sup> Such conduct merits summary condemnation to prevent long, expensive investigations and litigation over conduct that is almost certain to cause harm to consumers.<sup>157</sup> Most of the time, however, “conduct cannot be adjudged illegal without an analysis of its market context to determine whether those engaged in the conduct or restraint are likely to have sufficient power to harm consumers.”<sup>158</sup> Depending on the case, the necessary analysis can be sweeping or relatively constrained.<sup>159</sup> As several panelists noted, antitrust investigations are factually intensive, and “antitrust cases have to be done one at a time.”<sup>160</sup>

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<sup>155</sup> *Id.*

<sup>156</sup> HEALTH CARE STATEMENTS, *supra* note 133, § 8, at 47, 57 n.36, *citing Broadcast Music, Inc. v. Columbia Broadcasting Sys., Inc.*, 441 U.S. 1, 21-22 (1979).

<sup>157</sup> *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940); *cf.* Kanwit 9/9 at 197-98 (“I think we also need to remember what per se rules apply to. They apply to price fixing, boycotts and market allocations. I just cannot see the benefit to consumers . . . in a time of [rising] health care costs of having the DOJ or the FTC spend three years looking at a physician group to determine under the rule of reason whether a certain arrangement is or is not violative of the antitrust laws. That is not going to benefit consumers.”).

<sup>158</sup> *Polygram Holding*, No. 9298 at 29.

<sup>159</sup> *Id.* at 29-35.

<sup>160</sup> *See, e.g.,* Feldman 4/23 at 96; Lerner 4/23 at 97-98 (“So, I think a lot of these things, I agree, you have to look at the case you’re dealing

## **B. Application of Competition Law to Health Care**

Courts, lawmakers, and commentators once believed that health care markets should not be subject to competition. Thus, it was widely understood that there was a “learned professions” exception to the antitrust laws; government enforcers or private parties only rarely pursued anticompetitive conduct in health care.<sup>161</sup> The existence of this exemption remained an open issue until 1975 when the Supreme Court explicitly determined that the antitrust laws apply to “learned professions.”<sup>162</sup> One year later, the Supreme Court held that the alleged acts of a hospital were “sufficient to establish” a “substantial effect” on interstate commerce under the Sherman

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with and figure out what makes sense”); Monk 4/23 at 98 (“[W]hen you’re looking at a specific market, you do have to factor in what the characteristics that are in that market at that time and whether the characteristics changed because there was a change in - either the market was currently in balance or out of balance”).

<sup>161</sup> The Supreme Court applied the antitrust laws to the activities of the American Medical Association, but it did not expressly decide whether a physician’s medical practice constituted “trade” under the Sherman Act, leaving unsettled the extent to which the antitrust laws could be applied to the activities of the health care professions generally. *Am. Med. Ass’n v. United States*, 317 U.S. 519, 528 (1943). *See also* Gaynor 5/27 at 71-72.

<sup>162</sup> *Goldfarb v. Va. State Bar*, 421 U.S. 773, 787 (1975) (observing that the “nature of an occupation, standing alone, does not provide sanctuary from the Sherman Act . . . nor is the public-service aspect of professional practice controlling in determining whether § 1 includes professions”).

Act.<sup>163</sup>

In *Arizona v. Maricopa County Medical Society*, the Supreme Court emphasized that the antitrust laws applied fully to the health care marketplace.<sup>164</sup> The Court found that an agreement among physicians to set maximum prices charged to policyholders was a *per se* violation of the Sherman Act.

For almost three decades, the Agencies have continued to enforce the competition laws by initiating investigations, filing and litigating complaints, filing amicus briefs in private litigation, and writing advisory opinions and business review letters for the health care industry.<sup>165</sup>

The Agencies took an additional step in the application of competition law and policy to health care by issuing the joint *Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care (Health Care Statements)* in

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<sup>163</sup> *Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 739-40 (1976).

<sup>164</sup> 457 U.S. 332 (1982).

<sup>165</sup> For a comprehensive review of antitrust health care cases brought by the Commission, see HEALTH CARE SERVICES & PRODUCTS DIV., FEDERAL TRADE COMM’N, FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2004), at <http://www.ftc.gov/bc/hcupdate0404.pdf>; BUREAU OF COMPETITION, FEDERAL TRADE COMM’N, FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS (April 2004), at <http://www.ftc.gov/bc/0404rxupdate.pdf>. See also Muris 2/26 at 6; Simons 9/9/02 at 99-108; Beales 9/9/02 at 108-113; Scheffman 9/9/02 at 113-118.

1993.<sup>166</sup> The Agencies designed the *Health Care Statements* “to advise the health care community in a time of tremendous change, and to address . . . the problem of uncertainty concerning the Agencies’ enforcement policy.”<sup>167</sup>

In response to comments and changes in the health care marketplace the Agencies expanded the *Health Care Statements* in 1994 and amplified them again in 1996. The *Health Care Statements* currently specify a range of circumstances that will not provoke enforcement actions (also known as “safety zones”) for hospital mergers, hospital and physician joint ventures, physicians’ provision of information to purchasers, multi-provider networks, and joint purchasing arrangements among health care providers. The *Health Care Statements* also provide a number of examples applying antitrust analytical principles to a particular set of health-care related organizational arrangements. The Agencies also offer prospective guidance relating to health care through advisory opinions and business review letters.<sup>168</sup>

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<sup>166</sup> HEALTH CARE STATEMENTS, *supra* note 133.

<sup>167</sup> *Id.* at 1.

<sup>168</sup> Prospective guidance was considered at a hearing session on June 26, 2003. A complete lists of the participant on this panel is available in Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf>. Two panelists noted the importance of prospective guidance. Grimes 6/26 at 176 (“I think a number of panelists have pointed out that the advisory opinions and business review letters are a critical part of this effort.”); Johnson 6/26 at 171 (“[S]taff advisory

Finally, the Agencies have jointly filed amicus briefs in a number of cases, including a recent brief filed in the Sixth Circuit, explaining the Agencies' analysis of how the state action doctrine should be applied to the conduct of subordinate state entities, such as public hospitals.<sup>169</sup>

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opinions and business review letters are valuable components of the government's overall antitrust enforcement efforts. The processes ensure compliance by the requesting parties, frequently with implementation of competitive safeguards that private counsel might not have deemed necessary. Further, and perhaps more importantly, publication of detailed reviews allows private practitioners to better counsel their clients, discourages submission of duplicative requests, and fosters enhanced antitrust compliance at relatively low cost.”).

One panelist discussed how state attorneys general handle advisory opinions. Cooper 6/26 at 184-193. Another panelist discussed how the Office of the Inspector General of HHS handles advisory opinions relating to the anti-kickback act. Robinson 6/28 at 193-203. The anti-kickback act is described in greater detail *infra* at notes 190-191, and accompanying text.

<sup>169</sup> See Amicus Brief of the U.S. Dep't of Justice, *Jackson v. West Tennessee Healthcare, Inc.* (6th Cir. 2004) (No. 04-5387), available at <http://www.usdoj.gov/atr/cases/f203800/203897.htm>; Amicus Brief of the Federal Trade Comm'n, *Jackson v. West Tennessee Healthcare, Inc.* (6th Cir. 2004) (No. 04-5387), available at <http://www.ftc.gov/os/2004/06/040604jacksonhospitalamici.pdf>; Amicus Brief of the U.S. Dep't of Justice, *Surgical Ctr. of Hammond, L.C. v. Hosp. Serv. Dist. No. 1 of Tangipahoa Parish* (5th Cir. 1998) (No. 97-30887), available at <http://www.usdoj.gov/atr/cases/f2000/2052.htm>; Amicus Brief of the Federal Trade Comm'n, *Surgical Ctr. of Hammond, L.C. v. Hosp. Serv. Dist. No. 1 of Tangipahoa Parish* (5th Cir. 1998) (No. 97-30887), available at <http://www.ftc.gov/ogc/briefs/surgical.htm>.

## 1. Commission Health Care Related Activities

The Commission has long challenged barriers to competition in health care markets to foster innovative and more efficient means of delivering and financing health care.<sup>170</sup> In the last several years, the Commission has made special efforts to protect competition in pharmaceutical markets, given rapidly rising drug expenditures that are causing great concerns among patients, employers, and government officials.<sup>171</sup> The Commission has been especially active in investigating and challenging conduct that excludes or unduly delays generic competition from pharmaceutical markets.<sup>172</sup> It has also reached important settlement agreements in mergers in the

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<sup>170</sup> *An Overview of Federal Trade Commission Antitrust Activities: Hearing Before the House Comm. on the Judiciary, Antitrust Task Force, 108th Cong. 2* (2003) (Testimony of Timothy J. Muris, Chairman, Federal Trade Commission), at <http://www.ftc.gov/os/2003/07/antitrustoversighttest.htm>.

<sup>171</sup> *Id.*

<sup>172</sup> See *In re Schering-Plough, No. 9297* (2003), available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf> (opinion of Commission). See also *In re Bristol-Myers Squibb Co.*, No. C-4076 (Apr. 14, 2003) (consent order); *In re Biovail Corp.*, No. C-4060 (Oct. 2, 2002) (consent order); *In re Biovail Corp. & Elan Corp., PLC.*, No. C-4057 (Aug. 20, 2002) (consent order); *In re Schering-Plough Corp.*, No. 9297 (Apr. 3, 2002) (consent order as to American Home Products Corp.); *In re Hoechst Marion Roussel, Inc.*, No. 9293 (May 8, 2001) (consent order); *In re Abbott Laboratories*, No. C-3945 (May 22, 2000) (consent order); *In re Geneva Pharmaceuticals, Inc.*, No. C-3946 (May 22, 2000) (consent order).

pharmaceutical markets,<sup>173</sup> and successfully argued in an amicus brief that improper pharmaceutical filings before the Food and Drug Administration are not immune from antitrust review.<sup>174</sup>

The Commission also issued a recent, comprehensive study on generic drug competition.<sup>175</sup> This study recommended legislative changes to the statutory framework governing generic drug entry to mitigate the possibility of abuse of this framework. Most of these recommendations were enacted by the Medicare Prescription Drug and Improvement Act of 2003.

Since the 1970s, the Commission has had an active law enforcement program targeting anticompetitive practices among physicians and other health care professionals. The types of conduct within the health care professions that have been subject to Commission challenge over the decades

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<sup>173</sup> Muris, *supra* note 170, at 2 (*citing* such cases as *Pfizer Inc.*, No. C-4075 (May 27, 2003) (consent order); *Baxter International Inc. and Wyeth*, No. C-4068 (Feb. 3, 2003); and *Amgen Inc. and Immunex Corp.*, No. C-4056 (Sept. 3, 2002)).

<sup>174</sup> See Brief of *Amicus Curiae* of the Federal Trade Comm'n, *In re Buspirone Patent Litigation & In re Buspirone Antitrust Litigation*, MDL Docket No. 1410 (JGK) (Jan. 8, 2002) (in opposition to defendant's motion to dismiss), at <http://www.ftc.gov/os/2002/01/busparbrief.pdf>; see also *In re Buspirone*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (adopting Commission's argument).

<sup>175</sup> FEDERAL TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002), at [www.ftc.gov/opa/2002/07/genericdrugstudy.htm](http://www.ftc.gov/opa/2002/07/genericdrugstudy.htm).

include agreements on price and price-related terms, agreements to obstruct the entry of innovative forms of health care financing and delivery, and restraints on advertising and other forms of solicitation.<sup>176</sup>

Since 2002, the Commission has entered into 17 consent agreements with physicians, their organizations, or their non-physician consultants and agents, settling charges that the respondents have engaged in unfair methods of competition – primarily involving joint contracting with payors and other forms of price-fixing.<sup>177</sup>

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<sup>176</sup> See generally HEALTH CARE SERVICES & PRODUCTS DIVISION, *supra* note 165.

<sup>177</sup> See, e.g., *In re Southeastern N.M. Physicians IPA, Inc.*, No. 0310134 (June 7, 2004); *In re Cal. Pac. Med. Group*, No. 9306 (May 11, 2004) (final order); *In re Tenet Healthcare Corp.*, C-4106 (Jan. 29, 2004) (final order); *In re Mem'l Hermann Health Network Providers*, C-4104 (Jan. 8, 2004) (final order); *In re Surgical Specialists of Yakima*, C-4101 (Nov. 14, 2003) (final order); *In re S. Ga. Health Partners, L.L.C.*, C-4100 (Oct. 31, 2003) (final order); *In re Physician Network Consulting, L.L.C.*, C-4094 (Aug. 27, 2003) (final order); *In re Me. Health Alliance*, C-4095 (Aug. 27, 2003) (final order); *In re Anesthesia Med. Group, Inc.*, C-4085, & *Grossmont Anesthesia Services Med. Group*, C-4086 (July 11, 2003) (final orders); *In re Washington Univ. Physician Network*, C-4093 (Aug. 22, 2003) (final order); *In re SPA Health Org.*, C-4088 (July 17, 2003) (final order); *In re Carlsbad Physician Ass'n*, C-4081 (June 13, 2003) (final order); *In re R.T. Welter & Assocs.* (Oct. 2, 2002) (final order); *In re Sys. Health Providers*, C-4064 (Oct. 24, 2002) (final order); *In re Aurora Associated Primary Care Physicians, L.L.C.*, C-4055 (July 16, 2002) (final order); *In re Physicians Integrated Services of Denver, Inc.*, C-4054 (July 16, 2002) (final order); *In re Obstetrics & Gynecology Med. Corp. of Napa Valley*, C-4048 (May 14, 2002) (final order). See also Palmisiano 9/9/02 at 244 ("In recent years,

Additionally, Commission staff are currently evaluating the effects of consummated hospital mergers in several cities. The Commission will announce the results of these retrospective studies after determining whether the mergers in question were harmful to consumers.<sup>178</sup> One case arising out of this investigation is currently in administrative litigation.<sup>179</sup>

## 2. Division Health Care Related Activities

During the last three years, the Division has pursued formal investigations across the full range of healthcare products and services. In addition to the matters on which it has taken formal enforcement or advisory action, the Division has examined, or is investigating, mergers and conduct of managed care organizations, including the review of four major mergers of health plans. In one of these matters, the Division publicly set forth the reasoning that led it to clear the formation of the

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physicians and physician organizations have been the subject of approximately 50 enforcement actions.”).

<sup>178</sup> The Commission announced on June 30, 2004 that it had closed an investigation into the acquisition of Provena St. Therese Medical Center by Vista Health Acquisition. See News Release, Federal Trade Comm’n, FTC Closes Investigation Into Merger of Victory Memorial Hospital and Provena St. Therese Medical Center (July 1, 2004), at <http://www.ftc.gov/opa/2004/07/waukegan.htm>.

<sup>179</sup> *In re* Evanston Northwestern Healthcare Corp., No. 9315 (Feb. 10, 2004) (administrative complaint), at <http://www.ftc.gov/os/caselist/0110234/040210emhcomplaint.pdf>.

nation’s largest health plan.<sup>180</sup>

The Division has examined both vertical contracting arrangements involving health plans and providers as well as allegations of horizontal agreements among plans. Additionally, the Division has or is investigating mergers and conduct of providers (both physicians and hospitals), including allegations of horizontal agreements. These investigations, while not resulting in challenges, have included criminal inquiries into the conduct of managed care plans, hospitals, and physicians.

The Division’s civil conduct investigations have encompassed hospital conduct, blood products, and retrospective examinations of a hospital joint operating agreement and a multi-hospital joint selling venture, the latter of which implemented mechanisms intended to achieve clinical integration without formal merger. The Division’s formal merger investigations have encompassed hospital mergers, senior assisted living facilities, and diagnostic imaging service providers. Finally, the Division has actively provided counsel to the Administration on health care policy matters.

The Division has taken several public enforcement actions, including a merger challenge involving critical care

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<sup>180</sup> See Dep’t of Justice, Department of Justice Antitrust Division Statement on the Closing of its Investigation of Anthem, Inc.’s Acquisition of Wellpoint Health Networks, Inc. (Mar. 9, 2004), at [http://www.usdoj.gov/atr/public/press\\_releases/2004/202738.htm#attach](http://www.usdoj.gov/atr/public/press_releases/2004/202738.htm#attach).



monitors and orthopedic equipment,<sup>181</sup> litigation resulting in a consent decree against the Federation of Physicians and Dentists,<sup>182</sup> a case brought against the dominant producer of prefabricated artificial teeth in the United States,<sup>183</sup> and a consent decree requiring dissolution of a physician organization of over 1000 members.<sup>184</sup> Additionally, the Division has issued favorable business review letters to two groups requesting guidance regarding fee surveys.<sup>185</sup>

### 3. Private Litigation

The majority of antitrust challenges to health care activities arise in private litigation. One study showed that the Agencies brought only six percent of the antitrust challenges to health care practices involving quality of

care from 1985 to 1999.<sup>186</sup> Most private antitrust challenges are not successful: the same study found that plaintiffs won favorable opinions only 14 percent of the time; 67 percent of the judicial opinions favored defendants, and the remaining 19 percent favored neither party.<sup>187</sup> The most common private antitrust health-care litigation claims involved staff privileges and exclusive contracting cases.<sup>188</sup>

### C. Health Law Overview

The states and the federal government extensively regulate health care.<sup>189</sup> Many of these regulations are described in greater detail in Chapters 2 - 8, *infra*. This section provides a basic introduction to several important provisions that are important to understand the health care marketplace.

#### 1. Anti-Kickback

##### The Medicare and Medicaid

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<sup>186</sup> Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 COLUM. L. REV. 545, 565 (2002).

<sup>187</sup> *Id.* at 575; Hammer 5/28 at 146.

<sup>188</sup> See Hammer & Sage, *supra* note 186, at 578. The incidence of private staff privileges cases seems to be declining. It is possible the enactment of the Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11,101-11,152 (1994), which offers limited protection from antitrust liability to peer review decisions, may be responsible for this trend. See Hammer & Sage, *supra* note 186, at 597-98; Hammer 9/10/02 at 22.

<sup>189</sup> For example, depending on the state and the type of provider, there may be restrictions on entry, structure, and conduct.

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<sup>181</sup> United States v. Gen. Elec. Co., 2004-1 Trade Cas. (CCH) ¶ 74,313 (D. D.C. 2004)

<sup>182</sup> United States v. Fed'n of Physicians & Dentists, Inc., 2002 Trade Cas. (CCH) ¶ 73,868 (D. Del 2002).

<sup>183</sup> United States v. Dentsply Int'l, Inc., 277 F. Supp. 2d 387 (D. Del. 2003). The case is currently pending before the United States Court of Appeals for the Third Circuit. The Division's briefs may be found at <http://www.usdoj.gov/atr/cases/indx102.htm>.

<sup>184</sup> United States v. Mountain Health Care, P.A., 2004 WL 938495 (4th Cir. N.C. May 3, 2004).

<sup>185</sup> See Letter from Charles A. James, U.S. Dep't of Justice, to Jerry B. Edmonds, Williams, Kastner & Gibbs PLLC (Sept. 23, 2002), at <http://www.usdoj.gov/atr/public/busreview/200260.htm>; Letter from R. Hewitt Pate, U.S. Dep't of Justice, to Diana West (May 25, 2004), at <http://www.usdoj.gov/atr/public/busreview/203831.htm>.

Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)) broadly criminalizes the solicitation or receipt of remuneration in connection with items or services for which payment is made under Medicare or Medicaid.

There are statutory exceptions for discounts, payments pursuant to a bona fide employment relationship, group purchasing organizations, waiver of coinsurance obligations, and risk-sharing agreements of managed care organizations. There are also administrative regulations creating specific safe harbors and advisory opinions covering a number of other arrangements.<sup>190</sup>

Those who violate the anti-kickback statute are subject to criminal and civil penalties and/or exclusion from participation in the Medicare and Medicaid programs. The anti-kickback statute has had an important effect on the structure of the health care marketplace.<sup>191</sup>

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<sup>190</sup> See, e.g., safe harbors set forth at 57 Fed. Reg. 52,723 (Nov. 5, 1992) and 56 Fed. Reg. 35,952 (codified at 42 C.F.R. 1001.952).

<sup>191</sup> See Blumstein 2/27 at 36; Hammer 2/27 at 63 (“Things that are necessary to police fraud and abuse in a fee-for-service realm impairs substantially what a hospital can do in terms of structuring its business arrangements.”); Paul E. Kalb, *Health Care Fraud and Abuse*, 282 JAMA 1163 (1999); David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and “the Trust Reposed in the Workmen,”* 30 J. LEGAL STUDIES 531 (2001); James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, 15 HEALTH AFFAIRS 118 (Winter 1996); James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Healthcare Marketplace: Life in the Healthcare Speakeasy*, 22 AM. J. L. & MED. 205

## 2. Self-Referral Amendments

The Self-Referral Amendments (42 U.S.C. §1395nn) prohibit physicians from referring Medicare and Medicaid patients to ancillary providers in which they or their family members hold a financial interest and prohibit service providers from billing for services performed as a result of such referrals.

The Self-Referral Amendments apply to certain designated health services. A financial interest includes an ownership interest or a compensation arrangement (the latter includes both the giving and receiving of compensation). There are certain defined situations in which a physician is permitted to receive payment for the referral of a Medicare or Medicaid patient to an entity in which he or she has a direct or indirect financial interest, including when the physician has an ownership interest in a whole hospital.

The Self-Referral Amendments create a strict liability offense, with violation punishable by program exclusion and substantial civil penalties. Like the anti-kickback statute, the Self-Referral Amendments have had an important effect on the structure of the health care marketplace.<sup>192</sup>

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(1996).

<sup>192</sup> See *infra* Chapter 3 (discussing the rise of single-specialty hospitals (SSHs)). Physicians are able to invest in SSHs and refer to them without running afoul of the Self-Referral Amendments because they have invested in a “whole hospital.” See also Mallon 6/10 at 189, 193-94 (noting that “payment shades practice” and effects of self-referral

### 3. EMTALA

The Emergency Medical Treatment and Labor Act (42 U.S.C. §1395dd) requires hospitals that receive Medicare funding and have an emergency department (ED) to provide an appropriate medical screening examination to any individual who comes to the ED and requests one. Stabilizing treatment must be provided to individuals with an emergency medical condition. Violations are punishable with civil penalties, program exclusion, and private lawsuits brought against individual hospitals. Like the anti-kickback and Self-Referral Amendments, EMTALA has had an important effect on the health care marketplace.<sup>193</sup>

### 4. Medical Malpractice

Medical malpractice litigation is governed by state tort law. To prevail in a medical malpractice claim, the plaintiff must prove that the provider-defendant owed a duty of care to the plaintiff, that the provider-defendant breached this duty by failing to adhere to the standard of care expected, and that this breach of duty caused an injury (with associated damages) to the plaintiff. Malpractice

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provisions on physician-owned physical therapy services); Hammer 2/27 at 63; Kahn 2/27 at 76 (“One of the unintended consequences of the Stark Law is this issue of physician-owned specialty hospitals.”); Fine 9/9/02 at 198.

<sup>193</sup> See Brian Kamoie, *EMTALA: Dedicating an Emergency Department Near You*, 37 J. HEALTH L. 41 (2004); David A. Hyman, *Patient Dumping and EMTALA: Past Imperfect/Future Shock*, 8 HEALTH MATRIX 29 (1998).

litigation seeks to compensate negligently injured consumers, deter unsafe practices, and achieve corrective justice.

Numerous panelists and commentators stated that the medical malpractice system is in the midst of a crisis.<sup>194</sup> The American Medical Association (AMA) has declared a malpractice crisis in twenty states, claiming that important health care services are in short supply.<sup>195</sup> Complete consideration of this issue lies beyond the scope of this Report, but it significantly affects the health care

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<sup>194</sup> See Lomazow 6/10 at 196; Gingrich 6/12 at 25-26; M. Young 6/12 at 90; Michelle Mello et al., *Caring for Patients in a Malpractice Crisis: Physician Satisfaction and Quality of Care*, 23 HEALTH AFFAIRS 42 (July/Aug. 2004); David Studdert et al., *Medical Malpractice*, 350 NEW ENG. J. MED. 283 (2004); Kenneth E. Thorpe, *The Medical Malpractice ‘Crisis’: Recent Trends and the Impact of State Tort Reforms*, 2004 Health Affairs (Web Exclusive) W4-20; Michelle Mello et al., *The New Medical Malpractice Crisis*, 348 NEW ENG. J. MED. 2281 (2003); William M. Sage, *Understanding the First Malpractice Crisis of the 21<sup>st</sup> Century*, 2003 HEALTH LAW HANDBOOK; Office of the Assistant Secretary of Planning & Evaluation, Dep’t of Health & Human Services, *Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs By Fixing Our Medical Liability System* (2002), <http://aspe.hhs.gov/daltcp/reports/litrefm.pdf>.

<sup>195</sup> See American Medical Ass’n, *Massachusetts named state in medical liability crisis* (June 14, 2004), <http://www.ama-assn.org/ama/pub/article/9255-8629.html>. But see News Release, General Accounting Office, *Medical Malpractice: Implications of Rising Premiums on Access to Health Care* (Aug., 2003), <http://www.gao.gov/new.items/d03836.pdf>.

marketplace.<sup>196</sup>

#### **D. Obligational Norms**

Many members of the public view health care as a “special” good, not subject to normal market forces, with significant obligational norms to provide necessary care without regard to ability to pay.<sup>197</sup> Similarly, risk-based premiums for health insurance are perceived by many as inconsistent with obligational norms and fundamental fairness, because those with the highest anticipated medical bills will pay the highest

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<sup>196</sup> See *supra* note 194; Fred J. Hellinger & William E. Encinosa, U.S. Department of Health and Human Services, *The Impact of State Laws Limiting Malpractice Awards on the Geographic Distribution of Physicians* 12 (2003); David A. Hyman, *Medical Malpractice: What Do We Know and What (If Anything) Should We Do About It?*, 80 TEX. L. REV. 1639-1655 (2002); James F. Blumstein, *The Legal Liability Regime: How Well is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace?*, 11 ANNALS HEALTH L. 125 (2002); Patricia M. Danzon, *Liability For Medical Malpractice*, in HANDBOOK OF HEALTH ECONOMICS (Culyer & Newhouse, eds., 2000).

<sup>197</sup> See Blumstein 2/27 at 21-22 (“This is not purely a question about resource allocation, but it’s also a question about a normative overlay of why health care is different. Why do we care about access to health care in ways that we don’t care about access to certain other things? We worry about it because of our concern about, broadly speaking, redistributive values and some notion of egalitarianism.”); Hyman 6/25 at 86-87 (noting that many people describe health care as a “merit good”); Mark Schlesinger & Thomas Lee, *Is Health Care Different? Popular Support for Federal Health and Social Policies*, 18 J. HEALTH POLITICS, POL’Y & L. 551 (1993); Richard A. Epstein, *Why is Health Care Special?*, 40 U. KANSAS L. REV. 307 (1992).

premiums.<sup>198</sup> A wide array of regulatory interventions, ranging from EMTALA and mandated benefits to community rating and guaranteed issue, reflect these norms.<sup>199</sup>

#### **E. Conclusion**

Commentators have extensively analyzed the application of competition and antitrust law to health care. In general, these commentators have concluded that increased competition has empowered consumers, lowered prices, increased quality, and made health care more accessible.<sup>200</sup> The

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<sup>198</sup> See, e.g., TIMOTHY S. JOST, *DISSENTMENT? THE THREATS FACING OUR HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE* (2003); Deborah Stone, *The Struggle for the Soul of Health Insurance*, 18 J. HEALTH POL., POL’Y & L. 28 (1993).

<sup>199</sup> See *infra* Chapters 2-8.

<sup>200</sup> See generally Gaynor 5/28 at 73 (“[A]ntitrust enforcement is a critical element of health policy”); Greenberg 5/28 at 316; Greaney 9/10/02 at 303 (“There are countless economic studies, I think that show the demonstrable consumer benefits that have flowed from the competition in the health care industry.”); Greaney 2/27 at 135; Hanson 9/9/02 at 163 (“Competition often leads to quality improvements, innovation and enhanced access to medical services.”)

See also Thomas Leary, *Special Challenges for Antitrust in Health Care*, ANTITRUST, Spring, 2004 at 23; Thomas L. Greaney, *Chicago’s Procrustean Bed: Applying Antitrust Law in Health Care*, 71 ANTITRUST L. J. 857 (2004); Stuart M. Butler, *A New Policy Framework for Health Care Markets*, 23 HEALTH AFFAIRS 22 (Mar./Apr. 2004); Clark Havighurst, *I’ve Seen Enough! My Life and Times in Health Care Law and Policy*, 14 HEALTH MATRIX 107 (2004); DEBORAH HAAS-WILSON, *MANAGED CARE AND MONOPOLY POWER: THE ANTITRUST CHALLENGE* (2003); Thomas Greaney, *Whither Antitrust: The Uncertain Future of Competition Law in Health Care*, 21 HEALTH

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AFFAIRS 185 (Mar./Apr. 2002); Frank A. Sloan & Mark A. Hall, *Market Failures and the Evolution of State Regulation of Managed Care*, 65 LAW & CONTEMP. PROBS. 169 (Autumn, 2002); RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE? (1997); H.E. FRECH, COMPETITION & MONOPOLY IN MEDICAL CARE (1996); AMERICAN HEALTH POLICY: CRITICAL ISSUES FOR REFORM (Robert Helms, ed. 1993); COMPETITIVE APPROACHES TO HEALTH CARE REFORM (Arnould, Rich & White, eds. 1993); Frances H. Miller, *Competition Law and Anticompetitive Professional Behavior Affecting Health Care*, 55 MODERN L. REV. 453 (1992); WARREN GREENBERG, COMPETITION, REGULATION AND RATIONING IN HEALTH CARE (1991); Paul Weller, "Free Choice" as a Restraint of Trade in *American Health Care Delivery and Insurance*, 69 IOWA L. REV. 1351 (1984); Thomas E. Kauper, *The Role of Quality of Health Care Considerations in Antitrust Analysis*, 51 LAW & CONTEMP. PROBS. 273 (1988); COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT AND FUTURE: PROCEEDINGS OF A CONFERENCE SPONSORED BY THE BUREAU OF ECONOMICS, FEDERAL TRADE COMMISSION (Warren Greenberg ed., 1978). See also DRANOVE, *supra* note 1; GLIED, *supra* note 1; ROBINSON, *supra* note 1; Sage & Hammer, *supra* note 32; Blumstein, *supra* note 53; Sage et al., *supra* note 53; GINGRICH ET AL., *supra* note 107; Epstein, *supra* note 197.

To be sure, panelists and commentators expressed concern about the use and/or direction of competition in health care markets. See, e.g., Feder 2/27 at 153-156, 162; Len M. Nichols et al., *Are Market Forces Strong Enough to Deliver Efficient Health Care Systems? Confidence is Waning*, 23 HEALTH AFFAIRS 8 (Mar./Apr. 2004); Michael E. Porter & Elizabeth Olmsted Teisberg, *Fixing Competition in U.S. Health Care*, HARV. BUS. REV. 65 (June, 2004); M. Gregg Bloche, *The Invention of Health Law*, 91 CAL. L. REV. 247 (2003); Clark Havighurst, *How the Health Care Revolution Fell Short*, 65 LAW & CONTEMP. PROBS. 55 (2002); Uwe Reinhardt, *Can Efficiency in Health Care Be Left to the Market?*, 26 J. HEALTH, POL., POL'Y & L. 967 (2001); THOMAS RICE, THE ECONOMICS OF HEALTH RECONSIDERED (1998); Thomas Rice, *Can Markets Give Us the Health Care System We Want?*, 22 J. HEALTH, POL., POL'Y & L. 383 (1997); James A. Morone, *The Case Against Competition*, in COMPETITIVE APPROACHES TO HEALTH CARE

Agencies have long held that standard antitrust analysis and doctrines apply to health care markets. With rare exceptions, the antitrust laws are rules of general applicability, and they govern health care markets in largely the same way that they govern other markets.

To be sure, as noted previously, health care is extensively regulated. The optimal balance between competition and regulation is an enduring issue. Just over thirty years ago, the Senate Judiciary Committee, Subcommittee on Antitrust and Monopoly held six days of hearings on Competition in the Health Services Market. Senator Philip A. Hart opened the hearings with the following prescient observations:

Over the years, health care service has been treated pretty much as a "natural monopoly." It has been assumed that a community could support only so many hospitals; that providers just naturally control supply and demand. And there may be validity to such ideas. But, in this area, as in many others which have long been thought of as "natural monopolies," today questions are being raised as to just how pervasive the monopolization must be. Isn't it just possible, some are asking, that turning competition loose, at least in some sections, may not only lower

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REFORM, *supra*; Lawrence D. Brown, *Competition and the New Accountability: Do Market Incentives and Medical Outcomes Conflict or Cohere?*, in COMPETITIVE APPROACHES TO HEALTH CARE REFORM, *supra*; Theodore R. Marmor and David A. Boyum, *The Political Considerations of Procompetitive Reform*, in COMPETITIVE APPROACHES TO HEALTH CARE REFORM, *supra*.

the costs of health care but improve its quality? . . . [W]e hope to develop some suggestions as to areas where restrictions on trade could be replaced with competition to the benefit of the health and pocketbooks of consumers.<sup>201</sup>

In the intervening thirty years, it has become clear that health care is not a natural monopoly, and that competition has an important role to play in ensuring that consumers can obtain the care they desire at a price they are willing to pay. The Agencies help maintain competition in the health care financing and delivery markets, and ensure that market participants can compete to satisfy consumer demand.

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<sup>201</sup> Senator Philip A. Hart, Hearings Before the Subcomm. on Antitrust & Monopoly of the Senate Comm. on the Judiciary, 93rd Cong., 2nd Sess. 1 (1974).

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## CHAPTER 2: INDUSTRY SNAPSHOT AND COMPETITION LAW: PHYSICIANS

### I. OVERVIEW

As Chapter 1 details, competition has spurred significant changes in the market for physician services in the past several decades. Chapter 2 discusses how many physicians have sought to use innovative joint ventures to provide consumers with higher quality care at lower prices, while others have sought to stifle competition through conduct such as price-fixing and restrictions on allied health professionals. Reflecting consumer concerns about the quality, availability, and price of physician services, we highlight the benefits to consumers of competitive markets and vigorous antitrust enforcement.

This chapter first considers two types of provider network joint ventures – independent practice associations (IPAs) and physician-hospital organizations (PHOs) – that are part of the rapidly changing marketplace for physician services. We then discuss physician payment arrangements, the messenger model, and physician collective bargaining. Next, the chapter evaluates the competitive impact of restricting physicians’ and allied health professionals’ market entry. Finally, we examine the application of antitrust law to certain aspects of the marketplace for physician services, including private antitrust litigation about credentialing, the Agencies’ analysis to assess the financial and clinical integration of joint ventures, and the ability of physicians to share and use information relating to quality improvements.

Representatives from physician groups and organizations, attorneys, economists, and scholars testified on these

matters over seven days of Hearings. Physician topic panels included Health Care Services: Provider Integration (September 9, 2002); Physician Hospital Organizations (May 8); Quality and Consumer Information: Physicians (May 30); Quality and Consumer Protection: Market Entry (June 10); Prospective Guidance (June 26); Physician Product and Geographic Market Definition (September 24); Physician Information Sharing (September 24); Physician IPAs: Patterns and Benefits of Integration (September 25); Physician IPAs: Messenger Model (September 25); and Physician Unionization (September 26).<sup>1</sup>

### II. INTRODUCTION

Spending on physician and clinical services accounts for approximately 22% of the \$1.6 trillion spent annually on health care services.<sup>2</sup> Total spending on physician services increased at an average annual rate of 12 percent from 1970-1993.<sup>3</sup> As Figure 1 reflects, the rate of increase in spending on physician services has varied in the intervening decade, but generally ranged

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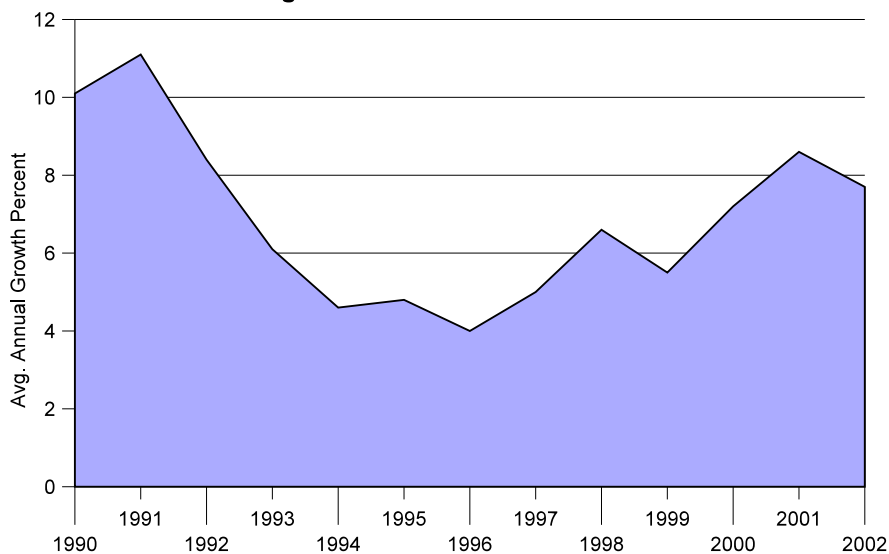
<sup>1</sup> Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcare/hearings/completeagenda.pdf>.

<sup>2</sup> See Stephen Heffler et al., *Trends: Health Spending Projections Through 2013*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-79, 80 ex.1 (2004), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.79v1.pdf>.

<sup>3</sup> *Id.* at 81 ex.2.

between four and seven percent per year.<sup>4</sup> Spending on physician services is projected to increase approximately seven percent per year for the next decade.<sup>5</sup> Nevertheless, the percentage of national health spending devoted to physician services is likely to decline given “[t]he continued shift of care to other professional services, negative updates to the Medicare physician payment rates, and faster growth in other sectors such as prescription drugs.”<sup>6</sup> Although physician services account for only 22 percent of total health care spending, the treatment decisions of physicians profoundly affect both the cost and quality of the other health care services that consumers receive.<sup>7</sup>

**Figure 1: National Physician and Clinical Services  
Average Annual Growth From Prior Year**



The cost and geographic distribution of physician services affect the accessibility of those services. For several reasons, including higher per capita incomes and economies of scale in complementary health care inputs, there are many more physicians per capita in metropolitan areas than in non-metropolitan and rural areas.<sup>8</sup>

<sup>4</sup> Centers for Medicare & Medicaid Services, *Health Accounts: National Health Expenditures 1965-2013, History and Projections by Type of Service and Source of Funds: Calendar Years 1965-2013*, at <http://www.cms.hhs.gov/statistics/nhe/default.asp#download> (last modified Mar. 24, 2004).

<sup>5</sup> Heffler et al., *supra* note 2, at 80 ex.1.

<sup>6</sup> Stephen Heffler et al., *Health Spending Projections For 2002-2012*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-54, 63, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.54v1.pdf>.

<sup>7</sup> Gail B. Agrawal & Howard R. Veit, *Back to the Future: The Managed Care Revolution*, 65 LAW & CONTEMP. PROBS. 11, 49 (2002) (stating that “reliance on medical judgment is inevitable in the complex cases that account for the majority of health care spending.”).

<sup>8</sup> See GENERAL ACCOUNTING OFFICE, PHYSICIAN SUPPLY INCREASED IN METROPOLITAN AND NONMETROPOLITAN AREAS BUT GEOGRAPHIC DISPARITIES PERSISTED 6 (2003) (reporting that metropolitan areas have more of the facilities and equipment on which physicians depend than nonmetropolitan areas and that specialists prefer to practice in metropolitan areas because they handle less prevalent but more complicated illnesses), available at <http://www.gao.gov/atext/d04124.txt>; INSTITUTE OF MEDICINE, THE NATION’S PHYSICIAN WORKFORCE: OPTIONS FOR BALANCING SUPPLY AND REQUIREMENTS 69 (1996) (“[A]n abundance of physicians will not solve the problems of maldistribution by geographic area or specialty.”).

### III. COMPETITION AND THE MARKET FOR PHYSICIAN SERVICES

Provider network joint ventures have the potential to reduce costs and improve quality. Some physicians, however, have responded to changes in the market for physician services by engaging in collusive anticompetitive conduct, seeking collective bargaining rights, and manipulating licensure regulations. The following sections describe these developments and assess their implications for the cost, quality, and availability of health care. Some of these sections contain recommendations to enhance the performance of the physician services market.

#### A. *Provider Network Joint Ventures*

As Chapter 1 discusses, the Supreme Court's decisions in *Goldfarb* and *Maricopa* clarified the antitrust laws' application to health care, and spurred numerous market changes, including the development of managed care. Many physicians responded to managed care's growth by implementing network joint ventures to facilitate contracting with managed care plans. This section focuses on two joint venture types (IPAs and PHOs) and describes their key features and potential efficiencies.<sup>9</sup> These joint venture types are not immutable categories; as managed care organizations (MCOs) have reduced reliance on capitation arrangements, some joint ventures have dissolved while others have implemented

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<sup>9</sup> Some of the potential efficiencies discussed in this Section may not constitute efficiencies for the purposes of the Agencies' antitrust analysis of physician network joint ventures.

messenger models or invested in clinical integration.<sup>10</sup> These joint ventures also compete with one another to recruit physician-members and to obtain MCO contracts.<sup>11</sup>

#### 1. IPAs

##### a. *Description of IPAs*

IPAs are networks of independent physicians that contract with MCOs and employers.<sup>12</sup> IPAs may be organized as sole proprietorships, partnerships, or professional

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<sup>10</sup> For a discussion of the messenger model, see *infra* notes 110-132, and accompanying text. For a discussion of clinical integration, see *infra* notes 249-281, and accompanying text. As discussed in Chapter 1, capitation involves a physician assuming responsibility for a certain number of patients and receiving a fixed amount for each of these patients regardless of whether those patients seek care.

<sup>11</sup> Joint ventures employ varying payment options, including capitated contracts, fee-for-service payment, and pay-for-performance incentives. For a discussion of physician payment arrangements, see *infra* notes 97-109, and accompanying text, and *supra* Chapter 1. Joint ventures also employ varying strategies to make themselves more attractive to MCOs, including integrating financially, clinically, or both. For a discussion of integration, see *infra* notes 249-281, and accompanying text.

<sup>12</sup> Gordon D. Brown, *Independent Practice Associations*, in *INTEGRATING THE PRACTICE OF MEDICINE: A DECISION MAKER'S GUIDE TO ORGANIZING AND MANAGING PHYSICIAN SERVICES* 289, 290 (Ronald B. Connors ed., 1997); Peter R. Kongstvedt et al., *Integrated Health Care Delivery Systems*, in *ESSENTIALS OF MANAGED HEALTH CARE* 35 (Peter R. Kongstvedt ed., 4th ed. 2003); Kevin Grumbach et al., *Independent Practice Association Physician Groups in California*, 17 *HEALTH AFFAIRS* 227, 227 (May/June 1998). For a discussion of MCOs, see *supra* Chapter 1.

corporations.<sup>13</sup> Physician-members generally own IPAs, although individual doctors, hospitals or physician practice management companies also own some IPAs.<sup>14</sup> IPAs contract with physicians on both an exclusive and nonexclusive basis.<sup>15</sup> IPAs have historically included primary care physicians and specialists, although some commentators have noted a trend toward the formation of single-specialty IPAs.<sup>16</sup> Many IPAs are nonprofit.<sup>17</sup>

IPAs can be integrated (financially, clinically, or both) to varying degrees or not at all. Physicians participating in financially integrated IPAs share financial risks. Clinically integrated IPAs seek to improve the quality of care their member-physicians provide through varied strategies. Physicians

who eschew financially or clinically integrating an IPA may use a messenger model to convey price and price-related information to the payor.

Most IPAs emerged in the 1980s as a reaction to managed care.<sup>18</sup> Panelists stated that some physicians in smaller practices thought that payors had the upper hand so they formed IPAs to gain bargaining leverage.<sup>19</sup> Physicians were also concerned about missing out on managed care contracts, particularly contracts that included capitation provisions.<sup>20</sup> One commentator stated that the Health Maintenance Organizations Act of 1973 spurred the growth of IPAs by recognizing them as an acceptable form of organized medical practice and providing funds for their development.<sup>21</sup> As MCOs have abandoned capitation arrangements with providers, the number of IPAs has declined in recent

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<sup>13</sup> See Brown, *supra* note 12, at 290-92.

<sup>14</sup> See Lawrence Casalino, *IPA Overview 4* (9/25/02) (slides) [hereinafter Casalino Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030925lawrencecasalino.pdf>; Robin R. Gillies et al., *How Different is California? A Comparison of U.S. Physician Organizations*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-492, 494 (observing that hospitals or HMOs own 18% of non-Californian IPAs, physicians own nearly 70%, and non-physician managers own about 12%. In California hospitals or HMOs own more than 20% of IPAs, physicians own approximately 50%, and non-physician managers own about 25%), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.492v1.pdf>.

<sup>15</sup> Grumbach et al., *supra* note 12, at 230 (noting that 40 percent of Californian IPAs use exclusive contracts for some physicians).

<sup>16</sup> Lawrence Casalino et al., *Growth of Single Specialty Medical Groups*, 23 HEALTH AFFAIRS 82 (Mar./Apr. 2004); Kongstvedt et al., *supra* note 12, at 35; Ginsburg 2/26 at 67.

<sup>17</sup> Kongstvedt et al., *supra* note 12, at 35.

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<sup>18</sup> Casalino 9/25 at 10 (stating that IPAs “were really more of a defensive strategy against managed care.”); Asner 9/25 at 31-32.

<sup>19</sup> Casalino 9/25 at 15, 97; Holloway 9/25 at 100; Asner 9/25 at 126; Doran 2/27 at 217 (stating that physicians bargaining alone lack data and an understanding of the negotiating process); TIMOTHY LAKE ET AL., MEDICARE PAYMENT ADVISORY COMM’N, MPR NO. 8568-700, HEALTH PLANS’ SELECTION AND PAYMENT OF HEALTH CARE PROVIDERS, 1999, at 120 (2000) (final report) (“Most of the entities were also formed to improve negotiating power or leverage with health plans (67 percent) and to protect market share (78 percent).”).

<sup>20</sup> Casalino 9/25 at 15 (stating that “if you’re a small practice, you might be left out of HMO contracts, but in a large IPA, you’re not likely to be.”); Asner 9/25 at 31; Kongstvedt et al., *supra* note 12, at 35.

<sup>21</sup> Brown, *supra* note 12, at 290.

years.<sup>22</sup>

Statistics on the number and size of IPAs vary.<sup>23</sup> A panelist representing an IPA trade association stated that there presently are approximately 2,000 IPAs nationwide.<sup>24</sup> One survey found that the number of IPAs decreased from 1223 in 1996 to 771 in 2002.<sup>25</sup> A national survey of physician organizations found that there were at least 463 IPAs that contained more than 20 physician members in 2002.<sup>26</sup>

One panelist noted that IPAs can vary in size from about a dozen to more than 1,000 physician members.<sup>27</sup> A national survey of physician organizations found the average number of doctors in an IPA was 233.<sup>28</sup> Another study calculated an average of 387 physicians per IPA nationwide, while in California the average was 418.<sup>29</sup>

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<sup>22</sup> Casalino 9/25 at 7, 12-13, 93 (explaining that “absent risk contracting, IPAs are struggling to find a reason to exist”); Meier 9/25 at 70. *But see* Asner 9/25 at 32 (stating “IPAs are still a very successful model in the State of California”).

<sup>23</sup> *See, e.g.*, Casalino 9/25 at 6.

<sup>24</sup> Holloway 9/25 at 74.

<sup>25</sup> HEALTH FORUM, LLC, AFFILIATE OF THE AMERICAN HOSPITAL ASS’N, HOSPITAL STATISTICS 8 tbl.3 (2000 ed.); HEALTH FORUM, LLC, AFFILIATE OF THE AMERICAN HOSPITAL ASS’N, HOSPITAL STATISTICS 10 tbl.3 (2004 ed.).

<sup>26</sup> Casalino Presentation, *supra* note 14, at 3; Casalino 9/25 at 6; Gillies et al., *supra* note 14, at 502.

<sup>27</sup> Meier 9/25 at 68.

<sup>28</sup> Casalino 9/25 at 7.

<sup>29</sup> Gillies et al., *supra* note 14, at 494.

## b. IPA Efficiencies

### (i) Costs and Related Efficiencies

Panelists and commentators disagreed about the impact of IPAs on the cost of care and whether IPAs can create efficiencies. Panelists stated that IPAs reduce contracting costs by lowering administrative and search costs for physicians and allowing payors to contract efficiently with pre-existing networks.<sup>30</sup> Additionally, they asserted that IPAs may generate efficiencies by integrating information technology and billing systems, using their collective purchasing power to receive volume discounts, and performing credentialing of physician-applicants.<sup>31</sup>

Others expressed concern that physicians may use IPAs to obtain increased fees from payors.<sup>32</sup> IPAs that engage in payor contracting and are not integrated run

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<sup>30</sup> *See* Asner 9/25 at 32-34; Casalino 9/25 at 14-16; American Medical Ass’n, *Physician IPAs: Patterns and Benefits of Integration, and Other Issues* (Sept. 25, 2003) 4 (Public Comment).

<sup>31</sup> Asner 9/25 at 31-33; Peter R. Kongstvedt, *Primary Care in Managed Health Care Plans*, in *ESSENTIALS OF MANAGED HEALTH CARE*, *supra* note 12, at 92-93; Casalino 9/25 at 14-15. For a discussion of private antitrust litigation involving physician credentialing, see *infra* notes 241-247, and accompanying text.

<sup>32</sup> *See* Kongstvedt, *supra* note 31, at 90 (contending that “[i]f relations between the IPA and the health plan become problematic, the IPA can hold a considerable portion (or perhaps all) of the delivery system hostage to negotiations.”); Casalino 5/28 at 126; Scott D. Danzis, *Revising the Revised Guidelines: Incentives, Clinically Integrated Physician Networks and the Antitrust Laws*, 87 VA. L. REV. 531, 535 (2001).

the risk of antitrust liability if they facilitate price agreements among their members.<sup>33</sup> IPAs also create an additional layer of administration, which can increase administrative costs – although physician-members in the IPA have an incentive to minimize these expenses.<sup>34</sup>

One panelist suggested that financial integration creates an incentive for physician-members to provide “quality care at the most cost effective price.”<sup>35</sup> Another panelist suggested that “pay for performance” (P4P) strategies, which are described in greater detail in Chapter 1 may be a new form of financial integration.<sup>36</sup> A third panelist noted that P4P strategies have been adopted on an industry-wide basis in

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<sup>33</sup> See, e.g., *In re Physician Network Consulting, L.L.C.*, No. C-4094 (Aug. 27, 2003) (decision and order), available at <http://www.ftc.gov/os/2003/08/physnetworkdo.pdf>; *In re Tex. Surgeons, P.A.*, No. C-3944 (May 18, 2000) (decision and order), available at <http://www.ftc.gov/os/2000/05/texas.do.htm>; *In re N. Lake Tahoe Med. Group, Inc.*, No. C-3885 (July 21, 1999) (decision and order), available at <http://www.ftc.gov/os/1999/08/northtahoe.do.htm>; *In re Mesa County Physicians Indep. Practice Ass’n, Inc.*, 127 F.T.C. 564 (1999); *In re Southbank IPA, Inc.*, 114 F.T.C. 783 (1991).

<sup>34</sup> See Casalino 9/25 at 17, 19; JAMES C. ROBINSON, *THE CORPORATE PRACTICE OF MEDICINE* 148 (1999) (physician-members are “motivated to . . . hold down expenses.”).

<sup>35</sup> Asner 9/25 at 38.

<sup>36</sup> Meier 9/25 at 64 (stating that pay for performance “very well could be another example of financial integration.”); see also Casalino 9/25 at 97 (observing that if physicians were paid based on quality, they would “be more interested in developing organized processes to improve quality.”).

California.<sup>37</sup> One study found that IPAs in California use 35-50 percent more care management strategies than physician organizations in other parts of the country.<sup>38</sup> The study identified two factors that strongly correlated with this difference: IPAs in California have greater exposure to external incentives to improve services and greater access to information technology than non-Californian IPAs.<sup>39</sup>

Panelists also considered whether clinical integration can reduce the cost of health care and create efficiencies. One panelist stated physicians in clinically integrated IPAs can do a better job monitoring and managing patients with chronic illnesses.<sup>40</sup> Such patients typically comprise five percent of the patient population but generate between 60 and 80 percent of health care costs.<sup>41</sup> Another panelist stated that clinical integration allows physicians to share information more

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<sup>37</sup> Asner 9/25 at 36-37 (also stating “[t]here are 25 other programs that are starting up across the country that are using the pay-for-performance model from California,” which cannot be implemented “with physicians in individual private practices.”).

<sup>38</sup> Gillies et al., *supra* note 14, at 496-98, 499. Care management strategies include disease management programs, use of guidelines and critical pathways, use of hospitalists, and the like.

<sup>39</sup> External incentives include outside reporting of patient satisfaction and outcome data, and recognition for quality such as receiving better contracts. *Id.*

<sup>40</sup> Asner 9/25 at 40.

<sup>41</sup> *Id.* at 39.

effectively.<sup>42</sup> Two panelists reported that some IPAs employ care management teams to coordinate patient care.<sup>43</sup> On the other hand, commentators noted that clinical integration is very expensive, and cautioned that physicians may prove unwilling to make the necessary investment.<sup>44</sup>

(ii) Quality of Care and Related Efficiencies

Some have stated that financial integration provides physicians with incentives to improve quality of care.<sup>45</sup>

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<sup>42</sup> Burkett 9/9/02 at 144-45 (stating that his organization’s clinical integration program provides “benefits for the patients, for the health plans and for the providers, all for different reasons, but much of it revolves around the ability to share the information that we use for patient care.”).

<sup>43</sup> Asner 9/25 at 40; Casalino 9/25 at 11 (noting that some IPAs pro-actively try to manage care to control costs and improve quality).

<sup>44</sup> See Hill 9/25 at 145; Hoangmai H. Pham et al., *Financial Pressures Spur Physician Entrepreneurialism*, 23 HEALTH AFFAIRS 70, 75-76 (Mar./Apr. 2004); DEP’T OF JUSTICE & FEDERAL TRADE COMM’N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE § 8(B)(1) (1996) (holding that the Agencies require physician network joint ventures to make a “significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize” sufficient clinical integration efficiencies to enable collective price-setting) [hereinafter HEALTH CARE STATEMENTS], available at <http://www.ftc.gov/reports/hlth3s.pdf>.

<sup>45</sup> Peter R. Kongstvedt, *Compensation of Primary Care Physicians in Managed Health Care*, in ESSENTIALS OF MANAGED HEALTH CARE, *supra* note 12, at 118 (“[C]apitation eliminates the FFS incentive to overutilize”). *Id.* at 120 (“[A] very large body of literature shows that managed care systems have provided equal or better care to members than

Nevertheless, many physicians state that financial incentives including capitation arrangements reduce quality of care.<sup>46</sup> One commentator observed that “[t]he degree to which capitation encourages organizations to compete on quality and efficiency depends on the market context within which it is used.”<sup>47</sup>

Panelists stated that clinical integration can improve quality of care.<sup>48</sup> One panelist observed that clinically integrated IPAs can “provide technology, clinical, and population management programs to improve patient care and outcomes.”<sup>49</sup> A capitated IPA that implemented certain clinical integration initiatives “exerted a dramatic impact on patterns of utilization and expenditure,” noted one commentator.<sup>50</sup> One study found that, although many IPAs have implemented organized care management programs to improve the quality of care for their patients,

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uncontrolled FFS systems.”).

<sup>46</sup> See, e.g., Kevin Grumbach, *Primary Care Physicians’ Experience of Financial Incentives in Managed-Care Systems*, 339 NEW ENG. J. MED. 1516, 1518-19 (1998).

<sup>47</sup> Lawrence Casalino, *Canaries in a Coal Mine: California Physician Groups and Competition*, 20 HEALTH AFFAIRS 97, 99 (July/Aug. 2001).

<sup>48</sup> Burkett 9/9/02 at 148; Asner 9/25 at 40 (observing that “under clinical integration there can be monitoring and managing chronic patients, and this will ensure high-quality, cost-effective care.”).

<sup>49</sup> Asner 9/25 at 33.

<sup>50</sup> ROBINSON, *supra* note 34, at 147 (“Cardiology in the . . . region experienced a 30 percent drop in hospital utilization and a 20 percent drop in claims costs in the first year.”).

the use of such processes is still “relatively uncommon.”<sup>51</sup> Some experts contend that an integrated, or “closely knit” IPA may provide a good environment for testing whether quality programs can deliver hoped-for results.<sup>52</sup>

## 2. PHOs

### a. Description of PHOs

A PHO is a joint venture between a hospital and physicians who generally have admitting privileges at the hospital.<sup>53</sup> Physician and hospital members of a PHO sometimes contract jointly with MCOs for providing care to a population of patients. PHOs typically vary along four parameters: exclusivity, integration, ownership/control, and organizational base.<sup>54</sup>

First, PHOs can accept hospital medical staff on an exclusive or nonexclusive basis. Open PHOs allow most medical staff to join and have minimum credentialing requirements; specialists

usually dominate these PHOs.<sup>55</sup> Closed PHOs limit physician membership by practice profiling or specialty type and are more likely to form exclusive relationships with physicians.<sup>56</sup> PHOs that employ practice profiling seek to use objective practice data to determine which physicians they should invite to join the PHO.<sup>57</sup> PHOs that recruit physician-members based on specialty type reportedly focus on the number of patients that the physician-member will see.<sup>58</sup>

Second, PHOs are integrated (whether financially, clinically, or both) to varying degrees or not at all.<sup>59</sup> Many PHOs employ financial risk-sharing arrangements

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<sup>51</sup> Lawrence Casalino et al., *External Incentives, Information Technology, and Organized Process to Improve Health Care Quality for Patients with Chronic Disease*, 289 JAMA 434, 439 (2003).

<sup>52</sup> Thomas Bodenheimer et al., *Primary Care Physicians Should Be Coordinators, Not Gatekeepers*, 281 JAMA 2045, 2048 (1999).

<sup>53</sup> Lawton R. Burns & Darrell P. Thorpe, *Physician-Hospital Organizations: Strategy, Structure, and Conduct*, in INTEGRATING THE PRACTICE OF MEDICINE, *supra* note 12, at 352; Miles 5/8 at 6; Guerin-Calvert 5/8 at 15.

<sup>54</sup> See generally Marren 5/8 at 30 (remarking that “if you have seen one PHO, you have seen one PHO.”); Guerin-Calvert 5/8 at 20.

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<sup>55</sup> Kongstvedt et al., *supra* note 12, at 43; Burns & Thorpe, *supra* note 53, at 353; Alison Evans Cuellar & Paul J. Gertler, *Strategic Integration of Hospitals and Physicians* 9 (May 1, 2002) (unpublished manuscript), at [http://faculty.haas.berkeley.edu/gertler/working\\_papers/hospital\\_VI\\_5\\_10\\_02.pdf](http://faculty.haas.berkeley.edu/gertler/working_papers/hospital_VI_5_10_02.pdf).

<sup>56</sup> Cuellar & Gertler, *supra* note 55, at 10; Kongstvedt et al., *supra* note 12, at 43, 45 (mentioning the emergence in recent years of closed PHOs with only one type of specialist); Marren 5/8 at 37 (nothing that there are not many exclusive PHOs); Burns & Thorpe, *supra* note 53, at 353.

<sup>57</sup> Kongstvedt et al., *supra* note 12, at 43-44. Many PHOs have found it difficult to get the necessary information in a timely manner so as to profile physician-members comprehensively. An additional complication is dealing with physicians who refuse to adhere to profiling requirements after they become members of a PHO. For a discussion of the antitrust issues related to physician credentialing, see *infra* notes 241-247, and accompanying text.

<sup>58</sup> Kongstvedt et al., *supra* note 12, at 43.

<sup>59</sup> For a discussion of the antitrust issues associated with clinical and financial integration, see *infra* notes 252-281, and accompanying text.



with physician-members, such as partial or full-risk contracts, although PHOs, as a whole, appear to be moving away from full-risk contracts.<sup>60</sup>

Third, ownership, control, and capital structure vary. Physician-members and hospitals jointly own most PHOs, but some hospitals are sole owners.<sup>61</sup> Although hospitals generally provide a majority of initial capitalization, some PHOs strive for equal physician-hospital ownership.<sup>62</sup> Physicians may own interests in a PHO individually or through an entity such as an IPA.<sup>63</sup> PHOs can take the form of a limited liability company, a general partnership, a nonprofit corporation, or a general business corporation.<sup>64</sup>

Finally, PHOs can have different organizational bases. PHOs can have a hospital, multiple hospitals, or a hospital system as their organizational base.<sup>65</sup>

Commentators often describe PHOs that involve multiple hospitals or joint ventures between multiple PHOs as super-PHOs.<sup>66</sup>

Panelists and commentators stated that PHOs emerged in the 1980s largely as “a defensive provider reaction to increasing managed care penetration.”<sup>67</sup> PHOs subsequently became the most common form of vertical integration among physicians and hospitals.<sup>68</sup> Approximately 60 percent of PHOs are nonprofit and 40 percent are for-profit.<sup>69</sup> In 2002, 74 percent of PHOs were open and 26 percent were closed.<sup>70</sup>

Panelists noted that PHOs have changed substantially in recent years.<sup>71</sup> Many PHOs initially engaged in full or partial risk contracting. As insurers and providers abandoned capitated payment

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<sup>60</sup> See, e.g., Guerin-Calvert 5/8 at 15, 18-20.

<sup>61</sup> Kevin J. Egan & Rebecca L. Williams, *Vertically Integrated Networks*, in HEALTH CARE CORPORATE LAW: MANAGED CARE § 5.12.2, at 5-105 to 5-107 (Mark A. Hall & William S. Brewbaker III eds., 1999 & Supp. 1999); Kongstvedt et al., *supra* note 12, at 42.

<sup>62</sup> Kongstvedt et al., *supra* note 12, at 42; Egan & Williams, *supra* note 61, § 5.12.2, at 5-105.

<sup>63</sup> Egan & Williams, *supra* note 61, § 5.12.2, at 5-105.

<sup>64</sup> Julie Y. Park, *PHOs and the 1996 Federal Antitrust Enforcement Guidelines: Ensuring the Formation of Procompetitive Multiprovider Networks*, 91 NW. U. L. REV. 1684, 1692 (1997).

<sup>65</sup> See Burns & Thorpe, *supra* note 53, at 353.

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<sup>66</sup> See Miles 5/8 at 9; Burns & Thorpe, *supra* note 53, at 353; Weis 5/8 at 38-39 (describing the Advocate Health Care Network, which comprises eight PHO joint ventures, including 2,400 independently practicing physicians and eight Advocate hospitals).

<sup>67</sup> Burns & Thorpe, *supra* note 53, at 352; see also Weis 5/8 at 38; Miles 5/8 at 4; Kongstvedt et al., *supra* note 12, at 41-42; Egan & Williams, *supra* note 61, § 5.12.2, at 5-105.

<sup>68</sup> Burns & Thorpe, *supra* note 53, at 352.

<sup>69</sup> STEPHEN J. KRATZ, TAYLOR & COMPANY AND AMERICAN ASS'N OF INTEGRATED HEALTHCARE DELIVERY SYSTEMS (AAIHDS), PERSPECTIVES ON INTEGRATED DELIVERY SYSTEMS AND IDS EXECUTIVES 2 (1998/99).

<sup>70</sup> HEALTH FORUM (2004 ed.), *supra* note 25, at 10 tbl.3.

<sup>71</sup> See Guerin-Calvert 5/8 at 14-15; Miles 5/8 at 6-7.

arrangements in favor of preferred provider organizations (PPOs) and point of service plans (POS plans), many PHOs scrambled to identify a new role to fill.<sup>72</sup> Numerous PHOs have dissolved or failed in the last eight years.<sup>73</sup> One antitrust lawyer panelist stated that his recent experience with PHOs primarily involves converting them into messenger model networks.<sup>74</sup> PHOs that engage in payor contracting and are not integrated run the risk of antitrust liability if they facilitate price agreements among their members.<sup>75</sup>

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<sup>72</sup> Miles 5/8 at 4; Guerin-Calvert 5/8 at 17-18 (establishing that fewer PHOs are involved in full-risk contracting); Weis 5/8 at 76; Ginsburg, 2/26 at 67-68 (noting “a sharp decline in physician hospital organizations”); Lesser 9/9/02 at 83-84 (stating that PHOs are less relevant following the decline in risk contracting). *But see* Babo 5/8 at 41 (describing Advocate Health Partners’ use of full risk contracts with managed care). For a discussion of PPOs, see *infra* Chapter 5.

<sup>73</sup> See Miles 5/8 at 4-5; Marren 5/8 at 36-37; Nathan S. Kaufman, *Market Dominance of PHO Entities*, HEALTHCARE FIN. MGMT., Aug. 1998 (“Many PHOs are either unprofitable, unsuccessful at developing new business, or stalemated by politics”); Lawton R. Burns & Mark V. Pauly, *Integrated Delivery Networks: A Detour on the Road to Integrated Health Care?*, 21 HEALTH AFFAIRS 128, 128 (July/Aug. 2002).

One survey found that the number of PHOs declined from 1446 in 1994 to 1114 in 2002. HEALTH FORUM (2000 ed.), *supra* note 25, at 8 tbl. 3; HEALTH FORUM (2004 ed.), *supra* note 25, at 10 tbl.3.

<sup>74</sup> See Miles 5/8 at 6-7.

<sup>75</sup> The Agencies have brought a number of cases alleging that PHOs violated the antitrust laws. See, e.g., *In re Piedmont Health Alliance, Inc.*, No. 9314 (Dec. 24, 2003) (complaint), available at <http://www.ftc.gov/os/caselist/0210119/031222comp0210119.pdf>; *In re S. Ga. Health Partners, L.L.C.*, No. C-4100 (Oct. 31, 2003) (complaint), available at

b. *PHO Efficiencies*

(i) Costs and Related Efficiencies

Panelists and commentators differ on whether PHOs can reduce costs or otherwise result in efficiencies. Some contend that PHOs can reduce the cost of negotiating contracts between payors and physicians and hospitals by offering “one-stop shopping.”<sup>76</sup> As such, PHOs may enable payors to contract more efficiently with physicians with whom they have no existing contractual arrangements. PHOs could also allow providers to contract directly with self-insured employers and certain Medicare and Medicaid risk or managed contracts.<sup>77</sup>

Commentators and panelists also stated that PHOs may deliver economies of scale by sharing administrative and integration costs among physician-members

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<http://www.ftc.gov/os/2003/11/sgeorgiacomp.pdf>; *In re Me. Health Alliance*, No. C-4095 (Aug. 27, 2003) (complaint), available at <http://www.ftc.gov/os/2003/08/mainehhealthcomp.pdf>; *United States v. Health Choice of Nw. Mo.*, No. 95-6171-CV-SJ-6 (W.D. Mo., filed Sept. 13, 1995) (complaint); *United States v. Healthcare Partners*, No. 3:95CV01946 (D. Conn., filed Sept. 13, 1995) (complaint); *United States v. Women’s Hosp. Found.*, No. 96-389-BM2 (M.D. La., filed Apr. 23, 1996) (complaint).

<sup>76</sup> Egan & Williams, *supra* note 61, § 5.12.6, at 5-110; Kongstvedt et al., *supra* note 12, at 44; Burns & Thorpe, *supra* note 53, at 354; Weis 5/8 at 44; Park, *supra* note 64, at 1695.

<sup>77</sup> See Kaufman, *supra* note 73, at 3; Egan & Williams, *supra* note 61, § 5.12.6, at 5-110. Presumably, such PHOs are integrated sufficiently to avoid per se condemnation under the antitrust laws.

and hospitals.<sup>78</sup> They further said that PHOs may result in more efficient deployment of physician resources, because these arrangements allow physician-members to concentrate on practicing medicine.<sup>79</sup> Finally, they added that PHOs may reduce legal expenses for hospitals and physicians by enabling them to “present a unified front and a common defense in the event of malpractice claims.”<sup>80</sup>

Others contend that the primary advantage for physicians and hospitals in forming a PHO is the increased bargaining power gained from “presenting a united front to payers.”<sup>81</sup> They assert that providers can use this additional bargaining power to obtain higher prices from payors, particularly if providers “raise barriers to

entry by forming exclusive relationships.”<sup>82</sup> A panelist representing a health insurance plan stated that PHOs have given providers “greater negotiation leverage” and “contributed to some of the runaway inflation in health care costs.”<sup>83</sup>

Empirical studies of PHO pricing have found mixed results.<sup>84</sup> A recent study of hospital and physician integration based on organizations in Arizona, Florida, and Wisconsin found that integration is associated with an increase in prices, especially when the integrated organization is exclusive and located in less competitive markets.<sup>85</sup> Other studies have concluded that physician-hospital affiliations generally do not result in higher hospital prices.<sup>86</sup>

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<sup>78</sup> Egan & Williams, *supra* note 61, § 5.12.6, at 5-110; Dalkir 5/8 at 68 (observing that efficiencies can be derived from physicians organizing as a group and from physicians and hospitals integrating).

<sup>79</sup> See Egan & Williams, *supra* note 61, § 5.12.6, at 5-110; Miles 5/8 at 10 (explaining that PHO physicians can refer their patients to other PHO participants, which has “obvious[] pro-competitive and efficiency justifications.”). *But cf.* Buxton 5/8 at 50 (suggesting intra-organization referrals may result in overuse).

<sup>80</sup> Egan & Williams, *supra* note 61, § 5.12.6, at 5-110.

<sup>81</sup> Burns & Thorpe, *supra* note 53, at 353; see also Burns 4/9 at 70; Kongstvedt et al., *supra* note 12, at 41-42. *But see* Miles 5/8 at 79 (observing that managed care plans can have a phobia of dealing with provider networks because the plans assume the networks form only to obtain higher fees).

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<sup>82</sup> Cuellar & Gertler, *supra* note 55, at 7; see also Guerin-Calvert 5/8 at 21-23; Dalkir 5/8 at 26; Buxton 5/8 at 51-52 (listing examples of physician groups demanding significant fees). For further discussion of physician collective bargaining, see *infra* notes 133-178, and accompanying text.

<sup>83</sup> Buxton 5/8 at 50; see also Hurley 4/9 at 18.

<sup>84</sup> STEPHEN M. SHORTELLET AL., REMAKING HEALTH CARE IN AMERICA: THE EVOLUTION OF ORGANIZED DELIVERY SYSTEMS 26 (2nd ed. 2000).

<sup>85</sup> Cuellar & Gertler, *supra* note 55, at 25-26.

<sup>86</sup> Federico Giliberto & David Dranove, The Effect of Physician-Hospital Affiliations on Hospital Prices in California 1 (Nov. 30, 2003) (unpublished manuscript) (finding that highly integrated hospital and physician structures may slightly reduce prices); Kaufman, *supra* note 73, at 1 (discussing research that “showed no correlation between a hospital’s physician integration strategy and its payments under managed care. There is, however, a high correlation between a hospital’s payments under managed care and its institutional market position. Dominant hospital systems got paid better than marginal

Some commentators doubt whether PHOs actually lower the costs associated with contracting.<sup>87</sup> One commentator stated that PHOs have not resulted “in any meaningful improvement in contracting ability. In many cases, MCOs already have provider contracts in place and see little value in going through the PHO.”<sup>88</sup>

(ii) Quality of Care and Related Efficiencies

Panelists and commentators differed on the ability of PHOs to improve quality of care. Some stated that PHOs can significantly improve quality by coordinating patient care delivered to consumers in the doctor’s office and the hospital.<sup>89</sup> They also stated that PHOs can implement shared information systems.<sup>90</sup> As Chapter 1 reflects, many commentators state such investments in information infrastructures are a necessary first step in improving quality of care.

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hospitals regardless of whether they had a PHO.”).

<sup>87</sup> See Kongstvedt et al., *supra* note 12, at 44-45; Burns & Thorpe, *supra* note 53, at 354.

<sup>88</sup> Kongstvedt et al., *supra* note 12, at 44-45.

<sup>89</sup> Marren 5/8 at 34; Weis 5/8 at 46 (discussing the crucial role clinical integration can play in creating efficiencies and improving patient safety); Miles 5/8 at 79-80; Guerin-Calvert 5/8 at 23; Babo 5/8 at 60; Vogt 9/9/02 at 69; Park, *supra* note 64, at 1693-94 (stating that “PHOs may permit . . . consumers to obtain high quality at a lower price by conducting or developing systems for utilization review and quality assurance.”); Cuellar & Gertler, *supra* note 55, at 4. *But see* Burns 4/9 at 77-78.

<sup>90</sup> See Cuellar & Gertler, *supra* note 55, at 4; Guerin-Calvert 5/8 at 18-19.

One panelist representing a PHO contended that financially integrated PHOs can reduce costs and improve quality by clinically integrating.<sup>91</sup> This panelist also suggested that physicians practicing individually or in small groups that are not financially or clinically integrated have limited ability to improve quality, reduce costs, and capture related efficiencies.<sup>92</sup> The same panelist suggested that physicians practicing in large groups do not readily cooperate with one another, and hospitals are the most likely entities to implement programs to improve health care quality and reduce costs.<sup>93</sup>

Another panelist noted PHOs must make significant investments in clinical integration to improve quality of care.<sup>94</sup> A third panelist suggested that clinical integration is improbable because of its high implementation costs and potential antitrust risks.<sup>95</sup> A panelist representing a health

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<sup>91</sup> See Weis 5/8 at 41-42, 60-62.

<sup>92</sup> *Id.* at 60-62.

<sup>93</sup> See *id.* at 60-62; Marren 5/8 at 31-32 (stating that physicians do not self-organize very well). *But see* Kaufman, *supra* note 73, at 2 (stating that “[h]ospitals . . . are less motivated than [physician practice management companies] to extract profit growth from the physician practices they purchase and/or manage.”).

<sup>94</sup> Guerin-Calvert 5/8 at 17; *see also* Marren 5/8 at 34-35, 36-37; Weis 5/8 at 61 (observing that “some form of clinical or financial integration is necessary in order to achieve quality improvement, cost reduction and better patient safety.”); Burns & Thorpe, *supra* note 53, at 354.

<sup>95</sup> Miles 5/8 at 5, 7 (citing antitrust concerns and the refusal of a state antitrust bureau to accept clinical integration for antitrust analysis purposes); *see also* Timothy S. Snail & James C. Robinson,

insurance plan stated that “there appears to be no difference in the quality of care offered by a PHO than that offered by physicians and hospitals that contract separately.”<sup>96</sup> Although opinions regarding PHOs vary significantly, there is relatively little empirical research on PHOs, quality of care, and clinical integration with which to resolve these competing claims, and the available evidence is decidedly mixed.

### 3. Summary

Physicians have historically been solo or small-group practitioners, competing only with other such practitioners in their particular product and geographic market. As the market for physician services has evolved, and antitrust enforcement has addressed anticompetitive conduct, competition has emerged along multiple dimensions. IPAs and PHOs compete for physician-members and to contract with payors. The forms and modes of competition in the market for physician services will inevitably vary over time as conditions and preferences change. Competition helps deliver an optimum mix of physician services at the lowest cost and highest quality. The Agencies are committed to vigorous price and non-price competition and not to any particular model for delivering health care.

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*Organizational Diversification in the American Hospital*, 19 ANN. REV. PUB. HEALTH 417, 423 (1998).

<sup>96</sup> Buxton 5/8 at 49-50 (suggesting also that intra-organization referrals may result in overuse).

## B. Physician Compensation

### 1. Physician Payment Arrangements

Insurers and others typically pay physicians on an FFS, salaried, or capitated basis.<sup>97</sup> In FFS payment an insurer directly pays an individual provider based on the number and type of services that provider performs.<sup>98</sup> Some state that FFS improves quality by rewarding physicians who do more for their patients.<sup>99</sup> Other commentators are concerned that FFS payment creates incentives for physicians to over-provide healthcare resources because a physician’s income is directly related to the volume and intensity of services rendered.<sup>100</sup>

Capitation involves a physician assuming responsibility for a certain number of patients and receiving a fixed amount for each of these patients regardless of whether

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<sup>97</sup> Sherry Glied, *Managed Care*, in 1A HANDBOOK OF HEALTH ECONOMICS (Anthony J. Culyer & Joseph P. Newhouse, eds. 2000). The payment arrangement that insurers use to pay a physician network joint venture may be different from the arrangement those joint ventures use to pay their physician members. See James C. Robinson, *Blended Payment Methods in Physician Organizations Under Managed Care*, 282 JAMA 1258, 1258 (1999).

<sup>98</sup> See Academy for Health Management, *A Glossary of Managed Care Terms*, at <http://www.aahp.org/glossary/index.html> (last visited June 22, 2004).

<sup>99</sup> See, e.g., Kongstvedt, *supra* note 45, at 123 (noting that sicker patients require more care and doctors practicing on a FFS basis get paid more for their time, energy and skills applied to such patients).

<sup>100</sup> See, e.g., David Orentlicher, *Paying Physicians More To Do Less: Financial Incentives to Limit Care*, 30 U. RICH. L. REV. 155, 158 (1996); GLIED, *supra* note 97, at 723-25.

those patients seek care.<sup>101</sup> Although some state that capitation reduces the incentive to provide excessive care,<sup>102</sup> others are concerned that capitation creates an incentive for physicians to increase the number of patients for whom they provide care and simultaneously decrease the services they actually provide.<sup>103</sup>

Physicians employed by the government, hospitals, or medical groups typically receive a salary.<sup>104</sup> Some commentators state that medical groups or organizations can align more carefully the incentives of the physician with those of the group by paying salaries.<sup>105</sup> Others are concerned that such arrangements also create an incentive for physicians to decrease the number of patients they are responsible for and the services they provide.<sup>106</sup>

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<sup>101</sup> Orentlicher, *supra* note 100, at 158-159; Casalino 9/25 at 7; GLIED, *supra* note 97, at 714-16.

<sup>102</sup> Kongstvedt, *supra* note 45, at 118.

<sup>103</sup> See, e.g., Orentlicher, *supra* note 100, at 158-59.

<sup>104</sup> See Carol K. Kane & Horst Loeblich, *Physician Income: The Decade in Review*, in AMERICAN MEDICAL ASS'N, PHYSICIAN SOCIOECONOMIC STATISTICS 7 (2002 ed.) (noting that approximately 35 percent of physicians are salary-based employees).

<sup>105</sup> Kongstvedt et al., *supra* note 12, at 48 (discussing the use of salaries to capture economies of scales and to apply capital resources most effectively).

<sup>106</sup> Orentlicher, *supra* note 100, at 159; Henry T. Greely, *Direct Financial Incentives in Managed Care: Unanswered Questions*, 6 HEALTH MATRIX 53, 57 (1997).

Medicare reimburses physicians on an FFS basis, using the resource-based relative value scale (RBRVS).<sup>107</sup> The Centers for Medicare & Medicaid Services determine the RBRVS based on the cost of physician labor, practice overheads, materials, and liability insurance. The resulting figure is adjusted for geographical differences and is updated annually.<sup>108</sup> Many private payors and MCOs base their payment of physicians on this schedule.<sup>109</sup>

## 2. Messenger Model

### a. Description of the Messenger Model

The messenger model is an arrangement that allows contracting between providers and payors, while avoiding price-fixing among competing providers.<sup>110</sup> *Health Care Statement 9* provides that messenger models “can be organized and operated in a variety of ways.”<sup>111</sup> One

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<sup>107</sup> See generally American Medical Ass'n, *RVS Update Process* (2002), at <http://www.ama-assn.org/ama1/pub/upload/mm/380/rucbooklet.pdf>. For a discussion of trends in Medicare spending on physician services, see GENERAL ACCOUNTING OFFICE, *MEDICARE PHYSICIAN PAYMENTS* (2004), available at <http://www.gao.gov/new.items/d04751t.pdf>.

<sup>108</sup> See American Medical Ass'n, *supra* note 107.

<sup>109</sup> Kongstvedt, *supra* note 45, at 127 (stating that private payors paid physicians 20 percent more than the Medicare amount in 1999).

<sup>110</sup> HEALTH CARE STATEMENTS, *supra* note 44, § 9(C); Raskin 9/25 at 174.

<sup>111</sup> HEALTH CARE STATEMENTS, *supra* note 44, § 9(C); see also Arthur N. Lerner & David M. Narrow, *PPO Programs and the Antitrust Laws*, in THE NEW HEALTHCARE MARKET: A GUIDE TO PPOS

panelist described the traditional messenger model as one involving a payor submitting fee schedules to an agent or third party, who transmits this schedule to the network physicians.<sup>112</sup> This panelist elaborated that each physician decides individually whether to accept or reject the fee schedule and the messenger or agent communicates those decisions to the payor.<sup>113</sup> The payor may then initiate another round of negotiations with the network physicians or enter into contracts with those physicians who accepted its offer, observed the panelist.<sup>114</sup>

Commentators have discussed a variation that involves the messenger conveying to payors information obtained individually from providers about the prices or price-related terms that those providers are willing to accept.<sup>115</sup> The messenger may

aggregate this information into a comprehensive schedule and market the schedule to payors, and may receive authority from individual physicians to accept contractual offers on their behalf, commentators have noted.<sup>116</sup> They also stated that agents must convey offers that do not meet a physician's preferred rate to those physicians, because they are not empowered to reject offers.<sup>117</sup> Agents also may help physicians understand the contracts offered, for example, by providing objective or empirical information about the terms of an offer.<sup>118</sup> Messenger models can be used creatively to facilitate contracting between payors and providers, so long as they do not facilitate anticompetitive agreements on price or other terms.<sup>119</sup>

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(Peter Boland ed., 1985).

<sup>112</sup> Douglas C. Ross, *Physician IPAS: Messenger Model 5* (9/25) (slides) [hereinafter Ross Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030925douglasross.pdf>; Ross 9/25 at 150-51 (also acknowledging that physicians infrequently implement the traditional messenger model).

<sup>113</sup> Ross Presentation, *supra* note 112, at 5; Ross 9/25 at 150; Kim H. Roeder, *The 1996 Antitrust Policy Statements: Balancing Flexibility and Certainty*, 31 GA. L. REV. 649, 671 (1997) ("The key to the Messenger Model [is] that the individual providers [make] independent, unilateral decisions irrespective of what other providers would do and regardless of the views of the agent acting as the messenger.").

<sup>114</sup> Ross 9/25 at 150.

<sup>115</sup> Edward Hirshfeld, *Interpreting the 1996 Federal Antitrust Guidelines for Physician Joint Venture Networks*, 6 ANN. HEALTH L. 1, 29 (1997);

Ross 9/25 at 151.

<sup>116</sup> Hirshfeld, *supra* note 115, at 29; Ross 9/25 at 151.

<sup>117</sup> Hirshfeld, *supra* note 115, at 29; Miles 9/25 at 170.

<sup>118</sup> Hirshfeld, *supra* note 115, at 29; Miles 9/25 at 167-68.

<sup>119</sup> Commission staff recently issued an advisory opinion that involved the messenger collecting minimum payment levels for certain procedures from each physician member. If a payor's offer exceeded these minimum payment levels for more than 50% of network physicians, then the messenger would contract on these physicians' behalf. If the payor's offer met the minimum payment level for less than 50% of physician members, then the payor would have to agree to bear contract administration costs before the messenger could enter a contract. Commission staff emphasized in the advisory opinion that this arrangement would be acceptable only if it were not used to facilitate price collusion. See Letter from Jeffrey W. Brennan, Federal Trade Commission, to Martin J. Thompson, Manatt, Phelps & Phillips, LLP (Sept. 23, 2003) (FTC Staff advisory opinion regarding Bay Area

Physician networks purporting to use the messenger model have given rise to considerable antitrust enforcement activity. In recent years, the Agencies have brought numerous cases alleging physicians involved in messenger models engaged in anticompetitive conduct.<sup>120</sup> These cases have involved a diverse array of allegations.<sup>121</sup>

*b. Messenger Model Efficiencies and Antitrust Concerns*

Panelists and commentators expressed differing views on whether the messenger model can reduce costs for providers and payors. Some stated that the messenger model simplifies contracting and contract administration, thereby reducing

physicians' and payors' transaction costs.<sup>122</sup> Two panelists observed that an agent can significantly reduce physicians' transaction costs by educating them about the terms of a contract.<sup>123</sup> Panelists also explained that a properly implemented messenger model cannot result in higher prices for payors, because it is incapable of creating countervailing market power for physicians.<sup>124</sup> Finally, one panelist observed that networks risk incurring administration costs for limited gain if only a minority of network physicians accept a payor's offer.<sup>125</sup>

In contrast, some panelists and commentators stated that the messenger model is not a viable business strategy and can increase costs for providers and

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Preferred Physicians), available at <http://www.ftc.gov/bc/adops/bapp030923.htm>.

<sup>120</sup> See, e.g., *In re Physician Network Consulting, L.L.C.*, No. C-4094 (Aug. 27, 2003) (decision and order), available at <http://www.ftc.gov/os/2003/08/physnetworkdo.pdf>; *In re Carlsbad Physician Ass'n*, No. C-4081 (June 13, 2003) (decision and order), available at <http://www.ftc.gov/os/2003/06/carlsbaddo.htm>; *In re SPA Health Org.*, No. C-4088 (July 17, 2003) (decision and order), available at <http://www.ftc.gov/os/2003/07/spahealthdo.pdf>; *United States v. Fed'n of Physicians & Dentists, Inc.*, 2002-2 Trade Cas. (CCH) ¶ 73,868 (D. Del., 2002); *United States v. Mountain Health Care, P.A.*, 2003-2 Trade Cas. (CCH) ¶ 74,162 (W.D.N.C. 2003).

<sup>121</sup> For example, so-called "messengers" in several instances allegedly negotiated prices with payors, refused to transmit price offers that were deemed insufficient, or orchestrated price agreements among network physicians.

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<sup>122</sup> See Miles 9/25 at 167 (stating also that "messenger networks can help market their provider's services, hopefully increasing provider volume"); Lerner 9/25 at 235-36 (suggesting that the messenger model could facilitate a new payor's entry into local markets by creating provider networks with which the payor could readily contract); Robert Leibenluft, *Why Physician Cartels Do Not Need a "Fresh Look" – a Response to the AMA's Testimony at the FTC Health Care Competition Workshop 5* (Public Comment) [hereinafter links to FTC Health Care Workshop Public Comments are available at <http://www.ftc.gov/os/comments/healthcarecomments/index.htm>].

<sup>123</sup> Miles 9/25 at 167-168 (stating that messengers can educate physicians and their staff "to make more rational contracting decisions"); Hill 9/25 at 228 (remarking that physicians are not trained to understand contracts and that many physicians have limited interest in such contracts).

<sup>124</sup> Miles 9/25 at 168-169; Lerner 9/25 at 200; Ross 9/25 at 223-224.

<sup>125</sup> Ross 2/25 at 150-151.



payors.<sup>126</sup> Panelists contended that such arrangements have high administrative costs because they are complex to implement and difficult to maintain.<sup>127</sup> They observed that agents frequently cannot determine the antitrust implications of a particular course of conduct and therefore require expensive legal advice.<sup>128</sup> Others noted that certain messenger model variations actually can prolong contract negotiations and increase provider and payor transaction costs.<sup>129</sup>

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<sup>126</sup> Raskin 9/25 at 173 (“I have never found . . . any business person, any administrator or healthcare professional in any segment of the industry who advocates the use of the messenger model for any business purpose.”); Miles 9/25 at 214-215 (stating that “[m]essenger models are worthless, except as interim tools.”).

<sup>127</sup> Hill 9/25 at 147 (declaring that the messenger model “is cumbersome, it’s difficult to administer, and it’s not surprising that the messenger model is often despised by physicians, hospitals, and to our understanding even payors.”); J. Edward Hill, *Physician IPAs; Messenger Model 4* (9/25), at <http://www.ama-assn.org/ama1/pub/upload/mm/368/drhllftstatement.pdf>; Miles 9/25 at 169 (stating that the messenger model is so “cumbersome” to implement and maintain that it is “a pain in the butt”); Jack R. Bierig, *Physician-Sponsored Managed Care Networks: Two Suggestions for Antitrust Reform*, 6 HEALTH MATRIX 115, 122 (1996) (“The messenger model is universally recognized as inefficient and cumbersome, particularly given the thousands of medical procedures and the large numbers of physicians involved in physician networks.”). One panelist noted the concern that physicians might adopt the network fee schedule for use in their own individual practices, thereby leading to increased prices for payors and consumers. This panelist further stated that such concerns have never been empirically established. See Raskin 9/25 at 179-80.

<sup>128</sup> Hill 9/25 at 228; Miles 9/25 at 169-71.

<sup>129</sup> Ross 9/25 at 156 (stating that some versions of the messenger model can lead to “going back and forth potentially forever”); Hill 9/25 at 147;

Panelists and commentators also differed on the messenger model’s usefulness in avoiding antitrust concerns. Some stated that messenger arrangements are useful in preventing violations of the antitrust laws and lower the risk of being compelled to disband a network to settle an Agency investigation.<sup>130</sup> One panelist noted the model has been particularly useful for erstwhile financially integrated physician networks that need an alternative contracting mechanism as risk sharing arrangements have become less common.<sup>131</sup>

Others noted that physician networks purporting to use the messenger model have been the focus of multiple Agency investigations and consent settlements.<sup>132</sup>

### 3. Physician Collective Bargaining

Some physicians have lobbied heavily for statutory or other legal changes that would enable independent physicians to bargain collectively by exempting them from the antitrust laws.<sup>133</sup> Those who support

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Miles 9/25 at 157 (stating that physicians may provide “very, very high, unrealistic rates” under some messenger arrangements because “they’re not quite sure what they’re getting into”), 171.

<sup>130</sup> Raskin 9/25 at 182-83.

<sup>131</sup> Miles 9/25 at 166-7.

<sup>132</sup> Marx 9/25 at 193-94; Raskin 9/25 at 173-174; Miriam L. Clemons, *Don’t Shoot the Messenger: Independent Physicians and Joint Payment Contracting Using the Messenger Model*, 32 U. MEM. L. REV. 927, 949 (2002).

<sup>133</sup> See American Medical Ass’n, Position Paper on Antitrust Relief Legislation [hereinafter AMA Position Paper], at <http://www.ama-assn.org/ama/pub/article/5910-6004.html> (Last

such exemptions contend that physicians need to bargain collectively to exercise countervailing market power against payors.<sup>134</sup> The Agencies have consistently opposed such exemptions because they are likely to harm consumers by increasing costs

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updated Oct. 6, 2003); Letter from Michael D. Maves, American Medical Ass'n, to Spencer Bachus & John Conyers, Jr., U.S. House of Representatives (Mar. 21, 2003) (regarding HR 1120, the "Health Care Antitrust Improvements Act of 2003") (asserting that "insurers are using these contracts to gain increased control over how medical care is delivered") [hereinafter AMA Letter], at <http://www.ama-assn.org/ama/pub/article/5908-7508.html>. See generally Foreman 5/7 at 20-26 (representing the AMA); Stephen Foreman, *Countervailing Market Power* (5/7) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507foreman.pdf>; Donald Palmisano, *Taking the Payer Side Seriously: Why the Federal Trade Commission Should Redirect Its Efforts in Health Care Antitrust Enforcement* (9/9/02) [hereinafter Palmisano (stmt)], at <http://www.ama-assn.org/ama/pub/article/5911-6710.html>; Crane 5/7 at 34-40 (noting health plan consolidation and trend away from HMOs and capitation, and suggesting that the FTC and Justice Department revise Health Care Statement 8 of the Health Care Statements to allow more latitude to IPAs); Donald Crane, *Statement* (5/7), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507doncrane.pdf>; Fred Hellinger & Gary Young, *An Analysis of Physician Antitrust Exemption Legislation: Adjusting the Balance of Power*, 286 JAMA 83 (2001).

<sup>134</sup> Levy 9/26 at 45; Connair 9/26 at 23 (stating that "insurers have been able to strong-arm physicians into signing one-sided contracts that give managed care insurers the legal right to deny care, compromise optimal care, and unfairly squeeze doctors financially."). Countervailing power involves sellers (or buyers) faced with buyer (or seller) market power acquiring their own market power (*i.e.*, by negotiating collectively and engaging in other behavior that would otherwise be prohibited by the antitrust laws) to offset that monopsony or monopoly power. See *infra* notes 150-165, and accompanying text.

without improving quality of care. This section describes the legal landscape for physician collective bargaining, discusses the competitive impact of countervailing power, and considers the impact of collective bargaining on the cost and quality of health care.

a. *Legal Landscape*

Both labor and antitrust laws affect the ability of workers to bargain collectively.<sup>135</sup> Antitrust law prohibits competitors from price-fixing and engaging in group boycotts. Labor law provides exemptions from antitrust liability under certain circumstances.<sup>136</sup> Pursuant to the National Labor Relations Act (NLRA), employed physicians are generally allowed to unionize and bargain collectively.<sup>137</sup> Physicians who are self-employed or independent contractors generally may not collectively bargain without violating the

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<sup>135</sup> Sujit Choudhry & Troyen A. Brennan, *Collective Bargaining by Physicians – Labor Law, Antitrust Law, and Organized Medicine*, 345 NEW ENG. J. MED. 1141 (2001).

<sup>136</sup> See, e.g., Marc L. Leib, *White Coats and Union Labels: Physicians and Collective Bargaining*, 42 ARIZ. L. REV. 803, 812-13 (2000).

<sup>137</sup> National Labor Relations Act (NLRA), 29 U.S.C. § 157 (2004); Leib, *supra* note 136, at 813 (stating that the NLRA creates "a legally enforceable right for employees to organize," requires "employers to bargain with employees through employee elected representatives," and gives "employees the right to engage in concerted activities for collective bargaining purposes or other mutual aid or protection."); Flaherty 9/26 at 30-31. Employee bargaining rights vary, depending on whether the physician works for a firm or the federal or state government.

antitrust laws.<sup>138</sup> A few states have passed legislation that exempts self-employed physicians from the antitrust laws and provides for state regulation of physician collective bargaining.<sup>139</sup> Other states and Congress have also considered such legislation.<sup>140</sup> Commission staff submitted

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<sup>138</sup> Jeremy Lutsky, *Is Your Physician Becoming a Teamster: The Rising Trend of Physicians Joining Labor Unions in the Late 1990's*, 2 DEPAUL J. HEALTH CARE L. 55, 78 (1997); Levy 9/26 at 41-42. Some commentators have suggested however that the National Labor Relations Board and the courts “may yet conclude that some physicians that contract with MCOs are de facto employees and thus should be entitled to bargain collectively under the NLRA.” William S. Brewbaker III, *Physician Unions and the Future of Competition in the Health Care Sector*, 33 U.C. DAVIS L. REV. 545, 564; Leib, *supra* note 136, at 819-23.

In this Report, “collective bargaining” can refer to bargaining by union members, which is authorized by the NLRA, or non-unionized physicians’ attempts to obtain the right to bargain collectively.

<sup>139</sup> See Flaherty 9/26 at 32 (stating that in certain states, including Texas and New Jersey, the state attorney general regulates physician collective bargaining); Ameringer 9/26 at 16; Tobey 5/7 at 47-52 (discussing Texas’s experience); Mark Tobey, *Prepared Remarks (5/7)*, at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507tobeytestimony.pdf>. For a discussion of the state action doctrine, see *infra* note 286, and accompanying text, and *infra* Chapter 8.

<sup>140</sup> See TODD J. ZYWICKI ET AL., FEDERAL TRADE COMM’N, NO. P011200, REPORT OF THE STATE ACTION TASK FORCE 67 (2003) (stating that legislatures in Ohio, Washington, and Alaska considered passing such legislation in 2002), at <http://www.ftc.gov/os/2003/09/stateactionreport.pdf>; Leib, *supra* note 136, at 830 (writing in 2000 that “Illinois, Delaware, the District of Columbia, New Hampshire, New Jersey, New York, and Pennsylvania have introduced bills to allow collective bargaining by physicians.”) (footnote omitted); Quality Health-Care Coalition Act of 1999, H.R. 1304, 106th

competition advocacy letters commenting on three such bills in Ohio, Washington, and Alaska.<sup>141</sup>

Until recently, physician interest in unionization and collective bargaining was limited. Organized medicine long opposed physician unions.<sup>142</sup> According to one panelist, physicians began making more concerted efforts to unionize and bargain collectively in the 1970’s in response to the emergence of large health care organizations and changes in physician fees.<sup>143</sup> The same panelist noted that many physicians believed that organized medicine was failing to respond to these changes.<sup>144</sup>

The AMA remained opposed to unionization until 1999 when it approved the formation of Physicians for Responsible

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Cong. (1999) (sponsored by Rep. Tom Campbell); Health Care Antitrust Improvements Act of 2003, H.R. 1120, 108th Cong. (2003).

<sup>141</sup> Letter from Richard A. Feinstein, Federal Trade Commission, to Robert R. Rigsby, Government of the District of Columbia (Oct. 29, 1999), at <http://www.ftc.gov/be/hilites/rigsby.htm>; Letter from Joseph J. Simons, Federal Trade Commission, to Dennis Stapleton, Ohio House of Representatives (Oct. 16, 2002), at <http://www.ftc.gov/os/2002/10/ohb325.htm>; Letter from Joseph J. Simons, Federal Trade Commission, to Lisa Murkowski, Alaska House of Representatives (Jan. 18, 2002), at <http://www.ftc.gov/be/v020003.pdf>.

<sup>142</sup> Ameringer 9/26 at 10-12 (stating that organized medicine “saw unions as a threat to professional . . . turf, and as antithetical to professional values of individualism and autonomy.”).

<sup>143</sup> *Id.* at 7-8.

<sup>144</sup> *Id.*

Negotiations (PRN).<sup>145</sup> Initially, PRN was “an AMA-affiliated labor organization dedicated to representing physicians in collective bargaining with employers.”<sup>146</sup> Panelists primarily attributed the AMA’s support for physician unionization to an ongoing decline in the AMA’s total membership and a determined lobbying effort by the AMA’s younger physician members.<sup>147</sup>

News reports indicate that PRN’s membership in 2002 was “only a few hundred” individual members, its advocacy for two Chicago physicians’ groups had stalled, and that “AMA leaders, who fear that union-management tensions would compromise patient care, ha[ve] stymied the group.”<sup>148</sup> In March 2004, the AMA and

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<sup>145</sup> The AMA also supported federal legislation that would allow physicians to bargain collectively, claiming it would “reduce the critical imbalance in the health care marketplace and restore some power to physicians so they can act in the best interests of their patients.” AMA Letter, *supra* note 133. The Pennsylvania Medical Society has similarly suggested that “regulatory and countervailing power approaches may produce welfare-improving outcomes.” Stephen Foreman & Dennis Olmstead, *Written Comments of the Pennsylvania Medical Society* 3 (9/9/02, dated Sept. 30, 2002), at <http://www.ftc.gov/ogc/healthcare/pms.pdf>.

<sup>146</sup> Flaherty 9/26 at 29.

<sup>147</sup> See Ameringer 9/26 at 15-16; Flaherty 9/26 at 29.

<sup>148</sup> Joseph Weber, *I Dreamed I Saw Dr. Joe Hill Last Night; Tensions are running high in the American Medical Assn. over a divisive question: Should doctors form labor unions?*, BUS. WEEK ONLINE, June 20, 2002; see also Lindsey Tanner, *Doctors Union Battles for Survival*, ASSOCIATED PRESS, May 9, 2002; Sara D. White, *For the Record*, CRAIN’S CHICAGO BUSINESS, May 13, 2002.

PRN separated; PRN now operates as an independent physician labor organization.<sup>149</sup>

#### b. *Countervailing Power*

Some physicians claim they need countervailing market power to offset the market power they allege health care insurers possess. They contend that monopsony power enables health plans to approach “contract negotiations with a ‘take-it-or-leave-it’ attitude that puts physicians in the untenable position of accepting inappropriate contract terms.”<sup>150</sup> The AMA asserts that these terms include unreasonably low fees and provisions that may harm quality of care.<sup>151</sup>

Some participants asserted that there are numerous markets in which health care insurers exercise monopsony power.<sup>152</sup>

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<sup>149</sup> News Statement, Michael D. Maves, American Medical Ass’n, *AMA separation from PRN* (Mar. 10, 2004), at <http://www.ama-assn.org/ama/pub/article/1617-8441.html>; Physicians for Responsible Negotiation, at <http://www.4prn.org> (last visited July 8, 2004).

<sup>150</sup> AMA Letter, *supra* note 133.

<sup>151</sup> See, e.g., AMA Position Paper, *supra* note 133; AMA Letter, *supra* note 133 (asserting that “insurers are using these contracts to gain increased control over how medical care is delivered”); Catherine Hanson, *On Integration, Physician Joint Contracting, and Quality: Taking a Fresh Look at Some “Settled” Questions* (9/9/02), at <http://www.ftc.gov/ogc/healthcare/hanson.pdf>; Palmisano (stmt), *supra* note 133.

<sup>152</sup> See Foreman 5/7 at 54; Crane 5/7 at 35 (stating that California is a “a textbook example of monopsony power” because health care insurer mergers have left California with fewer, more dominant health care insurers); George Koenig, *Additional Testimony Subsequent to FTC Workshop*

Others disagreed, however, arguing that physicians, rather than insurers, often exercise market power.<sup>153</sup> Although there may be disparities in bargaining position between some payors and some providers, the available evidence does not indicate that there is a monopsony power problem in most health care markets.<sup>154</sup>

A proponent of countervailing power theory stated that providers need this power if health care insurers exercise monopsony power.<sup>155</sup> Nonetheless, those physicians seeking to bargain collectively have sought blanket exemptions from the antitrust laws. Several speakers opposed such exemptions.<sup>156</sup> As one panelist stated, “it’s

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*on Health Care and Competition Law and Policy (Sept. 16, 2002) 2 (Public Comment); Meghrijian 9/24 at 85; American Medical Ass’n, Competition in Health Insurance: A Comprehensive Study of U.S. Markets Executive Summary (2003), at <http://www.ama-assn.org/ama/pub/category/12246.html>.*

<sup>153</sup> See Leibenluft 5/7 at 42-43; Noether 5/7 at 29, 32; MONICA NOETHER ET AL., CHARLES RIVER ASSOCIATES, COMPETITION IN HEALTH INSURANCE AND PHYSICIAN MARKETS: A REVIEW OF “COMPETITION IN HEALTH INSURANCE: A COMPREHENSIVE STUDY OF US MARKETS” BY THE AMERICAN MEDICAL ASSOCIATION (2002) (Public Comment) (Submitted by Robert Leibenluft).

<sup>154</sup> See generally *infra* Chapter 6.

<sup>155</sup> See, e.g., Foreman 5/7 at 21-22.

<sup>156</sup> See, e.g., Noether 5/7 at 138; Monica Noether, *Health Insurance/Providers: Countervailing Market Power (5/7)* (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507noether.pdf>; Gaynor 5/7 at 138; Greaney 2/27 at 221-222; Matthews 9/24 at 137; Carson-Smith 2/27 at 193; American Bar Ass’n, *Comments Regarding The Federal Trade Commission’s Workshop on Health Care and Competition Law and Policy (Oct. 2002) 10-13* (Public Comment) [hereinafter ABA (public

clear that a blanket exemption to the antitrust laws for the purpose of allowing the creation of countervailing power is inappropriate.”<sup>157</sup> Another speaker similarly testified that allowing providers to acquire countervailing market power is unnecessary, impossible to implement, and bad public policy.<sup>158</sup>

The Agencies believe that antitrust enforcement to prevent the unlawful acquisition or exercise of monopsony power by insurers is a better solution than allowing providers to exercise countervailing power. Joel Klein, the Assistant Attorney General in 1999, noted that a “better approach [than allowing countervailing market power] is to empower consumers by encouraging price competition, opening the flow of accurate, meaningful information to consumers, and ensuring effective antitrust enforcement both with regard to buyers (health care insurance plans) and sellers (health care professionals) of provider services.”<sup>159</sup>

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<sup>157</sup> Gaynor 5/7 at 19; Martin Gaynor, *Countervailing Power in Health Care Markets 12-13 (5/7)* (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507gaynor.pdf>.

<sup>158</sup> See Leibenluft 5/7 at 40-46; Robert Leibenluft, *Statement on Behalf of the Antitrust Coalition for Consumer Choice in Health Care 1-2, 10 (5/7)*, at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507liebenluftt.pdf>; Robert Leibenluft, *Letter to Member of Congress (Apr. 12, 2002)* (Public Comment) (On Behalf of The Antitrust Coalition For Consumer Choice in Health Care).

<sup>159</sup> *The Quality Health-Care Coalition Act of 1999: Hearing on H.R. 1304 Before the House Comm. on the Judiciary*, 106th Cong. 14 (1999) (Statement of Joel I. Klein, Assistant Attorney General, U.S. Department of Justice) [hereinafter

Former FTC Chairman Robert Pitofsky likewise remarked that “[f]rom a policy and enforcement perspective, the most effective response to the emergence of excessive buyer power is not to permit the aggregation of some form of countervailing power. Rather, the appropriate response is to try to prevent the aggregation of excessive buying power in the first place.”<sup>160</sup> As Chapter 6 reflects, the Justice Department has investigated and challenged health insurer mergers that likely would have resulted in monopsony power and challenged health insurers’ use of most favored nations clauses in contracts with health care providers.

Panelists agreed that it is preferable to use antitrust enforcement to address monopsony concerns than to allow physicians to accumulate countervailing market power. One panelist stated, for example, that the best policy response to the existence of market power on one side of the market is to remove it on a case-by-case basis.<sup>161</sup> Even a panelist who spoke in favor of allowing countervailing market power noted that restoring competition is the ideal solution to a health insurer’s acquisition of monopsony power.<sup>162</sup>

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DOJ, *H.R. 1304 Statement*], at <http://www.usdoj.gov/atr/public/testimony/2502.htm>.

<sup>160</sup> Robert Pitofsky, Thoughts on “Leveling the Playing Field” in Health Care Markets, Remarks Before the National Health Lawyers Association, Twentieth Annual Program on Antitrust in the Health Care Field (Feb. 13, 1997), at <http://www.ftc.gov/speeches/pitofsky/nhla.htm>.

<sup>161</sup> Gaynor 5/7 at 9; *see also* Noether 5/7 at 32.

<sup>162</sup> Foreman 5/7 at 22, 25.

Indeed, even if we assume physicians confront a monopsonist health plan that neither unlawfully acquired nor unlawfully exercised that power, authorizing physicians to engage in collusive conduct will not serve the interests of consumers.<sup>163</sup> A health insurer with monopsony power is likely to impose quantity restrictions that will increase prices for consumers. If providers were to acquire countervailing market power, the result is likely to be further quantity restrictions – increasing the prices paid by consumers above those already imposed by the monopsonist.<sup>164</sup>

Providers that obtain countervailing market power also likely will cause competitive harm to other market participants that do not possess monopsony power. One panelist suggested, for example, that physicians may use their countervailing market power to disadvantage non-physician competitors, such as nurse midwives and nurse anesthetists, or health care insurers other than the monopsonist health care insurer.<sup>165</sup>

The Agencies believe that statutory or other legal changes allowing countervailing market power are ill-advised and unnecessary. To the extent monopsony power exists in some markets, the Agencies and state Attorneys General should address such matters on a case-by-case basis.

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<sup>163</sup> *But see id.* at 23-24.

<sup>164</sup> *See* Gaynor 5/7 at 12, 13, 16-17; Brewbaker 9/26 at 58 (stating that “it’s just as likely that we would see an additional economic welfare loss from the addition of the second monopoly on the seller’s side”).

<sup>165</sup> Leibenluft 5/7 at 45-46.

c. *Physician Collective Bargaining Harms Consumers*

The Agencies have consistently opposed the creation of antitrust exemptions for physician collective bargaining. In congressional testimony, the Agencies have identified various ways in which physician collective bargaining likely will harm consumers and other participants in the health care system.<sup>166</sup>

These harms include: (i) consumers and employers facing higher prices for health insurance coverage; (ii) consumers facing higher out-of-pocket expenses as copayments and other unreimbursed expenses increase; (iii) consumers receiving reduced benefits as costs increase; (iv) senior citizens participating in Medicare HMOs receiving reduced benefits; (v) the federal government paying more for health coverage for its employees; (vi) state and local governments incurring higher costs to provide health benefits to their employees; (vii) state Medicaid programs incurring higher costs to provide health benefits, forcing them to increase taxes, cut benefits, or reduce the number of beneficiaries; and (viii) the number of uninsured increasing due to more costly health insurance. The balance of this section focuses on the impact of physician collective bargaining on cost and quality.

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<sup>166</sup> *Prepared Statement Concerning the "Quality Health-Care Coalition Act of 1999": Hearing on H.R. 1304 Before the House Comm. on the Judiciary, 106th Cong. 5 (1999) (Statement of Robert Pitofsky, Chairman, Federal Trade Commission) [hereinafter, FTC, H.R. 1304 Statement], at <http://www.ftc.gov/os/1999/06/healthcaretestimony.htm>; DOJ, H.R. 1304 Statement, *supra* note 159, at 5.*

Collective bargaining is likely to increase substantially the price of health care services, because providers collectively are likely to demand higher fees and refuse to negotiate individually.<sup>167</sup> The Agencies have extensive experience with the consequences of alleged physician collective bargaining. For example, the Commission alleged approximately 500 physicians and 15 hospitals that comprised the vast majority of providers covering a large area of southern Georgia conspired to fix prices and not to deal with payors on an individual basis.<sup>168</sup> According to the complaint, respondents restrained competition among the providers and forced payors to pay higher prices to its providers, thereby increasing the cost of healthcare for consumers.<sup>169</sup>

In *United States v. Federation of Physicians And Dentists*, the Division alleged that the Federation had successfully recruited virtually all of the private practice orthopedic surgeons in Delaware, who ultimately agreed to designate the Federation as their exclusive agent to negotiate fee levels with a particular payor. The Federation then organized nearly all of its members to terminate their contracts with

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<sup>167</sup> FTC, H.R. 1304 Statement, *supra* note 166; Brewbaker, *supra* note 138, at 549-50 (“Legalized collective bargaining would permit physician unions to function as doctors’ cartels, raising physician fees and organizing professional boycotts of MCOs and other institutions.”).

<sup>168</sup> *In re S. Ga. Health Partners, L.L.C.*, No. C-4100 (Oct. 31, 2003) (decision and order), available at <http://www.ftc.gov/os/2003/11/sgeorgia.do.pdf>.

<sup>169</sup> *In re S. Ga. Health Partners, L.L.C.*, No. C-4100 (Oct. 31, 2003) (complaint), available at <http://www.ftc.gov/os/2003/11/sgeorgiacomp.pdf>.

this payor with the expectation that this would force that payor to accede to their fee demands.<sup>170</sup> There are many other examples of such conduct.<sup>171</sup>

The Congressional Budget Office (CBO) estimated that proposed federal legislation to exempt physicians from antitrust scrutiny and allow collective bargaining “would increase expenditures on private health insurance by 2.6 percent.”<sup>172</sup> The CBO also predicted that such legislation would increase direct federal spending on healthcare programs such as Medicaid by \$11.3 billion and decrease tax revenue by \$10.9 billion over ten years.<sup>173</sup> Other estimates of the cost of an antitrust waiver were substantially higher.<sup>174</sup> Physician

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<sup>170</sup> See R. Hewitt Pate, *Opening Day Comments* (2/26), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030226pate.pdf>; see also *United States v. Fed’n of Physicians & Dentists, Inc.*, 2002-2 Trade Cas. (CCH) ¶ 73,868 (D. Del., 2002).

<sup>171</sup> See *supra* Chapter 1.

<sup>172</sup> CONG. BUDGET OFFICE, 106TH CONG., H.R. 1304: QUALITY HEALTH-CARE COALITION ACT OF 1999, at 2 (Cost Estimate, Mar. 15, 2000), at <ftp://ftp.cbo.gov/18xx/doc1885/hr1304.pdf>.

<sup>173</sup> *Id.*

<sup>174</sup> See HEALTH INSURANCE ASS’N OF AMERICA, THE COST OF PHYSICIAN ANTITRUST WAIVERS (2002) (incorporating findings of CHARLES RIVER ASSOCIATES, THE NATIONAL COST OF PHYSICIAN ANTITRUST WAIVERS (2002) (5 percent to 7 percent increase)); H.E. FRECH III & JAMES LANGENFELD, THE IMPACT OF ANTITRUST EXEMPTIONS FOR HEALTH CARE PROFESSIONALS ON HEALTH CARE COSTS 3-4 (2000) (Prepared for the American Ass’n of Health Plans) (estimating “that H.R. 1304 will increase health care expenditures by \$141 billion over a five year period, or 8.6 percent of private health care costs during its peak year” and “that by 2003 the bill would cause approximately 3

groups have argued that the actual cost of physician collective bargaining is likely to be modest.<sup>175</sup>

Whatever the impact on costs, proponents of antitrust exemptions for physicians often suggest that collective bargaining will result in increased quality of care.<sup>176</sup> However, physician collective bargaining has historically focused on physician compensation and not on patient care issues.<sup>177</sup> Moreover, as Chapter 1 explains, current antitrust law already permits physicians to work collectively on legitimate quality of care issues. Given these considerations, physician collective

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million more individuals to become uninsured.”), at <http://www.aaahp.org/DocTemplate.cfm?Section=Anti-trust&template=/ContentManagement/ContentDisplay.cfm&ContentID=1849>.

<sup>175</sup> William S. Brewbaker III, *Will Physician Unions Improve Health System Performance?*, 27 J. HEALTH POL. POL’Y & L. 575, 597 (2002); see generally Jacqueline M. Darrah, *Perspectives on Competition Policy and the Health Care Marketplace* 11 (2/27) (“However you cut the pie, physician costs today are simply not a significant factor driving growth in overall healthcare costs.”), at <http://www.ama-assn.org/ama1/pub/upload/mm/368/febftctestimony.pdf>.

<sup>176</sup> Monique A. Anawis, *The Ethics of Physician Unionization: What Will Happen If Your Doctor Becomes a Teamster?*, 6 DEPAUL J. HEALTH CARE L. 83, 87 (2002); Brewbaker, *supra* note 175, at 585-86; Jeffrey Rugg, *An Old Solution to a New Problem: Physician Unions Take the Edge Off Managed Care*, 34 COLUM. J.L. & SOC. PROBS. 1, 7 (2000); Levy 9/26 at 41, 44-46; Flaherty 9/26 at 74-75.

<sup>177</sup> See, e.g., Brewbaker, *supra* note 175, at 588-594; Brewbaker, *supra* note 138, at 575-577 (noting that the principal purpose of unionization is to enhance the working conditions of the unionized employees, with salary a major bargaining point).



bargaining is unlikely to improve the quality of care that consumers receive.<sup>178</sup>

### C. *Licensure, Market Entry, and Practice Restrictions*

Licensure impacts marketplace competition. Through licensure requirements, states may restrict market entry by physicians and allied health professionals (AHPs), and further limit the scope of authorized practice.<sup>179</sup> Most state licensing boards are primarily composed of licensed providers, although some states require broader representation.<sup>180</sup> The Commission recently initiated administrative litigation against a state licensing board,

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<sup>178</sup> See Roger D. Blair & Jill Boylston Herndon, *Physician Cooperative Bargaining Ventures: An Economic Analysis*, 71 ANTITRUST L.J. 989, 1014-15 (2004).

<sup>179</sup> AHPs are individuals trained to support, complement, or supplement the professional functions of physicians, dentists, and other health professionals in the delivery of health care to patients. They include physician assistants, dental hygienists, medical technicians, nurse midwives, nurse practitioners, physical therapists, psychologists, and nurse anesthetists. PATRICIA FRANKS ET AL., UNIV. OF CALIFORNIA, ALLIED HEALTH: 1970S-2000S: A REVIEW OF KEY REPORTS 23-24 (2002) (citing U.S. DEP'T OF HEALTH, EDUCATION, & WELFARE, A REPORT ON ALLIED HEALTH PERSONNEL, DHEW NO. (HRA) 80-28 (1979)), at [http://www.futurehealth.ucsf.edu/pdf\\_files/Allied%20Health%20Key%20Reports%207-30-02%20final.101502.doc](http://www.futurehealth.ucsf.edu/pdf_files/Allied%20Health%20Key%20Reports%207-30-02%20final.101502.doc). See also Ass'n of Schools of Allied Health Professionals, *Definition of Allied Health*, at <http://www.asahp.org/definition.html> (last visited July 8, 2004); Hawkinson 9/25 at 42-44 (describing the education, role, and expertise of physician assistants).

<sup>180</sup> INSTITUTE OF MEDICINE (IOM), ALLIED HEALTH SERVICES: AVOIDING CRISES 238, 241 (1989), available at <http://books.nap.edu/books/0309038960/html/R1.html#pagetop>.

alleging that it had taken steps unlawfully to restrict AHPs from obtaining direct access to consumers.<sup>181</sup>

Many states have only limited or no reciprocity for licensing out-of-state physicians and AHPs seeking to practice in-state.<sup>182</sup> A number of state licensing boards have also sought to restrict the practice of telemedicine. This section considers each of these issues and recommends strategies for addressing the anticompetitive risks of state regulation of the nature and form of professional practice.

#### 1. **Mechanisms to Regulate Physician and AHP Market Entry**

The states have traditionally assumed responsibility for regulating physicians and AHPs using three distinct mechanisms: (i) occupational licensing or licensure; (ii) certification; and (iii) registration.<sup>183</sup> Licensure, the most restrictive method of regulation, typically involves a mandatory system of state-imposed standards that practitioners must meet to practice a given

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<sup>181</sup> See, e.g., *In re S.C. Bd. of Dentistry*, No. 9311, at 1 (Sept. 12, 2003) (complaint), available at <http://www.ftc.gov/os/2003/09/socodentistcomp.pdf>.

<sup>182</sup> U.S. DEP'T OF HEALTH & HUMAN SERVICES, TELEMEDICINE REPORT TO CONGRESS 21-24 (2001) [hereinafter HHS, TELEMEDICINE (2001)], available at <http://telehealth.hrsa.gov/pubs/report2001/2001REPO.PDF>; American Medical Ass'n (AMA), *Physician Licensure: An Update of Trends*, at <http://www.ama-assn.org/ama/pub/category/2378.html#introduction> (last updated Sept. 4, 2003).

<sup>183</sup> See IOM, *supra* note 180, at 235-37; Sue A. Blevins, *The Medical Monopoly: Protecting Consumers or Limiting Competition?* 7 (Cato Institute, Policy Analysis No. 246, 1995), at <http://www.cato.org/pubs/pas/pa-246.html>.

profession.<sup>184</sup> Autonomous boards, comprised largely of members of the regulated profession, determine applicants' eligibility requirements, develop standards of practice, and enforce disciplinary actions.<sup>185</sup> Physicians and other licensed professionals must satisfy these requirements to practice within the state.

Certification generally refers to a voluntary system of standards that practitioners can choose to meet to demonstrate accomplishment or ability in their profession.<sup>186</sup> Nongovernmental agencies or associations typically set certification standards.<sup>187</sup> Certified health

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<sup>184</sup> Morris M. Kleiner, *Occupational Licensing*, 14 J. ECON. PERSP. 189, 191 (2000). For a discussion of the state action doctrine issues that licensure raises, see *infra* note 286, and accompanying text, and *infra* Chapter 8.

<sup>185</sup> See BENJAMIN SHIMBERG ET AL., OCCUPATIONAL LICENSING: PRACTICES AND POLICIES 14 (1972) (stating that licensing boards "serve as gatekeepers to determine the qualifications and competence of applicants" and ensure "that standards are adhered to by practitioners and, when necessary, adjudicate disputes between the public and members of the regulated occupation."); CAROLYN COX & SUSAN FOSTER, FEDERAL TRADE COMM'N, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION 1, 3 (1990); National Council of State Boards of Nursing, Inc., *Comments Regarding Hearings on Health Care and Competition Law and Policy (July 31, 2003)* (Public Comment) (Submitted by Donna M. Dorsey).

<sup>186</sup> SHIMBERG ET AL., *supra* note 185, at 9 (citing U.S. DEP'T OF HEALTH, EDUCATION, & WELFARE, REPORT ON LICENSURE AND RELATED HEALTH PERSONNEL CREDENTIALING (1971)).

<sup>187</sup> *Id.* See also Nat'l Council of State Boards of Nursing, Inc., *Comments Re: Letter from the National Boards for Certification of Hospice and Palliative Nurses (Jan. 8, 2004)* (Public Comment)

professionals may use a predetermined title. Uncertified health professionals may still practice within the field but may not use the relevant title.<sup>188</sup> Certification can serve as a substitute for and a complement to licensure. Many physicians become board certified within a specialty, in order to establish that they have an appropriate level of knowledge, skills, and experience.<sup>189</sup>

Registration is the least restrictive mechanism for regulating health care professionals because individuals simply must file their name, address, and qualifications with a government agency to practice.<sup>190</sup> Professionals generally are not required to meet educational or experience requirements to practice under a registration system.<sup>191</sup>

a. *Regulation's Impact on Cost, Quality, and Access*

Commentators state that limits on

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(Submitted by Donna M. Dorsey).

<sup>188</sup> COX & FOSTER, *supra* note 185, at 43; Blevins, *supra* note 183, at 7; Kleiner 6/10 at 35.

<sup>189</sup> See American Medical Ass'n, *Becoming An M.D.*, at <http://www.ama-assn.org/ama/pub/category/2320.html> (last updated Dec. 4, 2003); Bureau of Labor Statistics, U.S. Dep't of Labor, *Physicians and Surgeons*, at <http://www.bls.gov/ocos/ocos074.htm> (last modified Feb. 27, 2004).

<sup>190</sup> See Blevins, *supra* note 183, at 7; COX & FOSTER, *supra* note 185, at 49; MINNESOTA OFFICE OF THE LEGISLATIVE AUDITOR, OCCUPATIONAL REGULATION (99-05), at xii (1999), available at <http://www.auditor.leg.state.mn.us/ped/pedrep/9905-a11.pdf>.

<sup>191</sup> COX & FOSTER, *supra* note 185, at 49.

entry increase health care costs.<sup>192</sup> However, commentators and panelists disagreed on the effects of licensing on quality of care. Several commentators contend that a state-enforced minimum quality standard is an efficient response to the “limited information patients have about quality and the relatively high costs of obtaining information.”<sup>193</sup> Another commentator noted that “[o]ccupational licensure creates a greater incentive for individuals to invest in more occupation-specific human capital because they will be more able to recoup the full returns to their investment if they need not face low-quality substitutes for their services.”<sup>194</sup> Others argue that licensure may not improve quality of care because the requirements do not correspond to the factors that influence quality.<sup>195</sup> Moreover, some maintain that licensure may decrease the overall quality of care that consumers receive by increasing prices, which can cause some consumers to forego care.<sup>196</sup>

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<sup>192</sup> See Kleiner 6/10 at 42; COX & FOSTER, *supra* note 185, at vi (“Mandatory entry requirements and business practice restrictions increase the cost of providing professionals’ services and, as result, increase prices as well.”).

<sup>193</sup> SHERMAN FOLLAND ET AL., *THE ECONOMICS OF HEALTH CARE* 343 (2004); see also COX & FOSTER, *supra* note 185, at 4-16 (discussing rationales for licensure including asymmetric information on quality, externalities, and the dual role of professional as diagnostician and treatment specialist).

<sup>194</sup> Kleiner, *supra* note 184, at 191.

<sup>195</sup> COX & FOSTER, *supra* note 185, at vii; Kleiner 6/10 at 37-38.

<sup>196</sup> See, e.g., Lawrence Shepard, *Licensing Restrictions and the Cost of Dental Care*, 4 J.L. & ECON. 185 (1978).

Empirical studies have found that licensing regulation increases costs for consumers.<sup>197</sup> There are fewer studies on the impact of licensure on quality, and these studies have found mixed results.<sup>198</sup> One study found that licensure requirements can reduce the likelihood of adverse outcomes and increase quality of care.<sup>199</sup> Another study found that consumers in states with tougher licensure requirements do not receive higher quality care, because the resulting increase in the price of care limits consumer access.<sup>200</sup> A third study found that licensure benefits the segment of consumers who place more emphasis on quality.<sup>201</sup>

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<sup>197</sup> See, e.g., Kleiner 6/10 at 42; Morris M. Kleiner, *Occupational Licensing and Health Services: Who Gains and Who Loses?* 5-6 (6/10) (slides) (discussing study) [hereinafter Kleiner Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030610kleiner.pdf>.

<sup>198</sup> See Kleiner 6/10 at 39-40; Kleiner, *supra* note 184, at 197.

<sup>199</sup> Kleiner Presentation, *supra* note 197, at 5-6.

<sup>200</sup> Morris M. Kleiner & Robert T. Kudrle, *Does Regulation Affect Economic Outcomes? The Case of Dentistry*, 43 J.L. & ECON. 547 (2000); see also Sidney L. Carroll & Robert J. Gaston, *Occupational Restrictions and the Quality of Service Received: Some Evidence*, 47 S. ECON. J. 959 (1981) (finding that licensure of electricians increased the number of electrocutions because consumers responded to the increased prices of licensed electricians by doing repairs themselves); Kleiner 6/10 at 42 (discussing the “Mercedes Benz effect” of licensure, which enables consumers to “get a high quality service . . . or no service at all because no other services are legally available.”).

<sup>201</sup> See Kleiner Presentation, *supra* note 197, at 5-6; see also Lomazow 6/10 at 259-60 (“[T]his whole issue of lesser trained versus more trained . . . simply flies in the face of logic. I mean, and you can

Studies consistently have found that state-based licensure can harm consumer welfare by serving as a barrier to provider mobility.<sup>202</sup>

*b. Certification's Impact on Cost, Quality, and Access*

Some commentators state that certification, rather than licensure, is a better way to protect quality, increase consumer choice, broaden access to care, and enhance market competition.<sup>203</sup> They state that providing consumers with a choice of certified or uncertified providers allows consumers to receive care they might forego under a licensure regime.<sup>204</sup> Some commentators also contend that certification spurs competition and innovation by creating increased opportunities for market entry.<sup>205</sup>

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talk about studies and studies and studies, but it's just illogical. You want the best. You want the people that are best trained, the best qualified to do the thing. Do you want a certified plumber or do you want some guy next door to come over?").

<sup>202</sup> See Stanley J. Gross, *Professional Licensure and Quality: The Evidence* (Cato Institute, Policy Analysis No. 79, 1986) (citing studies on the effects of professional licensing arrangements on mobility in discussion of "Interstate Mobility"), at <http://www.cato.org/pubs/pas/pa079.html>; Kleiner, *supra* note 184, at 198; Kleiner 6/10 at 39, 49 (discussing the role of the Federal government and practitioners in monitoring provider mobility and licensure standards); Gingrich 6/12 at 16-17.

<sup>203</sup> See, e.g., COX & FOSTER, *supra* note 185, at 44-45.

<sup>204</sup> See generally *id.*

<sup>205</sup> See, e.g., *id.* at 45; Nat'l Board for Certification of Hospice & Palliative Nurses, *NBCHPN Response to Hearings on Health Care and*

Others argue, however, that certification does not adequately protect consumers from low quality care and suggest that consumers may not factor in certain externalities when they select uncertified health care providers.<sup>206</sup> Moreover, if health plans only choose to cover certified health care providers, a certification regime may not markedly increase the choices available to consumers.

There currently is insufficient empirical evidence to assess whether certification provides many of the benefits of licensure with fewer disadvantages.<sup>207</sup> The Agencies encourage further study of the advantages and disadvantages of these two methods for regulating physician and AHP market entry.

## **2. AHPs and Provider Control of Licensure Boards**

Most state statutes delegate authority for establishing and enforcing licensure standards to state Boards of Medical Examiners.<sup>208</sup> These boards typically

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*competition Law and Policy Regarding Advanced Practice Registered Nurse Task Force of the National Council for State Boards of Nursing, Inc. (Sept. 30, 2003) 1-5 (Public Comment).*

<sup>206</sup> See COX & FOSTER, *supra* note 185, at 45 ("[C]ertification may not lessen quality problems associated with externalities (footnote omitted). A consumer who chooses a noncertified doctor, for example, may not take into account the possible effect of his quality decision on others . . .").

<sup>207</sup> See Morrisey 6/10 at 254.

<sup>208</sup> AMA, *supra* note 182; Blevins, *supra* note 183, at 7 ("Professional health care associations have been influential in setting the standards for licensure laws in the United States.").

promulgate regulations governing physicians and related AHPs.<sup>209</sup> Because most board members are industry participants with economic interests at stake, the potential exists for the board to make decisions that are contrary to consumers' interests.<sup>210</sup> Panelists and commentators have identified varying ways in which provider-controlled state-based licensure boards can limit competition and harm consumers.<sup>211</sup>

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<sup>209</sup> Fed'n of State Medical Boards, *Getting a License - The Basics*, at <http://www.ama-assn.org/ama/pub/category/2644.html> (last updated Sept. 29, 2003); Byrd 6/10 at 67.

<sup>210</sup> See COX & FOSTER, *supra* note 185, at 1 ("Although the professions may seek to benefit consumers, the possibility of a conflict of interest exists. The regulators, in many cases, have a financial interest in the profession they are regulating. Since professionals' self-interest may not coincide with the public's best interest, many have come to regard self-regulation with growing skepticism."); IOM, *supra* note 180, at 241; Apold 6/10 at 119; Bauer 6/10 at 227; Carolyn Buppert, *Comments Regarding Competition Law and Policy & Health Care* (Aug. 30, 2002) (Public Comment); American Congress on Electroneuromyography, *Comments Regarding Health Care and Competition Law and Policy* (July 15, 2003) (Public Comment); Melissa M. English, *Comments Re: Anti-Competition Practices* (July 22, 2003) (slides) 1-2 (Public Comment).

<sup>211</sup> See Gross, *supra* note 202 (discussing empirical studies that have found "licensing has had a profoundly negative effect" on the utilization of paraprofessionals); Apold 6/10 at 119. Commentators and panelists also discussed other barriers to entry for AHPs. See Mallon 6/10 at 187-188; Newman 6/10 at 203-205; Lynne Odell-Holzer, *Comments Regarding FTC/DOJ Hearings Regarding Anticompetitive Practices in Healthcare Industry* (Public Comment); Joe Holzer, *Comments Regarding Hearings on Healthcare Competition Law and Policy* (July 10, 2003) (Public Comment); Christine A. Sullivan, *Comments Regarding Hearings on Health Care Competition Law and Policy* (Sept. 19, 2003) (Public Comment); Cathryn Wright, *Comments*

A panelist representing a dental hygienists' trade association described the efforts of certain Boards of Dentistry to prevent dental hygienists from obtaining direct access to consumers.<sup>212</sup> This panelist stated that such Boards determinedly seek to maintain control over dental hygienists and contended that this control denies consumers access to dental care.<sup>213</sup>

This panelist also asserted that the Boards of Dentistry in certain states have prevented dental hygienists from obtaining direct payment, despite those states' Departments of Health authorizing such hygienists to provide certain services to

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*Regarding Hearings on Health Care Competition Law and Policy* (July 22, 2003) (Public Comment); American Ass'n of Nurse Anesthetists, *Comments Regarding Hearings on Health Care and Competition Law and Policy* (Nov. 20, 2003) (Public Comment) (Submitted by Frank Purcell); American Ass'n of Nurse Anesthetists, *New Economic Perspectives on the Market for Anesthesia Services: Achieving Desired Reforms Through Fair Competition*, Nov. 2003 (Public Comment) (Presented by Jeffrey C. Bauer); American Chiropractic Ass'n, *Comments Regarding Health Care and Competition Law and Policy* (Nov. 24, 2003) (Public Comment) (Submitted by Donald J. Krippendorf & George B. McClelland). *But see* American Medical Ass'n, *Health Care and Competition Law and Policy - Quality and Consumer Information: Market Entry* (June 10, 2003) (Public Comment); Frank A. Sloan & Roger Feldman, *Competition Among Physicians, in COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE: PROCEEDINGS OF A CONFERENCE SPONSORED BY THE BUREAU OF ECONOMICS, FEDERAL TRADE COMMISSION* pt.2, at 57-131 (Warren Greenberg ed., 1978).

<sup>212</sup> See Byrd 6/10 at 67-70, 75.

<sup>213</sup> See *id.* at 69-70.

consumers without a dentist’s supervision.<sup>214</sup> These arrangements, argued the panelist, increase dental costs and decrease consumers’ access to dental care.<sup>215</sup>

The Commission recently alleged the South Carolina State Board of Dentistry “restrained competition in the provision of preventive dental care services by unreasonably restricting the delivery of dental cleanings, sealants, and topical fluoride treatments in school settings by licensed dental hygienists.”<sup>216</sup> The Board contends that its challenged actions were necessary to protect school children from substandard care, including possible injury.<sup>217</sup>

Many commentators state that widening the membership of state licensure boards will decrease the probability that provider-dominated licensure boards will

harm competition.<sup>218</sup> The Institute of Medicine (IOM) recommended that “states strengthen the accountability and broaden the public base of their regulatory statutes and procedures.”<sup>219</sup> In particular, the IOM recommended that “[l]icensure boards should draw at least half of their membership from outside the licensed occupation; members should be drawn from the public as well as from a variety of areas of expertise such as health administration, economics, consumer affairs, education, and health services research.”<sup>220</sup>

States should consider adopting the IOM’s recommendation to expand the membership of state licensure boards. Such reform may reduce the possibility that these boards will engage in conduct that increases prices or decreases access to health care.

### 3. State Restrictions on the Interstate Practice of Telemedicine

Interstate communications between health professionals historically have not been subject to licensing requirements.<sup>221</sup>

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<sup>214</sup> *Id.* at 74.

<sup>215</sup> *Id.* at 74-75, 135 (stating that “the people that are suffering the most [from restrictions on direct payment] are our elderly and our underprivileged and our school children who don’t have access to offices on Monday through Thursday from eight to five.”).

<sup>216</sup> *In re* S.C. Bd. of Dentistry, No. 9311, at 1 (Sept. 12, 2003) (complaint), at <http://www.ftc.gov/os/2003/09/socodentistcomp.pdf>. For discussion of the state action issues this case raises, see *infra* note 286, and accompanying text, and *infra* Chapter 8. See generally Loeffler 6/10 at 79.

<sup>217</sup> *In re* S.C. Bd. of Dentistry, No. 9311, at 8 (Oct. 22, 2003) (memorandum to support motion to dismiss), at <http://www.ftc.gov/os/adjpro/d9311/031021scdentmemoinsupdismiss.pdf>.

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<sup>218</sup> IOM, *supra* note 180, at 249 (“Widening the membership of regulatory boards has been one of the most consistent recommendations made by critics of state occupational regulation (e.g., Public Health Service, 1977; Begun, 1981; Cohen, 1980; Shimberg, 1982).”).

<sup>219</sup> *Id.* at 256.

<sup>220</sup> *Id.*

<sup>221</sup> U.S. DEP’T OF HEALTH & HUMAN SERVICES, TELEMEDICINE REPORT TO CONGRESS § III.B. (1997) (noting that physician-to-physician communication can take varied forms including “the mailing of x-rays, clinical histories and pathological and laboratory specimens for evaluation and interpretation, and oral or written inquiries to another

As the Department of Health and Human Services (HHS) noted, “the consulted physician or other health professional [was] regarded either as practicing medicine only in his or her home state or as exempt from licensure under the ‘consultation exception’ in the patient’s state.”<sup>222</sup> Developments in technology have facilitated the practice of telemedicine, which involves the use of electronic communication and information technologies to provide or support clinical care at a distance.<sup>223</sup>

Telemedicine can benefit consumers in at least three ways.<sup>224</sup> First, telemedicine can give physicians and other health care professionals the ability to provide high

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out-of-state physician involved in the patient’s care or in the form of a specific consultative request to a physician with special expertise”) [hereinafter HHS, TELEMEDICINE (1997)], *available at* <http://www.ntia.doc.gov/reports/telemed>; AMA, *supra* note 182.

<sup>222</sup> See HHS, TELEMEDICINE (1997), *supra* note 221, § III.B.

<sup>223</sup> See HHS, TELEMEDICINE (1997), *supra* note 221, § I.A.; *see also* INSTITUTE OF MEDICINE, TELEMEDICINE: A GUIDE TO ASSESSING TELECOMMUNICATIONS IN HEALTH CARE 16 (1996).

<sup>224</sup> Telemedicine is not subject to the risks of Internet fraud that have led the Commission to bring over 300 law enforcement cases involving auction fraud, investment fraud, “Nigerian scams,” cross-border Internet fraud and identity theft. *See generally Prepared Statement on Efforts to Fight Fraud on the Internet: Before the S. Spec. Comm. on Aging*, 108th Cong. (Mar. 23, 2004) (Statement of Howard Beales, Director of the Bureau of Consumer Protection, Federal Trade Commission), *at* <http://www.ftc.gov/os/2004/03/bealsfraudtest.pdf>; GENERAL ACCOUNTING OFFICE, INTERNET PHARMACIES: SOME POSE SAFETY RISKS FOR CONSUMERS AND ARE UNRELIABLE IN THEIR BUSINESS PRACTICES (2004), *available at* <http://www.gao.gov/new.items/d04888t.pdf>.

quality medical services to rural or other underserved areas.<sup>225</sup>

Second, telemedicine can significantly reduce a range of health-care-related costs, including travel expenses and costs arising from the duplication of services, technologies, and specialists.<sup>226</sup> With telemedicine, for example, a single pathologist can provide services to a number of locations. Finally, telemedicine networks can enhance training and education in new technologies for health care professionals, particularly for those located in rural areas.<sup>227</sup> After surveying empirical studies on the costs and benefits of telemedicine, HHS observed “there may be real cost savings to be realized from telemedicine.”<sup>228</sup>

Telemedicine can harm consumers in at least four ways. First, telemedicine can subject consumers to substandard care,

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<sup>225</sup> See HHS, TELEMEDICINE (1997), *supra* note 221, § I.A. (“Telemedicine also has the potential to improve the delivery of health care in America by bringing a wider range of services such as radiology, mental health services and dermatology to underserved communities and individuals in both urban and rural areas.”); Waters 10/9 at 639-40; Parente 10/9 at 640-41.

<sup>226</sup> *See, e.g.*, Waters 10/9 at 617; Parente 10/9 at 640-41.

<sup>227</sup> HHS, TELEMEDICINE (1997), *supra* note 221, § I.A. (“[T]elemedicine can help attract and retain health professionals in rural areas by providing ongoing training and collaboration with other health professionals.”).

<sup>228</sup> HHS, TELEMEDICINE (2001), *supra* note 182, at 41, 44-45; *see also* Parente 10/9 at 641; Waters 10/9 at 652-53.

possibly from unlicensed providers.<sup>229</sup> Individual states have a legitimate interest in ensuring that out-of-state health professionals meet the same standards as professionals licensed within the state.<sup>230</sup> Second, providers could use telemedicine to perpetrate fraud against consumers.<sup>231</sup> Third, “[t]elemedicine consultations might involve personal medical records being shipped over computer lines to other regions of the country,” creating privacy and confidentiality concerns.<sup>232</sup> Finally, “[t]here is significant uncertainty regarding whether malpractice insurance policies cover services provided by telemedicine.”<sup>233</sup>

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<sup>229</sup> See FLA. STAT. ch. 456.065 (1) (2004); Gary Winchester, Executive Summary, Prepared for the Federal Trade Commission Office of Policy Planning, Public Workshop: Possible Anticompetitive Efforts to Restrict Competition on the Internet 3 (Oct. 9, 2002), at <http://www.ftc.gov/opp/e-commerce/anticompetitive/panel/winchester.pdf>; Winchester 10/9 at 624-25, 643-44.

<sup>230</sup> HHS, TELEMEDICINE (1997), *supra* note 221, § III.C.

<sup>231</sup> See, e.g., Winchester 10/9 at 624-25; Stephen Parente, *A Review of the Internet-Enabled Medical Marketplace*, Written Statement Prepared for the Federal Trade Commission Office of Policy Planning, Public Workshop: Possible Anticompetitive Efforts to Restrict Competition on the Internet 2 (Oct. 9, 2002), at <http://www.ftc.gov/opp/e-commerce/anticompetitive/panel/parente.pdf>.

<sup>232</sup> Edward T. Schafer, *Telemedicine: An Emerging Technology With Exciting Opportunities for North Dakota*, 73 N. DAK. L. REV. 199, 204 (1997); Roman J. Kupchynsky II & Cheryl S. Camin, *Legal Considerations of Telemedicine*, 64 TEX. B. J. 20, 27-28 (2000).

<sup>233</sup> WESTERN GOVERNORS’ ASS’N, TELEMEDICINE ACTION REPORT (1995); Parente 10/9 at 642-43.

The practice of telemedicine has thus crystallized tensions between the states’ role in ensuring patients have access to quality care and the anticompetitive effects of protecting in-state physicians from out-of-state competition.<sup>234</sup> Many states have responded to telemedicine by enacting legislation to restrict such practices. HHS reported that 11 states had implemented laws restricting the interstate practice of telemedicine in 1997, and 26 states had implemented such laws by 2001.<sup>235</sup> These states mostly require a physician to obtain either a special license to engage in the out-of-state practice of medicine or a full unrestricted state medical license.<sup>236</sup> Some contend these laws may create a barrier to entry that significantly increases costs and decreases access without improving quality of care for physicians who want to practice telemedicine.<sup>237</sup>

Commentators have debated varied approaches to encourage the practice of telemedicine. Some have argued that

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<sup>234</sup> AMA, *supra* note 182; Parente, *supra* note 231, at 4-5.

<sup>235</sup> HHS, TELEMEDICINE (2001), *supra* note 182, at 21; see also AMA, *supra* note 182; Robert J. Waters, *Anticompetitive Efforts to Restrict Telehealth Services on the Internet*, Written Statement Prepared for the Federal Trade Commission Office of Policy Planning, Public Workshop: Possible Anticompetitive Efforts to Restrict Competition on the Internet 8-15 (Oct. 9, 2002), at <http://www.ftc.gov/opp/e-commerce/anticompetitive/panel/waters.pdf>.

<sup>236</sup> See AMA, *supra* note 182; HHS, TELEMEDICINE (2001), *supra* note 182, at 21; Waters 10/9 at 619-22 (discussing Oregon, Texas and Nevada).

<sup>237</sup> See, e.g., Parente, *supra* note 231, at 4-5; Parente 10/9 at 619.



Congress should pass national telemedicine licensure laws to stop individual states from protecting the economic interests of their providers to the detriment of their citizens' access to healthcare.<sup>238</sup> Others contend that telemedicine should be regulated on a state-by-state basis.<sup>239</sup> The American Telemedicine Association (ATA) has proposed an alternative, which it argues is "a compromise between full national licensure and state-imposed unreasonable barriers" to telemedicine.<sup>240</sup> The ATA contends that states should regulate physical face-to-face encounters between physicians and patients within state borders, but not virtual consultations across state borders. They also recommend that states should not restrict a duly licensed physician from consulting a physician in another state.

When used properly, telemedicine has considerable promise as a mechanism to broaden access, lower costs, and increase healthcare quality. When used improperly, telemedicine has the potential to lower health care quality and increase the incidence of consumer fraud. To foster telemedicine's likely pro-competitive benefits and to deter its potential to harm consumers, states should consider implementing uniform licensure standards or

reciprocity compacts. Uniform licensure standards and reciprocity compacts could operate both to protect consumers and to reduce barriers to telemedicine. State regulators and legislators should explicitly consider the pro-competitive benefits of telemedicine before restricting it.

#### IV. ANTITRUST ENFORCEMENT IN THE PHYSICIAN MARKETPLACE

This section examines the application of competition law to the marketplace for physician services. It first discusses the significance of private antitrust litigation involving physician privileges and credentialing. The section then discusses the Agencies' analysis of provider network joint ventures, focusing on market developments in financial and clinical integration. Finally, this section addresses the ability of physicians to share and use quality-related information and the application of the state action doctrine to licensure and physician collective bargaining.

##### A. *Private Litigation Involving Physician Privileges and Credentialing*

The most common type of private healthcare-related antitrust litigation raises physician privilege or credentialing issues.<sup>241</sup>

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<sup>238</sup> See, e.g., Parente 10/9 at 615-616.

<sup>239</sup> See AMA, *supra* note 182.

<sup>240</sup> *ATA Policy Regarding State Medical Licensure: Hearings on Telemedicine Before the Subcomm. on Sci., Tech. & Space, S. Comm. on Commerce, Sci. & Transp.*, 106th Cong. (1999) (Attachment to Statement of Dr. Ronald K. Poropatich, Member, Board of Directors, American Telemedicine Association), at <http://www.senate.gov/~commerce/hearings/0915por2.pdf>; see also Waters 10/9 at 618-620.

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<sup>241</sup> Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 COLUM. L. REV. 545, 568 (2002) (noting that 35 percent of health care antitrust disputes involving quality between 1985 and 1999 raised these issues). The Commission has brought enforcement actions involving physician privileging and credentialing issues. See *In re Med. Staff of Mem'l Med. Ctr.*, 110 F.T.C. 541 (1988) (consent order) (alleging the

These cases usually involve physicians asserting that a hospital and/or its physician peer review committee denied them privileges for anticompetitive reasons.<sup>242</sup> Physicians with hospital privileges may also sue hospitals and/or their peer review committee because these privileges have been revoked or curtailed.

Commentators state that the courts largely have been “inhospitable” to these cases, except when there has been “clear evidence of bad faith by rival physicians on the hospital’s medical staff[, which has] resulted in large damage awards.”<sup>243</sup> An empirical study found that plaintiff physicians prevail in only seven percent of these cases.<sup>244</sup> One set of commentators are concerned, however, that these “staff privileges cases have had problematic effects on the legal analysis of quality-based competition” because the “courts began

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medical staff of a hospital in Savanna, Georgia, acting through its credentials committee, conspired to suppress competition by denying a certified nurse-midwife’s application for hospital privileges without a reasonable basis); *In re Eugene M. Addison, M.D.*, 111 F.T.C. 339 (1988) (consent order).

<sup>242</sup> For a description of physician peer review processes, see Hammer & Sage, *supra* note 241, at 619. See generally Meghrigian 9/24 at 83-84. See also American College of Nurse-Midwives, *Addendum of Cases and Articles For Statement of Lynne Loeffler for the American College of Nurse-Midwives* (Public Comment).

<sup>243</sup> Sage et al., *Why Competition Law Matters To Health Care Quality*, 22 HEALTH AFFAIRS 31, 37 (Mar./Apr. 2003).

<sup>244</sup> Hammer & Sage, *supra* note 241, at 575. The authors note that these figures raise questions about the extent to which private counsel inform clients of their dismal prospects before pursuing such cases. See *id.* at 601.

using quality to remove conduct from the purview of competition law, rather than factoring quality into an overall competitive mix.”<sup>245</sup>

Congress created an antitrust safe harbor for peer review decisions involving quality that meet certain procedural requirements in the *Health Care Quality Improvement Act of 1986*.<sup>246</sup> This legislation also enabled prevailing defendants to seek recovery of attorney’s fees. The number of physician privilege antitrust cases dropped by approximately 10 percent in the decade following the passage of this Act.<sup>247</sup>

### **B. Provider Network Joint Ventures**

The antitrust analysis of joint ventures and multi-provider networks has received considerable attention from the Agencies and commentators in recent years.<sup>248</sup> This issue is not unique to health care; as the Commission recently stated, “no analytical exercise is more important to U.S. competition policy than defining the bounds of acceptable cooperation between direct rivals.”<sup>249</sup> As noted previously, the Agencies

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<sup>245</sup> Sage et al., *supra* note 243, at 37.

<sup>246</sup> 42 U.S.C. S. § 11151 (1986).

<sup>247</sup> Hammer & Sage, *supra* note 241, at 569, 597, 619. Although the number of cases dropped after this legislation’s passage, the success rate for plaintiffs did not change. *Id.*

<sup>248</sup> See, e.g., Thomas L. Greaney, *A Perfect Storm on the Sea of Doubt: Physicians, Professionalism and Antitrust*, 14 LOY. CONSUMER L. REV. 481 (2002).

<sup>249</sup> *In re Polygram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 15,453 at 22,456 (FTC 2003), available at <http://www.ftc.gov/os/2003/07/poly>

have brought numerous enforcement actions against physician networks, and also issued statements, advisory opinions, and business review letters on this subject.

## 1. The Agencies' Antitrust Analysis of Provider Network Joint Ventures

*Health Care Statement 8* describes how the Agencies evaluate physician network joint ventures. This statement sets forth antitrust safety zones for exclusive and non-exclusive physician network joint ventures that, absent extraordinary circumstances, the Agencies are unlikely to challenge. *Statement 8* then outlines the analytical framework for joint ventures that fall outside the antitrust safety zones. It states that like transactions in other sectors of the economy, "physician network joint ventures will be analyzed under the rule of reason, and will not be viewed as per se illegal, if the physicians' integration through the network is likely to produce significant efficiencies that benefit consumers, and any price agreements (or other agreements that would otherwise be per se illegal) by the network physicians are reasonably necessary to realize those efficiencies."<sup>250</sup>

This statement further notes that financial risk-sharing and clinical integration may involve sufficient integration to demonstrate that the venture is likely to produce significant efficiencies. Finally, *Statement 8* outlines the Agencies' rule of reason analytical framework and applies the

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<sup>250</sup> HEALTH CARE STATEMENTS, *supra* note 44, § 8(B)(1).

principles set forth in the statement to seven examples of physician network joint ventures.<sup>251</sup>

## 2. Financial Integration

*Statement 8* notes that financial risk sharing can generate significant efficiencies by providing physicians with incentives to cooperate in controlling the cost and improving the quality of services they render. It provides examples of arrangements through which participants in a physician network joint venture can share substantial financial risk, including capitation, global fee arrangements, fee-withholds, and cost or utilization-based bonuses or penalties.<sup>252</sup> *Statement 8* also establishes that only those physician networks that share substantial financial risk can qualify for an antitrust safety zone on the basis of their financial integration.

As Chapter 1 outlines and the *Health Care Statements* acknowledge, financing and delivery arrangements for health care have changed substantially over the past several decades.<sup>253</sup> Some commentators and panelists state P4P arrangements may have important procompetitive benefits for consumers.<sup>254</sup> Chapters 1 and 3 describe

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<sup>251</sup> Some panelists stated the Agencies may increasingly confront physician network joint ventures that require rule of reason analysis. *See* Wiegand 9/24 at 4-5; Guerin-Calvert 9/24 at 26; Feller 9/24 at 73.

<sup>252</sup> HEALTH CARE STATEMENTS, *supra* note 44, § 8.

<sup>253</sup> *Id.* § 8(A)(4).

<sup>254</sup> *See, e.g.*, Asner 9/25 at 36; *see also supra* note 36.

these arrangements and consider their potential to lower costs and increase quality.

In determining whether a physician network joint venture is sufficiently financially integrated to warrant rule of reason analysis, the Agencies will consider the extent to which a particular P4P arrangement constitutes the sharing of substantial financial risk among the members of the joint venture, whether that sharing is likely to produce efficiencies, and whether any price or otherwise per se illegal agreements among the members are reasonably necessary to achieve those efficiencies.

### 3. Clinical Integration

*Health Care Statement 8* notes that clinical integration can be evidenced by a “network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”<sup>255</sup>

This statement identifies three arrangements that a clinical integration program might include: (i) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (ii) selectively choosing network physicians who are likely to further these efficiency objectives; and (iii) the significant investment of capital, both monetary and human, in the necessary infrastructure and

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<sup>255</sup> HEALTH CARE STATEMENTS, *supra* note 44, § 8(B)(1).

capability to realize the claimed efficiencies.

This section discusses commentators’ perspectives on clinical integration and presents a series of inquiries the Agencies are likely to pose when considering whether a physician network joint venture is sufficiently clinically integrated to avoid summary condemnation.

Commission staff stated in an advisory opinion to a proposed initiative involving clinical integration that the venture, as designed, did not warrant summary condemnation.<sup>256</sup> Commission staff also closed an investigation into a physician collaboration that created a substantial degree of market concentration, because the parties demonstrated the collaboration created considerable efficiencies (including improvements in the quality of care).<sup>257</sup>

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<sup>256</sup> Letter from Jeffrey W. Brennan, Federal Trade Commission, to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002) (FTC Staff advisory opinion regarding MedSouth, Inc.) [hereinafter FTC MedSouth Letter], at <http://www.ftc.gov/bc/adops/medsouth.htm>. See generally Thomas B. Leary, *The Antitrust Implications of “Clinical Integration:” An Analysis of FTC Staff’s Advisory Opinion to MedSouth*, 47 ST. LOUIS L.J. 223 (2003); Thomas B. Leary, *The Antitrust Implications of “Clinical Integration:” An Analysis of FTC Staff’s Advisory Opinion to MedSouth*, Speech Before Saint Louis University Health Law Symposium (Apr. 12, 2002), at <http://www.ftc.gov/speeches/leary/eicreview.pdf>.

<sup>257</sup> Timothy J. Muris, *Everything Old is New Again: Health Care and Competition in the 21st Century*, Prepared Remarks for the 7th Annual Competition in Health Care Forum (Nov. 7, 2002), at <http://www.ftc.gov/speeches/muris/murishealthcarespeech0211.pdf>.

a. *Indicia of Clinical Integration*

Commentators and industry experts describe various techniques and programs for achieving clinical integration. Commentators primarily focus on four indicia of clinical integration: (1) the use of common information technology to ensure exchange of all relevant patient data; (2) the development and adoption of clinical protocols; (3) care review based on the implementation of protocols; and (4) mechanisms to ensure adherence to protocols.

Panelists and industry experts also have discussed other indicia of clinical integration including physician credentialing, case management, preauthorization of medical care, and review of associated hospital stays.<sup>258</sup> Some also have discussed the use of payment systems to collect clinical data.<sup>259</sup>

Commentators described varied information technology (IT) systems that can facilitate, monitor, and control the utilization

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<sup>258</sup> See California Ass'n of Physician Groups, *Clarifying the Health Care Statements' Policies of Clinical Integration and Ancillarity* 7-9 (Public Comment) [hereinafter CAPG (public cmt)]; Robert F. Liebenluft & Tracy E. Weir, *Clinical Integration: Assessing the Antitrust Issues*, in HEALTH LAW HANDBOOK (forthcoming 2004 ed.) (manuscript at 29-35, on file with the authors). For a discussion of private antitrust litigation involving physician credentialing, see *supra* notes 241-247, and accompanying text.

<sup>259</sup> See, e.g., Bartley Asner, *An IPA Based Model for Clinical Integration in a PPO Setting*, in CAPG (public cmt), *supra* note 258, at i (discussing a system of payment from an insurance company to a PPO, which would enable the PPO to track claims and gather additional data).

of health care services.<sup>260</sup> The FTC MedSouth Letter discussed, for example, an IT system that included “a web-based electronic clinical data record system that will permit MedSouth physicians to access and share clinical information relating to their patients.”<sup>261</sup>

Some suggest that these systems can significantly improve quality of care by enabling physicians to collect and track information about individual patients.<sup>262</sup> One industry expert noted the “management of information as it relates to promoting health, treating illness and managing disease” is a “major component of clinical integration.”<sup>263</sup> Some have observed that clinical care information technology systems are expensive to implement.<sup>264</sup> One study

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<sup>260</sup> See, e.g., SHORTELL ET AL., *supra* note 84, at 159.

<sup>261</sup> FTC MedSouth Letter, *supra* note 256.

<sup>262</sup> See, e.g., Robert H. Miller & Ida Sim, *Physicians' Use of Electronic Medical Records: Barriers and Solutions*, 23 HEALTH AFFAIRS 116, 116 (Mar./Apr. 2004) (stating that electronic medical records have “the most wide-ranging capabilities and thus the greatest potential for improving quality.”); STEPHEN M. SHORTELL ET AL., REMAKING HEALTHCARE IN AMERICA: BUILDING ORGANIZED DELIVERY SYSTEMS 40-41 (1996) (“It is not possible to create clinically integrated care . . . without certain functions such as information systems and quality management in places.”).

<sup>263</sup> Teresa Mikenas Jacobsen & Maria Hill, *Achieving Information Systems Support for Clinical Integration*, in CLINICAL INTEGRATION: STRATEGIES AND PRACTICES FOR ORGANIZED DELIVERY SYSTEMS 129, 129 (Mary Crabtree Tonges ed., 1998).

<sup>264</sup> Miller & Sim, *supra* note 262, at 119 (“In most practices we studied, up-front costs [for electronic medical records] ranged from \$16,000 to

found that California-based IPAs are among the most successful in implementing and using IT systems, in part because they employ more technical support staff.<sup>265</sup>

Commentators describe physicians' selection and adoption of care management protocols (CMPs) as another indicia of clinical integration.<sup>266</sup> A trade association representing Californian physician groups stated that these protocols can "delineate utilization and quality goals for various diagnoses."<sup>267</sup> This trade association also described the process by which an IPA might develop and revise clinical protocols.<sup>268</sup> MedSouth proposed to implement between 100 and 150 such protocols that would cover 80-90 percent of the diagnoses that were prevalent in their physician members' practices.<sup>269</sup>

Commentators have observed that the selection and implementation of CMPs can improve quality and generate efficiencies for physician networks and

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\$36,000 per physician. Some practices incurred additional costs (in the form of decreased revenue) from seeing fewer patients during the EMR transition period."); Liebenluft & Weir, *supra* note 258 (manuscript at 32).

<sup>265</sup> Gillies et al., *supra* note 14, at 494-96.

<sup>266</sup> See, e.g., CAPG (public cmt), *supra* note 258, at 5; Liebenluft & Weir, *supra* note 258 (manuscript at 29-30); Brown, *supra* note 12, at 289. See generally ABA (public cmt), *supra* note 21, at 19-22.

<sup>267</sup> CAPG (public cmt), *supra* note 258, at 5.

<sup>268</sup> See *id.* at 5.

<sup>269</sup> FTC MedSouth Letter, *supra* note 256.

payors.<sup>270</sup> Several commentators contend, however, that clinical integration requires networks to monitor and ensure compliance with CMPs.<sup>271</sup>

*b. Are Joint Negotiations on Price Reasonably Necessary to Achieve Clinical Integration?*

A joint venture will escape summary condemnation when joint price negotiations are reasonably necessary to achieve substantial efficiencies arising from the clinical integration.<sup>272</sup> Panelists and commentators identified varying reasons

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<sup>270</sup> See Liebenluft & Weir, *supra* note 258 (manuscript at 16-17).

<sup>271</sup> See Peter R. Kongstvedt, *Physician Behavior Change in Managed Health Care*, in ESSENTIALS OF MANAGED HEALTH CARE, *supra* note 12, at 425 ("Physicians, like all of us, have habits and patterns in their lives. Habits also extend to clinical practices that are not cost-effective but that are difficult to change."); Liebenluft & Weir, *supra* note 258 (manuscript at 30-31, 33-34); FTC MedSouth Letter, *supra* note 256 (proposing several steps to ensure compliance with CMPs).

See also CAPG (public cmt), *supra* note 258, at 5-6 (networks must review their "physicians' delivery of care to ensure compliance with efficiency and quality goals identified in clinical protocols"); Brian J. Anderson, *Values and Value: Perspectives on Clinical Integration*, in CLINICAL INTEGRATION, *supra* note 263, at 39, 54 (stating that "an integrated system must be able to apply performance measures across the span of care and service sites."); Susan A. Creighton, *Diagnosing Physician-Hospital Organizations*, Remarks Before American Health Lawyers Association Program on Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions 2 (Jan. 22, 2004), at <http://www.ftc.gov/speeches/other/creightonphospeech.htm>.

<sup>272</sup> HEALTH CARE STATEMENTS, *supra* note 44, § 8(B)(1).

why joint negotiations may be reasonably necessary to implement and maintain a clinical integration program.

A trade association representing Californian physician groups contended that joint negotiation of contracts will ensure that sufficient physicians across multiple specialties participate in the venture.<sup>273</sup> Physicians participate in IPA networks, this association argued, because they can delegate “the time and hassle of negotiating contracts with payers” to the IPA.<sup>274</sup> Moreover, the trade association suggested that payors’ overall costs may not necessarily increase, because a clinically integrated IPA will deliver cost-effective and efficient care. This trade association also argued that clinically integrated IPAs “can offer payers a single, comprehensive, and integrated network” and should therefore “be priced in the aggregate, not through individual contracts with physicians.”<sup>275</sup>

Commentators similarly asserted that joint pricing is necessary to ensure the active and ongoing participation of an entire group’s members.<sup>276</sup> These commentators

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<sup>273</sup> CAPG (public cmt), *supra* note 258, at 8.

<sup>274</sup> *Id.* at 9.

<sup>275</sup> *Id.* at 10. *See also* Liebenluft & Weir, *supra* note 258 (manuscript at 39) (explaining that a physician network that has implemented a clinical integration program “can sell a ‘new product’ – that is, an integrated package consisting of more than merely the individual physician services, but, rather, an integrated package of those services tied to the network’s clinical program.”).

<sup>276</sup> Liebenluft & Weir, *supra* note 258 (manuscript at 39).

also contend that joint negotiations are necessary to help physician members recover the substantial time and financial commitments that are necessary to implement a clinical integration program.<sup>277</sup> Finally, they argue that joint negotiations are necessary to prevent physician members from free-riding on the contributions of their colleagues.<sup>278</sup>

The extent to which joint contracting is reasonably necessary to achieve efficient clinical integration will vary, depending on the facts and circumstances.<sup>279</sup> The Agencies will consider multiple factors to determine whether collective negotiation is reasonably necessary to accomplish the goal of achieving clinical integration. Participants in a joint venture that is not sufficiently integrated (whether financially or clinically) face significant antitrust risk if they attempt to contract jointly.

*c. Further Guidance on Clinical Integration*

Commentators and panelists asserted that there is uncertainty regarding the nature and extent of clinical integration that would, in the Agencies’ view, avoid summary condemnation of collective price setting or other horizontal agreements on competitive terms among physicians who participate in

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<sup>277</sup> *Id.* (manuscript at 39).

<sup>278</sup> *Id.* (manuscript at 39).

<sup>279</sup> *See, e.g.,* Leary, *supra* note 256, at 16-17 (discussing the relationship between joint contracting and non-exclusivity).

clinically integrated joint ventures.<sup>280</sup> Several panelists and commentators requested that the Agencies provide additional guidance to address such uncertainty.<sup>281</sup>

The Agencies are committed to eliminating unlawful restraints on vigorous price and non-price competition in physician markets, but not to any particular model for financing and delivering health care. The Agencies do not suggest particular structures with which to achieve clinical integration that justifies joint pricing, because it would risk channeling market behavior rather than encouraging market participants to develop structures responsive to their particular efficiency goals and the market conditions they favor.

Nonetheless, to help further guide practitioners and counsel on the issue, below is a broad outline of some of the kinds of questions that the Agencies are likely to ask when analyzing the competitive implications

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<sup>280</sup> See, e.g., Liebenluft & Weir, *supra* note 258 (manuscript at 15).

<sup>281</sup> See Holloway 9/25 at 27 (stating that it “is desirable for the FTC to issue definitive and clear guidelines as to what level of clinical integration and oversight is required”); Asner 9/25 at 85 (remarking that “[w]e’re looking for somewhat of a road map. It can be very broad, but not as broad as exists in the current guidelines. It doesn’t have to be specific, a list of things that you have to do. There is something in between.”); Section of Antitrust Law, American Bar Ass’n, *Comments on the Public Hearings on Health Care and Competition Law and Policy* 15-17 (Public Comment); American College of Surgeons, *Comments Regarding the Federal Trade Commission (FTC) Workshop on Health Care Competition Law and Policy (Sept. 30, 2003)* 3-4 (Public Comment) (Submitted by Thomas R. Russell). See generally ABA (public cmt), *supra* note 21, at 25-26.

of a physician network joint venture that justifies joint action involving price or other competitively significant terms on the grounds that it is clinically integrated. The Agencies emphasize that this list is not exhaustive, and that these questions may be more or less relevant, depending on factual circumstances. Other questions, not listed here, may be important, again depending on the facts at issue.

1. What do the physicians plan to do together from a clinical standpoint?
  - What specific activities will (and should) be undertaken?
  - How does this differ from what each physician already does individually?
  - What ends are these collective activities designed to achieve?
2. How do the physicians expect actually to accomplish these goals?
  - What infrastructure and investment is needed?
  - What specific mechanisms will be put in place to make the program work?
  - What specific measures will there be to determine whether the program is in fact working?
3. What basis is there to think that the individual physicians will actually attempt to accomplish these goals?
  - How are individual incentives being changed and re-aligned?
  - What specific mechanisms will be used to change and re-align the individual incentives?



4. What results can reasonably be expected from undertaking these goals?
  - Is there any evidence to support these expectations, in terms of empirical support from the literature or actual experience?
  - To what extent is the potential for success related to the group's size and range of specialities?
  
5. How does joint contracting with payors contribute to accomplishing the program's clinical goals?
  - Is joint pricing reasonably necessary to accomplish the goals?
  - In what ways?
  
6. To accomplish the group's goals, is it necessary (or desirable) for physicians to affiliate exclusively with one IPA or can they effectively participate in multiple entities and continue to contract outside the group?
  - Why or why not?

### C. Physician Information Sharing

The sharing of information among physicians can have procompetitive benefits, but may also facilitate collusion or otherwise reduce competition on prices or compensation. *Health Care Statement 6* sets forth a safety zone for provider exchange of price and cost information that the Agencies will not challenge, absent extraordinary circumstances.<sup>282</sup> The statement also outlines the Agencies' antitrust analysis of

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<sup>282</sup> HEALTH CARE STATEMENTS, *supra* note 44, § 6.

information exchanges that fall outside this safety zone.<sup>283</sup>

The Agencies have issued a number of business review letters and advisory opinions that apply the analytical framework in *Statement 6* to evaluate the antitrust implications of physicians' collecting and disseminating information concerning insurer payments for physician services.<sup>284</sup>

In general, the sharing of quality-related information among physicians and consumers can reduce costs and increase quality of care. As Areeda and Hovenkamp note, "the great majority of exchanges of information that do not pertain to either price or output should be regarded as harmless, at least when concerted refusals to deal are not in issue."<sup>285</sup> The Agencies encourage such information sharing, as long as there are adequate safeguards to ensure information exchange is not used for anticompetitive ends.

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<sup>283</sup> *Id.* § 6.

<sup>284</sup> See Letter from Charles A. James, Department of Justice, to Jerry B. Edmonds, Williams, Kastner & Gibbs PLLC (Sept. 23, 2002), at <http://www.usdoj.gov/atr/public/busreview/200260.pdf>; Letter from Jeffrey W. Brennan, Federal Trade Commission, to Gerald Niederman, Faegre & Benson (Nov. 3, 2003), at <http://www.ftc.gov/bc/adops/mgma031104.pdf>; Letter from Jeffrey W. Brennan, Federal Trade Commission, to Gregory G. Binford, Benesch Friedlander Coplan & Aronoff LLP (Feb. 6, 2003), at <http://www.ftc.gov/bc/adops/030206dayton.htm>; American Medical Ass'n, *Physician Information Sharing 1* (Public Comment).

<sup>285</sup> See XIII PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2111d1, at 49 (2nd ed. 2004).

***D. Physician-Related Conduct  
Implicating the State Action  
Doctrine***

As Chapter 8 describes in greater detail, anticompetitive physician conduct can be shielded from federal antitrust scrutiny if it constitutes state action. Through enforcement actions and competition advocacy, the Commission has recently addressed this issue.<sup>286</sup>

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<sup>286</sup> See *supra* Chapter 1.

**CHAPTER 3:           INDUSTRY SNAPSHOT: HOSPITALS**

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## CHAPTER 3: INDUSTRY SNAPSHOT: HOSPITALS

### I. OVERVIEW

This chapter describes how hospitals are paid, trends in hospital pricing, the pressures hospitals face, and delivery innovations, including hospital networks. Chapter 3 considers a number of current controversies, including payor complaints that hospitals are exercising market power and hospital complaints about single-specialty hospitals. Chapter 3 also examines how government purchasing of hospital services affects the health care marketplace.

The next chapter considers hospital competition law issues, beginning with mergers. Chapter 4 describes and evaluates geographic and product market definitions, entry and efficiency issues, and the significance of a hospital's non-profit status. Chapter 4 also describes group purchasing organizations, their potential efficiencies, structure and incentives, contracting practices, and *Health Care Statement 7*.

Representatives from hospitals and hospital organizations, as well as legal, economic, and academic experts, and government officials spoke at the Hearings. Hospital topic panels included Perspectives on Competition Policy and the Health Care Marketplace (February 27); A Tale of Two Cities (February 28, April 11); Hospital Round Table (March 26); Defining Product Markets for Hospitals (March 26); Defining Geographic Markets for Hospitals (March 26); Single Specialty Hospitals (March 27); Contracting Practices (March 27); Issues in Litigating Hospital Mergers (March 28); Hospitals - Horizontal Networks and Vertical Arrangements (April 9, 2003); Hospitals - Non-profit Status (April 10); Hospital Joint Ventures and Joint Operating

Agreements (April 10); Hospitals - Post-Merger Conduct (April 11); Physician Hospital Organizations (May 8, 2003); Quality and Consumer Information: Hospitals (May 29); and Group Purchasing Organizations (September 26).<sup>1</sup> Many industry representatives and experts also testified at the Commission's 2002 Health Care Workshop.<sup>2</sup>

### II. INTRODUCTION

In cities and towns throughout the United States, hospitals are a key part of the health care delivery system. Hospitals are there when Americans give birth or die, are injured, or live with a chronic illness. Hospitals respond to the health care challenges in their communities, whether the problem is SARS or syphilis, anthrax or chicken pox, obesity or influenza. Hospitals provide care to the rich and poor, the well insured and the uninsured.

Currently, payments to hospitals for inpatient care account for approximately 31 percent of total health care expenditures in the United States.<sup>3</sup> The percentage of total

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<sup>1</sup> For lists of participants in these and other panels *see infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcarehearings/completeaagenda.pdf>.

<sup>2</sup> A list of participants in the September 2002 FTC Health Care Workshop is available at <http://www.ftc.gov/ogc/healthcare/agenda.htm>.

<sup>3</sup> Katharine Levit et al., *Health Spending Rebound Continues in 2002*, 23 HEALTH AFFAIRS 147, 155 (Jan./Feb. 2004).

expenditures devoted to inpatient care has declined over the past two decades, along with declines in hospital length-of-stay and the per capita rate of hospitalization.<sup>4</sup>

During the period 1993-98, spending on hospital inpatient care increased by 3.4 percent per year. The past four years have seen annual increases that are double or triple that amount.<sup>5</sup>

**Figure 1: National Hospital Care Expenditures  
Average Annual Growth from Prior Year**

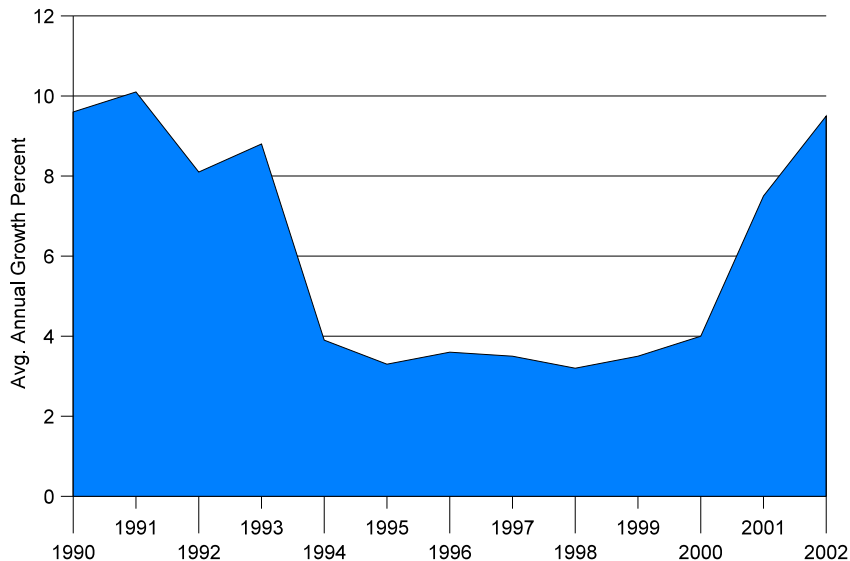


Figure 1 illustrates how hospital expenditures and expenditure growth have accelerated in recent years, after modest or negative growth during the prior five years.<sup>6</sup> Expenditures for inpatient care for the next two years are projected to grow by approximately 6.2 percent per year.<sup>7</sup>

Federal and state governments are responsible for almost 60 percent of payments to hospitals for inpatient care.<sup>8</sup> For some services, the Centers for Medicare & Medicaid Services (CMS) is the sole payor.<sup>9</sup> CMS's substantial share of hospital spending influences the rest of the financing

<sup>4</sup> CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS), THE CMS CHART SERIES, PROGRAM INFORMATION ON MEDICARE, MEDICAID, SCHIP, AND OTHER PROGRAMS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES §1, at 16, 18 (2002), available at <http://www.cms.hhs.gov/charts/series/>.

<sup>5</sup> Levit, *supra* note 3, at 154-55.

<sup>6</sup> Centers for Medicare & Medicaid Services, *Health Accounts: National Health Expenditures 1965-2013, History and Projections by Type of Service and Source of Funds: Calendar Years 1965-2013*, at <http://www.cms.hhs.gov/statistics/nhe/default.asp#download> (last modified Mar. 24, 2004).

<sup>7</sup> Stephen Heffler et al., *Health Spending Projections Through 2013*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-79, 89, at <http://content>.

[healthaffairs.org/cgi/reprint/hlthaff.w4.79v1.pdf](http://healthaffairs.org/cgi/reprint/hlthaff.w4.79v1.pdf).

<sup>8</sup> See Levit, *supra* note 3, at 154. Because private insurance tends to cover a younger and typically healthier population, it accounts for a smaller share of overall health care spending. See also Scully 2/26 at 27 (estimate by former Administrator of CMS that it is responsible for 40-50% of the average hospital's gross revenue).

<sup>9</sup> CMS was previously known as the Health Care Financing Administration (HCFA). CMS is responsible for administering the Medicare program and oversight of the administration of the Medicaid program by individual states. Day-to-day claims processing for the Medicare program is handled by approximately fifty carriers and intermediaries. CMS is the sole payor for End Stage Renal Disease care and is a significant payor for cataract surgeries.

and delivery markets for hospital services.

Although CMS uses an administered pricing system for Medicare, hospitals engage in non-price competition to attract Medicare and Medicaid beneficiaries, and engage in price and non-price competition for private payors and patients. As detailed below, competition in the market for hospital inpatient services has enhanced quality and lowered prices. Private and public payors are encouraging these improvements by giving providers financial and nonfinancial incentives to increase quality and disseminate quality-related information to patients.<sup>10</sup>

### III. DESCRIPTION OF HOSPITALS

Hospitals fall into one of three categories: (1) publicly owned hospitals, (2) nonprofit hospitals, and (3) for-profit hospitals. Although these classifications might appear distinct and immutable, they are not. Many nonprofit hospitals own for-profit institutions or have for-profit subsidiaries. For-profit systems manage nonprofit and publicly owned hospitals. Hospitals also may change their institutional status. One study demonstrated that over a thirteen year period, approximately one percent of hospitals changed their institutional status every year.<sup>11</sup>

Nonprofit hospitals currently make up about 61 percent of community hospitals and have roughly 71 percent of inpatient beds.<sup>12</sup> For-profit hospitals comprise approximately 15 percent of community hospitals and 13 percent of inpatient beds. The remaining 24 percent of community hospitals are run by federal, state, and local governments, and account for 16 percent of inpatient beds. Figure 2 shows the distribution of beds among the categories of hospitals and shows that these patterns have not changed significantly over the past thirty years.<sup>13</sup>

Hospitals are also frequently categorized as primary, secondary, tertiary, and quaternary, dependent on the level and complexity of care provided. For example, a primary care hospital offers basic services such as an emergency department and limited intensive care facilities. A secondary care hospital generally offers primary care, general internal medicine, and limited surgical and diagnostic capabilities. A tertiary care hospital provides a full range of basic and sophisticated diagnostic and treatment services, including many specialized services.

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<sup>10</sup> See *supra* Chapter 1.

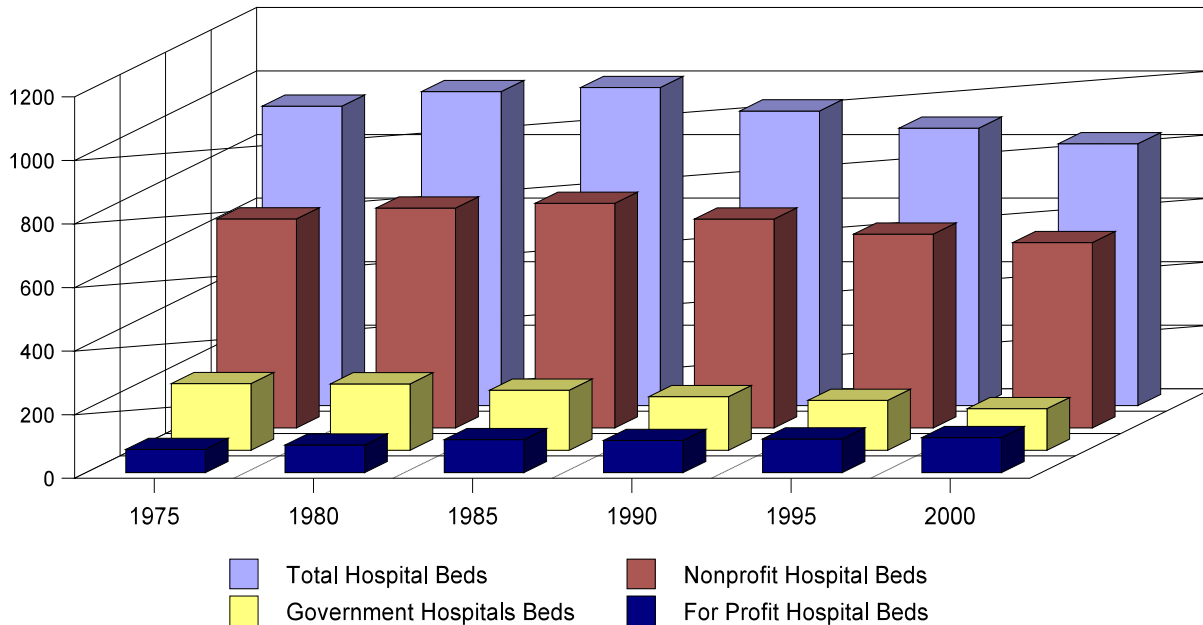
<sup>11</sup> Jack Needleman et al., *Hospital Conversion Trends*, 16 HEALTH AFFAIRS 187, 189-90 (Mar./Apr. 1997). Every conceivable conversion permutation occurred; for-profits converted to nonprofits and public hospitals; public hospitals converted to for-profits and nonprofits; and nonprofits converted to for-profits and public hospitals. *Id.*

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<sup>12</sup> The American Hospital Association defines a community hospital as “all nonfederal, short-term general, and special hospitals whose facilities and services are available to the public.” In 2002, there were approximately 1,136 state and local government hospitals, 3,025 nonprofit hospitals, and 766 for-profit hospitals that are classified as community hospitals. AMERICAN HOSPITAL ASS’N, HOSPITAL STATISTICS 2 tbl.1 (2004 ed.).

<sup>13</sup> AMERICAN HOSPITAL ASS’N, *supra* note 12, at 2 tbl.1.

**Figure 2: Community Inpatient Beds (in thousands)**



A quaternary hospital typically provides sub-specialty services, such as advanced trauma care and organ transplantation. These distinctions, however, are not always clear in practice, as hospitals are not restricted to only offering the services associated with one category.

Hospitals provide either general inpatient services or specialize in a particular kind of patient (*e.g.*, pediatric and women’s hospitals) or condition (*e.g.*, cardiac, orthopedic, psychiatric and rehabilitation hospitals).

Regardless of how one categorizes private hospitals, they face similar market pressures and competitive constraints. Hospitals seek to provide cost-effective care and generate sufficient margins to continue to provide care to the community. Indeed, it is a misnomer to use the word “nonprofit;” as hospital administrators are fond of saying,

“no margin, no mission.”<sup>14</sup>

#### IV. HOW ARE HOSPITALS PAID: A HISTORICAL PERSPECTIVE

Prior to 1983, Medicare and most other insurers paid hospitals on a cost-based reimbursement system.<sup>15</sup> Under the cost-based reimbursement system, hospitals informed payors of the cost of the care that was provided, and those amounts were then

<sup>14</sup> LAURIE E. FELLAND ET AL., THE HEALTH CARE SAFETY NET: MONEY MATTERS BUT SAVVY LEADERSHIP COUNTS 4 (Ctr. for Studying Health Sys. Change, Issue Brief No. 66, 2003), available at <http://www.hschange.org/CONTENT/591>; Michigan Health & Hospital Ass’n, *No Margin No Mission: The Financial Realities of Michigan’s Nonprofit Hospitals*, at <http://members.mha.org/margin/> (last visited July 7, 2004).

<sup>15</sup> PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 385 (1983).

paid. Although there were some constraints on how much a hospital could claim as its costs, the result was to reward volume and discourage efficiency. Payors picked up the cost of each service, each ordered test, and each day in the hospital. Additionally, comprehensive health insurance (both private and public) imposed minimal out-of-pocket costs on patients. Thus, insured patients had little incentive to select lower cost procedures or more efficient providers. As a passive payor of bills, the payor had no control over expenditures.

This payment system led to substantial increases in health care spending. Payors sought to curb these costs through various methods. Medicare implemented a prospective payment system in 1983, and has experimented with a range of strategies for creating incentives for hospitals to constrain their pricing. Private payors have done the same, in many instances piggy-backing off strategies developed by CMS. Medicaid programs have also adopted their own pricing strategies. The rise of managed care and other delivery-side innovations have also had a significant impact on hospital pricing.<sup>16</sup>

#### **A. Public Payors**

The most significant public payor is CMS, which administers the Medicare and Medicaid programs. In 1983, Congress directed CMS largely to abandon cost-based reimbursement for acute inpatient care delivered to Medicare beneficiaries, and adopt the inpatient prospective payment

system (IPPS).<sup>17</sup> The IPPS was intended to moderate the rising federal expenditures, create a more “competitive, market-like environment, and ... curb inefficiencies in hospital operations engendered by reimbursement of incurred cost.”<sup>18</sup> Under the IPPS, the amount a hospital receives for treating a patient is based on the diagnosis-related group (DRG) for the episode of hospitalization. The DRG assigned to a particular episode of hospitalization is based on the diagnosis at discharge that justified the hospitalization. Each DRG has a payment weight assigned to it, based on the average cost of treating patients in that DRG. The average DRG cost reflects both the very ill patients that require more intensive care and the “healthy” ill who do not cost as much to treat. Hospitals receive this predetermined amount regardless of the actual cost of care.

Certain hospitals receive an adjusted payment in excess of the standard DRG amount. Teaching hospitals and hospitals treating a disproportionate share of low-

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<sup>17</sup> Some specialty hospitals are excluded from the IPPS. Psychiatric hospitals, pediatric hospitals, and certain designated cancer hospitals remain under a cost-based system of reimbursement. CMS, however, has recently proposed a regulation to shift psychiatric hospitals to prospective payment methods as well. Long-term hospitals (average length of stay is at least 25 days) and rehabilitation hospitals are paid under a prospective payment system that differs from the IPPS but operates on the same principle.

<sup>18</sup> Gregory C. Pope, *Hospital Nonprice Competition and Medicare Reimbursement Policy*, 8 J. HEALTH ECON. 147 (1989).

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<sup>16</sup> See *supra* Chapter 1.



income patients receive higher payments.<sup>19</sup> All DRGs include a wage index, tied to the geographic location of the hospital. Moreover, if the treatment of a particular patient is exceptionally costly, an “outlier” adjustment is added.<sup>20</sup>

Prior to August 1, 2000, CMS paid hospitals for outpatient care on a cost-based system. Since that date, hospitals, pursuant to the Balanced Budget Act of 1997, are paid for outpatient care under the outpatient prospective payment system (OPPS). Under OPPS, hospitals receive a predetermined amount for all outpatient services or procedures, based on which one of the approximately 750 ambulatory payment classifications (APCs) the episode of care falls into. The OPPS encompasses all

evaluation and management services and procedures provided by hospitals on an outpatient basis. For example, the APC for a particular outpatient surgical procedure includes payment for all operating and recovery room services, anesthesia, and surgical supplies. Each APC is assigned a general weight based on the median cost of providing the service.<sup>21</sup>

Effective October 1, 2000, Medicare adopted a prospective payment system for home health care services.<sup>22</sup> Moreover, as of 2007, Medicare is scheduled to begin employing a competitive bidding system to determine which providers will offer durable medical equipment to Medicare beneficiaries.<sup>23</sup>

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<sup>19</sup> See Centers for Medicare & Medicaid Services, *Acute Inpatient Prospective Payment System*, at <http://www.cms.hhs.gov/providers/hipps/ippsover.asp> (last modified Mar. 10, 2003). These adjustments were made because Congress concluded that Medicare should pay more to hospitals that incurred greater expenses as a result of having a residency program, or having more patients who were poor. See generally SEC’Y OF THE U.S. DEP’T OF HEALTH & HUMAN SERVICES, HOSPITAL PROSPECTIVE PAYMENT FOR MEDICARE: REPORT TO CONGRESS 48-49 (1982). See also COMM. ON WAYS & MEANS, BACKGROUND MATERIAL AND DATA ON THE PROGRAMS WITHIN THE JURISDICTION OF THE COMMITTEE ON WAYS AND MEANS, H.R. REP. NO. 108-6, § 2, at 2-32, 2-44 (2004 Green Book), available at <http://waysandmeans.house.gov/Documents.asp?section=813>.

<sup>20</sup> CMS adjusted its treatment of outlier payments in 2003, in response to concerns about manipulation of the outlier payment adjustment by some hospitals. See CENTERS FOR MEDICARE & MEDICAID SERVICES, HEALTH CARE INDUSTRY MARKET UPDATE: ACUTE CARE HOSPITALS 11 (2003), available at [http://www.cms.hhs.gov/reports/hcimu/hcimu\\_07142003.pdf](http://www.cms.hhs.gov/reports/hcimu/hcimu_07142003.pdf).

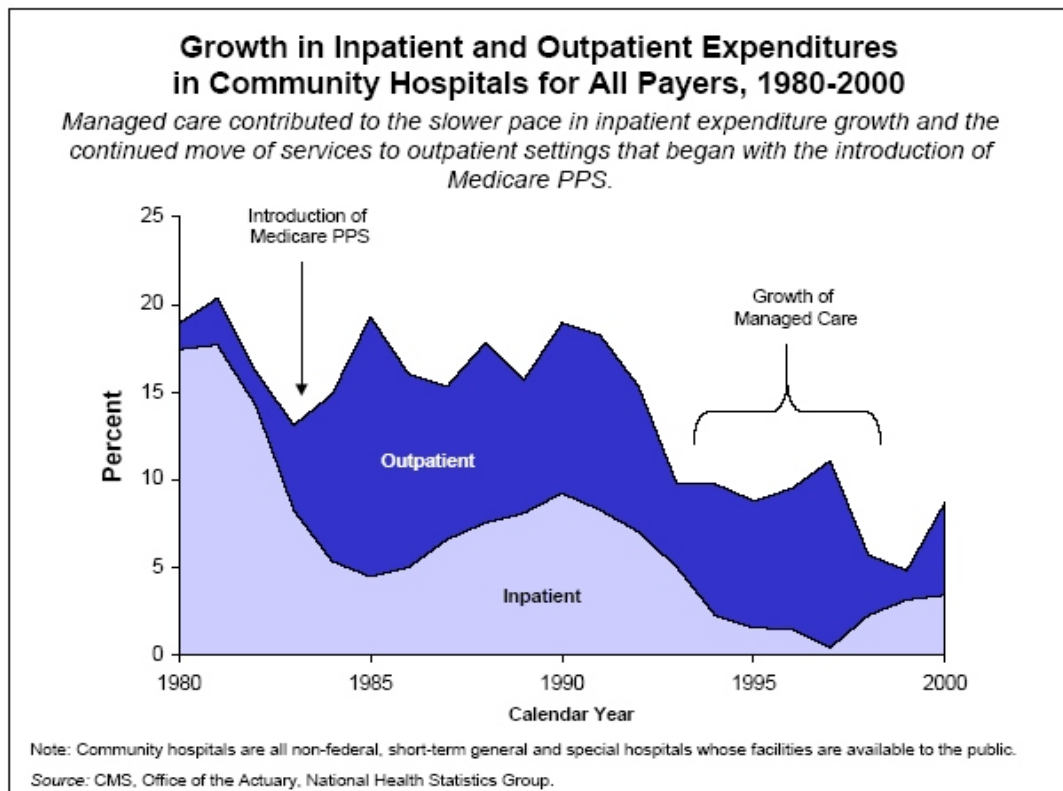
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<sup>21</sup> See II CENTERS FOR MEDICARE & MEDICAID SERVICES, HEALTH CARE INDUSTRY MARKET UPDATE: ACUTE CARE HOSPITALS, APPENDIX: MEDICARE PAYMENT SYSTEMS (2002), available at [http://www.cms.hhs.gov/reports/hcimu/hcimu\\_04292002\\_append.pdf](http://www.cms.hhs.gov/reports/hcimu/hcimu_04292002_append.pdf).

<sup>22</sup> Centers for Medicare & Medicaid Services, *The Home Health Prospective Payment System (PPS)*, at <http://www.cms.hhs.gov/providers/hhapps/> (last modified June 3, 2004).

<sup>23</sup> The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) instituted a phased-in competitive bidding program for durable medical equipment, prosthetics, and orthotics. CMS is required to establish competitive bidding in the 10 largest metropolitan statistical areas (MSAs) in 2007 and expand the program to the 80 largest MSAs in 2009. Prices negotiated in those areas may be applied nationwide. The legislation includes provisions to ensure quality, protect small suppliers, and mandate multiple winners.

**Figure 3:**



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The IPPS system was designed to control rising inpatient hospital costs and shift more care to the outpatient setting. The OPSS was designed to control rising outpatient costs. As Figure 3 reflects, both systems constrained costs more effectively than the cost-based systems they replaced.<sup>24</sup> Because the government establishes prices in the IPPS and OPSS, neither system adequately reflects the prices that would prevail in a competitive market.

As described in greater detail in

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<sup>24</sup> Figure provided by Centers for Medicare & Medicaid Services, *Program Information on Medicare, Medicaid, SCHIP, and Other Programs*, § 1, at 18 (June 2002), at <http://www.cms.hhs.gov/charts/series/sec1.pdf>.

Chapter 5, each state also has a Medicaid program, which pays for care provided to the poor and disabled.<sup>25</sup> Within broad guidelines established by Federal law, each state sets its own payment rate for Medicaid services and administers its own program. Medicaid programs either pay health care providers directly on a fee-for-service basis, or use prepayment arrangements such as health maintenance organizations (HMOs). Many states have aggressively adopted prepayment arrangements for the Medicaid

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<sup>25</sup> See U.S. Census Bureau, *Types of Health Insurance Coverage*, at <http://www.census.gov/hhes/hlthins/hlthinstypes.html> (last revised Apr. 21, 2004).

population.<sup>26</sup> As Chapter 5 details, there are other public payors.

## **B. Private Payors**

In some instances, private payors copied the reimbursement strategies of the Medicare program, or used Medicare DRGs as a reference price for negotiation.<sup>27</sup> Thus, some payors negotiate either a specified discount or a specified payment relative to the amount CMS would pay for a specified treatment episode. More often, private payors and hospitals negotiate discounts from charges (*e.g.*, they pay 85 percent of billed charges) or a per diem rate. Some contracts provide for a fixed payment for inpatient services on a per-case basis. Outpatient payment provisions are typically structured on a percentage-of-billed charges or fee-schedule basis.

## **V. RISING HOSPITAL PRICES**

Expenditures on hospital services have grown over the past two decades, but the rate of spending growth has varied. As noted previously, IPPS slowed the rate of hospital expenditure growth. The rise of managed care slowed the rate of expenditure growth further; from 1993 through 1998,

hospital expenditures increased at an average annual rate of 3.7 percent and in some areas of the country, the per diem price of a hospital stay actually decreased.<sup>28</sup>

In the past five years, rising hospital prices have driven spending on hospitals higher, even though hospital utilization is declining.<sup>29</sup> Analysts attribute rising hospital prices to a variety of factors including “hospitals’ increasing ability to negotiate higher prices from private payors.”<sup>30</sup>

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<sup>26</sup> CENTERS FOR MEDICARE & MEDICAID SERVICES, STATE MEDICAID MANUAL, PART 2 – STATE ORGANIZATION AND GENERAL ADMINISTRATION §§ 2102(C), 2103(A), at [http://www.cms.hhs.gov/manuals/45\\_smm/sm\\_02\\_2\\_2100\\_to\\_2106.2.asp](http://www.cms.hhs.gov/manuals/45_smm/sm_02_2_2100_to_2106.2.asp); CENTERS FOR MEDICARE & MEDICAID SERVICES, 2002 MEDICAID MANAGED CARE ENROLLMENT REPORT (2002).

<sup>27</sup> See, *e.g.*, Shoptaw 4/11 at 61 (stating that in the Little Rock market, “[r]eimbursement, . . . is largely discounted with fee for service with DRGs and per diems . . .”).

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<sup>28</sup> See *supra* Figure 3. See also Altman 2/28 at 13; Stuart H. Altman, *Testimony of Stuart H. Altman, Ph.D.* 4 (2/28) (1997 marked the fourth consecutive year for which the rate of spending growth for inpatient hospital use declined) [hereinafter Altman (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/altmanstuarth.pdf>; Stuart H. Altman, *Testimony of Stuart H. Altman, Ph.D.* 3 Chart 2 (2/28) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/altmanstuart2.pdf>.

<sup>29</sup> See Bradley C. Strunk & Paul B. Ginsburg, *Tracking Health Care Costs: Trends Turn Downward in 2003*, 2004 HEALTH AFFAIRS (Web Exclusive) W354, 356-57 (spending on hospital inpatient care per privately insured person rose 6.5 percent; spending on hospital outpatient care per privately insured person rose 11 percent), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.354v1>.

See also William Brewbaker, *Overview of the Health Care Marketplace: Structural, Legal and Policy Issues* 8 (9/2/02) (slides), at <http://www.ftc.gov/ogc/healthcare/brewbaker.pdf>; Centers for Medicare & Medicaid Services, Office of the Actuary, *The Nation’s Health Dollar: 2002* (reproducing charts entitled “Where It Came From” and “Where It Went” from the Office of the Actuary, National Health Statistics Group), at <http://www.cms.gov/statistics/nhe/historical/chart.asp> (last modified Jan. 8, 2004).

<sup>30</sup> Levit, *supra* note 3, at 154-55. See also Strunk & Ginsburg, *supra* note 29, at W357 (“This trend is consistent with qualitative research, which

Two recent studies project spending on inpatient hospital services will continue to increase in the coming decade. CMS estimated that expenditures on inpatient care will grow at an average rate of 6.4 percent per year until 2005, and then grow at a slower rate of 5.6 percent through 2013.<sup>31</sup> Thus, spending on hospital care is estimated to total \$934 billion in 2013, or a 55 percent real increase per capita.<sup>32</sup> These estimates are premised on the expectation that rising health care costs and a slowing economy will make employers and consumers more willing to accept restrictions on coverage. Similarly, another paper projected expenditures on hospital services will increase by 75 percent per capita.<sup>33</sup> Thus, experts predict spending on inpatient care will increase much faster than inflation in the coming decade.

## VI. PRESSURES ON HOSPITALS

Panelists listed a number of pressures facing hospitals. These pressures included increasing costs from the public's

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has showed that many hospitals solidified their negotiating leverage over plans during 2002 and 2003 and continued to use their formidable power to demand large payment rate increases.”).

<sup>31</sup> Heffler, *supra* at 7, at W4-90.

<sup>32</sup> *Id.* at W4-80.

<sup>33</sup> David Shactman et al., *Outlook for Hospital Spending*, 22 HEALTH AFFAIRS 12, 15 (Nov./Dec. 2003). The specific factors these authors identified were the resurgence of inpatient spending, rising outpatient care spending, increasing technology costs, stable inpatient lengths of stay, expectations of the baby-boom generation, and the increasing number of obese and overweight individuals.

demand for the latest technology,<sup>34</sup> the aging of the population,<sup>35</sup> shortages of nursing staff and other hospital personnel (which have forced hospitals to increase salaries),<sup>36</sup> increased regulatory requirements,<sup>37</sup> payor demands for information,<sup>38</sup> patient safety

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<sup>34</sup> See Varney 2/27 at 201 (“[P]atients are being treated earlier with more aggressive and new, very expensive technologies ....”); Andrew 3/26 at 15; Morehead 3/26 at 25. One panelist acknowledged the new and improved technology was an important factor in rising costs, but suggested that enhancements in the quality of care would ultimately result in lower payments to hospitals. R. Ryan 3/26 at 33-34.

<sup>35</sup> Sacks 3/26 at 41.

<sup>36</sup> See, e.g., Harrington 4/11 at 41-42, 44 (describing a recent increase of nurses’ salaries by \$7 million, as well as capital investments in nursing schools to increase enrollment); Kahn 2/27 at 71 (stating the primary driver, i.e., “the big banana,” of hospital expenditures is compensation and benefits); Varney 2/27 at 201 (“[C]ontributing to falling margins is the skyrocketing growth of labor costs.”); Strunk 3/27 at 160 (same); Argue 4/11 at 249-50 (same).

One New York hospital testified that approximately 15 percent of nursing positions at its facility are vacant and that radiology technicians are also in short supply. The shortages create a cycle of employees switching back and forth between competing institutions, with each move increasing the salary that is paid. See Andrew 3/26 at 10; Morehead 3/26 at 25 (an Ohio hospital system reporting a 30 percent raise for nurses over a three-year period); R. Ryan 3/26 at 29-30 (a Washington, DC hospital system noting a 20 to 30 percent vacancy rate of its permanent staff positions); Bates 4/11 at 87.

<sup>37</sup> Andrew 3/26 at 17.

<sup>38</sup> Charles N. Kahn, III, *Statement of the Federation of American Hospitals* 4-5 (5/29), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030529charleskahn.pdf>.

initiatives,<sup>39</sup> meeting homeland security requirements,<sup>40</sup> the rising cost of liability premiums<sup>41</sup> and prescription drugs,<sup>42</sup> and the obligation of providing care to the uninsured.<sup>43</sup> Hospital representatives also

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<sup>39</sup> Sacks 3/26 at 44.

<sup>40</sup> Harrington 4/11 at 43.

<sup>41</sup> Varney 2/27 at 202.

<sup>42</sup> Bates 4/11 at 86-87; Strunk 3/27 at 160; Argue 4/11 at 250.

<sup>43</sup> See Varney 2/27 at 202 (noting uncompensated care amounted to \$21.5 billion in 2001); Kahn 2/27 at 72; Waxman 2/28 at 68; Mansfield 4/25 at 84 (describing how one hospital system had provided a total of \$29 million of expenses for unreimbursed services for 112,000 persons).

In 2000, uninsured patients accounted for an average of 4.8 percent of all inpatient discharges, and 10.2 percent of emergency department discharges. Catherine G. McLaughlin & Karoline Mortensen, *Who Walks Through the Door? The Effect of the Uninsured on Hospital Use*, 22 HEALTH AFFAIRS 143, 150 (Nov./Dec. 2003). These averages do not reflect an equally shared burden; the percentage of the uninsured varies significantly from state to state, and at individual hospitals within those states. For example, in Little Rock, Arkansas, 13 percent of the people are uninsured; in Boston, Massachusetts, 6.1 percent of the people are without insurance. See K. Ryan 4/11 at 15-18; Allen 4/25 at 101; JOHN F. HOADLEY ET AL., CTR. FOR STUDYING HEALTH SYS. CHANGE, COMMUNITY REPORT NO. 12, HEALTH CARE MARKET STABILIZES, BUT RISING COSTS AND STATE BUDGET WOES LOOM IN BOSTON (2003), at <http://www.hschange.org/CONTENT/611/>. In at least one Southwestern state, the percentage of the uninsured is approximately 25 percent. See ROBERT J. MILLS & SHAILESH BHANDARI, U.S. DEP'T OF COMMERCE, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2002 (2003), at <http://www.census.gov/prod/2003pubs/p60-223.pdf>. Over the next five to ten years, uninsured inpatient stays are projected to increase by less than 1 percent, emergency department use by the uninsured is

emphasized the impact of managed care and the cuts imposed by the Balanced Budget Act of 1997 on reimbursement.<sup>44</sup> Panelists asserted that these pressures explained and justified recent hospital price increases.<sup>45</sup>

## VII. REORGANIZATION OF THE HOSPITAL SYSTEM

Over the past 20 years, hospitals have been consolidating into multi-hospital systems.<sup>46</sup> In 2001, almost 54 percent of

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projected to increase 3.1 percent, and uninsured outpatient visits are expected to increase by approximately 2.3 percent. McLaughlin & Mortensen, *supra*, at 151-52.

<sup>44</sup> Kahn 2/27 at 70 (asserting that in the mid 1990s, “hospitals arguably underpriced their products to meet the demands of managed care contracts, . . . and significant Medicare reductions”); Altman 2/28 at 18-19; Altman (stmt), *supra* note 28, at 6 (between 1997 and 2000 hospital operating margins in the U.S. declined every year and by 2000 the operating margin was 2 percent; in Massachusetts the operating margin in 2000 averaged negative 1.4 percent); Fine 9/9/02 at 224 (“Hospitals have deferred and deferred acting on plant, but now we have a situation with the baby boomers coming through where demand for services far outstrips our ability to meet that demand.”).

<sup>45</sup> Sacks 3/26 at 43 (*e.g.*, in 2001 Advocate Health Care’s operating margin was 2.59 percent; in 2002 it dropped to 1.8 percent “despite significant cost reductions and efficiencies, \$20 million savings from our system-wide supply chain initiative, centralized information systems, administrative services that have taken real dollars in the tens of millions out of our expense structure”); Shelton 3/26 at 48 (even hospitals with a positive cash flow do not have enough cash to upgrade equipment, expand services, or meet the growing utilization needs of an aging population).

<sup>46</sup> DEBORAH HAAS-WILSON, MANAGED CARE AND MONOPOLY POWER: THE ANTITRUST CHALLENGE 28 (2003). See also Deborah Haas-Wilson & Martin Gaynor, *Increasing*

hospitals operated as part of a system, with an additional 12.7 percent working in looser health networks. In 1979, only about 31 percent of hospitals were part of a system.<sup>47</sup> Consolidation presents an opportunity for hospitals to compete more efficiently. Consolidated hospitals can employ mechanisms to improve the quality of care and limit duplication of services or administrative expenses. Consolidated

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*Consolidation in Healthcare Markets: What Are the Antitrust Policy Implications?*, 33 HEALTH SERVICES RES. 1403 (1998) (“Healthcare providers and insurers have been aligning in a plethora of coalitions as mergers, networks, joint ventures, and contracts have developed and dissolved with great rapidity. The implications of this reorganization for healthcare competition, and thus for costs, quality, and innovation, are profound. The key questions are to what extent these changes enhance efficiency and quality, and to what extent they facilitate collusion and market power.”); MARTIN GAYNOR & DEBORAH HAAS-WILSON, CHANGE, CONSOLIDATION AND COMPETITION IN HEALTH CARE MARKETS 19 (Nat’l Bureau of Econ. Research, Working Paper No. 6701, 1998) (“The most extensive research evidence on competitive conduct by firms in health care markets is on hospitals; Dranove and White (1994) offer an extensive survey. These studies use differing product and geographic market definitions and research methods, yet the consistency of the results is striking. Increased concentration is associated with increased prices in markets for hospital services.”), available at <http://papers.nber.org/papers/w6701.pdf>; David L. Redfern, *Competition in Healthcare Workshop* (Oct. 8, 2003) (Public Comment).

<sup>47</sup> Bazzoli 5/29 at 12; Gloria J. Bazzoli, *The US Hospital Industry: Two Decades of Organizational Change?* 7 (5/29) (slides) (same) [hereinafter Bazzoli Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030529bazzoli.pdf>. Not all mergers or consolidation into systems have gone smoothly. See Waxman 2/28 at 64 (noting that the CareGroup system “merger has not been stellar. Cultures clashed; strong central leadership was not established; and over a period of several years large amounts of money were lost.”).

hospitals may also be able to improve quality if they centralize performance of complex procedures for which greater volume leads to higher quality. Consolidated hospitals could also use their combined resources to track established clinical quality measures and develop new ones.

Initially, national systems acquired hospitals throughout the United States, but recent acquisitions have been more localized.<sup>48</sup> For example, according to one panelist, St. Louis has 31 hospitals. Four of those hospitals are independent; the remaining hospitals have joined one of four local systems.<sup>49</sup> Similarly, one academic described the consolidation in San Francisco: by 1999 “almost all hospitals ... became part of one of four not-for-profit hospital systems.”<sup>50</sup> Another panelist

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<sup>48</sup> David Dranove & Richard Lindrooth, *Hospital Consolidation and Costs: Another Look at the Evidence*, 22 J. HEALTH ECON. 983, 984 (2003); Alison Evans Cuellar & Paul J. Gertler, *Trends in Hospital Consolidation: The Formation of Local Systems*, 22 HEALTH AFFAIRS 77, 80 (Nov./Dec. 2003).

<sup>49</sup> Probst 5/29 at 84; Louise Probst, *Hearing on Hospital Market Competition* 3 (5/29) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030529probst.pdf>; Scicchitano 3/27 at 182-83 (describing the Long Island hospital environment as having “25 hospitals in Nassau and Suffolk [counties], with 21 of them grouped into three health systems”).

<sup>50</sup> HAAS-WILSON, *supra* note 46, at 28. See also Joanne Spetz et al., *The Growth of Multihospital Firms in California*, 19 HEALTH AFFAIRS 224, 225 (Nov./Dec. 2000) (Study of the California hospital industry revealed at least half of all hospitals are affiliated with multisite systems; by 1996, 83 percent of Sacramento’s hospitals beds were held by three hospital systems and in San Francisco three hospital systems control 43 percent of the region’s hospital

described the Boston metropolitan area consolidation as being one where “through mergers and acquisitions ... the PCHI [Partners Community HealthCare Inc.] network now numbers 15 hospitals and more than 5,000 physicians.”<sup>51</sup> One study noted dramatic consolidation in numerous communities, including Cleveland, “where two local hospital systems now control nearly 70 percent of the area’s inpatient capacity,” and Indianapolis and Phoenix, where “hospitals have carved out strongholds in key urban and suburban areas, at times creating virtual monopolies in geographic submarkets.”<sup>52</sup>

Hospitals may consolidate within a single market or across markets, and consolidation can occur over a broad spectrum of possibilities.<sup>53</sup> At one end of

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beds.).

<sup>51</sup> See Berman 2/28 at 80.

<sup>52</sup> CARA S. LESSER & PAUL B. GINSBURG, BACK TO THE FUTURE? NEW COST AND ACCESS CHALLENGES EMERGE (Ctr. for Studying Health Sys. Change, Issue Brief No. 35, 2001), available at <http://www.hschange.org/CONTENT/295/>. Not all systems have succeeded. Some deals have come apart because of discrepancies over control and differences in mission and some deals have met problems because the systems’ financial performance was strained by assuming the debt load and excess capacity of financially weak hospitals. See CARA S. LESSER ET AL., CENTER FOR STUDYING HEALTH SYSTEM CHANGE, COMMUNITY REPORT NO. 12, CONSOLIDATION CONTINUES, FINANCIAL PRESSURES MOUNT: NORTHERN NEW JERSEY (1999), at <http://www.hschange.org/CONTENT/108/>.

<sup>53</sup> “Within market” consolidation is the merger of two hospitals within the same product and geographic market. “Across market” consolidation is the joining of hospitals producing similar services in different geographic and/or product markets.

the spectrum, consolidating hospitals have a shared license and common ownership, report unified financial records, and eliminate duplicative facilities.<sup>54</sup> At the other end of the spectrum, a common governing body owns the consolidating hospitals, but the hospitals maintain separate hospital facilities, retain their individual business licenses, and keep separate financial records.

Hospital systems have varying degrees of centralized control. One panelist noted that some systems have a parent organization that sets policy and makes key decisions. At the other extreme, the same panelist noted that some systems offer little more than centralized administrative oversight and capital financing.<sup>55</sup> Another panelist noted that “the various hospital mergers that were particularly frequent in the mid-1990s tended not to follow through when it came to clinical integration ...”<sup>56</sup>

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<sup>54</sup> See Cuellar & Gertler, *supra* note 48, at 77; Dranove & Lindrooth, *supra* note 48, at 984; Patricia Cameron, *Personal Views of Patricia Cameron* 1 (Public Comment) (stating that “[w]hen two hospitals in one market area . . . merge, and consolidate services that were otherwise duplicative (including management, overhead and advertising), it appears that patients and physicians have benefitted”); K. Smith 4/11 at 174-75 (stating that one hospital system, as a result of its consolidation efforts, had “eliminated almost all duplicative overhead and patient care services that our system had” and created “a single medical record for all three hospitals” that is also “shared electronically amongst all physicians”).

<sup>55</sup> See Bazzoli 5/29 at 18-19; Bazzoli Presentation, *supra* note 47, at 16.

<sup>56</sup> Ginsburg 2/26 at 61-62. See also C. Baker 2/28 at 42 (alleging that in Massachusetts “the hospitals that made up [one] care delivery system continued to operate on a stand-alone basis with little

Panelists identified several reasons for hospital consolidation, including the reduction of excess capacity, the rise of managed care, increased ability to assume capitated financial risk, expansion of the hospital's delivery network, and service consolidation and coordination.<sup>57</sup> Analysts have also suggested other factors that might be driving consolidation, including the desire to obtain economies of scale in purchasing or production, access to capital markets, and "specialization in labor or

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clinical or systems integration"); Vincent Scicchitano, *Contracting Practices* 6-8 (3/27), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030327vincentscicchitano.pdf>.

<sup>57</sup> Ginsburg 2/26 at 62-63 (as hospitals "were pressed to cut their costs, they had motivation to take excess capacity out of the system"); Varney 2/27 at 215 (noting that in some areas with multiple hospitals, each was operating "at 20, 30, 40 and in the best cases, 60 percent capacity"); Eugene Anthony Fay, *Statement of the Federation of American Hospitals – Hospital's Non-Profit Status* 4 (4/10) ("Consolidation of operations brings efficiencies and cost savings to the systems."), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030410fay.pdf>; Fay 4/10 at 27 (same). The cost of excess capacity can be daunting. One study found that an empty bed cost \$48,826 in 1995 dollars. Martin Gaynor & Gerard F. Anderson, *Uncertain Demand, the Structure of Hospital Costs and the Cost of Empty Hospital Beds*, 14 J. HEALTH ECON. 291 (1995). See also Morehead 3/26 at 20-22 (one panelist noting one of the ways that its hospital system has addressed the shift from inpatient to outpatient focus is to create a regional network that includes large and small hospitals, as well as ambulatory care centers); Lawton R. Burns & Mark V. Pauly, *Integrated Delivery Networks: A Detour on the Road to Integrated Health Care?*, 21 HEALTH AFFAIRS 128, 129 (July/Aug. 2002).

management techniques."<sup>58</sup>

Some panelists assert hospital consolidation has promoted efficiency, led to savings, and instilled life back into failing hospitals.<sup>59</sup> Other panelists believe the primary result of consolidation has been the creation of hospital market power against payors.<sup>60</sup> One study examining consolidation through mergers found that hospitals that merged tended to be in less-concentrated markets and in areas with higher HMO penetration.<sup>61</sup> Merging hospitals were also more likely to have been a member of a system, were larger, had higher occupancy rates and case-mix indexes, and higher pre-merger expenses and

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<sup>58</sup> Timothy S. Snail & James C. Robinson, *Organizational Diversification in the American Hospital*, 19 ANN. REV. PUB. HEALTH 417, 419 (1998). Empirical studies have shown, however, that economies of scale in the production of hospital inpatient services primarily occur in the 200 to 400 bed range. *Id.* at 435. See also Spetz et al., *supra* note 50, at 226.

<sup>59</sup> See, e.g., Welch 2/28 at 112-113; F. Miller 2/28 at 92; Mongan 2/28 at 32-33. But see Greaney 2/27 at 237 (noting "there are a number of studies that question whether efficiencies – promised efficiencies – were realized").

<sup>60</sup> See, e.g., Berman 2/28 at 80-81, 83; Desmarais 2/27 at 168; Washington Business Group on Health, *Comments Regarding Competition Law and Policy & Health Care (Sept. 30, 2002)* (Public Comment).

<sup>61</sup> Robert A. Connor et al., *Which Types of Hospital Mergers Save Consumers Money?*, 16 HEALTH AFFAIRS 62, 65 (Nov./Dec. 1997) (The data set includes 122 within-market-area horizontal hospital sets; merger is defined as two or more similar corporations coming together into a single surviving entity).



revenues.<sup>62</sup>

One recent review examined the operational consequences of hospital consolidation.<sup>63</sup> It found that when hospitals that consolidated were geographically distant, they generally had similar staffing ratios, similar occupancy rates, and substantial service duplication. For these distant hospitals, typically both were financially viable. Duplicative acute care services were generally not eliminated, unless one of the hospitals was more specialized, was economically weaker or had different staffing levels, or there existed a substantial degree of competition between the merging hospitals.<sup>64</sup> One recent study indicated that when systems acquired hospitals, efficiencies did not materialize, because of the failure to combine operations.<sup>65</sup>

Most studies of the relationship between competition and hospital prices generally find increased hospital concentration is associated with increased

prices.<sup>66</sup> One study found that merged hospitals experience larger price and cost increases than those that have not merged, except in less concentrated areas where these patterns were reversed.<sup>67</sup> Another study using similar data and methods found that merger cost and price savings were lower than the first study when merging hospitals were compared against rival institutions.<sup>68</sup>

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<sup>66</sup> David Dranove et al., *Price and Concentration in Hospital Markets: The Switch from Patient-Driven to Payer-Driven Competition*, 36 J.L. & ECON. 179, 201 (1993) (finding that market concentration in California led to rate increases); Glenn A. Melnick et al., *The Effect of Market Structure and Bargaining Position on Hospital Prices*, 11 J. HEALTH ECON. 217 (1992) (finding market concentration appears to increase hospitals' bargaining power with insurers and self-insurers); Ranjan Krishnan, *Market Restructuring and Pricing in the Hospital Industry*, 20 J. HEALTH ECON. 213, 215 (2001) (mergers that increase hospital market share in specific hospital services, as measured 33 DRGs, show a corresponding increase in prices of those services). *But see* Charles N. Kahn, III, *Statement of the Federation of American Hospitals 2 (2/27)* (questioning the validity of various studies of cost increases as related to consolidation), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030227kahniii.pdf>.

<sup>67</sup> Connor et al., *supra* note 61, at 68.

<sup>68</sup> Heather Radach Spang et al., *Hospital Mergers And Savings for Consumers: Exploring New Evidence*, 20 HEALTH AFFAIRS 150, 156 (July/Aug. 2001). The changes included removing rural hospitals from the sample, excluding hospitals that are part of hospital systems from the "nonmerging" group, and separating nonmerging hospitals into nonmerging rival hospitals and nonmerging nonrival hospitals. *But see* Guerin-Calvert 4/10 at 209 ("And I think again in general, what the studies show is that some mergers do result in price increases that can't be explained by cost increases but that overall the patterns that we see is actually pricing increasing at a slower rate than cost increases.").

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<sup>62</sup> Connor et al., *supra* note 61, at 71.

<sup>63</sup> Snail & Robinson, *supra* note 58, at 434-35.

<sup>64</sup> *Id.* See also DAVID DRANOVE, *THE ECONOMIC EVOLUTION OF AMERICAN HEALTH CARE* 122 (2000) ("I have asked many providers why they wanted to merge. Although publicly they all invoked the synergies mantra, virtually everyone stated privately that the main reason for merging was to avoid competition and/or obtain market power.").

<sup>65</sup> Dranove & Lindrooth, *supra* note 48, at 996.

One set of commentators has observed that most empirical studies on concentration and consolidation do not differentiate among transactions that occur within markets and those that occur across markets, even though these transactions “might reflect very different hospital strategies and consequently, could have different effects on efficiency.”<sup>69</sup>

According to several panelists, hospital systems try to make sure they have at least one “must have” hospital in each geographic market in which they compete.<sup>70</sup> A “must have” hospital or hospital system is one that health care plans believe they must offer to their beneficiaries to attract employers to their plan. According to some panelists, this status allows the hospital or

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<sup>69</sup> See Cuellar & Gertler, *supra* note 48, at 77; Snail & Robinson, *supra* note 58, at 440.

<sup>70</sup> See, e.g., Berman 2/28 at 80-81 (hospitals “have planned these mergers and affiliations strategically to include anchor community hospitals”); Charles D. Baker, *Testimony of Charles Baker* 9 (2/28) (Brigham and Massachusetts General “are probably the two best-known tertiary hospitals in New England and they contract together .... The fact that they represent only two of many teaching hospitals in Massachusetts doesn’t really matter. For certain kinds of services, they are virtually the only choice around.”) [hereinafter C. Baker (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030228baker.pdf>; C. Baker 2/28 at 46-48 (same); Probst 5/29 at 85 (“[T]here’s one hospital in one of the systems that, for different reasons, by many consumers, is seen as a must-have hospital, which makes it a little bit tougher, but really, every one of the systems has a must-have hospital for a given employer or a given, you know, consumer population, and all the systems require – it’s all or nothing.”); Scicchitano 3/27 at 183-84; Strunk 3/27 at 157-58.

hospital system to demand price increases.<sup>71</sup>

Consolidation has resulted in complaints by payors about the exercise of market power by hospitals.<sup>72</sup> Some panelists and commentators believe an important motivation for the creation of multi-hospital

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<sup>71</sup> See, e.g., Berman 2/28 at 81-82 (Hospital systems that own “virtually every hospital” in an MSA aggregate power that makes them “literally ... a must-have hospital system for area employers and consumers.” Hospital systems then “use[] this position to demand price increases ....”); C. Baker (stmt), *supra* note 70, at 7 (consumer and employer preferences make it very difficult for health plans to discontinue their relationship with any hospital in its service delivery area); C. Baker 2/28 at 46-47; C. Baker (stmt), *supra* note 70, at 8 (Harvard Pilgrim Health Care members pay more today for services from hospital systems than if each hospital contracted individually). See also Zwanziger 3/26 at 95 (“[I]n every market that we looked at, where there is a tertiary center, then every plan, without exception, had at least one tertiary center in their network .... I suspect that that’s because they really regard having one tertiary center at least as an important part of their ability to compete effectively.”); Jack Zwanziger, *Defining Hospital Markets* 5 (3/26) (slides) (same), at <http://www.ftc.gov/ogc/healthcarehearings/docs/zwanziger.pdf>; Fred Dodson, *Health Insurance Monopoly Issues – Competitive Effects* 7-8 (4/23) (noting that provider systems impact insurance product offerings, when systems refuse to participate in tiering), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030423freddodson.pdf>.

<sup>72</sup> As one pair of analysts noted, however, “traditional economic theory says that a monopolist firm in one market cannot leverage monopoly power in a separate, competitive market, which makes it difficult from the standpoint of market power to understand why some hospital systems” are national. Cuellar & Gertler, *supra* note 48, at 84. They further note that more recent theories focusing on the nature of bargaining between managed care firms and providers may leave room to challenge this theory. *Id.* See also David Dranove & William D. White, *Emerging Issues in the Antitrust Definition of Healthcare Markets*, 7 HEALTH ECON. 167 (1998).

systems has been to gain market power to secure higher reimbursement from payors.<sup>73</sup> One panelist stated the various hospital mergers occurring in the mid-1990s “tended not to follow through when it came to clinical integration and ultimately providers have regained the leverage with health plans that they had lost.”<sup>74</sup> Another study examined the relationship between market power and pricing in nonprofit, multi-hospital systems. The investigation led to two primary findings: (1) nonprofit

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<sup>73</sup> Spetz et al., *supra* note 50, at 226. See also Kanwit 2/27 at 98 (“[H]ospital consolidation is causing a rise in health care costs and affecting ... the health plans’ ability to contract cost effective care ...”); American Ass’n of Health Plans, *Additional Talking Points in Response to AHA’s Study on Hospital Costs* (Public Comment); Kahn 2/27 at 111 (stating that consolidation has not been prevalent across the country, but also noting that “hospitals reduced their sizes in response to constraints for managed care, in response to Medicare cutbacks, and now that there are less beds and, in a sense, [hospitals have] more market power in negotiating with payors”); Binford 9/24 at 131 (noting “the advent of hospital networks and the acquisition of many heretofore independent and competing physician practices, [] has enabled hospitals to really control the negotiating process of not only their own contracts, but physician contracts”); Langenfeld 4/11 at 192 (noting his observation that “[p]re-merger, perhaps the acquired hospital has lower rates to private payors than the acquiring hospital has. After the merger, the acquiring hospital raises the rates up to its higher level, which on average is a price increase. And I have also observed that these rate increases can be as much as 50 percent, or sometimes even more.”); Greaney 2/27 at 136-37 (same). But see MARGARET E. GUERIN-CALVERT ET AL., *ECONOMIC ANALYSIS OF HEALTHCARE COST STUDIES COMMISSIONED BY BLUE CROSS BLUE SHIELD ASSOCIATION* (2003) (finding hospital merger activity does not explain the increases in spending for hospital services), at [http://www.hospitalconnect.com/aha/press\\_room-info/content/EconomistReport030225.pdf](http://www.hospitalconnect.com/aha/press_room-info/content/EconomistReport030225.pdf).

<sup>74</sup> Ginsburg 2/26 at 61-62.

hospitals that were members of national or regional systems appear to have priced their services “more aggressively in the presence of market power” than the hospitals did when operating independently or as members of local systems; and (2) nonprofit systems showed a tendency to exercise market power in the form of higher prices.<sup>75</sup>

The rise of hospital systems has affected market concentration in certain markets. One study found that if hospital system members within metropolitan statistical areas (MSA) are treated as one entity, nineteen MSAs became concentrated between 1995 and 2000.<sup>76</sup> Seven of the 19 MSAs showed an increase in HHI of at least 1,700.

As discussed in Chapter 4, the Agencies will continue to evaluate hospital consolidation to determine whether consolidation (or potential consolidation) in any given market is anticompetitive.<sup>77</sup>

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<sup>75</sup> Gary J. Young et al., *Community Control and Pricing Patterns of Nonprofit Hospitals: An Antitrust Analysis*, 25 J. HEALTH POL., POL’Y & L. 1051, 1073 (2000).

<sup>76</sup> Cuellar & Gertler, *supra* note 48, at 82. The study used a change in the Herfindahl-Hirschmann Index (HHI) of 1,700 as the benchmark for determining whether a market became highly concentrated.

<sup>77</sup> The Commission recently challenged a consummated merger between Evanston Northwestern Healthcare Corporation and Highland Park Hospital. *In re* Evanston Northwestern Healthcare Corp., No. 9315 (Feb. 10, 2004) (complaint), at <http://www.ftc.gov/os/caselist/0110234/040210emhcomplaint.pdf>. Moreover, the Commission’s Bureaus of Economics and Competition are evaluating the effects of consummated hospital mergers in several cities. The

## VIII. ENTRY OF SPECIALTY HOSPITALS AND AMBULATORY SURGERY CENTERS

Specialty hospitals provide care for a specific specialty (*e.g.*, cardiac, orthopedic, or psychiatric) or type of patient (*e.g.*, children or women).<sup>78</sup> Specialty hospitals tailor their care and facilities to fit the chosen type of condition, patient, or procedure on which they focus. Specialty hospitals are not new to the hospital industry. Pediatric and psychiatric hospitals have existed for decades. More recently, numerous cardiac and orthopedic surgery hospitals have opened or are under construction. These single-specialty hospitals (SSHs) differ from their predecessors in that many of the physicians who refer patients have an ownership interest in the facility.<sup>79</sup> SSHs may compete

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Commission will announce the results of these retrospective studies as they are completed. The Commission announced on June 30, 2004 that it had closed an investigation into the acquisition of Provena St. Therese Medical Center by Vista Health Acquisition. *See* Press Release, Federal Trade Comm'n, FTC Close Investigation Into Merger of Victory Memorial Hospital and Provena St. Therese Medical Center (July 1, 2004) and related documents at <http://www.ftc.gov/opa/2004/07/waukegan.htm>.

<sup>78</sup> G. Lynn 3/27 at 27 (“Historically, they were children’s hospitals or psych. hospitals; now they include heart hospitals, cancer hospitals, ambulatory surgery centers, dialysis clinics, pain centers, imaging centers, mammography centers and a host of other narrowly focused providers generally owned, at least in part, by the physicians who refer patients to them.”).

<sup>79</sup> Lesser 3/27 at 9-10 (A “key characteristic of the specialty hospitals is physician ownership, and this is something that really distinguishes the specialty hospitals of today from the traditional acute

with both inpatient and outpatient general hospital surgery departments as well as with ambulatory surgery centers.

There are relatively few SSHs. In October 2003, the General Accounting Office identified 100 existing SSHs with an additional 26 under development. SSHs are located in 28 states, but two-thirds are located in only seven states.<sup>80</sup> The GAO concluded that “the location of specialty hospitals is strongly correlated to whether states allow hospitals to add beds or build new facilities without first obtaining state approval for such health care capacity increases.”<sup>81</sup> Ninety-six percent of the opened SSHs and all 26 SSHs under

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care hospitals and from some of the children’s hospitals and other single-specialty hospitals that we’ve seen in the past.”).

As Chapter 1 notes, the Self-Referral Amendments limit the ability of providers to receive payment from Medicare for designated health services delivered when the provider refers a consumer to a facility in which the provider has an ownership or investment interest. Investment in a “whole hospital,” however, is not considered a designated health service under the Self-Referral Amendments.

<sup>80</sup> U. S. GENERAL ACCOUNTING OFFICE, GAO-04-167, SPECIALTY HOSPITALS: GEOGRAPHIC LOCATIONS, SERVICES PROVIDED AND FINANCIAL PERFORMANCE 3-4 (2003) (Report to Congressional Requesters) [hereinafter GAO, SPECIALTY HOSPITALS], at <http://www.gao.gov/new.items/d04167.pdf>. The seven states are Arizona, California, Texas, Oklahoma, South Dakota, Louisiana, and Kansas. Of those seven states, only three (Texas, Oklahoma and Arizona) require all hospitals to have an emergency room. *Id.*

<sup>81</sup> GAO, SPECIALTY HOSPITALS, *supra* note 80, at 15. *See also infra* Chapter 8 (discussing Certificate of Need programs).

development are located in such states.<sup>82</sup> The recently imposed moratorium on Medicare payments to SSHs, and the results of two Congressionally mandated studies on the industry are likely to affect the future development of these hospitals.<sup>83</sup> Under the

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<sup>82</sup> GAO, SPECIALTY HOSPITALS, *supra* note 80, at 15. According to the GAO report, as of 2002, “37 states maintained certificate of need (CON) requirements to varying degrees. Overall, 83 percent of all specialty hospitals, 55 percent of general hospitals, and 50 percent of the U.S. population are located in states without CON requirements.” *Id.* See also Lawrence P. Casalino et al., *Focused Factories? Physician-Owned Specialty Facilities*, 22 HEALTH AFFAIRS 56, 58-59 (Nov./Dec. 2003).

<sup>83</sup> Under the MMA, the Medicare Payment Advisory Commission (MedPAC) is required to study the differences in costs between specialty hospitals and community hospitals, the selection of patients, the financial impact specialty hospitals have on community hospitals, and the proportions of payment between specialty hospitals and community hospitals. HHS will study the referral patterns of the physicians with an ownership interest in specialty hospitals, the quality of care provided, and the provision of uncompensated care. Congress has placed a moratorium on Medicare payments to any new specialty hospital while the studies are ongoing. Congress has given the two agencies 15 months from the date of enactment to complete the studies. MMA § 507(C)(1)-(2).

CMS issued guidance for exceptions to the specialty hospital moratorium. See CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEP’T OF HEALTH & HUMAN SERVICES, CMS MANUAL SYSTEM, PUB. 100-20 ONE-TIME NOTIFICATION: CHANGE REQUEST 3036 (Mar. 19, 2004), at [http://www.cms.hhs.gov/manuals/pm\\_trans/R62OTN.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R62OTN.pdf); CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEP’T OF HEALTH & HUMAN SERVICES, MANUAL SYSTEM, PUB. 100-20 ONE-TIME NOTIFICATION: CHANGE REQUEST 3193 (May 7, 2004), at [http://www.cms.hhs.gov/manuals/pm\\_trans/R79OTN.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R79OTN.pdf). At least one forthcoming surgical hospital, offering heart and surgical care, claims it will not fall within Congress’s definition of a specialty hospital because it will offer other services,

moratorium, physicians may not refer Medicare patients to a specialty hospital in which they have an ownership interest, and Medicare may not pay specialty hospitals for any services rendered as a result of a prohibited referral.<sup>84</sup>

Panelists identified a number of market developments that encouraged the emergence of SSHs, including: less tightly managed care;<sup>85</sup> the willingness of providers to invest in a SSH;<sup>86</sup> physicians’ desire to “provide better, more timely patient care”;<sup>87</sup> physicians looking for ways to supplement declining professional fees;<sup>88</sup> and the growth of entrepreneurial firms, such as MedCath and National Surgical Hospitals.<sup>89</sup> Panelists also stated that some providers desire greater control over management decisions that

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including thoracic treatment and ear, nose and throat ailments as well as an emergency room with one bed and one procedure room. See Hugo Martin, *Group Plans Hospital in Loma Linda*, L. A. TIMES, Apr. 26, 2004, at <http://www.latimes.com/news/local/state/la-me-hospital26apr26,1,6653902.story?coll=la-new-s-state>.

<sup>84</sup> MMA § 507.

<sup>85</sup> Lesser 3/27 at 10-11.

<sup>86</sup> *Id.* at 10-11.

<sup>87</sup> Alexander 3/27 at 34. See also Nat’l Surgical Hospitals, *Single Specialty Hospitals* (Mar. 27, 2003) (Public Comment).

<sup>88</sup> J. Wilson 4/11 at 66 (noting that as doctors make less money from insurance companies, they will “get into buying MRI machines, [] get into surgery centers ... What [doctors are] doing is we’re getting into ancillary activities in order to maintain our standard of income and living”).

<sup>89</sup> Lesser 3/27 at 10-11.

affect their incomes and productivity.<sup>90</sup> Several panelists suggested efficiency was an important consideration for many providers: specialty hospitals allow “surgeons to start on time, do more cases in a given amount of time, and get back to their office on time.”<sup>91</sup> One panelist asserted that physicians view SSHs as a “a blank slate” and an “opportunity to make improvements in the care delivery process” by “redesign[ing] the care delivery process in a

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<sup>90</sup> See, e.g., D. Kelly 3/27 at 70 (“[I]t’s because of the care, the control we have over the care provided for their patients in the in-patient setting; the empowerment within the hospital to help govern and set up the operating standards ....”); Kane 4/11 at 74 (stating that many physicians are not looking to increase their declining income, rather they are starting specialty hospitals because they are dissatisfied with general hospitals “because of the inability to manage their day-to-day patient interactions and their inability to provide high-quality medical care”); Dan Caldwell, *Health Care Competition Law and Policy Hearings 2* (Public Comment) (listing physicians participation in the governance of a facility and physician efficiency as influencing the development of SSH).

<sup>91</sup> Rex-Waller 3/27 at 51. See also Rex-Waller 3/27 at 50 (specialty hospitals are responding to a “demand born out of frustration with local acute care hospital management that is unresponsive” to surgeon and patient requirements). See also D. Kelly 3/27 at 70 (describing “the productivity enhancement it provides to them because all of them are getting busier and they need to find ways to be more productive”); D. Kelly 3/27 at 81 (noting the savings on expenses: “instead of spending 40 to 60 percent of your total operating expense on labor, which is typical in the United States in a fully integrated health system, we do that at around 30 percent on a fully allocated basis”); Alexander 3/27 at 35 (stating that operating rooms in some markets “are at capacity” and it is very difficult for physicians to schedule elective surgeries at general hospitals).

way to be more effective and efficient.”<sup>92</sup>

Several panelists contended that SSHs achieve better outcomes through increased volume, better disease management, and better clinical standards.<sup>93</sup> They attribute these positive outcomes to their focus on a single specialty.<sup>94</sup> For example, MedCath stated that its focus has allowed it to increase access to cardiac monitored beds, “improve access to emergency services,” “improve clinical outcomes” and lower the cost of care by having shorter hospital stays, discharging a higher percentage of patients directly home, and using the nursing labor pool efficiently.<sup>95</sup>

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<sup>92</sup> Lesser 3/27 at 14. See also Alexander 3/27 at 33 (“Specialized facilities are a natural progression and are a recognition that the system needs to be tweaked, perhaps overhauled, to achieve lower costs, higher patient satisfaction, and improved outcomes.”).

<sup>93</sup> Lesser 3/27 at 14-15 (noting that specialty hospitals across the country have stated that by “concentrating more cases in a particular facility, specialty hospitals may help to lower per-case costs and boost quality”). See also NEWT GINGRICH ET AL., *SAVING LIVES AND SAVING MONEY* (2003); REGINA HERZLINGER, *MARKET DRIVEN HEALTH CARE: WHO WINS, WHO LOSES IN THE TRANSFORMATION OF AMERICA’S LARGEST SERVICE INDUSTRY* (1997).

<sup>94</sup> Numerous empirical studies indicate that there is a relationship between the number of particular procedures performed and the probability of a good outcome. Harold S. Luft et al., *Should Operations Be Regionalized? The Empirical Relation Between Surgical Volume and Mortality*, 301 N. ENG. J. MED. 1364 (1979); John D. Birkmeyer, *Hospital Volume and Surgical Mortality in the United States*, 346 N. ENG. J. MED. 1128 (2002); Colin B. Begg, *Impact of Hospital Volume on Operative Mortality for Major Cancer Surgery*, 280 JAMA 1747 (1998).

<sup>95</sup> D. Kelly 3/27 at 72.

A panelist representing MedCath presented a study showing that 90 percent of its patients were discharged directly to home, compared to “72 percent for the peer community hospitals and 70 percent for the teaching facilities.”<sup>96</sup> According to this panelist, for each early discharge, MedCath hospitals saved “Medicare over \$1,000 per discharge.”<sup>97</sup> Other panelists stated that physician-investors send healthier, lower-risk patients to the SSH and sicker patients to the general hospital.<sup>98</sup> Several panelists argued that this allows SSHs “to produce service less expensively, while often being paid the same or more than community hospitals.”<sup>99</sup> An April, 2003 GAO report found that patients at specialty hospitals tended to be less sick than patients with the

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<sup>96</sup> *Id.* at 74. See also Dennis I. Kelly, *Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy* 10 (3/27) (slides) (average length of stay for MedCath patient 3.84 days compared against peer community hospital stay of 4.74 days; average mortality rate for MedCath patient 1.94 percent compared against peer community hospital rate of 2.35 percent; case mix index for MedCath patient is 1.42 compared against peer community hospital 1.17 case mix index), at <http://www.ftc.gov/ogc/healthcarehearings/docs/dkelly.pdf>.

<sup>97</sup> D. Kelly 3/27 at 74.

<sup>98</sup> See, e.g., G. Lynn 3/27 at 30 (Specialty providers decisions about whether and where to provide care “have an effect on the physicians personal financial interest.”); Mulholland 3/27 at 60 (“Physician ownership interests influence referrals. That’s almost intuitive and there have been some studies that suggest that utilization increases.”).

<sup>99</sup> G. Lynn 3/27 at 28. One panelist disputed the claim that physicians send sicker patients to general hospitals, stating that they want their “sick patients in the heart hospital [where] I can take care of them better.” Kane 4/11 at 80.

same diagnoses at general hospitals.<sup>100</sup>

Similarly, several panelists noted that some SSHs do not provide emergency departments and thus avoid the higher costs of trauma treatment and indigent care.<sup>101</sup> Those panelists believe this gives SSHs an unfair competitive advantage over 24-hour hospitals with emergency departments.<sup>102</sup> The October 2003 GAO study analyzed

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<sup>100</sup> Letter from A. Bruce Steinwald, Director, Health Care-Economic and Payment Issues, General Accounting Office, to Bill Thomas, Chairman, Committee of Ways and Means, House of Representatives & Jerry Kleczka, House of Representatives 11-12 (Apr. 18, 2003) (GAO-03-683R), at <http://www.gao.gov/new.items/d03683r.pdf>. The GAO examined all inpatient discharge data from 25 urban specialty hospitals and found that 21 of the 25 treated lower proportions of severely ill patients than did area general hospitals. *Id.* at 4.

<sup>101</sup> As Chapter 1 explains, if a SSH does not have an emergency department or offer emergency medical services, it is not required by the Emergency Medical Treatment and Labor Act to provide an appropriate medical screening examination to any individual that requests one, and stabilizing treatment to individuals with emergency medical conditions.

<sup>102</sup> See, e.g., G. Lynn 3/27 at 29; George Lynn, *Perspectives on Competition Policy and the Health Care Marketplace: Single Specialty Hospitals* 2 (3/27), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030327georgeflynn.pdf>; Lesser 3/27 at 10-11; Cara Lesser, *Specialty Hospitals: Market Impact and Policy Implications* 6 (3/27) (slides) (considerable variation in scope of emergency services provided) [hereinafter Lesser Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/lesser.pdf>; Dan Mulholland, *Competition Between Single-Specialty Hospitals and Full-Service Hospitals: Level Playing Field or Unfair Competition?* 3 (3/27) (slides) [hereinafter Mulholland Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/mulholland.pdf>. See also GAO, SPECIALTY HOSPITALS, *supra* note 80, at 4, 22.

whether SSHs provided care to Medicare and Medicaid patients and had emergency departments. As Table 1 shows, the study found that there were modest differences between the percentage of Medicare and Medicaid patients who received treatment at general hospitals and SSHs.<sup>103</sup>

**Table 1:**

	General Hospitals	Specialty Hospitals
Orthopedic Medicaid Admissions	10 %	8%
Cardiac Care Medicaid Admissions	6%	3%
Medicaid Admissions for Women’s Health	37%	28%

One panelist observed that general hospitals are reluctant to have their performance compared to specialty providers who do not handle the same case mix or have the same cost structures.<sup>104</sup> Some panelists argued that the SSHs and ambulatory surgery centers are inherently risky for patients with multiple conditions. They argued that chronic disease management, rather than fragmented specialty services, will serve those patients

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<sup>103</sup> GAO, SPECIALTY HOSPITALS, *supra* note 80, at 18. There were larger differences in the frequency of emergency departments (ED) at SSHs and general hospitals. In particular, 92 percent of general hospitals had an ED, but by contrast 72 percent of cardiac hospitals, 50 percent of women’s hospitals, 39 percent of surgical hospitals, and 33 percent of orthopedic hospitals had an ED. *Id.*

<sup>104</sup> Probst 5/29 at 95.

better.<sup>105</sup>

Several panelists were concerned that SSHs would siphon off the most profitable procedures and patients, leaving general hospitals with less money to cross subsidize other socially valuable, but less profitable, care.<sup>106</sup> As one panelist stated, “it is the profitable services they are taking away that jeopardizes a hospital’s capability of providing unprofitable services.”<sup>107</sup> Panelists expressed concern that “the community [will] lose[] access to specific services or ultimately to all hospital services as the general hospital deteriorates or closes.”<sup>108</sup> Several panelists also suggested that physicians that have an ownership

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<sup>105</sup> Andrew 3/26 at 12 (Hospitals believe that the single-specialty hospitals do not take the more difficult cases with comorbidities, “with patients with greater acuity,” “the frailest of the frail, and the poorest of the poor.”).

<sup>106</sup> Lesser 3/27 at 14-21; Lesser Presentation, *supra* note 102, at 14-15; Ginsburg 2/26 at 66 (stating the “threat for specialized services does have the potential to erode some of the traditional cross subsidies that the health system is run on”); Lesser 9/9/02 at 92. *See also* G. Lynn 3/27 at 31 (arguing that the Agencies must take into account the effect specialty hospitals have on “the medical safety net” of the community hospital).

<sup>107</sup> Morehead 3/27 at 42. *See also* Harrington 4/11 at 76-77 (“We can’t afford to continue to lose a percentage of our volume and thus our revenue, and be able to provide the same quality level of service that we provide ... if we continue to be niched away.”); G. Lynn 3/27 at 28 (specialty hospitals “threaten[] community access to basic health services and jeopardizes patient safety and quality of care”); Mulholland Presentation, *supra* note 102, at 7 (community hospitals may be victims of patient dumping and revenue loss threatens community services).

<sup>108</sup> G. Lynn 3/27 at 29.



interest in a SSH have an incentive to over-refer patients to that facility to maximize their income.<sup>109</sup>

The GAO summarized these competing perspectives on SSHs:

Advocates of these hospitals contend that the focused mission and dedicated resources of specialty hospitals both improve quality and reduce costs. Critics contend that specialty hospitals siphon off the most profitable procedures and patient cases, thus eroding the financial health of neighboring general hospitals and impairing their ability to provide emergency care and other essential community services.<sup>110</sup>

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<sup>109</sup> See, e.g., Lesser 3/27 at 16 (“Another area of concern for specialty hospitals is the potential for supply-induced demand, or demand that’s generated due to the presence of these facilities. Again, the health services research that has been done over the past decades really has shown that this issue of supply-induced demand is particularly problematic when physicians are owners and when there is excess capacity.”); G. Lynn 3/27 at 30 (Specialty providers’ decisions about whether and where to provide care “have an effect on the physicians personal financial interest.”); Mulholland 3/27 at 60 (“Physician ownership interests influence referrals. That’s almost intuitive and there have been some studies that suggest that utilization increases.”); Mulholland Presentation, *supra* note 102, at 6; David Morehead, *A System in the Making* 2-3 (3/27) (slides) (physician-investors have inherent conflict of interest, including financial conflicts) [hereinafter Morehead Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/morehead030326.pdf>.

<sup>110</sup> GAO, SPECIALTY HOSPITALS, *supra* note 80, at 1.

#### *Market Reaction to SSH Entry.*

According to several panelists, some general hospitals facing competition from SSHs have removed the admitting privileges of physicians involved with a specialty hospital.<sup>111</sup> Several panelists stated that such strategies are used to protect the viability of the general hospital and to avoid the conflict of interest that arises from a physician ownership interest in a facility to which they are referring patients.<sup>112</sup> These panelists do not believe that removing the hospital privileges of physician-investors harms competition, and suggest that a hospital is not required “to sacrifice the interests of [its] charitable institution in favor of the physician’s self-interest.”<sup>113</sup>

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<sup>111</sup> See, e.g., John G. Rex-Waller, *Federal Trade Commission & U.S. Department of Justice Joint Hearing on Health Care & Competition Law and Policy* 11 (3/27), at <http://www.ftc.gov/ogc/healthcarehearings/docs/rexwaller.pdf>; Dennis I. Kelly, *Statement of Dennis I. Kelly* 17-18 (3/27) [hereinafter D. Kelly (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030327denniskelly.pdf>; Kane 4/11 at 52. This strategy is sometimes referred to as economic credentialing. D. Kelly (stmt), *supra*, at 16-17 (stating that economic credentialing is harmful to potential and existing competition from SSHs). More generally, economic credentialing has been defined as “the use of economic criteria unrelated to quality of care or professional competency in determining an individual’s qualifications for initial or continuing hospital medical staff membership or privileges.” American Medical Association (AMA) House of Delegates Resolution, H-230.975.

<sup>112</sup> Morehead 3/27 at 43-46.

<sup>113</sup> *Id.* at 47 (noting “you just can’t be a partner and a competitor at the same time”); Morehead Presentation, *supra* note 109, at 4 (A “Board [is] not required to sacrifice charity’s interest in favor of physician’s self-interest.”).

Panelists also described a number of other responses by general hospitals to the emergence of SSHs. One panelist stated that some general hospitals have established their own specialized single-specialty wing or partnered with physicians on their medical staff to open a SSH.<sup>114</sup> Panelists also stated that some general hospitals have reacted to the competition by removing physicians from the on-call rotation; making scheduling surgeries more difficult; limiting physician access to operating rooms; limiting physicians' "extra assignments" under which the physician can earn professional fees;<sup>115</sup> and using certificate of need laws to encumber specialty hospital entry.<sup>116</sup>

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<sup>114</sup> Lesser 3/27 at 12 (describing some hospitals as taking a "kind of preemptive strike strategy where the hospital establishes its own specialty facility in an effort to ward off the establishment of the competing facility in the market"). *See also* The Wisconsin Heart Hospital's partnership with Covenant Healthcare, at <http://www.twhh.org>.

<sup>115</sup> Mulholland 3/27 at 66 ("Hospitals have also determined to deny medical staff leadership position or participatory rights, for example, votes or active staff membership, to physicians with investment interests in competitors."); D. Kelly 3/27 at 76; Opelka 2/27 at 183 ("With the emergence of physician-owned specialty hospitals, some general hospitals have been denying privileges to those who participate in these ventures, particularly in geographic areas where there has been significant consolidation of hospital ownership.").

<sup>116</sup> Rex-Waller 3/27 at 53-54; Alexander 3/27 at 38. A new Florida law that bars licensure of any specialty hospital illustrates an example of this allegation. The law bans specialty hospitals that treat a single condition, and it eliminates its CON requirement for new adult open-heart surgery and angioplasty programs at general hospitals. The law also exempts from CON the addition of beds to existing structures, but new structures will still be required to file a CON. Fla. Bill SJ 01740 (effective

Panelists also stated that general hospitals have entered into managed care contracts with health plans that either preclude SSH entry entirely, or result in the "deselection" of physicians who invest in the SSH from the insurance companies' list of preferred providers.<sup>117</sup> Representatives of SSHs noted that it is difficult to compete against this behavior by providing lower prices because they cannot provide the full panoply of services a health plan requires.<sup>118</sup>

One panelist summarized the SSH position as follows: general hospitals have engaged in "stiff and coordinated resistance ... driven not by quality, cost efficiency, or the desire to preserve the delivery of charity care to the community, but rather by the fear of having to compete, of having to look within their respective institutions to improve efficiencies and to enhance the

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July 1, 2004), *amending* FLA STAT. ch. 408.036, .0361 (2003). On Certificate of Need (CON) laws, *see infra* Chapter 8.

<sup>117</sup> Kane 4/11 at 52 ("[S]hortly after the heart hospital opened, we ran afoul of Blue Cross and Blue Shield in some areas, ... we were what we call deselected, and we were taken off the Blue Cross and Blue Shield panels."); D. Kelly 3/27 at 75. This deselection caused some physicians to cease their involvement with the SSH, after which they were reinstated on insurance panels. Kane 4/11 at 52 ("Some of our young doctors felt like they just couldn't make it without the Blue Cross business and they went elsewhere, .... Shortly after leaving our group, ... they were [on] the Blue Cross Blue Shield panels."). *But see* Mulholland 3/27 at 69-70 and Mulholland Presentation, *supra* note 102, at 17-22 (enumerating hospital actions against physicians who invest in specialty hospital, suggesting they are all "reasonable and pro-competitive responses to this type of competition").

<sup>118</sup> Rex-Waller 3/27 at 53.

timely delivery of patient care.”<sup>119</sup>

*Ambulatory Surgery Centers.*

Ambulatory surgery centers (ASCs) perform surgical procedures on patients who do not require an overnight stay in the hospital. Approximately half of the ASCs are single-specialty.<sup>120</sup> Single-specialty ASCs generally specialize in either gastroenterology, orthopedics, or ophthalmology.<sup>121</sup> Most ASCs are small (two to four operating rooms). ASCs’ ownership structures vary: some are completely physician owned; some are owned by joint ventures between physicians and private or publicly traded companies; some are owned by physician/hospital joint ventures; and some are owned by hospitals and hospital networks.<sup>122</sup> Innovations in technology have made it possible to offer a broad range of services in ASCs.<sup>123</sup>

ASCs require less capital than SSHs, and are generally less complex to develop because they do not require the facilities needed to offer care twenty-four hours a day,

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<sup>119</sup> Alexander 3/27 at 35. *See also id.* at 36 (“In an effort to forestall competition, two of the hospital systems in Columbus ... recently passed resolutions to revoke existing privileges of medical staff members and to withhold new privileges solely on the basis of a physician’s investment interest in NASH or any competing specialty hospital.”).

<sup>120</sup> Beeler 3/26 at 59.

<sup>121</sup> Casalino et al., *supra* note 82, at 59.

<sup>122</sup> Beeler 3/26 at 60.

<sup>123</sup> Rex-Waller 3/27 at 50 (stating that the growth of ASCs “has been driven by technology, technological advances, particularly in endoscopic surgery . . . in surgical techniques, and in advanced anesthetic agents”).

seven days a week. ASCs generally do not have emergency departments, and certificate of need regulations often are not as rigorous for ASCs, if they apply at all. ASCs were originally intended to compete with hospital inpatient units, but they now compete more against hospital outpatient surgery units.<sup>124</sup>

The number of ASCs has doubled in the past decade, and currently total 3,371.<sup>125</sup> Panelists indicated ASC development was influenced by many of the same factors spurring the growth of specialty hospitals. One panelist noted that ASCs were “a common-sense, intelligent response to a mature health care delivery system and industry gripped by inefficiencies and to health care spending being out of control.”<sup>126</sup> Other reasons for ASC growth listed by panelists included improved technology,<sup>127</sup> physician demand for efficient surgical

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<sup>124</sup> Casalino et al., *supra* note 82, at 59 (“ASCs primarily compete now with hospital outpatient surgery departments, where most outpatient surgery is performed.”). *See also* Beeler 3/26 at 63; Sacks 3/26 at 40.

<sup>125</sup> Casalino et al., *supra* note 82, at 59 (“In 2000, 242 new ASCs were created, and 343 were created in 2001, compared with an average of 166 annually in the preceding eight years.”).

<sup>126</sup> Alexander 3/27 at 32.

<sup>127</sup> Technological changes include the development of flexible fiberoptic scopes used for colon cancer screening and upper GI procedures as well as advancements in microsurgery and ultrasound techniques used in cataract lens replacement. *See* MEDICARE PAYMENT ADVISORY COMM’N (MEDPAC), REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY § 2F, at 140 (2003), at [http://www.medpac.gov/publications/congressional\\_reports/Mar03\\_Entire\\_report.pdf](http://www.medpac.gov/publications/congressional_reports/Mar03_Entire_report.pdf).

facilities,<sup>128</sup> control and specialized staff, as well as “patient demand for a non-institutional, friendly, convenient setting for their surgical care, and payor demand for cost efficiencies as evidenced by the ambulatory surgery center industry.”<sup>129</sup> One study also noted that ASCs offer patients more “convenient locations, shorter wait times, and lower coinsurance than a hospital department.”<sup>130</sup>

Medicare reimbursement has had a profound impact on the number of ASCs and the amount of surgery performed in them.<sup>131</sup> Congress first approved coverage of ASCs by Medicare in 1980, as part of an effort to control health care spending by providing low-risk surgeries in a less-

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<sup>128</sup> See, e.g., MEDPAC, *supra* note 127, § 2F, at 140 (noting that the specialized settings may have allowed physicians to perform procedures more efficiently than in an outpatient setting and allowed physicians to reserve surgical time).

<sup>129</sup> Rex-Waller 3/27 at 50. See also Beeler 3/26 at 62 (noting the “development of new technology and techniques for both the surgery itself and anesthesia” have allowed providers to discharge patients more quickly after surgery).

<sup>130</sup> MEDPAC, *supra* note 127, § 2F, at 140 (assessing coinsurance is 20 percent lower in an ASC).

<sup>131</sup> The anti-kickback statute, described in detail *supra* Chapter 1, has also had an effect on the rise of ASCs. The anti-kickback statute generally discourages physicians from investing in facilities to which they refer patients, but a regulatory safe harbor explicitly excludes ASCs from this prohibition. Office of the Inspector General, *Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule*, 64 Fed. Reg. 63,517 (Nov. 19, 1999).

expensive ambulatory setting.<sup>132</sup> Between 1982 and 1988, Medicare paid 100 percent of the reasonable charges for approved ambulatory procedures, and waived the deductible and copayment that would apply if the procedure were provided in an inpatient setting.<sup>133</sup> From 1988 to 2003, the fee schedule has been based on an inflation-adjusted 1986 cost survey for ambulatory surgery. The ASC payment schedule has not been adjusted for advances in technology and productivity over the last 16 years; some procedures that were once labor-and-resource intensive are now much less costly for ASCs to perform. The MMA freezes Medicare payment rates for ASCs from 2005 through 2009 and directs the Department of Health and Human Services to implement a new payment system by 2008.<sup>134</sup>

Although ASCs and hospital outpatient departments perform some of the same procedures, payment varies depending on where the services are provided. Higher reimbursement for services performed in a hospital outpatient department may make sense when a patient has multiple

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<sup>132</sup> Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 934, 94 Stat. 2599 (1980). See also Shelah Leader & Marilyn Moon, *Medicare Trends in Ambulatory Surgery*, 8 HEALTH AFFAIRS 158, 158-59 (Spring 1989).

<sup>133</sup> Leader & Moon, *supra* note 132, at 158-59.

<sup>134</sup> The MMA directs the GAO to conduct a study comparing the costs of procedures in ASCs to the cost of procedures furnished in hospital outpatient departments, and make recommendations about the appropriateness of using the outpatient prospective payment system as a basis for paying ASCs. MMA § 626(d).

**Table 2:  
Medicare Reimbursement Rates for Procedures Performed by Hospital Outpatient  
Department and ASCs**

Description	Hospital Outpatient Rate	ASC Rate	Percent Difference
Cataract removal/lens insertion	\$1,160	\$973	-19%
After cataract laser surgery	246	446	81
Colonoscopy, diagnostic	413	446	8
Upper gastrointestinal endoscopy, biopsy	387	446	15
Colonoscopy with removal of lesion by snare	413	446	8
Epidural injection, lumbar or sacral	250	333	33
Colonoscopy with biopsy	413	446	8
Colonoscopy with removal of lesion by forceps	413	446	8
Upper gastrointestinal endoscopy, diagnostic	387	333	-14
Cystoscopy	329	333	1

complicating factors making the surgery more complex. One panelist also asserted that hospitals should receive higher payments for outpatient services because they have higher overhead costs.<sup>135</sup> Yet, as Table 2 demonstrates, payment may be higher, lower, or the same at ASCs and hospital outpatient departments.<sup>136</sup> These

differences create predictable incentives for providers. As former CMS administrator Tom Scully noted, when the ASC rate is high “all of a sudden you start seeing ASCs pop up all over the place to do colonoscopies or to do outpatient surgery .... If the hospitals get paid a little more, they’re going to have more outpatient centers.”<sup>137</sup>

Many of the concerns expressed by panelists about SSHs were also expressed

<sup>135</sup> Andrew 3/26 at 118.

<sup>136</sup> MEDPAC 2003, *supra* note 127, § 2F, at 143, Table 2F-3.

<sup>137</sup> Scully 2/26 at 46.

about ASCs. Panelists asserted that ASCs are eroding the outpatient market share of hospitals that hospitals depend upon, that ASCs do not care for Medicaid beneficiaries, they “skim and cherry-pick on the front end regarding [] the finances of the patient,” and that ASCs only enter areas where business is profitable.<sup>138</sup> One ASC representative suggested that reimbursement should be modified based on the acuity of the patient, but denied that ASCs refuse to care for Medicaid patients.<sup>139</sup>

#### *Market Reaction to ASC Entry.*

Panelists indicated that many of the actions taken to curb entry of specialty hospitals are also being employed against ASCs. One panelist suggested that entry and competition for ASCs have been made difficult by hospitals engaging in legislative efforts to encumber ASCs with unnecessary regulation and mandatory services.<sup>140</sup> Another panelist described how some hospitals have negotiated discounted prices for inpatient services in exchange for exclusive contracts for outpatient surgery.<sup>141</sup> One panelist noted that some general hospitals have revoked privileges of physician-investors in ASCs, and used state certificate of need (CON) laws to inhibit ASC entry.<sup>142</sup>

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<sup>138</sup> Andrew 3/26 at 12; Sacks 3/26 at 41 (“It is the profitable business, and that continues to be picked away by this type of competition.”).

<sup>139</sup> Beeler 3/26 at 116-117; Andrew 3/26 at 14-15.

<sup>140</sup> Rex-Waller 3/27 at 53.

<sup>141</sup> Beeler 3/26 at 63-64.

<sup>142</sup> *Id.* at 64.

*Competitive Evaluation of Entry.* In general, the Agencies favor the elimination of anticompetitive barriers to entry, on the grounds that robustly competitive markets in which entry and exit is determined by market forces maximizes consumer welfare. Entry by SSHs and ASCs has had a number of beneficial consequences for consumers who receive care from these providers. It cannot be overlooked, however, that Medicare’s administered pricing system has substantially driven the emergence of SSHs and ASCs.

Generally speaking, antitrust law does not limit individual hospitals from unilaterally responding to competition either by terminating physician admitting privileges or by approaching state governments in connection with CON proceedings.<sup>143</sup> If there is specific evidence of anticompetitive conduct by individual hospitals or of hospitals colluding together against efforts to open a SSH or ASC, then the Agencies will aggressively pursue those activities.

## **IX. THE IMPACT OF GOVERNMENT PURCHASING**

CMS has tremendous bargaining power in the market for medical services, and providers are extremely responsive to the signals sent by CMS.<sup>144</sup> Prior to the

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<sup>143</sup> Of course, under some circumstances, a unilateral response can still constitute a violation of Section 2 of the Sherman Act, and there are sham and misrepresentation exceptions to the *Noerr-Pennington* doctrine. See *infra* Chapter 8.

<sup>144</sup> See, e.g., Hammer 2/27 at 51-52 (noting that Medicare should “be aware of its conduct that is both market-shaping and market-facilitating. When

adoption of the IPPS, average hospital length-of-stay had been stable for 7 years. Once IPPS went into effect, length of stay began an immediate decline, the number of inpatient cataract surgeries dropped precipitously (from 630,000 to 211,000 in one year), and the number of hospital outpatient cataract surgeries immediately increased by 128 percent.<sup>145</sup> Similarly, the adoption of prospective payment for home health care had an immediate impact on the number of beneficiaries that received services and the average number of visits.<sup>146</sup>

Medicare's administered pricing system can also (albeit generally inadvertently) make some services extraordinarily lucrative, and others unprofitable. The result of the pricing distortions is that some services are more or less available than they would be based on the demand for the services – which in turn triggers adaptive responses by providers.<sup>147</sup>

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Medicare chooses to reimburse a new technology, it creates a new market.”). It should be noted, however, that CMS would have even more power if it were permitted to engage in selective contracting.

<sup>145</sup> See Pope, *supra* note 18; See also AMERICAN HOSPITAL ASS'N, *supra* note 12, at 2 tbl.1; Leader & Moon, *supra* note 132, at 159.

<sup>146</sup> CMS, *supra* note 4, § 3(D), at 9 (Persons Served and Average Number of Visits by Home Health Agencies).

<sup>147</sup> See, e.g., Hammer 2/27 at 52 (noting that when CMS “has a misalignment of the regulatory pricing system, . . . it creates competition gaming the regulatory system); Scully 2/26 at 28, 46 (“So, when the government, either Federal or State, is fixing prices, the rest of the market’s flexibility to respond to that is kind of muted . . . I can tell you when I drive around the country and see where ASCs are popping up, I can tell who we’re overpaying.”).

One panelist noted these difficulties are compounded by the fact that the balance of the population relies for its health care services on an infrastructure built in response to the excesses and inadequacies of Medicare’s administered pricing system.<sup>148</sup>

Consider cardiac care.

Commentators and panelists suggested that CMS never made a deliberate decision to provide for greater profits for such services relative to the amounts paid for other inpatient services but the IPPS does so.<sup>149</sup> General hospitals use these profits to subsidize the provision of less profitable (or unprofitable) services, but the pricing distortion creates a direct economic incentive for SSHs to enter the market. In response, general hospitals complain to legislators and try to find ways to limit the expansion of competition. Absent the distortions created by the excess profits for cardiac services in Medicare’s administered pricing system, the incentive for SSH entry would be less.

These difficulties are magnified

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<sup>148</sup> Sage 5/29 at 148 (“Public purchasing distorts prices, overbuilds capacity, and skews the development and dissemination of technology.”).

<sup>149</sup> See, e.g., Ginsburg 2/26 at 65 (“Medicare sets the DRG rates, . . . but their productivity gains are much faster in cardiovascular services so that, in a sense, the rates become obsolete fairly quickly . . .”); KELLY DEVERS ET AL., SPECIALTY HOSPITALS: FOCUSED FACTORIES OR CREAM SKIMMERS? (Ctr. for Studying Health Sys. Change, Issue Brief No. 62, 2003), available at <http://www.hschange.com/CONTENT/552/> (reporting statements of hospital executives that certain surgical procedures (e.g., cardiovascular and orthopedic) are among the most profitable surgeries, and that it is unlikely that payors intended to create these distortions in payment rates).

when the government is the sole or primary purchaser of a good or service. Paying too much wastes resources, while paying too little reduces both output and capacity, lowers the quality of the services that are provided, and diminishes the incentives for innovation.<sup>150</sup> Some commentators have suggested that these adverse consequences have materialized in the market for vaccines.<sup>151</sup>

Although CMS can set prices, there are limitations to CMS's ability to create incentives that encourage price and non-price competition among providers. CMS does not have the freedom to respond as a private purchaser would to changes in the marketplace. For example, CMS has only limited authority to contract selectively with providers or to use competitive bidding to meet its needs.<sup>152</sup> With limited exceptions, CMS cannot force providers to compete for CMS's business or encourage suppliers to reduce their costs and enhance their quality by rewarding them with substantially increased volume or substantially higher

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<sup>150</sup> Pauly 2/26 at 93-94 (noting that “[i]f the regulated price is too high, you’ll get excessive socially inefficient quality. If the regulated price is too low, you’ll get socially deficient quality . . .”).

<sup>151</sup> BOARD ON GLOBAL HEALTH & INSTITUTE OF MEDICINE, *MICROBIAL THREATS TO HEALTH: EMERGENCE, DETECTION, AND RESPONSE* 187 (2003) (“[O]nly four leading companies worldwide have been responsible for developing new vaccines during the past two decades. It was not mergers and acquisitions that concentrated responsibility for vaccine innovation . . . rather, the economic forces that drove firms out of the industry were the rising costs of innovation, production . . . and the shrinking margins allowed by monopoly.”).

<sup>152</sup> 42 U.S.C. §§ 1395, 1395a, 1395b. *See also supra* Chapter 1.

payments if they do.<sup>153</sup>

Even straightforward purchasing initiatives, such as competitive bidding for durable medical equipment (DME), have generated considerable resistance. A pilot project resulted in Medicare savings between 17 and 22 percent with no significant adverse effects on beneficiaries.<sup>154</sup> Opponents of competitive bidding have argued, however, that the bidding process increased bureaucracy, decreased consumer choice, threatened the existence of small manufacturers, and lowered quality.<sup>155</sup> At least one industry representative has called for the repeal of the provisions mandating competitive bidding.<sup>156</sup>

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<sup>153</sup> *See* Pauly 5/28 at 48 (“Administered price can cause competition to be a function of quality.”); David A. Hyman, *Does Quality of Care Matter to Medicare?* 46 *PERSP. BIO. & MED.* 55-68 (2003).

<sup>154</sup> Centers for Medicare & Medicaid Services, *Evaluation of the Durable Medical Equipment Competitive Bidding Demonstration*, at <http://www.cms.hhs.gov/researchers/demos/DMECB.asp> (last modified Feb. 18, 2004). Centers for Medicare & Medicaid Services, *Medicare Pilot Project For Durable Medical Equipment in Polk County, Fla.* (May 29, 1998), at <http://www.cms.hhs.gov/healthplans/research/dmeshrt.asp>.

<sup>155</sup> American Ass’n for Homecare, *Myths and Facts About Medicare Competitive Bidding for Durable Medical Equipment* (Sept. 5, 2002), at <http://www.aahomecare.org/govrelations/myths-cb.pdf>. *See also* Nat’l Ass’n for Homecare & Hospice website, at [http://www.nahc.org/NAHC/LegReg/0304Landrieu\\_HME\\_signon.html](http://www.nahc.org/NAHC/LegReg/0304Landrieu_HME_signon.html).

<sup>156</sup> Cara C. Bachheimer, *Prescription for Change*, *HOME CARE*, Jan. 1, 2004, at [http://www.homecaremag.com/ar/medical\\_prescription\\_change/](http://www.homecaremag.com/ar/medical_prescription_change/).



As Chapter 1 reflects, with limited exceptions, CMS's payment systems do not reward higher quality care, or punish lower quality care. Indeed, as the Medicare Payment Advisory Commission (MedPAC) noted, the Medicare payment system is "largely neutral or negative towards quality. All providers meeting basic requirements are paid the same regardless of the quality of service provided. At times providers are paid even more when quality is worse, such as when the complications occur as the result of error."<sup>157</sup> Former CMS administrator Scully was more pointed: Medicare pays every hospital in a region "the exact same amount for hip replacement and the same amount for a heart bypass, if you're the best hospital or the worst hospital."<sup>158</sup>

To be sure, these problems are not unique to Medicare. The Institute of Medicine noted that "current [compensation] methods provide little financial reward for improvements in the quality of health care delivery, and may even inadvertently pose barriers to innovation."<sup>159</sup> The Agencies

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<sup>157</sup> MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO CONGRESS: VARIATION AND INNOVATION IN MEDICARE 108 (2003), at [http://www.medpac.gov/publications/congressional\\_reports/June03\\_Entire\\_Report.pdf](http://www.medpac.gov/publications/congressional_reports/June03_Entire_Report.pdf).

<sup>158</sup> Scully 2/26 at 34; Antos 9/30 at 123 ("We now have major financial rewards for the system to not work right."). See also Kahn 2/27 at 73 (noting that "at the end of the day, you have prices that are arbitrarily set that really don't relate very closely to any kind of market scheme that we could define").

<sup>159</sup> INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21<sup>ST</sup> CENTURY 193 (2001). See Carolyn Clancy, *AHRQ and HHS Efforts to Improve Quality* 28 (5/27)

encourage the use of payment strategies that create an incentive for providers to deliver higher quality care to consumers.

Medicare also includes a managed care option, the Medicare Advantage (MA) program.<sup>160</sup> MA programs provide Medicare beneficiaries with a range of managed care options, including HMOs and preferred provider organizations. MA allows Medicare beneficiaries to join privately operated managed care plans.<sup>161</sup> The plans are paid an administratively determined rate by Medicare and plans also may charge an additional premium and offer additional benefits.<sup>162</sup> Medicare beneficiaries who joined MA plans often received greater benefits (*e.g.*, prescription drug coverage) in exchange for accepting limits on their choice of providers.<sup>163</sup> In 2002, MA plans (then the

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(slides) (showing that only 10 percent of the population receive excellent quality health care), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030527clancy.pdf>.

<sup>160</sup> As part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Medicare+Choice program (M+C) was renamed to Medicare Advantage (MA).

<sup>161</sup> See U.S. DEP'T OF HEALTH & HUMAN SERVICES (HHS), *MEDICARE & YOU: 2004*, § 6, at 44-52, available at <http://www.medicare.gov/publications/pubs/pdf/10050.pdf>.

<sup>162</sup> Pizer 4/23 at 146-47; Steven Pizer, *Competition in the Medicare+Choice Program 5* (4/23) (slides) [hereinafter Pizer Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/pizer.pdf>; Steven Pizer & Austin Frakt, *Payment Policy and Competition in the Medicare+Choice Program*, 24 HEALTH CARE FIN. REV. 83 (2002).

<sup>163</sup> See HHS, *supra* note 160, § 6, at 44-52; Pizer Presentation, *supra* note 161, at 5; Pizer & Frakt, *supra* note 161.

Medicare+Choice (M+C) plan) provided health care to 5 million Medicare beneficiaries, down from 6.35 million enrollees in December 1999.<sup>164</sup> One panelist testified that although the Medicare program has attempted to introduce competitive pricing as a way to set payment rates to M+C plans, to date none of those plans have been successful.<sup>165</sup> As a result, Medicare continues to establish the payment rates administratively.<sup>166</sup> According to this speaker, to the extent plans compete, it typically has been on the benefits they provide.<sup>167</sup>

## X. HOSPITAL/PAYOR CONTRACTING IN THE PRIVATE MARKET

Contracting between hospitals and private payors has been controversial and contentious. Several panelists asserted that hospital systems routinely “terminate then negotiate” for large increases in reimbursement, and use the media to scare

the public.<sup>168</sup> Panelists also stated that hospital systems insist that all hospitals in the system be included in a payor network (“all or nothing contracts”), irrespective of whether the payor actually wants to include the entirety of the hospital system.<sup>169</sup> Panelists representing hospitals responded that they are protecting their institutions’

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<sup>164</sup> Pizer & Frakt, *supra* note 161, at 83 & n.1.

<sup>165</sup> Pizer 4/23 at 147.

<sup>166</sup> Beginning in 2006, however, MA plans will be paid under a new competitive method. Plan bids will be compared to benchmarks calculated for each area based on the costs of fee-for-service Medicare. If a plan bid is higher than the benchmark, the enrollee will pay the difference. If it is lower, 75 percent of the difference will go to the enrollee as extra benefits or as a rebate; the remaining 25 percent will be retained by the government. *See* Health Policy Alternatives, *Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Executive Summary 2* (Nov. 30, 2003), at <http://www.achp.org/media/hpaexecutive.pdf>.

<sup>167</sup> Pizer 4/23 at 147.

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<sup>168</sup> *See, e.g.*, Berman 2/28 at 80-82 (describing contract negotiations between Partners HealthCare and Tufts Health Plan); Spetz et al., *supra* note 50, at 226-27 (describing how, in Sacramento, Sutter Health threatened to cancel contracts with Blue Cross and other insurance plans if reimbursement was not increased; other hospital systems followed Sutter Health’s lead in Sacramento and in other regions in California); Strunk 3/27 at 161; Iselin 3/27 at 180 (“We’ve seen quite a bit of brinkmanship, . . . including . . . termination as a prelude to negotiation.”); Lesser 9/9/02 at 87; Kanwit 9/9/02 at 175.

If the contract between a hospital and payor includes an “evergreen” clause, the contract renews automatically unless one party serves the other party with a notice of termination. Thus, the termination notice may simply reflect the desire of one party to renegotiate the terms of the contract. *See* Fine 9/9/02 at 222-23 (noting that “hospital contracts all contain within them evergreen provisions, automatic renewal provisions, that if cancellation or termination is not effected within 60 or 90 days prior to the expiration date, that contract automatically rolls over for another three to five year term”).

<sup>169</sup> Kanwit 2/27 at 98-99 (describing a practice called “all or nothing” “where the hospital systems [] requir[e] health plans to contract with freestanding facilities, radiology facilities, [and] ambulatory surgery facilities”); Strunk 3/27 at 161 (“[W]e’ve observed systems that contain a highly reputable and desirable flagship hospital, threatening to cut ties with the plan, unless the plan is willing to contract with and provide favorable rates to the other hospitals in the system, even if the other hospitals are less desirable to the plan.”). Stephanie Kanwit, *Perspectives on Competition Policy and the Health Care Marketplace 4-5* (2/27), at <http://www.ftc.gov/ogc/healthcarehearings/docs/kanwitstephanie.pdf>.

interests and that their services had been artificially and unsustainably underpriced in the past.<sup>170</sup> These dynamics have played out in several markets in the past few years.<sup>171</sup> Although commentators have noted that particular hospitals and systems seem to have the upper hand in some markets, whether hospitals or health plans have bargaining advantages varies substantially within and among different markets.<sup>172</sup>

Generally speaking, payors seek to contract with hospitals that contribute to the marketability of their insurance products.<sup>173</sup> Factors that affect marketability include the

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<sup>170</sup> See, e.g., F. Miller 2/28 at 92; Mongan 2/28 at 110.

<sup>171</sup> JUSTIN WHITE ET AL., GETTING ALONG OR GOING ALONG? HEALTH PLAN-PROVIDER CONTRACT SHOWDOWNS SUBSIDE 2 (Ctr. for Studying Health Sys. Change, Issue Brief No. 74, 2004), available at <http://www.hschange.org/CONTENT/641/>.

<sup>172</sup> See, e.g., Scully 2/26 at 52 (describing the Alabama market and stating “there is one insurance in Alabama”); D. Hall 4/25 at 74-75 (stating that Blue Cross/Blue Shield “insure[s] and control[s] about 80 percent of all the non-governmental work in the State of Alabama”); Mansfield 4/25 at 86-88 (describing the Little Rock market as sharing one dominant hospital system and one dominant insurance provider which have entered a “partnership”); F. Miller 2/28 at 95-97 (describing the Boston market and her belief that one hospital system has negotiating power over insurers); Prairie Health Purchasing Alliance, *Comments Regarding Competition Law and Policy & Health Care* (Sept. 27, 2002) (Public Comment).

<sup>173</sup> See generally Gregory Vistnes, *Hospitals, Mergers and Two Stage Competition*, 67 ANTITRUST L. J. 671, 674 (2000). A marketable network is one that is not too expensive and includes hospitals that enrollees and plan physicians want. Complex rules can make a plan less marketable.

price of coverage, the number of hospitals at which care can be provided, the perceived quality, desirability, and accessibility of those institutions, and the alternative insurance products that are available in the market. Payors seek to balance the price of the hospital services they must purchase to offer insurance coverage against the desirability of the resulting network to the purchasers of their insurance products. If patients view several hospitals as adequate substitutes for one another, it will be easier for the payor to threaten credibly to exclude one or more of these hospitals. Conversely, if enrollees will drop an insurance plan if their preferred hospital is no longer in the network, the hospital will find it easier to insist on higher reimbursement.

Multi-hospital systems frequently seek to ensure that all system hospitals are included in a payor network. Consumer pressure for open networks has made it more difficult for payors to exclude an entire hospital system outright, which affects the bargaining dynamics. In a few markets, payors have sought to “tier” hospitals.<sup>174</sup> Tiering results in different consumer copayments (*i.e.*, high or low cost sharing)

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<sup>174</sup> Monk 4/23 at 44; Arthur Lerner, *Statement of Arthur Lerner 2-3* (3/27) [hereinafter Lerner (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030327arthurlerner.pdf>; Jill M. Yegian, *Tiered Hospital Networks*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-147, 148, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.147v1.pdf>; see GLEN P. MAYS ET AL., TIERED-PROVIDER NETWORKS: PATIENTS FACE COST-CHOICE TRADE-OFFS 2 (Ctr. for Studying Health Sys. Change, Issue Brief No. 71, 2003) (describing plans testing tiered networks in Seattle, Washington, Miami, Florida, Syracuse and northern New Jersey), available at <http://www.hschange.org/CONTENT/627>.

depending on the hospital at which care is provided.<sup>175</sup> Hospital tiers may be established using a wide variety of criteria. Tiering generally does not apply to emergency admissions, and may depend upon where routine and specialty services are offered.<sup>176</sup>

For payors, tiering offers a potential response to multi-hospital system pressure for inclusion of all system hospitals within a payor network. Tiering allows the payor to maintain a broad network, and include a “must-have” hospital, but simultaneously creates an incentive for consumers to use lower-cost providers.<sup>177</sup> Panelists offered a range of views on the prospects of tiering.<sup>178</sup>

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<sup>175</sup> O’Kane 5/30 at 71 (tiering seen as a way to reward quality); Robert Steinbrook, *The Costs of Admission: Tiered Copayments for Hospital Use*, 350 NEW ENGL. J. MED. 2539 (2004).

<sup>176</sup> James C. Robinson, *Hospital Tiers in Health Insurance: Balancing Consumer Choice with Financial Incentives*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-135, 137, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.135v1.pdf>.

<sup>177</sup> Lerner (stmt), *supra* note 173, at 12.

<sup>178</sup> See Strunk 3/27 at 206 (“We haven’t seen huge savings from them yet, but it is, you know, too early to tell. They had two tiers, a preferred and I guess a non-preferred, . . . but it ended up that [] a huge percentage of the hospitals ended up being in the preferred tier anyway. So, in the end, there wasn’t all that much steerage to do in the first place . . . .”); Iselin 3/27 at 180 (“[W]here people have tried tiering or floated it, it’s common that it is outright refused.”). Other panelists suggested that tiering may be an easy tool for payors. See Guerin-Calvert 3/27 at 147 (“I would agree completely that tiering of networks has proven to be the second easiest and most likely tool that payors are turning to . . . .”); Argue 3/28 at 50 (“[T]here are a number of new mechanisms that are showing up in the literature,” including tiering and “variable

Blue Shield of California provides one example of tiered hospital benefits. Blue Shield tiers within geographic areas and seeks to promote choice among community hospitals and teaching hospitals.<sup>179</sup> Hospitals are sorted by region and teaching status and coverage benefits are designed to operate within these groupings. Blue Shield also uses some quality performance measures in its tiering criteria.<sup>180</sup> Hospitals are assigned to a “choice” tier unless their prices exceed the average for their region and teaching status, in which case they are assigned to an “affiliate” tier.<sup>181</sup> Blue Shield introduced this product in April 2002. Approximately, one million of its 2.3 million members have a tiered network benefit package. Blue Shield tiers inpatient and outpatient services, ambulatory surgery centers, and radiation and chemotherapy services.<sup>182</sup>

Similarly, Tufts Health Plan also attempted to use tiering in Boston,

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premiums.”).

<sup>179</sup> Robinson, *supra* note 175, at 139.

<sup>180</sup> *Id.* at 140 (the measures are whether a hospital participates in the Leapfrog program and a facility’s scores on patient satisfaction surveys). Also in California, PacifiCare has instituted a narrow, two-tiered network and projects 6 to 16 percent premium savings for its beneficiaries. *Id.*

<sup>181</sup> Robinson, *supra* note 175, at 139-40 (the tiering payment schedule divides the hospitals within the individual market into the following categories: choice hospitals – HMO members have no admission copayment and PPO members have a 30 percent coinsurance; affiliate hospitals – HMO members have a \$150 admission copayment and PPO members have 40 percent coinsurance).

<sup>182</sup> Robinson, *supra* note 175, at 140.

Massachusetts.<sup>183</sup> Teaching hospitals provide the majority of hospital services within Boston and are typically more expensive than community hospitals.<sup>184</sup> Tufts tried to use tiering to steer its members to community hospitals.<sup>185</sup> After a very public battle, Tufts backed away from its plans and made tiering voluntary for its members.

Some hospitals resist tiering, and if they have sufficient bargaining power, they can credibly threaten to withdraw from a payor network if they are placed in an unfavorable tier.<sup>186</sup> Hospital systems can

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<sup>183</sup> Berman 2/28 at 123.

<sup>184</sup> Massachusetts Council of Community Hospitals (MCCH), *Cape Ann Economics Report for MCCH (June 2001)* (Public Comment) (“Massachusetts residents now utilize a teaching hospital setting for inpatient care 2.5 times the national average”); Altman 2/28 at 17 (“We are in love with our teaching hospitals . . . . And this is – it’s just the nature of Massachusetts health care, and if you are looking at teaching hospitals’ spending per capita in 1998, which our task force looked at, we spent \$168 per capita, where the rest of the country spent \$42 per capita.”).

<sup>185</sup> Robinson, *supra* note 175, at 140 (copayment for community hospital inpatient and outpatient services are \$350; copayment for tertiary centers is \$600).

<sup>186</sup> Ginsburg 2/26 at 72 (“[W]e have seen instances in our sites where hospitals have resisted tiered networks, such as in California, basically by threatening not to contract with the plan if they’re placed in the lower, less attractive tier.”); Lemer (stmt), *supra* note 173, at 3 (“[S]ome hospital systems are demanding that . . . [the system’s] services, be included in the richest benefit tier of every product the plan sells.”); Lesser 9/9/02 at 96-97. *See also* Milstein 2/27 at 103-04 (suggesting the Agencies “assure performance-based tiering of providers” and not allow “[a]ggregated provider organizations to

similarly threaten to pull all of their hospitals from a network if any system hospital is placed in an unfavorable tier. In some markets, hospital systems have taken preemptive steps to negotiate contract language with plans that prohibit tiering.<sup>187</sup> Panelists and analysts noted a number of reasons (beyond straight financial issues) why hospitals may resist tiering. Low-cost facilities fear being labeled as low quality and high-cost facilities fear being deemed inefficient.<sup>188</sup> If tiering is price-driven, it may be difficult for facilities to maintain expensive areas of care like burn units, trauma services, and emergency “standby” capabilities.<sup>189</sup> Hospital representatives also expressed concern that individual hospitals are not fungible substitutes, and tiering might result in bad consumer choices.<sup>190</sup> Hospital representatives have also expressed concern that tiering might force poor consumers to patronize only low-quality, low-cost hospitals.<sup>191</sup> One critic of hospital

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restrain insurers from classifying individual providers into performance tiers”).

<sup>187</sup> MAYS ET AL., *supra* note 173 (describing plan attempts to develop tiering thwarted by large hospital systems that refused to participate and threatened to drop out of the network).

<sup>188</sup> Robinson, *supra* note 175, at 143.

<sup>189</sup> Yegian, *supra* note 173, at 150.

<sup>190</sup> Panelists compared hospital tiering to pharmaceutical tiering, where there was greater agreement that tiering could beneficially encourage consumers to use generic drugs instead of branded pharmaceutical equivalents. *See, e.g.*, Altman 2/28 at 124-25.

<sup>191</sup> MAYS ET AL., *supra* note 173 (noting some fear that “designs based primarily on cost will result in the most desirable providers – which could be more costly – being placed in nonpreferred tiers,

tiering believes that tiering will put indigent care, teaching facilities, and innovative research at risk, and believes “there is no justification for putting patients in the middle of ... health care financing” – particularly when the available information about quality is less than perfect.<sup>192</sup>

Because tiering is a relatively new development, there are no systematic studies available on the prevalence or consequences of this strategy. Additional research would be useful in determining whether consumers in tiered plans actually use lower priced hospitals, and whether they would have used those hospitals without the tiering.

## **XI. CONSUMER PRICE SENSITIVITY AND INFORMATION**

Tiering represents an attempt to force consumers to bear some of the increased price associated with receiving care at a more expensive hospital.<sup>193</sup> Medical savings

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making them accessible only to those who can pay extra”). *But see* Robinson, *supra* note 175, at 145 (“[N]ontiered hospital networks do not subsidize the poor at the expense of the rich. Low-quality hospitals are not typically to be found in high-income neighborhoods, and well-heeled consumers do not drive across town to seek them.”).

<sup>192</sup> Thomas M. Priselac, *The Erosion of Health Insurance: The Unintended Consequences of Tiered Products by Health Plans*, 2003 HEALTH AFFAIRS (Web Exclusive) W158, 160, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.158v1.pdf>.

<sup>193</sup> Robinson, *supra* note 175, at 137 (“The tiered designs are not conceptualized as a means to insulate the health plans from hospital cost variation but, rather, as a means to inform and sensitize the patient, who previously was insulated from and

accounts are intended to accomplish the same goal.<sup>194</sup> That is, both strategies attempt to raise consumer sensitivity to the costs associated with the health care decisions. For these strategies to work effectively, however, consumers will need access to good information about the price and quality of the services they must choose between.<sup>195</sup> A consumer facing a 25 percent co-payment at one hospital and a 15 percent co-payment at another can not accurately assess the financial consequences of choosing one hospital over the other absent good

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indifferent to the cost implications of hospital choice.”); Yegian, *supra* note 173, at 147 (tiers make “cost differences among hospitals more transparent to consumers and allow consumers to decide whether a high-cost facility merits additional out-of-pocket spending”).

<sup>194</sup> Medical Savings Accounts (MSA) and Health Savings Accounts (HSA) are tax-exempt accounts that allow consumers to accumulate savings to pay for medical expenses. They have different contribution levels, deductible ranges, and maximum levels for out-of-pocket expenses. Both MSAs and HSAs are part of the movement to consumer-driven health care and put greater responsibility for health expenses on the consumer. *See* Press Release, U.S. Dep’t of Treasury, 21st Century Medicare: More Choices – Better Benefits: Health Savings Account (HSAs) (Dec. 22, 2003), at <http://www.ustreas.gov/offices/public-affairs/hsa/press/> (accessible through “Fact Sheet on Health Savings Account”); *infra* Chapter 5.

<sup>195</sup> *See, e.g.*, Commissioner Thomas B. Leary, *Special Challenges for Antitrust in Health Care*, ANTITRUST MAG. 25, Spring 2004 (“It is therefore worthwhile to consider the implications of a system that would provide more information on objective measures of the quality of medical care. If this were possible, it would facilitate cost-benefit tradeoffs by payors and ultimate consumers of medical products and services. It could also encourage compensation based more overtly on outcomes rather than on inputs, and perhaps lead to a more rational allocation of resources.”).

information about the price of the services that will be rendered at both hospitals.<sup>196</sup>

Most insured consumers are “rationally ignorant” of the price of the medical services they receive, because insurance largely insulates them from the financial implications of their medical treatment.<sup>197</sup> Consumers who pay the same co-payment regardless of the price of the treatment they receive have no reason to inquire into the price of the treatment, or to factor that price into their decision. Consumers who have co-payments that vary depending on where they receive care will still focus on the amount of the co-payment, and not on the total price of the services they receive. Even if consumers are interested in knowing the total price of the care they receive, they would find it extremely difficult to obtain that information, and are likely to find it to be complicated and obscure.<sup>198</sup> Proposals to increase consumer

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<sup>196</sup> Of course, consumers will also want information about the quality of the services they will receive at both hospitals. The availability of such information is addressed in *supra* Chapter 1.

<sup>197</sup> Herbert Simon, *A Behavioral Model of Rational Choice*, in *MODELS OF MAN* (1957).

<sup>198</sup> See Frech 3/26 at 198 (“[A] typical hospital will have at least tens, and maybe hundreds of payors with different prices. Not only that, the prices – they’re not only different, the very bases of the price, what gets priced, is different. You’ll have charges, fee for service, you’ll get discounts off of charges . . . .”); Herzlinger 5/27 at 89-90 (observing “there is virtually no price quality information. You ever try to find out what the price is for a certain procedure? I mean you’d think [its] probably easier to get some information out of the FBI.”); Busey 9/24 at 117-18 (“I think it’s fairly well known that there is a lack of information or an uneven amount of information among players in the health care industry, and I can illustrate that by asking any of you, do you

price sensitivity must confront this reality, and develop strategies to increase the transparency of hospital pricing. To be sure, these difficulties do not apply to payors, who deal with multiple providers in multiple geographic and product markets, and use pricing information to make contracting decisions.

## **XII. HOSPITAL PRICING: DISTINGUISHING AMONG BULK PURCHASING, PRICE DISCRIMINATION, COST SHIFTING, AND CROSS SUBSIDIES**

Understanding hospital pricing requires an understanding of four terms: bulk purchasing, price discrimination, cost shifting, and cross subsidies. The terms have distinct meanings, although there is some overlap between cost shifting and cross subsidies.

Bulk purchasing usually occurs when large organizations (*e.g.*, insurance companies) receive purchasing discounts because of the volume of their purchases.

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know how much your doctor charges for an office visit, and do you know how much you pay, and does it vary from the time of the year . . . . Again, that information is not as readily available in this market as it might be in other markets.”). See also Uwe E. Reinhardt, *Can Efficiency in Health Care Be Left to the Market?*, 26 *J. HEALTH POL., POL’Y & L.* 967, 986 (2001) (“[O]ne need only imagine a patient beset by chest or stomach pain in Anytown, USA, as he or she attempt to ‘shop around’ for a cost-effective resolution to those problems. Only rarely, in a few locations, do American patients have access to even a rudimentary version of the information infrastructure on which the theory of competitive market and the theory of managed care rest. The price of health services are jealously guarded proprietary information.”).

This type of purchasing can help reduce the cost of health care because the bulk purchasing capability can be used to obtain a large discount. For example, insurance companies often secure better hospital care rates for their beneficiaries than uninsured individual may obtain.<sup>199</sup> There is nothing unusual about this behavior and it has a long history in commercial practice, in the courts, and in economic analysis.

The conventional definition of price discrimination is different ratios of price (P) to marginal cost (MC) for the same service across different buyers. That is P/MC for consumer “j” is not equal to P/MC for consumer “k”.<sup>200</sup> For example, senior citizens may pay less to watch the same movie at the same time as other adults. Like bulk purchasing, price discrimination has a long history in commercial practice, in the courts, and in economic analysis.<sup>201</sup>

Cost shifting refers to raising the price charged to one group of consumers as a result of lowering the price to other consumers. An example would be a hospital

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<sup>199</sup> Fraser 5/29 at 273 (noting the “huge gap between the retail price and the negotiated price, the only people who pay retail are the uninsured”); Milstein 5/29 at 272 (“[R]ight now we have a circumstance in many markets in this country in which the difference between the negotiated price and the rack rate, the retail rate, is breathtaking and bears no resemblance to anything that would happen in virtually any other industry.”); Roy Meidinger, *Health Industry: Great Intentions Gone Bad* (Public Comment).

<sup>200</sup> See GEORGE J. STIGLER, *THE THEORY OF PRICE* 210 (4th ed. 1987).

<sup>201</sup> Certain types of price discrimination are, however, prohibited by Section 2 of the Clayton Act as amended in 1936.

raising the price to privately insured patients because the government lowered the price it paid for Medicare patients.<sup>202</sup> The hospital raises the privately insured prices closer to the profit maximizing level. There are three essential elements to cost shifting:<sup>203</sup> (1) the company or hospital must have market power that it has not exploited; (2) in response to a payor lowering its price, the company raises its prices to other payers; and (3) the ability to cost-shift is limited by the profit maximizing price. Some economists will concede that cost-shifting may exist as a matter of theory for non-profit maximizing firms, but question whether it actually occurs.<sup>204</sup>

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<sup>202</sup> See, e.g., Paul B. Ginsburg, *Can Hospitals and Physicians Shift the Effects of Cuts in Medicare Reimbursement to Private Payors?*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-472, 473 (“An example would be if hospitals raised prices to private payers in response to Medicare payment rate reductions.”), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.472v1.pdf>. One analyst believes that state legislators account for cost shifting when setting Medicaid rates, and are more willing to underpay hospitals than nursing homes because they know Medicaid “is only 10 percent of hospitals’ revenues on the patient side, but it’s 60, 70, 80 percent of nursing homes’ revenue.” Jason S. Lee et al., *Medicare Payment Policy: Does Cost Shifting Matter?*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-480, 485 (referring to comments made by Stuart Altman), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.480v1.pdf>.

<sup>203</sup> MICHAEL A. MORRISSEY, *COST SHIFTING IN HEALTH CARE: SEPARATING EVIDENCE FROM RHETORIC*, at Ch. 2 (AEI Press, 1994).

<sup>204</sup> Economists have been skeptical about the existence of cost-shifting. See David Dranove & William D. White, *Medicaid-Dependent Hospitals and Their Patients: How Have They Fared?*, 33 HEALTH SERVICES RES. 163, 165 (1998) (finding that “although California hospitals dependent on Medicaid were hit hard by Medicaid cutbacks in the



Cross subsidizing is the practice of charging supracompetitive prices to some payors or for some services and using the surpluses to subsidize other payors or other clinical services. Cross subsidization is similar to cost shifting in that it can occur if a non-profit-maximizing firm has market power. Cross-subsidies can occur if there are barriers to entry in a market and a non-profit-maximizing firm receives greater profits on some services (e.g., from Medicare for cardiac services) that it uses to underwrite the provision of other services.<sup>205</sup>

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period 1983-1992, they did not raise prices to privately insured patients .... This suggests either (a) that they were unable to cost-shift, and/or (b) that they were not desirable to managed care payers.”); MICHAEL A. MORRISEY, HOSPITAL COST SHIFTING, A CONTINUING DEBATE (Employee Benefit Research Inst., Issue Brief No. 180, 1996) (examining the evidence on hospital cost shifting and suggesting cost shifting, to the extent it may have once existed, no longer exists because of competition in hospital markets). See also Jack Zwanziger et al., *Can Cost Shifting Continue in a Price Competitive Environment?*, 9 HEALTH ECON. 211 (2000) (providing evidence of the empirical importance of cost-shifting). But see Desmarais 2/27 at 212-13 (stating that “our member [insurance] companies are concerned about cost shifting, in that the public payers are not paying the cost of the care for their recipients and beneficiaries, and as a result it just tends to add more pressure on the remainder of the marketplace to try to ‘make up the difference ....’”).

<sup>205</sup> Commentators state that for-profit hospitals are less likely to offer non-remunerative services. See Jill R. Horwitz, *Why We Need the Independent Sector: The Behavior, Law, and Ethics of Not-for-Profit Hospitals*, 50 UCLA L. REV. 1345, 1367-76 (2003) (finding increased probability of non-remunerative services offered by nonprofit hospitals); Linda B. Miller, *The Conversion Game: High Stakes, Few Rules*, 16 HEALTH AFFAIRS 112, 116 (Mar./Apr. 1997) (“These services – such as burn units, perinatal intensive care units, transplantations, and other sophisticated medical interventions – exist overwhelmingly in the nonprofit sector and represent

In a competitive market, such cross-subsidies are competed away.<sup>206</sup> Hospital panelists see cross subsidies not as a theory, but as a fact of life:

[If we] take away those profitable services and leave the hospital, the community hospital, with just the unprofitable services, one of two things is going to happen. Either services will be diminished to the community in a way that is not transparent, in a way that they cannot see that happening, or costs will be shifted back to other payors, and business and labor and consumers end up absorbing them, once again, not in a transparent way where they can see what’s happening.<sup>207</sup>

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an investment in a social good, not potential financial returns.”).

<sup>206</sup> See, e.g., Blumstein 2/27 at 30 (“[A]ntitrust evaluates conduct on grounds of competition and efficiency. It encourages competing away excess profits and cross-subsidization. This is something that the health system has lived on for many years, but it is hard to do when super-competitive profits are being competed away and that many monopolies are being targeted.”); Brewbaker 9/9/02 at 33 (“We expect markets to control cost for us, but we don’t like it when they eliminate the cross subsidies that allow hospitals, for example, to provide things like indigent care.”).

<sup>207</sup> G. Lynn 3/27 at 86. See also Opelka 2/27 at 180 (“Cost shifting was once the remedy to ensure a stable practice, but this [is] no longer a solution for surgeons.”); Mansfield 4/25 at 88-89 (“[A]cute care hospitals, ... [are] very dependent upon being able to cross subsidize the losses we have for patients who have medical DRGs by treating those who are surgically or procedurally oriented.”); Joyce Mann et al., *Uncompensated Care: Hospitals’ Responses To Fiscal Pressures*, 14 HEALTH AFFAIRS 263, 263 (Spring 1995) (“Hospitals historically have

As noted previously, Congress has created direct subsidies for certain hospitals. CMS pays more (approximately \$5.9 billion extra in 1999) to teaching hospitals and it pays more (approximately \$5 billion per year) to safety net hospitals that provide a disproportionate share of care to the poor.<sup>208</sup> More recently, the MMA includes a provision for \$250 million in extra payments to hospitals in states that border Mexico, to pay for the costs of providing emergency care to undocumented aliens.<sup>209</sup>

Reliance on cross-subsidies, instead of direct subsidies, to ensure access to care makes the availability of such care contingent on the location in which care is provided, the wealth and insurance status of

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taken it upon themselves to fill some of the gaps in the U.S. health insurance system by treating uninsured patients and then charging more to those who can pay to offset the costs. This practice, known as cost shifting, distinguishes the hospital sector from nearly all other sectors of the economy.”)

<sup>208</sup> MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: RETHINKING MEDICARE’S PAYMENT POLICIES FOR GRADUATE MEDICAL EDUCATION AND TEACHING HOSPITALS (1999), at [http://www.medpac.gov/publications/congressional\\_reports/august99.pdf](http://www.medpac.gov/publications/congressional_reports/august99.pdf).

<sup>209</sup> See Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens, Pub. L. 108-173, tit. X, § 1011, 117 Stat. 2432 (Dec. 8, 2003). See also U.S./MEXICO BORDER COUNTIES COALITION, MEDICAL EMERGENCY: COSTS OF UNCOMPENSATED CARE IN SOUTHWEST BORDER COUNTIES 47 (2002) (estimating more than \$200 million or about 25 percent of the uncompensated costs border hospitals incurred resulted from emergency medical treatment provided to undocumented immigrants), at <http://www.bordercounties.org/vertical/Sites/{B4A0F1FF-7823-4C95-8D7A-F5E400063C73}/uploads/{FAC57FA3-B310-4418-B2E7-B68A89976DC1}.PDF>.

those receiving care at any given hospital, and the un-competitiveness of the market for hospital services. Several panelists noted that in some communities, hospitals make substantial profits on one group and use those funds to provide charity care to the balance of the community.<sup>210</sup>

In other locations, this approach is not viable – particularly if those paying the bills identify alternative locations to provide care that choose not to engage in cross subsidization. Cross subsidies distort relative prices, resulting in inefficient decisions by payors and patients. Cross subsidies also complicate attempts to provide consumers with better price information. Finally, it is generally more efficient to subsidize directly, rather than pay higher prices elsewhere and cross subsidize.

### XIII. CROSS SUBSIDIES AND COMPETITION

As noted previously, cross subsidies require either the exercise of market power by a non-profit-maximizing firm, or a non-profit-maximizing firm that receives supra-competitive profits on some services in a market with barriers to entry. As competition becomes more effective in hospital markets, these cross subsidies will tend to be competed away.<sup>211</sup>

Competition can help make health care more affordable, but it cannot transfer resources to those who do not have them. SSHs and ASCs may well enhance quality

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<sup>210</sup> G. Lynn 3/27 at 29.

<sup>211</sup> See *supra* note 206.

of care, lower prices, and improve access. From the perspective of those receiving care at the SSH or ASC, that is a desirable outcome. From the perspective of the general hospital that relied on specialty care to cross subsidize unprofitable patients and services, and from the perspective of such patients and perhaps others that the hospital serves, the same outcome is undesirable.<sup>212</sup>

Competition has a number of effects on hospitals, including the potential to improve quality and lower costs. Competition will also undermine the ability of hospitals to engage in cross-subsidization, however. To address this issue, Congress and state legislatures should consider whether direct subsidies for desired conduct are advisable.<sup>213</sup>

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<sup>212</sup> *See, e.g.*, Lesser 3/27 at 17-18 (“While specialty facilities may lead to improved access for certain services ... there may be a cost from the broader system and societal perspective [] in terms of the ability of general hospitals to maintain the cross-subsidies necessary to fund other less profitable services.”).

<sup>213</sup> *See* COUNCIL OF ECONOMIC ADVISORS, ECONOMIC REPORT OF THE PRESIDENT, at Ch. 4 (2002) (“Competition need not threaten the quality of care received by those with the least ability to pay; rather, government support and oversight can be better directed to ensure that all Americans are able to participate effectively in a competitive health care system.”).

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## CHAPTER 4: COMPETITION LAW: HOSPITALS

### I. INTRODUCTION

Analyses of the likely competitive effects of hospital mergers have been an important part of antitrust enforcement since the FTC issued its first hospital merger complaint in 1981.<sup>1</sup> Most hospital mergers and acquisitions do not present competitive concerns.<sup>2</sup> The *Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care (Health Care Statements)* specifically set forth a safety zone for hospital mergers that will be rarely (if ever) challenged by the Agencies.<sup>3</sup> Indeed, since 1981, the

Commission and DOJ have challenged relatively few hospital mergers, in some instances seeking relief only for part of the transaction.<sup>4</sup> The Agencies have used consent orders to resolve competitive concerns about several of these mergers.<sup>5</sup>

Nonetheless, the Agencies have found some hospital mergers likely to have anticompetitive effects and had considerable early success in litigating hospital merger cases.<sup>6</sup> From 1994 through 2000, however, when there were approximately 900 hospital mergers, the Agencies and state antitrust enforcers lost all seven cases they litigated.<sup>7</sup>

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<sup>1</sup> *Am. Med. Int'l v. FTC*, 104 F.T.C. 1 (1984), *as modified by* 104 F.T.C. 617 (1984) and 107 F.T.C. 310 (1986). The Commission decision held that a for-profit hospital chain's acquisition of a competing hospital in the city and county of San Luis, Obispo, California, violated § 7 of the Clayton Act and § 5 of the FTC Act. The Commission found that the acquisition lessened both price and nonprice competition, and ordered divestiture of the acquired hospital.

<sup>2</sup> U.S. DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, ANTITRUST ENFORCEMENT POLICY STATEMENTS IN THE HEALTH CARE AREA § 1 (1996) [hereinafter HEALTH CARE STATEMENTS], *available at* <http://www.ftc.gov/reports/hlth3s.pdf>. Agency review of most proposed hospital mergers is typically completed in less than a month. *Id.* § 1. *See also* J. Jacobs 3/28 at 69.

<sup>3</sup> HEALTH CARE STATEMENTS, *supra* note 2, § 1. The safety zone encompasses mergers between two general acute-care hospitals "where one of the hospitals (1) has an average of fewer than 100 licensed beds over the three most recent years, and (2) has an average daily inpatient census of fewer than 40 patients over the three most recent years, absent extraordinary circumstances." *Id.* This safety zone does not necessarily apply if one of the hospitals is less than five years old. Transactions that fall outside the safety zone are not necessarily anticompetitive and may be pro-competitive.

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<sup>4</sup> The Agencies challenge relatively few mergers overall. In 2001, the Agencies were notified of 2,376 total mergers (the FTC challenged 23 and DOJ challenged 32) and a few of those were below the thresholds for notification. FEDERAL TRADE COMM'N STAFF, U.S. DEPARTMENT OF JUSTICE, ANTITRUST DIVISION, ANNUAL REPORT TO CONGRESS, FISCAL YEAR 2002 (2003), *available at* <http://www.ftc.gov/os/2003/08/hsrannualreport.pdf>.

<sup>5</sup> *See* HEALTH CARE SERVICES & PRODUCTS DIVISION, FEDERAL TRADE COMM'N, FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2003), *available at* <http://www.ftc.gov/bc/hcupdate031024.pdf>; U.S. Dep't of Justice Antitrust Division, *Health Care Task Force: Recent Enforcement Actions*, at [http://www.usdoj.gov/atr/public/health\\_care/2044.htm](http://www.usdoj.gov/atr/public/health_care/2044.htm); U.S. Dep't of Justice Antitrust Division *Summary of Antitrust Division Health Care Cases Since August 25, 1983*, at [http://www.usdoj.gov/atr/public/health\\_care/0000.pdf](http://www.usdoj.gov/atr/public/health_care/0000.pdf).

<sup>6</sup> Martin Gaynor & William B. Vogt, *Competition Among Hospitals*, 34 RAND J. ECON. 764, 764 (2003).

<sup>7</sup> *Id.* at 764. The seven cases were: *California v. Sutter Health Sys.*, 84 F. Supp. 2d 1057 (N.D. Cal.), *aff'd mem.*, 2000-1 Trade Cas. (CCH) ¶ 87,665 (9th Cir. 2000), *revised*, 130 F. Supp. 2d 1109 (N.D. Cal. 2001); *FTC v. Tenet Healthcare Corp.*, 17 F. Supp. 2d 937 (E.D. Mo. 1998), *rev'd* 186 F.3d

Some scholars have strongly criticized the courts' reasoning in these cases.<sup>8</sup>

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1045 (8th Cir. 1999); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121 (E.D.N.Y. 1997); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1300-1301 (W.D. Mich. 1996), *aff'd*, 1997-2 Trade Cas. (CCH) ¶ 71,863, 71,867-68 (6th Cir. 1997); *United States v. Mercy Health Services*, 902 F. Supp. 968 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997); *FTC v. Freeman Hosp.*, 911 F. Supp. 1213 (W.D. Mo.), *aff'd*, 69 F.3d 260 (8th Cir. 1995); *In re Adventist Health Sys.*, 117 F.T.C. 224 (1994). One of the seven cases was brought by state antitrust enforcers without either Agency's involvement. *See Sutter Health Sys.*, 84 F. Supp. 2d 1057.

<sup>8</sup> *See* Thomas L. Greaney, *Night Landings on an Aircraft Carrier: Hospital Mergers and Antitrust Law*, 23 AM. J.L. & MED. 191 (1997). As Professor Greaney notes, in *Freeman Hospital*, the FTC produced patient-origin data that showed a high percentage of patients stayed in the government's proposed geographic market, as well as forward looking testimony of market participants, including competitors, buyers, and consumers. The Court placed the Commission in a "Catch 22: hard evidence like historical patient-origin data was unacceptable because it did not address future contingencies, and managed care testimony was inadequate, although it addressed future contingencies, because it lacked the specificity of hard evidence." *Id.* at 207-08. Similarly, Professor Greaney noted that in *Mercy Health Systems*, the courts ignored most of DOJ's subjective and objective evidence designed to provide a dynamic analysis of the market and discounted opinion testimony of the most knowledgeable market participants, including third party payors and physicians. *Id.* at 209-212.

*See also* Peter Hammer & William Sage, *Critical Issues in Hospital Antitrust Law*, 22 HEALTH AFFAIRS 88, 90 (Nov./Dec. 2003) (noting merging hospitals have persuaded some courts "that nonprofit hospitals will not raise prices in the same manner as would for-profits or businesses outside of health care with comparable market share" and that relevant geographic markets include hospitals 70 to 100 miles away); William Sage et al., *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS

The Agencies analyze hospital mergers using the same analytical framework they use for other mergers. The *1992 Horizontal Merger Guidelines (Merger Guidelines)* specify that "mergers should not be permitted to create or enhance market power or to facilitate its exercise."<sup>9</sup> Market power "is the ability profitably to maintain prices above competitive levels for a significant period of time."<sup>10</sup> A merger also may "lessen competition on dimensions other than price, such as product quality, service, or innovation."<sup>11</sup>

To identify mergers that are likely to cause competitive problems, the *Merger Guidelines* provide for the examination of several issues, including:

- whether the merger, in light of market concentration and other

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31, 41-42 (Mar./Apr., 2003) (some courts presume nonprofit health facilities act in the public interest, and that increased revenues will be spent on quality improvements).

As the current Chairman of the Federal Trade Commission recently observed, "In hospital merger cases, the government is zero for the last seven. I don't know the specifics of every case, but what's striking is the zero. I can certainly accept the idea that the government should not have won them all. But it seems very unlikely the government should have lost them all." William M. Sage, *Protecting Competition and Consumers: A Conversation With Timothy J. Muris*, 22 HEALTH AFFAIRS 101, 103 (Nov./Dec. 2003).

<sup>9</sup> U.S. DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 0.1 (1992 rev. 1997, efficiencies section only) [hereinafter MERGER GUIDELINES], available at <http://www.ftc.gov/bc/docs/horizmer.htm>.

<sup>10</sup> MERGER GUIDELINES, *supra* note 9, § 0.1.

<sup>11</sup> *Id.* § 0.1 n.6.

factors that characterize the market, would be likely to have adverse competitive effects;

- whether entry would be timely, likely, and sufficient either to deter or to counteract the competitive effects of concern;
- whether there are efficiency gains from the merger that meet the Agencies' criteria for examination; and
- whether, but for the merger, either party to the transaction would be likely to fail, causing its assets to exit the market.<sup>12</sup>

Merger analysis can begin with an assessment of direct evidence of likely

anticompetitive effects.<sup>13</sup> The Supreme Court has stated that “the finding of actual, sustained adverse effects on competition ... is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis.”<sup>14</sup> A number of lower court decisions have followed this principle.<sup>15</sup>

Merger analysis also can begin with the identification of relevant product and geographic markets. A market is defined as a product(s) and a geographic area in which it is produced or sold, such that a hypothetical profit-maximizing firm that was the only present and future producer or seller of those products in that area likely would impose at least a “small but significant and non-transitory” increase in

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<sup>12</sup> *Id.* § 0.2. The last factor is sometimes referred to as the “failing firm defense.” As the guidelines explain:

A merger is not likely to create or enhance market power or facilitate its exercise if the following circumstances are met: 1) the allegedly failing firm would be unable to meet its financial obligations in the near future; 2) it would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act [11 U.S.C. §§1101-1174 (1988)]; 3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers of acquisition of the assets of the failing firm that would both keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger; and 4) absent the acquisition, the assets of the failing firm would exit the relevant market.

*Id.* § 5.1.

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<sup>13</sup> *e.g.*, *In re Schering-Plough Corp.*, No. 9297 at 16-17 (Dec. 18, 2003) (discussing *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986)), available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

<sup>14</sup> *Indiana Fed'n of Dentists*, 476 U.S. at 460-61.

<sup>15</sup> *See, e.g.*, *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) (evidence of “an actual adverse effect on competition ... arguably is more direct evidence of market power than calculations of elusive market share figures”); *Toys R' Us v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (market power can be proved “through direct evidence of anticompetitive effects”); *United States v. Baker Hughes Inc.*, 908 F.2d 981, 992 (D.C. Cir. 1990) (“Market share is just a way of estimating market power, which is the ultimate consideration,” and ... “[w]hen there are better ways to estimate market power, the court should use them” (quoting *Ball Mem'l Hosp. v. Mutual Hosp. Ins.*, 784 F.2d 1325, 1336 (7th Cir. 1986))).

price.<sup>16</sup> This market definition test is sometimes referred to as the “hypothetical monopolist” paradigm. A relevant market is a group of products and a geographic area that is no bigger than necessary to satisfy this test.<sup>17</sup> Analysis typically starts with a narrow area that is broadened until a price increase by the hypothetical firm would be profitable because consumers have insufficient substitution alternatives available to defeat it.<sup>18</sup>

Hospital merger analysis raises a number of significant issues, including how best to define the geographic and product markets, assess the prospects for entry and the likelihood and magnitude of efficiencies, and determine the relevance of a hospital’s institutional status (for-profit or nonprofit). This chapter considers each of these issues, and discusses relevant case law, academic commentary and research, and testimony and written presentations from the Hearings.

Chapter 4 also addresses the role of group purchasing organizations (GPOs) for health care systems, including the extent to which GPOs act as agents of their buyer-members or as agents of the sellers that pay the GPOs’ administrative fees. This section also discusses the antitrust issues GPOs may

raise and the applicability of the *Health Care Statements* to those issues. Chapter 4 concludes with a brief discussion of the antitrust implications of tiering and pay-for-performance.<sup>19</sup>

## II. GEOGRAPHIC MARKET DEFINITION

The Agencies define hospital geographic markets using the process set forth in the *Merger Guidelines*. Panelists agreed that the *Merger Guidelines* provide an appropriate framework for defining and analyzing hospital geographic markets.<sup>20</sup> Although there is widespread agreement on

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<sup>19</sup> See also *supra* Chapter 1.

<sup>20</sup> See, e.g., Guerin-Calvert 3/26 at 125, 130 (suggests using the merger guidelines and the hypothetical monopolist test; “although there is a great deal that is unique and specific about health care and hospitals in particular, [the best approach for analyzing hospital industry competition and transactions is] the same kinds of principles and the same kinds of fact-intensive analysis that is used in all other industries”); Margaret E. Guerin-Calvert, *Defining Geographic Markets for Hospitals* 6-11 (3/26) (slides) [hereinafter Guerin-Calvert Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030326guerincalvert.pdf>; Vistnes 3/26 at 147-148 (stating the geographic market definition “should be driven, principally if not exclusively, by the Merger Guidelines;” the key test is whether a plan could divert enough patients to a different hospital in a different region to make the price increase unprofitable); Gregory Vistnes, *Geographic Markets and Hospital Competition* 5 (3/26) (slides) [hereinafter Vistnes Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/vistnes.pdf>; Werden 3/26 at 201 (noting the merger guidelines’ hypothetical monopolist paradigm is the right approach); Gregory Werden, *Hospital Mergers and the Hypothetical Monopolist Test* 2 (3/26) (slides) [hereinafter Werden Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/werden.pdf>; David Argue 3/28 at 41-42.

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<sup>16</sup> MERGER GUIDELINES, *supra* note 9, § 1.0. This test further assumes that the hypothetical profit-maximizing firm is not subject to price regulation and that the terms of sale of all other products are held constant. *Id.*

<sup>17</sup> *Id.* § 1.0.

<sup>18</sup> Seth Sacher & Louis Silvia, *Antitrust Issues in Defining the Product Market for Hospital Services*, 5 INT’L J. ECON. BUS. 181, 182-83 (1998) at <http://www.ftc.gov/ogc/healthcarehearings/docs/030326sethsacher.pdf>.



the basic framework, two well-known health law scholars have written:

[T]he law concerning hospital [geographic] market definition is in a shambles. Common sense suggests that health care, like politics, is local. In the words of Judge Richard Posner, “People want to be hospitalized near their families and homes, in hospitals in which their own – local – doctors have privileges.” However, courts have stretched the geographic boundaries of markets to strip merging hospitals of market power and thereby shield them from antitrust liability.<sup>21</sup>

In this section, we discuss the controversies about how to define relevant geographic markets for hospitals. We discuss the use of the Elzinga-Hogarty test and critical loss analysis to define hospital geographic markets, including the views of proponents and critics. We then describe alternative analytical techniques and evidentiary sources that Hearing panelists and researchers proposed for defining hospital geographic markets. The final subsection summarizes the Agencies’ conclusions and recommendations concerning geographic market definition issues. This subsection includes the conclusion that, to date, the Agencies’ experience and research indicate that the Elzinga-Hogarty test is not valid or reliable in defining geographic markets in hospital merger cases.

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<sup>21</sup> Hammer & Sage, *supra* note 8, at 90, citing to *United States v. Rockford Mem’l Corp.*, 898 F.2d 1278, 1285 (7th Cir. 1990).

At the outset, we note that direct evidence of anticompetitive effects may make it unnecessary to define a relevant market. For example, consummated merger cases may present opportunities to assess competitive effects without using detailed market definitions.<sup>22</sup>

#### A. *Elzinga-Hogarty, Critical Loss, and the Alternatives*

Since 1995, the Agencies have lost several hospital merger cases because the courts accepted the merging parties’ use of patient flow data to perform either the Elzinga-Hogarty test<sup>23</sup> or critical loss analysis<sup>24</sup> to define the geographic market much more broadly than the plaintiff

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<sup>22</sup> See, e.g., Michael Vita & Seth Sacher, *The Competitive Effects of Not-For-Profit Hospital Mergers: A Case Study*, 49 J. INDUS. ECON. 63 (2001) (using a control group methodology to assess competitive effects). Here, the competitive effect of the transaction is identified by comparing the change in price at the merging hospitals to the change in price (measured over the same time period) at a set of “control” hospitals. The control hospitals are hospitals in other geographic areas that are otherwise similar to the merging hospitals. Note, however, that a price increase by itself may not be sufficient to prove anticompetitive effects.

<sup>23</sup> The Elzinga-Hogarty test is named for the two economists who first proposed this particular analysis. See Kenneth Elzinga & Thomas Hogarty, *The Problem of Geographic Market Delineation in Antitrust Suits*, 18 ANTITRUST BULL. 45 (1973) [hereinafter Elzinga & Hogarty, *The Problem*]; Kenneth Elzinga & Thomas Hogarty, *The Problem of Geographic Market Delineation Revisited: The Case of Coal*, 23 ANTITRUST BULL. 1 (1978) [hereinafter Elzinga & Hogarty, *The Problem Revisited*].

<sup>24</sup> The term “critical loss analysis” was first used in an article: Barry Harris & Joseph Simons, *Focusing Market Definition: How Much Substitution Is Necessary?* 12 RES. IN L. & ECON. 207 (1989).

Agency.<sup>25</sup> Commentators and panelists observed that these cases reflect judicial acceptance of implausibly large geographic markets, judicial approval of mergers that would not be permitted in any other industry, and the lessening of competition in the hospital services market.<sup>26</sup>

All panelists agreed that neither the parties nor the courts should use the Elzinga-Hogarty test as the sole basis for defining the geographic market.<sup>27</sup> As one panelist stated:

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<sup>25</sup> See *FTC v. Tenet Healthcare Corp.*, 17 F. Supp. 2d 937 (E.D. Mo. 1998), *rev'd* 186 F.3d 1045 (8th Cir. 1999). In this case, the Eighth Circuit relied on both an Elzinga-Hogarty test and a critical loss analysis to conclude that a broad geographic market was appropriate. Similarly, in *United States v. Mercy Health Services*, 902 F. Supp. 968 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997), the District Court relied on patient migration patterns, regional hospitals' outreach clinics, and the lack of evidence that patients' loyalty to their physicians would prevent them from defeating a price increase to find a broad geographic market. See also *J. Jacobs* 3/28 at 72-74 (noting DOJ lost the *Mercy Health* case on the geographic market definition for all of these reasons, but believes that the government could address successfully some of these issues today); *California v. Sutter Health Sys.*, 84 F. Supp.2d 1057 (N.D. Cal. 2000) (insufficient evidence of a relevant geographic market); *FTC v. Freeman Hosp.*, 911 F. Supp. 1213 (W.D. Mo.), *aff'd*, 69 F.3d 260 (8th Cir. 1995) (holding the Commission had failed to identify a relevant geographic market).

<sup>26</sup> See *Hammer & Sage*, *supra* note 8, at 90; *Frech* 3/26 at 189-191; *Greaney* 2/27 at 141-42; *Greaney*, *supra* note 8.

<sup>27</sup> See *Werden* 3/26 at 248-50 (the data may provide descriptive information, but you cannot draw strong conclusions); *Guerin-Calvert* 3/26 at 139; *Guerin-Calvert* Presentation, *supra* note 20, at 17; *Frech* 3/26 at 190-91 (noting that patient flow data and the Elzinga-Hogarty ratios are useful background, but make no sense when used as a bright line to define the geographic market); *Vistnes* 3/26 at 251-

“if [Elzinga-Hogarty] is the only tool that is being used . . . it blurs everyone's vision as to who really are the competitors and the alternatives that matter.”<sup>28</sup> Panelists and commentators identified numerous problems with the application of critical loss analysis, although panelists and commentators agreed that it can be a useful tool.<sup>29</sup>

Several panelists offered alternative analytical tools and other types of evidence to use in defining the geographic market for a hospital. Most panelists agreed that no one piece of information is sufficient to define a hospital's geographic market.<sup>30</sup> In essence,

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52; *Argue* 3/28 at 44 (Elzinga-Hogarty is a static analysis and does not address the dynamic nature of markets).

<sup>28</sup> *Guerin-Calvert* 3/26 at 139; *Guerin-Calvert* Presentation, *supra* note 20, at 17.

<sup>29</sup> See, e.g., *Harris* 3/26 at 171-78, 222-24; *Guerin-Calvert* 3/26 at 125, 130-31; *Werden* 3/26 at 201-205, 212-20, 248-50; *Frech* 3/26 at 189-90; Daniel O'Brien & Abraham Wickelgren, *A Critical Analysis of Critical Loss Analysis*, 71 ANTITRUST L.J. 161, 161-62 (2003); Michael Katz & Carl Shapiro, *Critical Loss: Let's Tell the Whole Story*, 17 ANTITRUST, Spring 2003, at 49-50; James Langenfeld & Wenqing Li, *Critical Loss Analysis in Evaluating Mergers*, 46 ANTITRUST BULL. 299, 299-301 (2001); Kenneth L. Danger & H.E. Frech III, *Critical Thinking About 'Critical Loss' in Antitrust*, 46 ANTITRUST BULL. 339, 340-42 (2001); David Scheffman & Joseph Simons, *The State of Critical Loss Analysis: Let's Make Sure We Understand the Whole Story*, 3 THE ANTITRUST SOURCE, Nov. 2003, at <http://www.abanet.org/antitrust/source/nov03/scheffman.pdf>.

<sup>30</sup> *Vistnes* 3/26 at 144, 147-49; *Vistnes* Presentation, *supra* note 20, at 4-5, 11-18; *Guerin-Calvert* 3/26 at 131-33; *Guerin-Calvert* Presentation, *supra* note 20, at 4, 12. See also *Leibenluft* 3/28 at 8-9 (“[On] geographic market, it's sort of a Catch 22. The courts require -- and, I think, rightfully so -- that

panelists agreed the courts should apply the *Merger Guidelines*' hypothetical monopolist test in hospital merger cases, just as they do in merger cases involving other industries and products. The question is how to implement the hypothetical monopolist test, and what analytical frameworks and evidence should be used to do so.

## 1. Elzinga-Hogarty Test

The Elzinga-Hogarty test was designed to analyze commodity movements, not hospital mergers. It was proposed by two economists in an article critiquing the Agencies' geographic market definitions in two non-hospital merger cases.<sup>31</sup> In one case, the government relied on LIFO ("little in from outside") data to argue that an entire state was the relevant geographic market for beer products. In the second case, the government relied on LOFI ("little out from inside") data to argue that the relevant geographic market for commercial banking

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the analysis be dynamic. What will happen if the hospitals merge? As a result of that, the plaintiff is faced with a difficult task. What they have is traditional hard evidence which relates to, for example, patient flow data, which reflects historical patient patterns, and is historical conduct. But that doesn't reflect what might happen in the future. But when the Government tries to find what may or look to what may suggest what will happen dynamically, then that evidence could be attacked as being speculative or anecdotal."); Feller 9/24 at 66 (discussing geographic markets for physician services and also noting that "zip code analysis, however, only presents a static and limited view of the relevant geographic market").

<sup>31</sup> Elzinga & Hogarty, *The Problem*, *supra* note 23; *see also* Elzinga & Hogarty, *The Problem Revisited*, *supra* note 23.

was limited to a four-county area.<sup>32</sup> Kenneth Elzinga and Thomas Hogarty argued that a proper geographic market analysis required the use of both LIFO and LOFI statistics, but observed that their analysis was not readily applicable to heterogeneous goods or differentiated products.<sup>33</sup> Hospitals generally provide heterogeneous or differentiated goods and services.<sup>34</sup>

Nonetheless, the "Elzinga-Hogarty test" has been used extensively in hospital merger cases. The movement of a patient who resides within the provisional geographic market to a facility outside of that area for hospital services is considered an importation of hospital services into that provisional geographic market, measured as LIFO. The movement of a patient who resides outside of the provisional geographic market to a facility inside the provisional geographic market for hospital services is considered an exporting of hospital services outside of the provisional geographical

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<sup>32</sup> Elzinga & Hogarty, *The Problem*, *supra* note 23, at 52-64.

<sup>33</sup> *Id.* at 72-75 & n.75 ("Where the appropriate product market is a set of heterogeneous goods, or where there is product differentiation, or where there are important physical differences among units within the product market, adding together physical units will be difficult if not impossible. In such cases, measuring output in sales instead of physical units might be necessary.").

<sup>34</sup> *See, e.g.*, Zwanziger 3/26 at 92 (The Elzinga-Hogarty approach "is poorly suited to hospital mergers" because it does not recognize the underlying heterogeneity on the supply or demand side of hospital services.); Jack Zwanziger, *Defining Hospital Markets 2* (3/26) (slides) [hereinafter Zwanziger Presentation], at <http://www.ftc.gov/ogc/healthcare/hearings/docs/zwanziger.pdf>.

market, measured as LOFI.<sup>35</sup> Thus, under the hospital application of the Elzinga-Hogarty test, evidence that few patients leave and few patients enter an area surrounding the merging hospitals is interpreted to support the conclusion that the area constitutes a relevant geographic market.<sup>36</sup>

Conversely, if the patient flow data show large numbers of patients coming into or going out of the area for inpatient hospital care, then the geographic market is hypothesized to be broader than originally thought, and must include hospitals further away from the merging hospitals. A geographic market definition is usually described as “strong” if less than 10 percent of discharged patients from the merging hospitals’ area come into or out of the area. If more than 10 percent (but less than 25 percent) of patients migrate in or out of the hospitals’ core geographic area for in-patient services, the market definition is considered “weak.”<sup>37</sup>

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<sup>35</sup> See Gregory Vistnes, *Hospitals, Mergers, and Two-Stage Competition*, 67 ANTITRUST L.J. 671, 689 (2000); Sacher & Silvia, *supra* note 18, at 192-93.

<sup>36</sup> See Vistnes, *supra* note 35, at 689; Elzinga & Hogarty, *The Problem*, *supra* note 23, at 72-76; Elzinga & Hogarty, *The Problem Revisited*, *supra* note 23, at 2-3.

<sup>37</sup> See Elzinga & Hogarty, *The Problem*, *supra* note 23, at 73-75; Elzinga & Hogarty, *The Problem Revisited*, *supra* note 23, at 2.

If the LIFO and LOFI are both 10 percent or less, then the geographic market satisfies the “strong” Elzinga-Hogarty test. If the LIFO and LOFI are both 25 percent or less then the geographic market satisfies the “weak” Elzinga-Hogarty test. Elzinga & Hogarty, *The Problem Revisited*, *supra* note 23, at 2.

Panelists identified a number of weaknesses with the use of the Elzinga-Hogarty test to define a geographic market for hospital services.<sup>38</sup> One panelist pointed out that the Elzinga-Hogarty test takes a leap in logic from a current level of patient migration to the conclusion that patients would respond to a small price increase by using hospitals outside of the merging hospitals’ core geographic area – a leap not justified by either economic analysis or past experience.<sup>39</sup> Patients decide whether or not to travel for health care services for a variety of reasons, including perceived and actual variations in quality, insurance coverage, out-of-pocket cost, sophistication of services, and family connections.<sup>40</sup>

Although patient flow data may show that patients go to hospitals beyond the core zip code area, this does not mean that their behavior reflects price sensitivity, or that other consumers would travel if prices increased.<sup>41</sup> Stated differently, patient flow data can show existing hospitalization patterns, but offer no insight into what patients will do in response to a price

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<sup>38</sup> Frech 3/26 at 190-97; Greaney 2/27 at 141-42 (noting that the courts naively interpret Elzinga-Hogarty in health care cases, and that because hospitals offer heterogeneous services and patients have highly diverse preferences, this results in “thoroughly wrong-headed precedents and subdoctrines”).

<sup>39</sup> Frech 3/26 at 190-95.

<sup>40</sup> *Id.* at 195.

<sup>41</sup> Zwanziger 3/26 at 232-33. See also *id.* at 97-99 (noting that large markets based on patient flow data and Elzinga-Hogarty are incompatible with research knowledge: travel distance is the most important criteria for a patient in deciding which hospital to use).

increase by the merged hospital.

Another panelist described this phenomenon as the “silent majority fallacy.”

The E-H [Elzinga-Hogarty] approach draws a conclusion about the entire market from the behavior of those consumers who express displeasure with their local sellers by traveling elsewhere. This is a valid logical leap when travelers and non-travelers have similar demands and related market experiences. However, if the two groups differ on dimensions other than location, then E-H gives rise to what we call the “silent majority fallacy.” That is, if travelers and non-travelers display fundamentally different demand behavior, either because they differ in their taste for travel or their need for local/non-local services, then there is no necessary relationship between the market experiences of these two groups post-merger. If travelers differ significantly from non-travelers, then the presence of a minority of travelers does not imply that local firms lack market power *vis-a-vis* the majority of consumers who are non-travelers.<sup>42</sup>

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<sup>42</sup> CORY CAPPS ET AL., THE SILENT MAJORITY FALLACY OF THE ELZINGA-HOGARTY CRITERIA: A CRITIQUE AND NEW APPROACH TO ANALYZING HOSPITAL MERGERS 1 (Nat’l Bureau of Econ. Research, Working Paper No. w8216, 2001) [hereinafter CAPPS ET AL., SILENT MAJORITY]. See also Cory Capps et al., *Geographic Market Definition in Hospital Merger Cases 4* (4/16) [hereinafter Capps et al. (stmt)], at <http://www.ftc.gov/ogc/healthcare/hearings/docs/030410capps2.pdf>; Cory Capps, *For-Profit and Non-Profit Pricing: The Empirical Evidence* (4/10) (slides), at

The silent majority fallacy is a particular problem with hospital merger analysis, because the goods and services are not fungible commodities, but are “highly differentiated by location and other dimensions.”<sup>43</sup> Empirical evidence confirms that “the majority of patients are truly reluctant to travel and do not view distant hospitals as close substitutes for most services, even though a sizable percentage of their neighbors may travel for care. Those who do travel have distinct reasons for doing so and the fact that they travel would not inhibit merging local hospitals from increasing prices substantially.”<sup>44</sup>

One panelist also noted that in some circumstances, the Elzinga-Hogarty test cannot be satisfied. If the initial specification of the geographic market does not meet the required threshold for LIFO and LOFI, expanding the geographic market may not satisfy the required threshold either. The result is that the geographic market expands without limit.<sup>45</sup> This problem alone casts

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<http://www.ftc.gov/opp/hc/030410corycapps.pdf> [hereinafter Capps Presentation]. See also Cory Capps et al., *Antitrust Policy and Hospital Mergers: Recommendations for a New Approach*, 47 ANTITRUST BULL. 677, 713-14 (2002) [hereinafter Capps et al., *Antitrust Policy*].

<sup>43</sup> CAPPS ET AL., SILENT MAJORITY, *supra* note 42, at 1-2.

<sup>44</sup> *Id.*

<sup>45</sup> Frech 3/26 at 195 (“[A]s you expand the area to get to a high enough percentage to call it a service area, you keep picking up more hospitals, and that keeps making it more difficult” to reach a cut-off.). Professor Frech noted that even at the 75 percent level, the defendant’s expert could not find a cut-off for the Poplar Bluff geographic market area in the *Tenet* case. *Id.* at 195.

serious doubt on the utility of the Elzinga-Hogarty methodology for hospitals.

This same panelist suggested that the Elzinga-Hogarty test systematically leads to expansive geographic markets when zip codes are selected based on the absolute number of patients that come from a zip code.<sup>46</sup> There is tremendous variability in the number of individuals that live in a particular zip code. A hospital may have a small share of total admissions from a particular zip code, even though it gets a significant number of patient admissions from that zip code – and the Elzinga-Hogarty test, as used in hospital mergers, will include such distant zip codes in the market. According to this panelist, “a zip code that has 20,000 people, that’s 40 miles away, might get included if the hospital gets 50 patients from there, whereas ten zip codes that are closer that only have a thousand people each, might send 40 people each, they would get excluded.”<sup>47</sup> He suggested that such large and distant zip codes are particularly likely to be cities that have hospitals in them, which skews the results of the analysis from the outset.<sup>48</sup>

## 2. Critical Loss Analysis

Critical loss analysis has the potential to provide a useful way to

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<sup>46</sup> Frech 3/26 at 192 (“[R]anking zip codes by the number of patients usually gives the largest market areas.”).

<sup>47</sup> *Id.* at 192-93. See also H.E. Frech, III et al., *Elzinga-Hogarty Tests and Alternative Approaches for Market Share Calculations in Hospital Markets*, 71 ANTITRUST L.J. 921, 928-29, 941-47 (2004).

<sup>48</sup> Frech 3/26 at 192-93.

implement the hypothetical monopolist test, but it must be applied with great care.<sup>49</sup> Problems with its application have led some commentators to question the value of critical loss analysis as an antitrust tool.<sup>50</sup>

Conventional critical loss analysis posits a particular price increase and asks what proportion of the hypothetical monopolist’s sales would have to be lost to yield a net decrease in the hypothetical monopolist’s profits.<sup>51</sup> When critical loss analysis is used to delineate a relevant market, the first step is to calculate the percentage loss in sales that would make a given price increase unprofitable for a hypothetical monopolist over a candidate market. This calculation depends on the price increase posited and on the contribution margin (*i.e.*, price minus marginal cost, all divided by price) on the sales that would be lost.<sup>52</sup>

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<sup>49</sup> *e.g.*, Scheffman & Simons, *supra* note 27, 61 at 2-3; Harris 3/26 at 170-75; Werden 3/26 at 201-04.

<sup>50</sup> See *supra* note 29.

<sup>51</sup> One also can ask how much of a reduction in its sales the hypothetical monopolist would be willing to tolerate to sustain a given price increase. Only asking this alternative calculation actually implements the Horizontal Merger Guidelines’ hypothetical monopolist test, but the analysis described in the text yields roughly the same result under plausible conditions. Werden 3/26 at 202-04; Werden Presentation, *supra* note 20, at 4-5.

<sup>52</sup> Harris 3/26 at 170-75. The formula for the critical loss for an  $x\%$  price increase is  $x/(x + m)$ , where  $m$  is the margin, expressed as a percentage price. For example, if the margin is 60 percent, the critical loss for a 5 percent price increase is  $5/(5 + 60) = .077$ , or 7.7 percent.

The second step is to estimate the likely actual loss in sales that would result from the hypothesized price increase, *e.g.*, what percentage of patients likely would stop patronizing the hospitals in the candidate market in response to the price increase.<sup>53</sup> The estimated actual loss is then compared to the calculated critical loss. If the estimated actual loss exceeds the critical loss, it is inferred that the price increase would be unprofitable and the candidate market is too small to be a market.<sup>54</sup>

One panelist described misuses of the critical loss technique that practitioners should avoid.<sup>55</sup> Notably, typical applications posit small (*e.g.*, five percent) price increases. Yet, the *Merger Guidelines*' methodology for delineation of relevant markets asks whether the profit-maximizing price increase would be at least a small but significant amount (*e.g.*, five percent). Even though a monopolist may find a five percent price increase unprofitable, it may find a larger price increase profitable.<sup>56</sup> This panelist presented an example based on the stylized facts of several hospital merger cases in which a five percent price increase would be unprofitable, but any price increase between 31 percent and 319 percent would be profitable, and the hypothetical

monopolist would maximize its profits by increasing price 175 percent.<sup>57</sup> Thus, the candidate market was a market under the *Merger Guidelines*' hypothetical monopolist test, even though a five percent price increase was unprofitable.

This panelist discussed other problems that occur in some implementations of critical loss analysis. The standard formula presumes constant marginal cost and no avoidable fixed costs, but actual cost functions may differ significantly from this assumption. Also, the standard formula implicitly assumes proportionate increases in all prices, but the profit maximizing strategy for hospitals may involve highly disproportionate price increases.<sup>58</sup> This panelist also explained that critical loss calculations must focus on the margins for the patients that likely would be lost in the event of a price increase.<sup>59</sup>

Much of the potential for abuse in critical loss analysis involves the second step – estimation of the actual loss. Some practitioners have relied in inappropriate ways on consumer surveys or patient flow

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<sup>53</sup> *Id.* at 174-75.

<sup>54</sup> Scheffman & Simons, *supra* note 29, at 2-3 (outlining a three-step process for conducting a critical loss analysis); *see also* Katz & Shapiro, *supra* note 29, at 49-50; O'Brien & Wickelgren, *supra* note 29, at 161.

<sup>55</sup> Werden 3/26 at 204-05; Werden Presentation, *supra* note 20, at 8.

<sup>56</sup> Werden 3/26 at 204-05; Werden Presentation, *supra* note 20, at 8, 11, 14.

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<sup>57</sup> Werden 3/26 at 209-17; Werden Presentation, *supra* note 20, at 15-19.

<sup>58</sup> Werden 3/26 at 204-05; Werden Presentation, *supra* note 20, at 14.

<sup>59</sup> Werden 3/26 at 219-20 (noting that it is important to properly calculate the margin, and that in hospital mergers it is possible that not all patients contribute the same margin – depending on which patients are likely to leave if faced with a price increase, the margin, and therefore, the critical loss, may differ). For similar critiques, *see* Danger & Frech, *supra* note 29; Langenfeld & Li, *supra* note 29.

data to estimate the actual losses in sales that would result from a price increase. For example, some practitioners use patient flow data to identify zip codes that are “contestable.”

These practitioners then argue that the share of patients in these zip codes that would stop patronizing certain hospitals in a candidate geographic market in response to a given price increase would be greater than the critical loss, and that the geographic area must therefore be expanded in order to constitute a relevant geographic market.<sup>60</sup> Data on existing travel patterns for residents in a zip code, however, say nothing about why patients select specific hospitals or how a change in relative prices would affect patient migration.<sup>61</sup> One cannot infer that just because some patients in a zip code currently choose more distant hospitals, others also would choose such hospitals if the prices of the merging hospitals increased.<sup>62</sup>

Recent commentary, some of it published after the Hearings, has stressed a link between the first and second steps of

critical loss analysis.<sup>63</sup> As a simple matter of arithmetic, the higher the contribution margin, the smaller the critical loss will be for a given price increase. The higher the margin, the more it costs the hypothetical monopolist to lose a sale, and so the smaller the sales loss required to offset the profit gain from making the remaining sales at a higher price.<sup>64</sup>

Yet if firms are maximizing profits before the merger, high margins indicate that those firms face low price elasticities of demand.<sup>65</sup> Otherwise, these firms could earn greater total profits by *reducing* prices and expanding sales. Moreover, a hypothetical monopolist over any candidate market must face a lower elasticity of demand than the individual firms in that candidate market, so high margins must imply a very low demand

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<sup>60</sup> Alternatively, these zip codes are identified as “at risk” or “overlapping.” Harris 3/26 at 177-78; Frech 3/26 at 189-190.

<sup>61</sup> See CAPPS ET AL., SILENT MAJORITY, *supra* note 42; Capps et al., *Antitrust Policy*, *supra* note 42, at 679-82, 690-92, 694-704.

<sup>62</sup> Frech 3/26 at 189-90 (noting that the predicted actual loss is an important part of how critical loss analysis is implemented, and as typically implemented, critical loss analysis leads to implausibly large geographic areas).

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<sup>63</sup> Danger & Frech, *supra* note 29 at 349-51; Katz & Shapiro, *supra* note 29, at 49-50, 52-53; Langenfeld & Li, *supra* note 29, at 302-03, 307-08; O’Brien & Wickelgren, *supra* note 29, at 161-63.

<sup>64</sup> See Katz & Shapiro, *supra* note 29, at 50; O’Brien & Wickelgren, *supra* note 29, at 161-62; Scheffman & Simons, *supra* note 29, at 4.

<sup>65</sup> See Katz & Shapiro, *supra* note 29, at 50-51; O’Brien & Wickelgren, *supra* note 29, at 162; Danger & Frech, *supra* note 29, at 349-51; Langenfeld & Li, *supra* note 29, at 308-09, 323; Michael Katz & Carl Shapiro, *Further Thoughts on Critical Loss*, 3 THE ANTITRUST SOURCE, Mar. 2004, at <http://www.abanet.org/antitrust/source/march04/katzshapiro.pdf>; Daniel O’Brien & Abraham Wickelgren, *The State of Critical Loss Analysis: Reply to Scheffman and Simons*, 3 THE ANTITRUST SOURCE, Mar. 2004, at <http://www.abanet.org/antitrust/source/march04/obrienwickel.pdf>. *But see* Scheffman & Simons, *supra* note 29, at 5 (disagreeing with critiques that attempt “to infer, with greater specificity, a value of AL [actual loss] from incremental margins and (too simple an) economic theory”).



elasticity for the candidate market.

Hospitals' experts commonly argue that merging hospitals' margins are high, which implies that the critical losses are low. They argue that post-merger price increases would be unprofitable because of the high per-unit foregone profits on lost sales. In essence, they argue that where the critical loss is low, the actual loss will exceed the critical loss. On this basis, they argue that relevant geographic markets for hospital mergers are broad.<sup>66</sup>

Yet, as discussed above, high margins also imply low demand elasticities. Low demand elasticities indicate that the merged firm's actual losses of sales would be low. Because the actual losses may be less than the critical losses when margins are high, the relevant geographic market may in fact be narrow.<sup>67</sup>

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<sup>66</sup> One panelist defended critical loss at the Hearings as an appropriate mechanism for analyzing proposed hospital geographic markets. Harris 3/26 at 167, 173-74. This panelist recommended that the parties and court closely examine documents, data, and testimony to determine the elasticity of demand and how many patients are likely to leave if faced with an anticompetitive price increase. Harris 3/26 at 222-24. He did not, however, address the argument that the premerger margin itself contains substantial information about the likely switching behavior of consumers.

<sup>67</sup> Katz & Shapiro advocate focusing on what they term the "aggregate diversion ratio" to indicate whether the elasticity of demand for the candidate market is sufficiently lower than the firm-level demand elasticities so that the candidate market is, in fact, a market. Suppose there are three products in the candidate market, A, B, and C, and the price of A is increased by five percent. The aggregate diversion ratio is the percentage of sales lost by A that is recaptured by B and C. Katz and Shapiro argue that the actual loss is less than the critical loss if

Other commentators also have described ways in which critical loss analysis has been carried out incorrectly, both for delineation of markets and for competitive effects analysis.<sup>68</sup> One article cites four key problems in how courts have applied critical loss analysis in recent hospital mergers.<sup>69</sup>

First, courts have failed to consider whether a price increase greater than five percent would be profitable. Second, courts have failed to consider the fact that high margins often mean a firm faces inelastic demand and, therefore, actual losses would be low. Third, courts did not consider that, if prices increased, some consumers might be diverted to one of the merged firms. Finally, courts have assumed, contrary to economic theory, that firms in the area

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and only if the aggregate diversion ratio exceeds the critical loss. Katz & Shapiro, *supra* note 29, at 53-54. *See also* O'Brien & Wickelgren, *supra* note 29, at 184 ("We have shown that the inference typically drawn from critical loss analysis – that high margins make a merger less likely to be anticompetitive – is often inconsistent with economic theory . . . . In our opinion, critical loss analysis has led to enormous confusion about the economic factors that govern firms' pricing incentives. The technique has been misused so frequently that arguments that are inconsistent with basic economic theory have almost gained a measure of legitimacy in antitrust cases.").

<sup>68</sup> Frech 3/26 at 189, *citing* to Danger & Frech, *supra* note 29. *See also* Langenfeld & Li, *supra* note 29, at 301, 313, 323-333; O'Brien & Wickelgren, *supra* note 29, at 162, 168-73, 177-84; Katz & Shapiro, *supra* note 29, at 50-51, 54-55.

<sup>69</sup> Langenfeld & Li, *supra* note 29, at 323-24, 332-33. Many of these same problems have been identified by other researchers. *See, e.g.*, Danger & Frech, *supra* note 29, at 341-42; O'Brien & Wickelgren, *supra* note 29, at 162, 184; Katz & Shapiro, *supra* note 29, at 52-55.

surrounding the merged firm would keep the same prices even though the merged firm raised its prices.<sup>70</sup> Thus, critical loss analysis may be useful in defining geographic markets and for competitive effects analysis only if it is applied appropriately.

### 3. Alternative Analytical Techniques

One panelist proposed an alternative analytical framework built on the observation that hospitals compete in two stages.<sup>71</sup> According to this panelist, the Agencies typically focus on first-stage competition, in which hospitals compete to be included in the networks of health plans. At this point, health plans are the buyers, and prices may be constrained if a health plan can credibly threaten to, or actually, exclude the merging hospitals from its provider network and divert patients to

alternative hospitals. The focus for defining the geographic market for this first stage of competition is on hospital locations, not patient locations.<sup>72</sup> Once a hospital is in the plan's network, or in some cases even if it is not, the hospitals then compete at the second stage – for the individual patient.

This panelist suggested that defendants typically focus on second-stage competition for patients and argue for broader geographic markets based on patient flow data.<sup>73</sup> This level of competition differs significantly from the first stage.<sup>74</sup> A two-stage analysis may result in different geographic markets and different competitive effects for each stage, because the two stages involve different customers, different means of competition, and different

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<sup>70</sup> Langenfeld & Li, *supra* note 29, at 332-333. The formula for critical loss is  $x/(x + m)$ , where  $x$  is the percentage price change of interest (e.g., 5%) and  $m$  is the premerger price cost margin  $((p-c)/p)$ , expressed as a percentage. In equilibrium,  $m = 1/\epsilon$ , where  $\epsilon$  is the elasticity of demand. If  $\epsilon$  is small and premerger margins are therefore high, it will also be true (by definition of elasticity) that a given price increase will induce only small changes in quantity. See O'Brien & Wickelgren, *supra* note 29, at 167-68; Katz & Shapiro, *supra* note 29, at 50-53; Danger & Frech, *supra* note 29, at 342-50; Langenfeld & Li, *supra* note 29, at 303-05, 334-337; *But see* Scheffman & Simons, *supra* note 29, at 5-8 (arguing that critiques of critical loss analysis that use the formula  $(m = 1/\epsilon)$ , or the Lerner Equation, use "the simplest economic model of pricing" to infer that actual loss would be equal or close to critical loss in equilibrium and thereby inappropriately shift the burden of proof to defendants).

<sup>71</sup> Vistnes 3/26 at 145-146; Vistnes Presentation, *supra* note 20, at 2, 4; Vistnes, *supra* note 35, at 671-692.

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<sup>72</sup> Vistnes 3/26 at 148; Vistnes Presentation, *supra* note 20, at 5; Vistnes, *supra* note 35, at 674-81, 692. See also Town 4/9 at 60-67 (discussing simulation study that showed significant post-merger price increases to HMOs even though an Elzinga-Hogarty analysis suggested little, if any competitive harm; this suggests that it is important to focus on the price negotiations between hospitals and payors and the ability of a payor to exclude a particular hospital if they cannot reach a price agreement).

<sup>73</sup> Vistnes 3/26 at 157-60; Vistnes Presentation, *supra* note 20, at 11-14; Vistnes, *supra* note 35, 671-74, 681-84, 688-92. See also Frech 3/26 at 196-98 (agreeing that with managed care, there are now two stages of competition, and that patient flow data is static and only reflects competition at the consumer or second-stage level, but not at the payor or first-stage level, because changes in payors' hospital networks move too slowly to be captured in the patient flow data).

<sup>74</sup> Vistnes 3/26 at 160; Vistnes Presentation, *supra* note 20, at 13-14; Vistnes, *supra* note 35, at 681-84.

evidence.<sup>75</sup> If anticompetitive effects are demonstrated at either stage, the merger should be enjoined, according to this panelist.<sup>76</sup>

Another panelist disagreed with the two-stage analysis, noting that it might be worth looking at “as a stylized construct,” but that “the appropriate model in which to analyze the factors that drive the pricing decisions and the profitability decisions of the hospitals are such that one cannot separate out the two stages.”<sup>77</sup> She suggested that the distinction is even less relevant now, because most plans have inclusive provider networks. In these circumstances, network inclusion provides no assurance that patients will seek care at a particular hospital.<sup>78</sup>

Another panelist submitted a joint statement proposing a different analytical framework for analyzing geographic markets in hospitals. The statement asserts that because potential patients select managed care organizations (*e.g.*, health insurers) prior to knowing what their medical needs will be, the subsequent *ex-ante* pricing makes the connection between patient flows

and pricing power tenuous.<sup>79</sup> For example, the statement suggests that “100% of patients place a high value on having access to a local hospital,” but if they are part of the 20 percent of the group that develop a serious medical condition, these same patients may be willing to travel any distance to go to the best hospital for their condition.<sup>80</sup>

As an alternative, the statement proposes a formal demand analysis model that would require data on patient and hospital characteristics in addition to the patient origin and destination data traditionally used. Although this model is more complex than patient flow analysis, the statement contends it provides “a measure of market power that, unlike patient flows, is theoretically valid for differentiated goods markets and is directly related to the prices that hospitals are able to charge.”<sup>81</sup>

## **B. Other Evidentiary Sources**

Panelists suggested numerous additional sources of evidence that should be

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<sup>75</sup> Vistnes 3/26 at 146-47; Vistnes Presentation, *supra* note 20, at 13-14; Vistnes, *supra* note 35, at 672-74, 688.

<sup>76</sup> Vistnes 3/26 at 160; Vistnes Presentation, *supra* note 20, at 14; Vistnes, *supra* note 35, at 672-73.

<sup>77</sup> Guerin-Calvert 3/26 at 230.

<sup>78</sup> *Id.* at 230-31. *But see* Vistnes 3/26 at 243 (arguing that even if all hospitals are in a plan’s network today, as long as the plan can credibly threaten to exclude the hospital, that possibility of exclusion is a constraint on pricing).

<sup>79</sup> Capps et al. (stmt), *supra* note 42, at 5.

<sup>80</sup> *Id.* at 5-6.

<sup>81</sup> *Id.* at 6. The authors refer readers to another paper (Cory Capps et al., *Competition and Market Power in Option Demand Markets* (April 2003) (unpublished manuscript)), in which they “provide a step by step derivation and empirical implementation of a market power measure that correctly incorporates the *ex-ante* nature of hospital pricing.” *Id.* at 6-7. These authors also published another article outlining option demand analysis, as well as two other analyses. The authors suggest that the other two analytical techniques are not as accurate as the formal option demand analysis, but they are useful in defining hospital geographic markets. *See* Capps et al., *Antitrust Policy*, *supra* note 42, at 681.

used to establish the geographic market for hospital services. The recommended sources include types of evidence typically assessed in non-hospital merger cases: strategic planning documents and testimony from the merging parties and their competitors, and documents and testimony from major purchasers of services from the merging parties – here, third-party payors.

Panelists also suggested the use of evidence that casts direct light on the distances patients are willing to travel and the reasons they are willing to do so, and evidence that demonstrates the role, if any, physicians can play in defeating a hospital’s post-merger, anticompetitive price increases. Each of these categories of evidence are considered below.

## 1. Hospital Strategic Planning Documents

The Agencies typically examine strategic planning documents from the merging parties and their competitors to assess relevant market and other key issues in merger analysis. Panelists suggested using strategic planning documents from the hospitals to help establish the proper geographic market.<sup>82</sup> Such documents may specify the geographic regions in which a hospital is marketing its services and the hospitals it sees as its primary competition.<sup>83</sup>

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<sup>82</sup> *Guerin-Calvert* 3/26 at 141-43, 226, 237-39; *Harris* 3/26 at 223.

<sup>83</sup> *See, e.g.*, *Guerin-Calvert* 3/26 at 141 (stating that documents show who the hospitals see as their competitors and strategic plans of hospitals competing with merging hospitals often show strategies for taking patients from another hospital); *Guerin-Calvert* Presentation, *supra* note 20, at 12.

In addition, a hospital’s strategic planning documents frequently disclose the hospital management’s assessment of the extent to which the proposed merger will increase the hospital’s negotiating power and its ability to raise prices. Hospital strategic planning documents can illuminate hospital competition for both inclusion in payor networks and for individual patients.

## 2. Payor Testimony

For non-hospital mergers, the Agencies regularly obtain the views of the merging firms’ major customers to assess issues such as relevant market definition and competitive effects. These market participants typically have the most price negotiation experience with the merging firms, as well as the most to lose from price increases (or quality or other degradations) if the proposed merger were to create market power. On the other hand, major customers also have much to gain from reduced prices if the proposed merger would likely create efficiencies that would be passed on to customers.

Courts, however, have been skeptical about testimony from third-party payors in hospital merger cases, even though these payors routinely negotiate with hospitals about price and other aspects of hospital care. In *Tenet*, for example, the Eighth Circuit questioned the district court’s reliance on payor testimony that they “would unhesitatingly accept a price increase rather than steer their subscribers to hospitals” outside of the core geographic area.<sup>84</sup> The Eighth Circuit believed that, although the

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<sup>84</sup> *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 & n.14 (8th Cir. 1999).

testimony might have been truthful, the payors “spoke to current competitor perceptions and consumer habits and failed to show where consumers could practically go for inpatient hospital services.”<sup>85</sup>

By contrast, panelists stated that payors can offer useful testimony on at least two distinct issues.<sup>86</sup> Payors have considerable insight into hospital geographic markets, because they must factor such matters into their decision whether to contract with a hospital in the first instance. Payors must strive to include a sufficient number of hospitals in each geographic market, because if they fail to do so, the plan is less appealing to purchasers, including benefit managers that must make recommendations and decisions for employers and other group purchasers.<sup>87</sup> Accordingly, payors can offer useful testimony on the extent to which particular hospitals engage in price and non-price competition with one another.

Second, panelists suggested that payor testimony also would be helpful in determining whether payors can steer patients to a lower-cost hospital if prices

increase post-merger.<sup>88</sup> Several panelists noted that payors used to create marketable plans with limited provider networks and thus could exclude a hospital if its prices were not acceptable to the plan.<sup>89</sup> Today, many consumers demand choice and open provider networks.<sup>90</sup> Therefore, payors frequently rely on mechanisms other than excluding hospitals to divert marginal

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<sup>85</sup> *Tenet Health Care*, 186 F.3d at 1054 & n.14. *See also* Greaney 2/27 at 142 (finding it inexplicable that two circuits have “adopted an evidentiary rule of thumb that discounts the credibility of the testimony of third party payers on facts that are really central to their business ... when [the testimony is] unimpeached, not impeached by a showing of bias or other defects”).

<sup>86</sup> *See, e.g.*, Leibenluft 3/28 at 15-16; Vistnes 3/26 at 147-57.

<sup>87</sup> *See, e.g.*, Vistnes 3/26 at 148-50; Eisenstadt 3/28 at 60-61.

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<sup>88</sup> *See, e.g.*, Guerin-Calvert 3/26 at 140-43 (suggesting looking not only at what payors say about which hospitals are critical to their networks, but at what payors have done in the past to respond to different market behaviors, such as price increases or quality decreases); Guerin-Calvert Presentation, *supra* note 20, at 13, 16, 18; *see also* Singer 3/28 at 37-38; Toby Singer, *Issues in Litigating Hospital Mergers 2-5* (3/28) (“In particular, the courts have not been willing to believe the testimony of health plans and others when it is contradicted by other evidence, such as statistical evidence on market definition,” *citing to California v. Sutter Health System*, 84 F. Supp. 2d 1057 (N.D. Cal.), *aff’d mem.*, 2000-1 Trade Cas. (CCH) ¶87,665 (9th Cir. 2000), *revised*, 130 F. Supp. 2d 1109 (N.D. Cal. 2001)); *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121 (E.D.N.Y. 1997); *Adventist Health System/Est*, 114 F.T.C. 458 (1991), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030328singertoby.pdf>; Argue 3/28 at 49-51.

To be sure, a court will wish to assess the consistency of a witness’s testimony with its documents and evidence of its previous actions. With respect to payor testimony, however, some judicial skepticism appears to be based, at least in part, on patient flow data. For the reasons discussed *supra*, patient flow data does not provide reliable information about what payors could do if faced with hospital price increases.

<sup>89</sup> Guerin-Calvert 3/26 at 138-39.

<sup>90</sup> *Id.* at 138-39. Some believe that the recent increases in insurance premiums are, at least in part, due to these demands for more choice and broader provider networks. *See supra* Chapter 1 and *infra* Chapter 5.

consumers to lower-cost alternatives.<sup>91</sup> For example, payors are currently experimenting with tiered networks that provide differing levels of coverage and co-payments based on the facility at which care is received.<sup>92</sup> Testimony regarding the feasibility and performance of such strategies would be helpful in determining the alternatives available to payors in the event of post-merger price increases.<sup>93</sup>

Panelists expressed different views on whether and to what extent payors can “steer” patients and the types of evidence that can help answer this question. One panelist noted that if payors actually can steer patients to (or away) from particular institutions, the distances traveled to hospitals should have grown in parallel with the rise of managed care.<sup>94</sup> In fact, the panelist noted, the distances patients travel to hospitals have not changed very much since the mid-1980s, and there is little distinction between the distances traveled

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<sup>91</sup> Guerin-Calvert 3/26 at 134, 141 (referring to cases where payors were able to move marginal patients); Vistnes 3/26 at 152-56 (listing possible strategies payors could use to divert patients: dropping a hospital from the network; adding hospitals to the network to “dilute” the patient base; creating incentives for patients to switch hospitals; creating incentives for physicians to admit elsewhere; and changing the physician panel); Vistnes Presentation, *supra* note 20, at 8; Harris 3/26 at 180 (stating payors use various mechanisms to shift patient choices, including different copays and deductibles, tiered plans, and cafeteria plans).

<sup>92</sup> See *supra* Chapter 3.

<sup>93</sup> See, e.g., Guerin-Calvert 3/26 at 140-43; Frech 3/26 at 186-88.

<sup>94</sup> Frech 3/26 at 186-88.

for HMO versus non-HMO patients.<sup>95</sup> Based on this evidence, the panelist maintained that courts should not assume that payors can effectively steer patients in response to price increases.<sup>96</sup>

Another panelist suggested that patient flow data may help show whether and, if so, how payors can steer patients.<sup>97</sup> This panelist asserted that payors have had enough success in moving marginal consumers to lower-cost hospitals that, in most cases, they can discipline hospital price increases.<sup>98</sup> She also concluded that in many cases, even if payors testify accurately that they must have the merging parties in their networks, that is not necessarily sufficient to give the hospitals unilateral power over

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<sup>95</sup> *Id.* See also H. E. Frech III & Lee Rivers Mobley, *Managed Care, Distance Traveled and Hospital Market Definition*, 37 INQUIRY 369-384 (2000).

<sup>96</sup> Frech 3/26 at 186-88; Zwanziger 3/26 at 98-99 (describing research that suggests that travel distance is the most important criteria for a patient in deciding which hospital to use, and in California, where managed care penetration went from 20 percent to 90 percent over a specific period of time, the average travel distance changed very little over that same period).

<sup>97</sup> Guerin-Calvert 3/26 at 134, 137, 141. *But see* Frech 3/26 at 197 (noting that turn-over among the hospitals included in a plan is sufficiently infrequent that patient flow data will often not capture the dynamics of first-stage competition).

<sup>98</sup> Guerin-Calvert 3/26 at 140-41, 143; see also Guerin-Calvert 3/26 at 252 (describing documents in some markets that have included letters from plans to physicians to use one hospital more than another, and patient flow data subsequently showed the shift of enrollees from one hospital to another).

price.<sup>99</sup>

Other panelists were more skeptical about these claims. One panelist stated that, although in theory payors have mechanisms they could use to divert patients to other hospitals, in practice these tactics are often costly and counter-productive to a health plan's marketability and profitability.<sup>100</sup> This panelist argued that it is difficult (if not impossible) to target incentives to the insured consumers who are most likely to be affected. A payor must consider the cost of providing a lower copayment to all patients, not just the marginal patients the payor is trying to steer.<sup>101</sup> Moreover, other hospitals may have higher prices than the merged hospitals, even assuming price increases as a result of the merger.<sup>102</sup>

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<sup>99</sup> See Guerin-Calvert 3/26 at 141-43 (noting that it is rare to find a compelling coordinated-effects story in hospital markets and that the Chattanooga case is the one exception where the court accepted a coordinated effects theory of harm, referring to the Seventh Circuit opinion in *Hospital Corp. of America v. FTC*, 807 F.2d 1381 (7th Cir. 1986)); Guerin-Calvert Presentation, *supra* note 20, at 18.

<sup>100</sup> Vistnes 3/26 at 150-60.

<sup>101</sup> *Id.* at 154-56.

<sup>102</sup> Vistnes 3/26 at 156; Vistnes Presentation, *supra* note 20, at 9. *But see* *FTC v. Tenet Healthcare Corp.*, 186 F.3d 1045, 1054 & n.14 (8th Cir. 1999), *rev'g* finding for plaintiff in *FTC v. Tenet Health Care Corp.*, 17 F.Supp. 2d 937 (E.D. Mo. 1998) (finding that district court erred in rejecting more distant hospitals that were more costly because in doing so it "underestimated the impact of nonprice competitive factors, such as quality").

### 3. Patients' Willingness to Travel – How Far and Why?

Several panelists suggested that courts should give more weight to empirical studies of patients' willingness to travel to receive health care. Studies indicate that most patients prefer to be hospitalized close to their homes.<sup>103</sup> Some patients appear willing to travel long distances for very serious or complicated procedures, but many patients prefer to receive such care in their local hospital, even if their local hospital has higher mortality rates and less experience with such procedures.<sup>104</sup> Some patients are willing to receive care in a distant city because they work or have family in that city, or because of the hospital's religious affiliation.<sup>105</sup>

Several panelists noted that such migration patterns are unlikely to be price sensitive, yet the application of the Elzinga-Hogarty test and critical loss analysis would result in a large geographic market in such circumstances, if enough patients traveled

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<sup>103</sup> See, e.g., Zwanziger 3/26 at 97-99; Zwanziger Presentation, *supra* note 34, at 10; Frech 3/26 at 186-88. See generally Robert Town & Gregory Vistnes, *Hospital Competition in HMO Networks*, 20 J. HEALTH ECON. 733, 746-48 (2001).

<sup>104</sup> See, e.g., Zwanziger Presentation, *supra* note 34, at 9-10; Zwanziger 3/26 at 97-99. See generally Town & Vistnes, *supra* note 103, at 746-48.

<sup>105</sup> Zwanziger 3/26 at 98; see also Frech 3/26 at 194 ("[C]ustomers migrate from small towns to larger cities for idiosyncratic reasons ... [including h]igher quality, more sophisticated services, [and] family connections.").

for these non-price reasons.<sup>106</sup>

#### **4. Physicians' Willingness and Ability to Steer Patients to Less Expensive Alternatives**

Several hearing participants suggested that payors may be able to provide financial incentives to physicians to steer patients to less expensive hospitals.<sup>107</sup> Some of the proposals included requiring physicians to agree to a financial risk-sharing contract, threatening physicians with exclusion from a plan's network, imposing financial penalties on physicians who admit patients to the higher-priced hospitals, and providing bonuses to physicians who admit to lower-priced hospitals.<sup>108</sup>

Even though such incentives are theoretically possible, it does not follow that payors would find them useful or desirable.<sup>109</sup> Indeed, such incentives could make a plan less marketable to employers and consumers who value open networks and unrestricted access to health care. Such incentives also could interfere with continuity of care, particularly if patients must use a different physician when they are

diverted to a different hospital.<sup>110</sup> These incentives also are unlikely to be effective if they require patients to travel long distances and physicians to travel those same distances to provide care.

#### **C. Summary**

The definition of a relevant geographic market has proven to be one of the most daunting components of a hospital merger case. Nonetheless, some guiding principles are clear. The hypothetical monopolist test of the *Merger Guidelines* should be used to define geographic markets in hospital merger cases. The types of evidence used in *all* merger cases – such as strategic planning documents of the merging parties and customer testimony and documents – should also be used to delineate relevant geographic markets in hospital merger cases. The Agencies believe that courts have given insufficient weight to payor testimony and documents in particular.

Empirical evidence is desirable on certain issues, such as the extent of patients' willingness to travel to distant hospitals in response to a small, but significant and non-transitory increase in price. Patient willingness to travel for non-price related reasons does not provide a sufficient basis to infer patient willingness to travel to distant hospitals in response to price increases.

The Agencies encourage further

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<sup>106</sup> See, e.g., CAPPS ET AL., SILENT MAJORITY, *supra* note 42; Capps et al. (stmt), *supra* note 42, at 1-6, 9; Zwanziger 3/26 at 97-99; Frech 3/26 at 194.

<sup>107</sup> Guerin-Calvert 3/26 at 252; Vistnes 3/26 at 153.

<sup>108</sup> See, e.g., Vistnes 3/26 at 153-57.

<sup>109</sup> See, e.g., *id.*

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<sup>110</sup> *Id.* at 153-54, 156-58 (suggesting looking at whether there are overlapping hospitals where physicians have or could likely have admitting privileges or determining how far physicians are willing to travel to perform daily rounds at the hospitals in which they have patients admitted).



research to determine the circumstances in which patients will travel to distant hospitals in response to price increases. Empirical evidence also is desirable on the extent to which physicians can and will steer patients to lower-cost hospitals in response to price increases. To be persuasive, direct evidence should show that such steering by physicians is feasible, cost-effective, and likely.<sup>111</sup> The Agencies also encourage additional research to validate or refute the alternative analytical techniques discussed *supra*.

To date, and for the reasons discussed *supra*, the Agencies' experience and research indicate that the Elzinga-Hogarty test is not valid or reliable in defining geographic markets in hospital merger cases. In addition, if critical loss analysis is used, it must be used with great care to avoid the problems of application discussed in this section. The use of the Elzinga-Hogarty test and the misapplication of critical loss analysis has led some courts to find hospital geographic markets that are improbably large.

### III. PRODUCT MARKET DEFINITION

The *Merger Guidelines* provide the framework for defining the relevant product market for hospital services. The product market has typically been defined as a broad group of medical and surgical diagnostic and treatment services for acute medical conditions where the patient must remain in a health care facility for at least 24 hours for

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<sup>111</sup> Some steering mechanisms could implicate federal and/or state anti-kickback and physician self-referral laws. See *supra* Chapter 1.

recovery or observation.<sup>112</sup>

Over the past twenty years, many hospital merger cases have considered and rejected outpatient services as part of the relevant product market for hospitals. For example, in *In re Hospital Corp. of America*, 106 F.T.C. 361 (1985), the Commission noted that, although outpatient care for certain services might be a separate relevant market or markets, the evidence demonstrated "that the core and vast majority of an acute care hospital's business is acute inpatient care" and non-hospital outpatient providers could not defeat post-merger anticompetitive behavior affecting hospital inpatients.<sup>113</sup>

The Seventh Circuit agreed, observing that "although hospitals increasingly are providing services on an out-patient basis ... most hospital services cannot be provided by nonhospital providers; as to these, hospitals have no competition from other providers of medical services."<sup>114</sup> Similarly, in *American Medical*

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<sup>112</sup> In *American Medical International, Inc.* and *Hospital Corp. of America*, the FTC defined the relevant product market as a group of general acute care hospital services. Am. Med. Int'l, 104 F.T.C. 1, 107 (1984); *In re Hosp. Corp. Am.*, 106 F.T.C. 361 (1985), *aff'd*, 807 F.2d 1381 (7th Cir. 1986).

<sup>113</sup> *Hosp. Corp. Am.*, 106 F.T.C. at 466. In that case, the Commission noted that although "the types of surgical procedures which can be handled on an outpatient basis by surgicenters are increasing, this suggests only that the cluster of inpatient services offered by acute care hospitals is changing and does not indicate that hospitals are becoming head-to-head competitors with such outpatient providers." *Id.*

<sup>114</sup> *Hosp. Corp. Am.*, 807 F.2d at 1388. Similarly, in *United States v. Rockford Memorial Corp.*, 898 F.2d 1278, 1284 (7th Cir. 1990), the

*International*, 104 F.T.C. 1 (1984), the Commission excluded outpatient services from the product market.<sup>115</sup> The Eleventh Circuit also accepted inpatient acute-care services as the relevant product market in *University Health*.<sup>116</sup> Only one court has included outpatient providers within the product market for inpatient services.<sup>117</sup>

Panelists agreed that providers of outpatient services, such as physicians' offices, urgent care centers, and ambulatory surgery centers, should generally not be included in the product market definition for hospital services.<sup>118</sup> Panelists indicated that from the perspective of payors and patients, inpatient services are complementary and bundled.<sup>119</sup> Even if hospital prices are

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Seventh Circuit again affirmed the product market definition as the "provision of inpatient services by acute-care hospitals," noting that other providers cannot compete for many acute-care hospital services. The court further explained that, although patients can choose in-patient hospital care or outpatient providers for some services, those services that can be provided on an outpatient basis are not a check on acute-care in-patient services, because the prices of the two are not linked.

<sup>115</sup> See *Am. Med. Int'l*, 104 F.T.C. at 107.

<sup>116</sup> *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1210-11, 1219 (11th Cir. 1991).

<sup>117</sup> *United States v. Carilion Health Sys.*, 707 F. Supp. 840 (W.D. Va.), *aff'd*, 892 F.2d 1042 (4th Cir. 1989) (unpublished opinion).

<sup>118</sup> See, e.g., *Sacher 3/26* at 66-70; *Zwanziger 3/26* at 95-96, 104-106.

<sup>119</sup> *Sacher 3/26* at 69-70; Seth Sacher, *Issues in Defining the Product Market for Hospital Services* 5 (3/26) (slides) [hereinafter *Sacher Presentation*], at <http://www.ftc.gov/opp/hc/030326sethsacher.pdf>; *Sacher & Silvia*, *supra* note 18, at 183-85. See also *Zwanziger 3/26* at 92-98 (discussing heterogeneity on

increased, patients and payors cannot separate nursing care, diagnostic tests, and room and board from the other treatments provided as part of a hospital stay and out-source them.<sup>120</sup> Similarly, demand-side substitution is improbable; a cancer or heart attack patient is not going to substitute obstetrical care if prices for cancer care or heart attacks increase. Because outpatient treatment is generally not a substitute for inpatient care, there was agreement among the panelists that outpatient providers are (and were) correctly excluded from the product market.<sup>121</sup>

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both the supply- and demand-side and suggesting that markets should be defined more narrowly to reflect the different treatments provided and requested); *Zwanziger Presentation*, *supra* note 34, at 2.

See *Am. Med. Int'l*, 104 F.T.C. at 107 ("Although each individual service that comprises the cluster of general acute care hospital services may well have outpatient substitutes, the benefit that accrues to patient and physician is derived from their complementarity. There is no readily available substitute supplier of the benefit that this complementarity confers on patient and physician. This is consistent with record evidence that shows that those in the market only recognized other hospitals, not suppliers of individual hospital services, as their competitors.")

<sup>120</sup> *Sacher 3/26* at 69-70.

<sup>121</sup> *Zwanziger 3/26* at 95-96; *Zwanziger Presentation*, *supra* note 34, at 6; see, e.g., *Univ. Health*, 938 F.2d at 1210-11; *United States v. Rockford Mem'l Corp.*, 898 F.2d 1278, 1284 (7th Cir. 1990) (Posner, J.); *Hosp. Corp. Am. v. FTC*, 807 F.2d 1381, 1388 (7th Cir. 1986) (Posner, J.), *aff'ing In re Hosp. Corp. Am.*, 106 F.T.C. 361 (1985). One panelist stated that despite the general acceptance of this definition, both the parties and the courts have suggested subtle differences in the product market definition over the years. *Sacher 3/26* at 65; *Sacher Presentation*, *supra* note 119, at 6-7; *Sacher & Silvia*, *supra* note 18, at 185-87, *citing Carilion Health Sys.*, 707 F. Supp. at 844-45 (noting the district court held

In the future it is likely that the Agencies will have to determine whether certain specialty hospitals should be included in an inpatient product market for particular proposed hospital mergers.

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product market included certain clinics and other providers of outpatient services, because, in a significant number of cases, “patients or their doctors can choose to have problems treated either in a hospital or in an outpatient clinic or doctor’s office”); *Rockford Mem’l*, 898 F.2d at 1284 (excluding outpatient services, and specifically stating that it found the district court’s discussion in *Carilion* “unpersuasive as well as inconsistent with [its] analysis in *Hospital Corporation of America*” and that the Fourth Circuit’s opinion affirming the district court was nonprecedential because the Fourth Circuit chose not to publish it); *United States v. Mercy Health Services*, 902 F. Supp. 968 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997) (excluding inpatient psychiatric care, substance abuse treatment, rehabilitation services, and open heart surgery); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 138-40 (E.D.N.Y. 1997) (rejecting DOJ’s argument that the relevant product market was “the bundle of acute care inpatient services provided by anchor hospitals to managed care plans,” and found separate primary/secondary care and tertiary care product markets based on its conclusion that the geographic markets for these services differed); and *FTC v. Tenet Healthcare Corp.*, 17 F. Supp. 2d 937, 943 (E.D. Mo. 1998), *rev’d* 186 F.3d 1045 (8th Cir. 1999) (product market included primary and secondary acute care inpatient services, but excluded tertiary and quaternary services).

The federal district court in *Carilion* refused to draw a line between inpatient and outpatient services, noting that primary care provided in hospital emergency departments and specialty clinics, as well as hospital-based outpatient surgery, chemotherapy, and radiology may compete to some degree with physicians’ office-based care and other free-standing health care. *Carilion Health Sys.*, 707 F. Supp. at 844-45. Other entities may include ambulatory surgical and imaging centers (*e.g.*, x-ray, CT, MRI). *Hosp. Corp. Am.*, 106 F.T.C. 361 (1985); *see also* *Sacher* 3/26 at 75.

Historically, the type of specialty hospital (children’s, psychiatric, VA, military, and rehabilitation) justified its exclusion from the product market.<sup>122</sup> In recent years, specialty hospitals focusing on cardiac or orthopedic care have emerged in numerous locations.<sup>123</sup> General acute-care hospitals view these specialty hospitals as competition in the provision of such services and have responded in a variety of ways.<sup>124</sup>

Several panelists discussed an approach for defining an inpatient hospital product market more narrowly. Instead of treating acute inpatient treatment as an aggregated group, panelists suggested the possibility of grouping diagnosis related groups (DRGs) together, based upon the

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<sup>122</sup> Psychiatric and rehabilitation hospitals provide a limited scope of care and do not offer general acute care services. Children’s and VA hospitals provide inpatient acute care similar to general acute care hospitals, but are dedicated to a specific group. Although a children’s hospital might compete with a general hospital for a subset of the general hospital’s patients, non-veterans cannot substitute the VA for a general hospital. *But see* *Eisenstadt* 3/28 at 59 (discussing issues about mergers between complements generally and, specifically, a merger between the premier adult hospital system and the premier children’s hospital in the Pittsburgh, Pennsylvania area. He noted that although “there would be some modest to slight or slight to modest increase in concentration in pediatrics, that was not the principal concern; rather, the primary concern related to the proposed combination of the preferred adult system and the premium pediatric hospital. In other words, the two premier brand manufacturers were merging. There was concern expressed about post-merger bundling, denial of access to Children’s or unilateral price increases” at one or more of the merging hospitals).

<sup>123</sup> *See supra* Chapter 3.

<sup>124</sup> *Id.*

types of diseases and medical conditions treated by particular types of physicians.<sup>125</sup> In one study, this approach resulted in 48 service categories. Patient flow data can be separately analyzed for each category.<sup>126</sup> Panelists recognized, however, that payors generally do not disaggregate services this finely.<sup>127</sup>

*Conclusion.* The Agencies continue to believe that inpatient acute-care services constitute a relevant product market. At the same time, the percentage of total health

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<sup>125</sup> Sacher 3/26 at 80-83; Sacher & Silvia, *supra* note 18, at 184, 190-98; Zwanziger 3/26 at 95-96; Zwanziger Presentation, *supra* note 34, at 5-7. DRGs are a system for determining hospital compensation based on the discharge diagnosis. Similar illnesses are aggregated together, and the hospital is paid a set amount per DRG, irrespective of the actual cost associated with the provision of services. Medicare and many private insurers use this system to compensate hospitals.

<sup>126</sup> Sacher 3/26 at 80-83; Sacher & Silvia, *supra* note 18, at 184, 190-98.

<sup>127</sup> Panelists noted that payors typically categorize services and hospitals by the complexity of care; some hospitals provide primary, secondary, and tertiary levels of care, others only primary or secondary. Zwanziger 3/26 at 95. One panelist noted that many payors believe they must have at least one tertiary care center in their hospital networks in order to compete for members. Zwanziger 3/26 at 95. Another panelist also noted that properly defining the relevant product market, such as determining whether tertiary care is or is not a part of the relevant market, is a prerequisite to properly defining hospital geographic markets. For example, if tertiary care is excluded from the relevant product market, neither patient flow data or other evidence related to tertiary care is relevant to geographic market definition. *See* Vistnes, *supra* note 35, at 684, 687-88. *See also* Guerin-Calvert 3/26 at 128-29 (discussing differences about geographic market definition often stem from disagreements about the product market definition).

care spending devoted to outpatient care is growing, and the percentage devoted to inpatient care is declining. Over time, the level of payment and changes in technology may shift the provision of many inpatient services into the outpatient setting.<sup>128</sup> The Agencies will continue to examine whether services provided in outpatient settings may constitute additional relevant product markets, and if so, whether those services might be adversely affected by a hospital merger. The Agencies will also continue to examine the competitive significance of specialty hospitals, including whether and under what circumstances payors might discipline prices for cardiac or other services at general acute care hospitals by shifting a larger percentage of patients to specialty hospitals that provide such services.

Although the Agencies currently doubt the advisability and practicability of conducting separate product market analyses for many discrete markets – particularly when payors do not define the product they are purchasing in this fashion – the Agencies will continue to examine whether smaller product markets exist in addition to the traditional product market definition. For example, if more specialized medical procedures raise more competitive concerns than primary care services, there may be some circumstances in which the product market should be defined narrowly to include only a specific service or limited number of services. Similarly, it is possible that expertise in one or more specific specialties may make a hospital a “must have” hospital for a payor’s network, which could justify a separate product market

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<sup>128</sup> *See, e.g.*, Sacher 3/26 at 75.

analysis.<sup>129</sup>

#### IV. ENTRY

The *Merger Guidelines* provide that entry should be considered if it is likely to occur within two years and to be sufficient to deter or counteract anticompetitive effects of a proposed hospital merger.<sup>130</sup> Entry into the inpatient general acute care hospital services market by constructing a new hospital or adding additional beds to an existing facility is likely to exceed this time-frame. If the state requires that a Certificate of Need (CON) be granted before building a new hospital or increasing bed capacity, the approval of the CON can take anywhere from 18 months to several years.<sup>131</sup> Compliance with other regulations will require additional time. Thus, the likelihood of timely and sufficient entry into the inpatient general acute care hospital services market is remote.

#### V. EFFICIENCIES

The *Merger Guidelines* make clear that efficiencies should be evaluated before determining whether a proposed merger is

likely to be pro- or anti-competitive.<sup>132</sup> Under the *Merger Guidelines*, the Agencies will not challenge a merger if cognizable efficiencies are of a character and magnitude such that the merger is not likely to be anticompetitive in any relevant market.<sup>133</sup> Efficiencies are cognizable when they are (1) merger-specific, (2) have been verified, and (3) do not arise from anticompetitive reductions in output or service.<sup>134</sup>

Hospitals often claim that their merger will produce significant efficiencies, and some courts have given significant weight to these arguments. Claimed efficiencies have included avoidance of capital expenditures, reductions in management and operational support jobs, consolidation of specific services to one location (*e.g.*, all cardiac care at Hospital A and all cancer treatments at Hospital B), and reducing operational costs, such as purchasing and accounting.

Some hospitals claim that after the merger they will be able to provide better and more complex services to their patients. For example, in *Tenet* the merging hospitals claimed they would realize significant efficiencies, including: eliminating unused

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<sup>129</sup> *But see* United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121, 138-40 (E.D.N.Y. 1997) (rejecting DOJ's argument that the relevant product market was "the bundle of acute care inpatient services provided by anchor hospitals to managed care plans").

<sup>130</sup> MERGER GUIDELINES, *supra* note 9, § 3.

<sup>131</sup> The FTC has opposed state CON requirements as an unnecessary impediment to competition in health care markets. See discussion *infra* Chapter 8 for a more detailed discussion of CON regulations and the competitive issues surrounding them.

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<sup>132</sup> MERGER GUIDELINES, *supra* note 9, § 4 (as revised April 8, 1997).

<sup>133</sup> *Id.* § 4.

<sup>134</sup> Merger-specific efficiencies are "only those efficiencies likely to be accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects." MERGER GUIDELINES, *supra* note 9, § 4. Cognizable efficiencies are assessed "net of costs produced by the merger or incurred in achieving those efficiencies." *Id.*

beds, bringing open heart surgery to Poplar Bluff, decreasing operating costs, consolidating services, reducing staff levels, and avoiding capital expenditures.<sup>135</sup> The district court rejected the hospitals' efficiency claims. The Eighth Circuit found that, although the district court may have properly rejected the hospitals' efficiencies, it should have nonetheless considered the claim that the merged entity would provide better care to its patients. The appellate court stated that "[t]he reality of the situation in our changing healthcare environment may be that Poplar Bluff cannot support two high-quality hospitals;" and admonished the district court for placing "an inordinate emphasis on price competition."<sup>136</sup>

Some panelists were skeptical about efficiency claims. Several panelists pointed out that promised efficiencies may not materialize.<sup>137</sup> One panelist noted that

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<sup>135</sup> *FTC v. Tenet Healthcare Corp.*, 17 F. Supp. 2d 937, 948 (E.D. Mo. 1998), *rev'd on other grounds*, 186 F.3d 1045 (8th Cir. 1999).

<sup>136</sup> *Tenet Healthcare Corp.*, 186 F.3d at 1055, 1054.

<sup>137</sup> *See, e.g.*, Taylor 4/11 at 162-169; Balto 4/11 at 207-210 (noting that Blodgett/Butterworth's claimed efficiencies were mostly in avoidance of capital expenditures, yet the hospitals have made significant capital investments and claim they have achieved \$300 million in efficiencies). *See also* Paul Pautler, *Evidence on Mergers and Acquisitions*, 48 ANTITRUST BULL. 119, 160-64, 172-76 (2003) (reviews several studies that looked at post-merger effects on prices and efficiencies, noting one study found that the efficiencies may take a long time to appear and that some studies found cost and price reductions, and others found few efficiencies and significant price increases); David Balto & Meleah Geertsma, *Why Hospital Merger Antitrust Enforcement Remains Necessary: A Retrospective on the Butterworth Merger*, 34 J. HEALTH L. 129 (2001).

efficiency studies are often conducted to support the HSR filing that the merging parties must make with the Agencies; this provides incentives for the parties to estimate unrealistically high savings.<sup>138</sup> Another noted that mergers can be great failures if hospitals do not have specific plans or are not willing to make tough decisions at the outset, such as closing facilities and consolidating hospital-based physician groups.<sup>139</sup> Institutional constraints can make it difficult for merged hospitals to combine and coordinate clinical operations.<sup>140</sup>

For example, in *Butterworth*, the district court accepted the merging hospitals' claims that the proposed merger would result in efficiencies in excess of \$100 million in the form of capital expenditure avoidance and operating efficiencies.<sup>141</sup> One

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*But see* Spectrum Health, *Comments Regarding Hearings on Health Care Competition Law and Policy 1* (Public Comment) (arguing that in connection with the Butterworth/Blodgett merger "[o]perational efficiencies have saved the community \$373 million through 2001") [hereinafter Spectrum (public cmt)].

<sup>138</sup> Taylor 4/11 at 162-169.

<sup>139</sup> Hopping 4/11 at 184-86 (she also noted mergers can be successful).

<sup>140</sup> *See, e.g.*, Balto 4/11 at 209-10 (noting failure to consolidate services at Blodgett/Butterworth because of physician resistance); Hopping 4/11 at 183-90 (noting she has been associated with hospital mergers that have realized efficiencies, but to work, the hospitals must have a specific plan and must be willing to make very hard choices).

<sup>141</sup> *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1300-1301 (W.D. Mich. 1996), *aff'd by an unpublished opinion*, 1997-2 Trade Cas. (CCH) ¶

panelist reported, however, that Blodgett/Butterworth never closed Blodgett and consolidated services, at least in part because physician groups did not want the facility closed.<sup>142</sup> Another panelist stated that, six years after the merger, Blodgett/Butterworth had realized less than half of the \$100 million of claimed efficiencies.<sup>143</sup>

Scholars have conducted numerous studies on the effect of hospital mergers on hospital costs.<sup>144</sup> The results are mixed: some studies have found that merged hospitals enjoy lower costs (or lower rates of cost increase) than nonmerging hospitals; others have found no differences in cost experience between merging hospitals and

otherwise similar nonmerging facilities. One recent study found that the degree of cost savings that merging hospitals realize varies significantly depending on the extent of consolidation. According to this study, hospitals operating under a single license post-merger generate “significant, robust, and persistent” savings.<sup>145</sup> In contrast, those hospitals that conduct business under separate licenses post-merger do not generate cost reductions. The authors attribute this difference to the ability of more fully merged hospitals to undertake substantial changes in the way they operate (including consolidation of services) that are not available to hospitals operating under separate licenses.<sup>146</sup>

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71,863 (6th Cir. 1997) (district court also noted that the efficiencies are, “by any account, a substantial amount, and represent savings that would, in view of defendants’ nonprofit status and the Community Commitment, invariably be passed on to consumers”).

<sup>142</sup> Balto 4/11 at 209-10.

<sup>143</sup> Taylor 4/11 at 167.

<sup>144</sup> Jeffrey A. Alexander et al., *The Short-Term Effects of Merger on Hospital Operations*, 30 HEALTH SERVICES RES. 827 (1996); Robert A. Connor et al., *Which Types of Hospital Mergers Save Consumers Money?* 16 HEALTH AFFAIRS 62 (Nov./Dec.1997); Robert A. Connor et al., *The Effects of Market Concentration and Horizontal Mergers on Hospital Costs and Prices*, 5 INT’L J. ECON. BUS. 159 (1998); David Dranove & Mark Shanley, *Cost Reductions Versus Reputation Enhancements as Motives for Mergers: The Logic of Multihospital Systems*, 16 STRATEGIC MGMT. J. 55 (1995); David Dranove et al., *Are Multihospital Systems More Efficient?* 15 HEALTH AFFAIRS 100 (Spring 1996); Heather Radach Spang et al., *Hospital Mergers and Savings for Consumers: Exploring New Evidence*, 20 HEALTH AFFAIRS 150 (July/Aug. 2001).

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<sup>145</sup> David Dranove & Richard Lindrooth, *Hospital Consolidation and Costs: Another Look at the Evidence*, 22 J. HEALTH ECON. 983, 996 (2003).

<sup>146</sup> *Id.* Another study similarly found that the impact of hospital mergers on quality differed by type of consolidation. Vivian Ho & Barton H. Hamilton, *Hospital Mergers and Acquisitions: Does Market Consolidation Harm Patients?* 19 J. HEALTH ECON. 767 (2000). Although the authors found no evidence that mergers measurably affect inpatient mortality, they found that post-acquisition, independent hospitals had higher readmission rates for heart attack patients and that post-acquisition, hospital systems discharged newborn babies earlier. *Id.* at 788. *See also* Smith 4/11 at 170-183 (discussing the 1993 consolidation of a 225 bed community hospital, a 325 bed Catholic hospital, and a small Catholic hospital serving several small communities to form Susquehanna Health System. He claimed the consolidated system saved \$105 million in costs and returned savings of \$117 million to the community and third party payors pursuant to a community commitment. This speaker also attributed many of the cost savings to the extensive consolidation and elimination of duplicative services among the three hospitals, which required compromises by all concerned.).

Even if a hospital merger is likely to create cognizable efficiencies, those cognizable efficiencies likely will not be sufficient to reverse a hospital merger's potential to harm consumers in the relevant market by preventing price increases in that market.<sup>147</sup>

As discussed in detail in Chapter 3, *supra*, most studies of the relationship between competition and hospital prices generally find that increased hospital concentration is associated with increased prices.<sup>148</sup> Some panelists and commentators believe an important motivation for the creation of multi-hospital systems has been to gain market power to secure higher reimbursement from payors.<sup>149</sup> Indeed, one academic health economist reported that "I have asked many providers why they wanted to merge. Although publicly they all invoked the synergies mantra, virtually everyone stated privately that the main reason for merging was to avoid competition and/or obtain market power."<sup>150</sup>

In several merger cases, hospitals have signed "community commitments" or agreements with State Attorneys General, promising not to raise prices for a specified

period or to pass onto consumers a specified amount of money from the claimed efficiencies.<sup>151</sup> Some State Attorneys General have signed these agreements in an attempt to translate merger-induced cost savings into price reductions to consumers. For example, in *Butterworth/Blodgett*, the merging hospitals agreed: (1) to freeze list prices for three years, (2) to freeze prices for managed care plans at pre-merger levels, (3) to limit profit margins by targeting a five-year rolling average for the merged entity that would not exceed the average of Moody's and Standard & Poor's upper quartile profit margin for other national

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<sup>147</sup> MERGER GUIDELINES, *supra* note 9, § 4 ("To make [a determination that a merger is not likely to be anticompetitive in any relevant market], the Agency considers whether cognizable efficiencies likely would be sufficient to reverse the merger's potential to harm consumers in the relevant market, e.g., by preventing price increases in that market.").

<sup>148</sup> See Chapter 3.

<sup>149</sup> *Id.*

<sup>150</sup> DAVID DRANOVE, THE ECONOMIC EVOLUTION OF AMERICAN HEALTH CARE 122 (2000).

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<sup>151</sup> See *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1302 (W.D. Mich. 1996), *aff'd by an unpublished opinion*, 1997-2 Trade Cas. (CCH) ¶ 71,863 (6th Cir. 1997); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 149 (E.D.N.Y. 1997). Other states also have entered into decrees with merging hospitals that provided for some type of community commitment. See, e.g., *Wisconsin v. Kenosha Hosp. & Med. Ctr.*, 1997-1 Trade Cas. ¶ 71,669 (E.D. Wis. 1996) (consent decree); *Pennsylvania v. Capital Health Sys.*, 1995-2 Trade Cas. ¶ 71,205 (M.D. Pa. 1995) (consent decree) (court ordered merged hospitals to pass at least 80 percent of the net cost savings to consumers); *Pennsylvania v. Providence Health Sys.*, 1994-1 Trade Cas. ¶ 70,603 (M.D. Pa. 1994) (consent decree). See also Eisenstadt 3/28 at 66-68 (describing economic modeling he and others conducted in connection with a Pittsburgh hospital merger that showed the component prices would increase and consumer welfare would decrease, but the community commitment did not address this issue, which in his view was one of the most troublesome aspects of the merger); E. Cooper 9/9/02 at 134 (noting State Attorneys General in Pennsylvania and Wisconsin "have crafted consent agreements that allow the transaction to proceed, but placed restrictions on the merged entity's future conduct. Such restrictions, usually characterized as regulatory by detractors and creative by proponents, typically require the new entry to pass along to consumers cost savings from efficiencies claimed from the merger.").



health care providers, (4) to serve the medically needy, and (5) to ensure that the board of the merged entity would continue to reflect the interests of western Michigan.<sup>152</sup> Similarly, the merging hospitals in *Long Island Jewish Medical Center* entered into an agreement with the Attorney General of the State of New York to “pass on to the community cost savings that will be achieved . . . [to] equal 100 million dollars during the five-year period commencing January 1, 1998.”<sup>153</sup> The agreement further provided that up to 50 million dollars of the cost savings could be used “to fulfill its mission to provide high quality health care to economically disadvantaged and elderly members of the community.”<sup>154</sup>

Community commitments are temporary and may not represent a binding constraint even during the period they are in effect. Furthermore, such commitments do not solve the underlying competitive problem when a hospital merger has changed market circumstances in ways that increase the likelihood that market power will be exercised. Community commitments represent a distinctly regulatory approach to what is, at bottom, a problem of competition – and that problem will remain after the

commitment has expired.<sup>155</sup>

The Agencies do not accept community commitments as a resolution to likely anticompetitive effects from a hospital (or any other) merger. The Agencies believe community commitments are an ineffective short-term regulatory approach to what is ultimately a problem of competition. Nevertheless, the Agencies realize that in some circumstances, State Attorneys General may agree to community commitments in light of the resource and other constraints they face.

## VI. NONPROFIT STATUS OF HOSPITALS

The significance of institutional form (nonprofit v. for-profit) has been an issue in several hospital merger cases. In three early cases, the Seventh and Eleventh Circuit Courts of Appeals rejected the claim that institutional form should figure in a merger analysis. Thus, in *HCA*, the Seventh Circuit noted that although “different ownership structures might reduce the likelihood of collusion, . . . this possibility is conjectural,” and that “adoption of the nonprofit form

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<sup>152</sup> *Butterworth Health*, 1997-2 Trade Cas. (CCH) ¶ 71,868. See also *Butterworth Health*, 946 F. Supp. at 1304-10; Spectrum (public cmt), *supra* note 137, at 1-7 (noting that they have honored the community commitment they entered in connection with the Butterworth/Blodgett merger).

<sup>153</sup> *Long Island Jewish Med. Ctr.*, 983 F.Supp. at 149.

<sup>154</sup> *Id.*

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<sup>155</sup> Sage et al., *supra* note 8, at 42-43; Kursh 10/1 at 89-91; Orlans 10/1 at 91-93. *But see* Donahue 10/1 at 36-44 (Chief Deputy Attorney General, Antitrust Section, Pennsylvania Office of the Attorney General, discussing the pros and cons of regulatory decrees used in connection with three separate hospital mergers in Pennsylvania); Singer 10/1 at 44-45 (suggesting structural relief or blocking the merger is an all-or-nothing solution, but the conduct or regulatory remedy allows a community to realize benefits from the merger, such as efficiencies, and still guard against potential anticompetitive effects).

does not change human nature.”<sup>156</sup> Similarly, in *University Health*, the Eleventh Circuit observed that “the Supreme Court has rejected the notion that nonprofit corporations act under such a different set of incentives than for-profit corporations that they are entitled to an implicit exemption from the antitrust laws.”<sup>157</sup> Finally, in *Rockford*, the Seventh Circuit repeated and elaborated its position that institutional form was irrelevant to a merger analysis:

We are aware of no evidence – and the [appellees] present none, only argument – that nonprofit suppliers of goods or services are more likely to compete vigorously than profit-making suppliers . . . . If the managers of nonprofit enterprises are less likely to strain after that last penny of profit, they may be less prone to engage in profit-maximizing collusion but by the same token less prone to engage in profit-maximizing competition.<sup>158</sup>

The relevant question for antitrust analysis is not whether nonprofit hospitals behave in a manner indistinguishable from for-profit institutions, but rather whether they would exploit merger-created market

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<sup>156</sup> *Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1390 (7th Cir. 1986).

<sup>157</sup> *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1224 (11th Cir. 1991), *citing* *Nat’l Collegiate Athletic Ass’n v. Board of Regents*, 468 U.S. 85, 100 n.22 (1984).

<sup>158</sup> *United States v. Rockford Mem’l Corp.*, 898 F.2d 1278, 1285 (7th Cir. 1990).

power in ways harmful to consumers.<sup>159</sup> Recently, some courts have asserted that institutional form should matter – and suggested that nonprofit hospitals, even if they acquire market power, will not harm competition or consumers. For example, in *Butterworth*, the district court relied on the nonprofit status of the merging hospitals as a reason why the merger would not have anticompetitive effects, and the Sixth Circuit emphasized this fact in its opinion affirming the district court.<sup>160</sup>

Similarly, in *Long Island Jewish Medical Center*, the court believed that the merging hospitals were nonprofit organizations that “have a genuine commitment to help their communities,” and “community service, not profit maximization, is the hospitals’ mission.”<sup>161</sup>

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<sup>159</sup> It is immaterial if nonprofit hospitals exploit market power in ways that differ from the ways in which for-profit hospitals would exercise it. The issue is whether market power is exploited.

<sup>160</sup> *FTC v. Butterworth Health Corp.*, 1997-2 Trade Cas. (CCH) ¶ 71,863, 71,867-68 (6th Cir. 1997) (“[T]he hospitals’ expert witness testified that there would be no economic incentive for the board members of a nonprofit hospital to raise prices above competitive levels when the board members themselves had an interest in maintaining low prices. Because the boards of these hospitals are comprised of community and business leaders whose companies pay the health care costs of their local employees, the district court found that undue price increases were unlikely.”).

<sup>161</sup> *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 149, 146 (E.D.N.Y. 1997). *See also* *Sage* 5/29 at 149-50 (“[C]ourts may misperceive antitrust claims involving hospital mergers as calling into question the overall trustworthiness of major community institutions . . . . [N]onprofit health facilities are widely presumed to be acting in the public interest, and this expectation is

The practical significance of a hospital's institutional form has been studied extensively. One panelist (who was an expert for the defendant in the *Butterworth/Blodgett* case) stated that economic incentives made it likely that a typical nonprofit hospital's pricing behavior would differ systematically from that of a typical for-profit hospital.<sup>162</sup>

This panelist argued that a number of studies, including work he had performed, indicated that nonprofits that attain market power behave differently from for-profits when it comes to pricing.<sup>163</sup> This panelist qualified this observation, noting that the observed price effects in these studies are averages and do not predict whether or not a particular nonprofit hospital merger will

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an important part of the reason for according them nonprofit status in the first instance. In *Butterworth*, for example, the court assumed that increased revenue to the merged hospital would be spent by the board of trustees on improving quality and helping the uninsured.”).

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<sup>162</sup> Lynk 4/10 at 8.

<sup>163</sup> *Id.* at 8, 19-20; William Lynk, *Joint FTC/DOJ Hearings on Health Care and Competition Law and Policy* 1-2 (4/10) (slides) [hereinafter Lynk Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030410williamjlink.pdf>. Lynk's 1995 study used California data from 1989 and looked at net prices in markets with more or less concentration, specifically controlling for the hospitals' for-profit or nonprofit status, as well as other factors. William J. Lynk, *Nonprofit Hospital Mergers and the Exercise of Market Power*, 38 J.L. & ECON. 437 (1995). Lynk then simulated the price effects of a merger and found that for-profit hospitals had more than an 8 percent increase in price and nonprofit hospitals had a 4.1percent decrease in price. *Id.* at 453. Lynk also referenced and described several other studies. Lynk Presentation, *supra*, at 1-2.

have an effect on price and do not preclude the possibility of price discrimination against certain customers.<sup>164</sup> Moreover, this panelist acknowledged that the empirical evidence of a price effect is mixed.<sup>165</sup>

By contrast, several panelists maintained that the best available empirical evidence indicated no significant differences between the pricing behavior of for-profit and nonprofit hospitals.<sup>166</sup> For example, one panelist stated that “the preponderance of the empirical evidence indicates that

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<sup>164</sup> Lynk 4/10 at 8, 20-2121-23; Lynk 4/10 at 11 (noting that different nonprofits can have different incentives; a nonprofit hospital with local governance and control may be aligned more with local community interests than a nonprofit hospital that is part of a larger nonprofit organization that views it as a profit center to support the larger organization's other activities). *See also* Touzin 4/10 at 86-87, 92 (consumer group representative stating that consumers perceive a difference between for-profit and nonprofit hospitals and that conversions of hospitals from nonprofit to for-profit status often result in boards comprised of out-of-state entities and the board's concern is its shareholders, not the community in which it is located).

<sup>165</sup> Lynk Presentation, *supra* note 163, at 7-10. We note also that all of the studies cited by the author are now dated; the most recent of these was published in 1991.

<sup>166</sup> *See, e.g.*, Capps 4/10 at 55-56; G. Young 4/10 at 33-37; Fay 4/10 at 24-25; Sloan 4/10 at 57, 65; Gaynor 5/27 at 77 (noting the “bulk of the evidence in my opinion, however, shows that not-for-profits do exercise market power if given the opportunity.”); Frank A. Sloan, *Hospital Ownership Conversions* 21 (4/10) (slides) (no evidence of upcoding studied diagnoses following conversion from non-profit to for-profit status), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030410sloan.pdf>; David Dranove & Richard Ludwick, *Competition and Pricing by Nonprofit Hospitals: A Reassessment of Lynk's Analysis*, 18 J. HEALTH ECON. 87 (1998).

nonprofit hospitals use their market power in roughly the same fashion as for-profit hospitals.”<sup>167</sup> Another panelist similarly reported that the “literature suggests that, on average, nonprofit hospitals do use market power to obtain higher prices.”<sup>168</sup>

Recent empirical studies of pricing behavior paint a fairly consistent picture. One study found that there was no significant difference in how for-profit and nonprofit hospitals exerted market power; for-profit hospitals generally had higher prices in 1986, but nonprofits increased their prices faster from 1986 to 1994.<sup>169</sup> A case study of a nonprofit hospital merger in Santa Cruz, California, found significant evidence of post-merger price increases.<sup>170</sup> Another study noted that “the most interesting result for antitrust policy is the finding that nonprofit hospital mergers lead to higher prices, not lower ones, and that the price increases resulting from a nonprofit merger

are getting larger over time.”<sup>171</sup>

Merger simulation studies have produced a similar picture. One study found nonprofit status did not lead to lower prices in urban markets, but did result in modestly lower prices in rural markets.<sup>172</sup> Other studies found no differences in pricing behavior resulting from institutional status.<sup>173</sup>

One panelist asserted that even if there are no pricing differences between for-profit and nonprofit hospitals, there can be

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<sup>167</sup> Capps Presentation, *supra* note 42, at 19, Capps 4/10 at 55-56.

<sup>168</sup> G. Young 4/10 at 33; Gary Young, *Nonprofit Ownership and Antitrust Policy* 3-4 (4/10) (slides), at <http://www.ftc.gov/opp/hc/030410garyyoung.pdf>.

<sup>169</sup> Robert Connor et al., *The Effects of Market Concentration From Horizontal Mergers on Hospital Costs and Prices*, 5 INT’L J. ECON. BUS. 159 (1998).

<sup>170</sup> Michael Vita & Seth Sacher, *The Competitive Effects of Not-For-Profit Hospital Mergers: A Case Study*, 49 J. INDUS. ECON. 63, 76-77 Tbls. III & IV, 80-82 (2001). An earlier study by different authors found that hospital mergers resulted, on average, in a 5 percent cost savings. Connor et al., *supra* note 169, at 159.

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<sup>171</sup> Emmett B. Keeler et al., *The Changing Effects of Competition on Nonprofit and For-Profit Hospital Pricing Behavior*, 18 J. HEALTH ECON. 69 (1999). *But see* Lynk 4/10 at 15; Lynk Presentation, *supra* note 163, at 7 (discussing this study’s results, but adding that it confirmed a statistically significant differential in price effects of concentration between nonprofit and for-profit hospitals); Elaine Silverman & Jonathan Skinner, *Medicare Upcoding and Hospital Ownership*, 23 J. HEALTH ECON. 369-89 (2004) (finding that between 1989 and 1996, for-profit hospitals upcoded the pneumonia and stroke DRGs for Medicare reimbursement more frequently than not-for-profit and government hospitals).

<sup>172</sup> Capps 4/10 at 50-51; Capps Presentation, *supra* note 42, at 12.

<sup>173</sup> *See* Town & Vistnes, *supra* note 103, at 749-50 (estimating hospital leverage in negotiations with managed care organizations and finding no statistically significant differences between non-profit and for-profit hospitals’ pricing behavior); Capps et al., *Competition and Market Power in Option Demand Markets* (2003) (unpublished manuscript, on file with Commission) (estimating consumers’ willingness to pay for the inclusion of specific hospitals in their health plan network, and using price regressions, predicted that leverage effects price and that there is no difference between the behavior of non-profits and for-profits). *See also* Capps 4/10 at 51-56; Capps Presentation, *supra* note 42, at 13-18.

other differences.<sup>174</sup> Nonprofit hospitals may have different long-term missions and have a different level of public accountability because of their long-term community obligations.<sup>175</sup> There is some empirical evidence that institutional status affects the mix of services provided by a hospital.<sup>176</sup>

This panelist also suggested that board members of a for-profit hospital had fiduciary duties to a different group of individuals than would be the case if the hospital was nonprofit.<sup>177</sup> Another panelist responded that “ownership variations are distinctions without a significant difference [and that all hospitals, irrespective of ownership] have the same mission: to provide the highest quality, appropriate medical care possible to the patients they serve, irrespective of the patient’s ability to

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<sup>174</sup> Jacobson 4/10 at 70; Peter D. Jacobson, *Who Owns the Health Care Enterprise: Is the Not-for-Profit Form Obsolete?* 3 (4/10) (slides) [hereinafter Jacobson Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/jacobson0304.pdf>.

<sup>175</sup> Jacobson 4/10 at 71-73; Jacobson Presentation, *supra* note 174, at 4.

<sup>176</sup> See generally Jill R. Horwitz, *Why We Need the Independent Sector: The Behavior, Law, and Economics of Not-For-Profit Hospitals*, 50 *UCLA L. REV.* 1345 (2003).

<sup>177</sup> Jacobson 4/10 at 81-82; Jacobson Presentation, *supra* note 174, at 12 (suggesting that directors of a for-profit entity have a fiduciary duty to maximize shareholder value, while directors of a nonprofit entity have a fiduciary duty to both the facility and to the community, requiring them to balance their margin against their mission). See also Roger G. Pariseau, *Comments* (Public Comment) (recommending that all entities involved in health care market should be nonprofit).

pay for such care.”<sup>178</sup> Government statistics indicate that on average, uncompensated care accounts for a similar percentage of total costs at for-profit and nonprofit hospitals.<sup>179</sup>

Although institutional status has loomed large in debates and legal disputes, the best available evidence indicates that nonprofits exploit market power when given the opportunity to do so. Accordingly, the profit/nonprofit status of the merging hospitals should not be considered a factor in predicting whether a hospital merger is likely to be anticompetitive.

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<sup>178</sup> Fay 4/10 at 24-25; Anthony Fay, *FTC/DOJ Hearings on Health Care and Competition Law and Policy Statement of the Federation of American Hospitals – Hospital’s Nonprofit Status* 3 (4/10), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030410fay.pdf>. See also Sofaer 5/30 at 201-202 (noting that references to a “managed care revolution” are misnomers, because there has been no managed care, only managed cost, and that although there was concern at one time about for-profit medicine, that really has not been a concern, “primarily because ... ‘non-profit’ facilities in health care often behave so much like for-profit facilities in health care.”).

<sup>179</sup> Vogt 9/9/02 at 52 (“[T]he literature is reasonably clear that the not for-profits don’t provide very much more charity care, if more charity care at all. In fact, what small difference there is in charity care is accounted for by the location of the not-for-profit hospitals.”); see also Sloan 4/10 at 57; David A. Hyman, *Hospital Conversions: Fact, Fantasy, and Regulatory Follies*, 23 *J. CORP. L.* 741 (1998); David Blumenthal & Nigel Edwards, *The Tale of Two Systems: The Changing Academic Health Center*, 19 *HEALTH AFFAIRS* 86 (May/June 2000); Gabriel Picone et al., *Are For-Profit Hospital Conversions Harmful to Patients and to Medicare?*, 33 *RAND J. ECON.* 507 (2002).

## VII. GROUP PURCHASING ORGANIZATIONS

A group purchasing organization (GPO) negotiates contracts with vendors of medical supplies on behalf of its members. GPO members include hospitals, nursing homes, home health agencies, and other health care systems. Some Hearing participants and industry commentators assert that GPOs, acting as their members' buying cooperatives, can be tremendous engines of efficiency, allowing medical buyers to pool their purchasing power to lower health care costs.

Nonetheless, others assert that certain GPO contracting practices may raise competitive concerns related to tying, bundling, and exclusive dealing. The Senate Judiciary Committee, through efforts by Chairman Mike DeWine and Ranking Member Herb Kohl of the Antitrust, Competition Policy and Consumer Rights Subcommittee, and the U.S. General Accounting Office have examined this issue in depth,<sup>180</sup> and the issue was an important

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<sup>180</sup> See, e.g., *Hospital Group Purchasing: Has the Market Become More Open to Competition?: Hearing Before the Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, GAO-03-998T, 108th Cong. (2003); *Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovations?: Hearing Before the Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, GAO-02-690T, 107th Cong. (2002); *Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products: Before the Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, 108th Cong. (2003) (testimony of U.S. General Accounting Office) [hereinafter GAO Senate Testimony, *Contracting*];

topic in the Hearings and the Commission's Health Care Workshop.<sup>181</sup>

In the sections that follow, we explain what a GPO is, describe its role as a purchasing intermediary, and provide an overview of the GPO industry structure. This section then discusses the various organizational structures GPOs may adopt, the potential incentives created by each, and the various contracting practices used by either GPOs or their suppliers and their potential impact on competition.

Finally, this section addresses concerns expressed during the Hearings and elsewhere that *Health Care Statement 7*, which governs GPOs, impedes the Agencies' ability to challenge GPO practices when, and if, they are anticompetitive. For the reasons discussed below, the Agencies believe these concerns are misplaced, and it is not necessary to revise *Health Care Statement 7*.<sup>182</sup> This statement does not provide a safety zone for the specific types of conduct that some commentators have criticized, including tying, bundling, or exclusive dealing. In such situations, the Agencies would analyze the conduct on a case-by-case basis to determine whether it may violate the antitrust laws.

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*Group Purchasing Organization: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices: Before the Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, 107th Cong. (2002) (testimony of U.S. General Accounting Office) [hereinafter GAO Senate Testimony, *Pilot Study*].

<sup>181</sup> See Transcript of Health Care Hearings 9/26 at 114-226; Transcript of Health Care Workshop 9/10/02 at 48-140.

<sup>182</sup> See discussion *infra* Section E.

**A. What is a GPO?**

GPOs are entities that aggregate health care providers' purchasing volume and contracting functions to negotiate discounts with manufacturers, distributors, and other vendors of medical products and services.<sup>183</sup> According to the Health Industry Group Purchasing Association (HIGPA), 96 percent of all acute care hospitals in the United States use the services of a GPO, and on average, hospitals use at least two GPOs.<sup>184</sup> More than 70 percent of hospital purchases are made through a contract

negotiated by a GPO.<sup>185</sup>

GPOs negotiate contracts with manufacturers of products that fall into two general categories – commodities and medical devices.<sup>186</sup> Cotton balls, bandages, and linens are examples of commodities for which hospital clinical staffs generally do not have strong preferences about the manufacturer. High technology medical devices such as pacemakers and stents are examples of medical devices for which hospital clinicians may have a preference as to the manufacturer.<sup>187</sup>

GPOs are not wholesalers or distributors, and they do not take possession of, or title to, the products for which they negotiate contracts.<sup>188</sup> Vendors of medical supplies and services generally submit bids to a GPO in response to a “Request For

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<sup>183</sup> See Health Industry Group Purchasing Ass'n (HIGPA), *Group Purchasing Organizations* 6 (Public Comment) (submitted by Robert Betz [hereinafter HIGPA (public cmt)]; HERBERT HOVENKAMP, COMPETITIVE EFFECTS OF GROUP PURCHASING ORGANIZATIONS' (GPO) PURCHASING AND PRODUCT SELECTION PRACTICES IN THE HEALTH CARE INDUSTRY 1 (2002) (prepared on behalf of Health Industry Group Purchasing Association). See also American Bar Ass'n, Section of Antitrust Law, *Comments Regarding The Federal Trade Commission's Workshop on Health Care and Competition Law and Policy* (Oct. 2002) 27-34 (Public Comment).

<sup>184</sup> HIGPA (public cmt), *supra* note 183, at 6 (discussing SMG MARKETING GROUP, 2002 SMG MHS/GPO MARKET REPORT1 (2002)). See also Robert Bloch et al., *An Analysis of Group Purchasing Organizations' Contracting Practices Under the Antitrust Laws: Myth and Reality* 1 (9/26) (virtually every hospital belongs to at least one GPO) [hereinafter Bloch (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030926bloch.pdf>; GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 5 (reporting that according to survey data from the American Hospital Association, 68 percent of hospitals belonged to GPOs in 2000; according to HIGPA, 96-98 percent of hospitals belonged to a GPO); Bailey 9/10/02 at 48-56 (discussing GAO's pilot study).

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<sup>185</sup> HIGPA (public cmt), *supra* note 183, at 6; Bloch (stmt), *supra* note 184, at 1 (citing Muse & Associates, *The Role of Group Purchasing Organizations in the U.S. Health Care System*, at 3 (March 2000)).

<sup>186</sup> GAO Senate Testimony, *Contracting*, *supra* note 180, at 3.

<sup>187</sup> *Id.* at 3-4. According to HIGPA, other products and services purchased through GPOs include pharmaceuticals, dietary resources, telecommunication services, and janitorial supplies. HIGPA (public cmt), *supra* note 183, at 6.

<sup>188</sup> See Bloch (stmt), *supra* note 184, at 7; HIGPA (public cmt), *supra* note 183, at 6 (“GPOs do not purchase products or force the purchase of a particular product. Their value is based solely on offering providers access to desired products at reduced prices. Because most hospitals belong to multiple GPOs, each with a unique set of contracts, hospitals have choices – either choosing among GPO contracts or going directly to the supplier to purchase a particular product.”).

Proposal.”<sup>189</sup> One panelist stated that GPOs “simply negotiate a contract with a supplier that all members of the GPO can access. This guarantees the GPO member that it will receive a price no worse than the pre-negotiated price on the GPO contract.”<sup>190</sup> Hospitals and other health care providers then purchase products and services directly from the vendor pursuant to the prices and contract terms specified in the GPO’s contract with that vendor.<sup>191</sup>

Others note that in many cases, the GPO’s contract does not bind the health care providers and they are free to negotiate separately with the vendor.<sup>192</sup> According to one commentator, “GPO members have substantial freedom to purchase alternative products and do so in significant volumes, particularly where the products in question are differentiated.”<sup>193</sup>

## B. GPO Industry Overview

The Hospital Bureau of New York, established in 1910, is the first known hospital GPO.<sup>194</sup> According to HIGPA, “[f]rom 1974 to 1999, the number of GPOs grew from forty to 633 . . . [and] it is estimated that approximately 200 GPOs contract directly with suppliers, and that twenty-six of these operate on a national level.”<sup>195</sup> One commentator asserted that “when markets in this industry are properly defined, no GPO has a market share as high as 20%. Further, there are many GPOs, and hospitals can and do join multiple GPOs or switch memberships.”<sup>196</sup>

In contrast, the GAO’s pilot study focused on seven national GPOs, each with purchasing volume of more than \$1 billion. The GAO stated that the seven GPOs collectively accounted for purchases totaling approximately \$43 billion, or “more than 85% of all hospital purchases nationwide

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<sup>189</sup> GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 7; Bloch (stmt), *supra* note 184, at 8.

<sup>190</sup> Bloch (stmt), *supra* note 184, at 7-8.

<sup>191</sup> GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 7.

<sup>192</sup> Bloch (stmt), *supra* note 184, at 8. *See also* HERBERT HOVENKAMP, GROUP PURCHASING ORGANIZATION (GPO) PURCHASING AGREEMENTS AND ANTITRUST LAW 2 (2004) (prepared for the Health Industry Group Purchasing Association) (agreements typically offer buyers a discount in exchange for the buyers’ commitment to purchase a minimum percentage of its needs from a specific vendor); GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 5.

<sup>193</sup> HOVENKAMP, *supra* note 192, at 2.

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<sup>194</sup> Bloch (stmt), *supra* note 184, at 3.

<sup>195</sup> *Id.* at 4-5 (also claiming there were approximately 900 GPOs in 2003, although many of these are subsidiaries of “parent” GPOs, and work regionally to recruit hospitals to participate in the contracts negotiated by the parent GPO).

<sup>196</sup> HOVENKAMP, *supra* note 192, at 6. In another paper, HOVENKAMP, *supra* note 183, Professor Hovenkamp reported “the following market shares for the ten largest GPOs, based on 2001 data:” Novation, 14.6%; Premier, 12.5%; AmeriNet, 4.6%; MedAssets, 4.5%; Managed Health, 3.3%; Consort, 2.2%; HealthCare Purchasing Partners, 1.1%; National Purchasing Alliance, 0.7%; AllHealth, 0.6%; and Innovatix, 0.6%. HOVENKAMP, *supra* note 192, at 9-10 & n.7. *See also* Bloch (stmt), *supra* note 184, at 19 (even largest GPO accounts for only 15 percent of total purchase volume of hospital purchases of supplies and equipment).



made through GPO contracts.”<sup>197</sup> Moreover, according to the GAO, the two largest GPOs in its study accounted for approximately 66 percent of total GPO purchasing.<sup>198</sup>

One panelist explained that the numbers may differ depending on the study, the years measured, and whether percentages are based on all hospital purchases or only on hospital purchases made through a GPO.<sup>199</sup> For example, this panelist noted that the largest GPO accounts for 15 percent of total purchases by hospitals, but 30 percent of purchases made by hospitals through a GPO. Similarly, the second largest GPO’s market share goes from 12 percent of all purchases to 25 percent of purchases made through a GPO.<sup>200</sup>

### C. *Structure and Incentives*

The GAO report explained that “GPOs differ in their corporate structures and their relationships with member hospitals.”<sup>201</sup> Member hospitals own some GPOs; in other cases, shareholders that are independent of the member hospitals own

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<sup>197</sup> GAO Senate Testimony, *Contracting*, *supra* note 180, at 4.

<sup>198</sup> *Id.* But see MUSE & ASSOCIATES, THE ROLE OF GROUP PURCHASING ORGANIZATIONS IN THE U.S. HEALTH CARE SYSTEM 3 (2000) (prepared for HIGPA) and Bloch (stmt), *supra* note 184, at 1 (GAO’s figures are in contrast to their estimates suggesting GPO contracts cover purchases with an annual value of approximately \$150 billion).

<sup>199</sup> Bloch 9/26 at 126-27.

<sup>200</sup> *Id.*

<sup>201</sup> GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 6.

the GPO.<sup>202</sup> In some instances, suppliers finance GPOs by paying administrative fees that often are calculated as a percentage of each member’s purchases of each supplier’s products.<sup>203</sup> These fees are designed to “cover [a] GPO’s operating expenses and serve[] as its main source of revenue.”<sup>204</sup> GPOs may distribute surplus fees to their member hospitals as well.<sup>205</sup> GPOs may be for-profit or nonprofit organizations.

Because of these differing structures, some panelists and commentators question the extent to which GPOs act as the agents of their buyer-members, or as the agents of the sellers that pay the GPOs’ administrative fees. Because suppliers pay GPO fees, some worry that GPOs may operate to increase suppliers’ revenues – and, correspondingly, GPO fees – rather than to minimize members’ purchasing costs.<sup>206</sup>

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<sup>202</sup> *Id.*

<sup>203</sup> *Id.* at 8. According to the GAO, the “Social Security Act, as amended in 1986 allows these fees, which would otherwise be considered “kickbacks” or other illegal payments to the GPO.” *Id.* See also 42 U.S.C. § 1320a-7b(b)(3)(C); 42 C.F.R. 1001.952 (j) (setting forth safe harbor under the Federal anti-kickback statute for certain GPO fees).

<sup>204</sup> GAO Senate Testimony, *Contracting*, *supra* note 180, at 5.

<sup>205</sup> *Id.* at 5 n.5.

<sup>206</sup> See, e.g., Strong 9/26 at 153-54; Bloch 9/26 at 127-30, 134-35; Clark 9/10/02 at 64, 118; Manley 9/10/02 at 69 (all suggesting GPOs are the buyers agent) but see Weatherman 9/26 at 180-81; Everard 9/26 at 170; EINER ELHAUGE, THE EXCLUSION OF COMPETITION FOR HOSPITAL SALES THROUGH GROUP PURCHASING ORGANIZATIONS 29-31 (2002); Hilal 9/26 at 143; Nova BioMedical, *Comments Regarding Hearings on Health Care*

Some panelists stated that when GPO members play important decision-making roles in the GPO, the GPO may be more likely to act as the agent of its buyer members. As one commentator put it, “[m]any GPOs are owned by their members, who sit on their boards, and are operated as cooperatives. These boards have no interest in procuring overpriced or substandard products [on] behalf of their own institutions.”<sup>207</sup> Similarly, one CEO stated that in his GPO the buyers

make all of the [GPO] contracting decisions ... [award] all of the contract[s] ... decide which suppliers get the contracts, what their compliance requirements are going to be, ... [and] the type of contract that’s going to be awarded, whether it’s a sole source contract, a dual source contract, or a multi-source contract ... [and that each health care system] has a seat on [the] Board of Directors ... see[s] financial statements every month, ... help[s] us set the budget ... [and has] a seat on every single contracting body.<sup>208</sup>

Another panelist stated that hospitals in such GPOs have “multiple opportunities through surveys, through advisory boards, advisory groups ... to have input into the suppliers that are selected for contract in

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*Competition and Policy (Nov. 7, 2003)* 3-5 (Public Comment) (all suggesting concerns that GPOs may be more concerned about suppliers’ interests) [hereinafter Nova (public cmt)].

<sup>207</sup> HOVENKAMP, *supra* note 183, at 5.

<sup>208</sup> Strong 9/26 at 154.

[their] group purchasing organization.”<sup>209</sup>

Other panelists asserted, however, that some GPOs act as the agents of the suppliers. One panelist asserted that the majority of GPOs “are financed and thereby controlled by large medical product companies rather than by the hospitals they are supposedly the agents for ... . Fees and other incentives running from large medical manufacturers to GPOs allow such manufacturers to inappropriately influence the buying policies of the GPOs, because the compensation of most GPO management is almost always based on this fee income rather than on the real savings to hospital members.”<sup>210</sup> As a result, another contended, GPOs “are selling protected market share to dominant suppliers in exchange for fees.”<sup>211</sup> Such seller payments “may reflect side-payments being made in exchange for the GPOs conferring a de facto exclusivity that enhances the market power of the incumbent device maker.”<sup>212</sup>

#### **D. Contracting Practices**

At the Hearings, panelists focused a significant portion of the discussion on

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<sup>209</sup> Clark 9/10/02 at 64, 118; *see also* Manley 9/10/02 at 69 (noting existence of product “evaluation committees”).

<sup>210</sup> Weatherman 9/26 at 180-81; *see also* Nova (public cmt), *supra* note 206, at 3-5.

<sup>211</sup> Everard 9/26 at 170.

<sup>212</sup> ELHAUGE, *supra* note 206, at 29. *See also* Einer Elhauge, *Antitrust Analysis of GPO Exclusionary Agreements (Sept. 26, 2003)* 19 (Public Comment) (prepared on behalf of the Medical Device Manufacturer’s Association) [hereinafter Elhauge (public cmt)].

whether certain GPO contracting practices – principally alleged tying, bundling, or exclusive dealing practices – injure competition. Such contracting practices include allegations that GPOs negotiate sole-source contracts with certain privileged manufacturers; require hospitals to purchase given volumes of certain supplies; bundle contracts that offer price discounts to purchasers of particular product groups; and enter contracts with manufacturers that last five years or more.<sup>213</sup>

GPOs’ critics stated that some suppliers, in league with GPOs with sufficiently large market share, can insist upon a variety of anticompetitive GPO contracting practices to exclude rival suppliers from serving the buyers.<sup>214</sup> They

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<sup>213</sup> See, e.g., Strong 9/26 at 156 (do not bundle disparate products, but do bundle branded prescription drugs with generics to get discount on branded); *id.* at 157 (generally, five year contracts only used if significant amount of time and money involved in product evaluation); Bloch 9/26 at 127-38 (noting GPOs under attack for various contracting practices and provided his antitrust analysis of these practices); Everard 9/26 at 166 (bundling); *id.* at 168 (even if contract not technically sole-source, hospitals are not really free to purchase elsewhere because they will lose significant discounts); Hilal 9/26 at 143-46 (discussing problems with bundling and large percent of market his company is sometimes locked out of as result of GPO contracting practices); Elhauge (public cmt), *supra* note 212, at 12-13, 20-21 (discussing problems with bundled and loyalty discounts and rebates). See also GAO Senate Testimony, *Contracting*, *supra* note 180, at 5-6; Novation, *Comment Regarding Competition Law and Policy & Health Care (Sept. 30, 2002)* 2-4 (Public Comment).

<sup>214</sup> See, e.g., Everard 9/26 at 168 (stating that “manufacturers with market power are able to exclude competitors, in some cases with the GPO support and in some cases without”); Hilal 9/26 at 141 (arguing that GPOs “defend[] market share of

argue that such practices can discourage competitors from entering to bring down prices, and can discourage the research and development efforts necessary to produce innovative health care products that may improve on the incumbent’s product.<sup>215</sup> Some charge, for example, that “if a large GPO negotiates a sole-source contract with a manufacturer, the contract could cause an efficient, competing manufacturer to lose business and exit from the market and could discourage other manufacturers from entering the market.”<sup>216</sup>

Similarly, GPOs’ critics challenge hospital “commitments” to purchase a given volume to obtain a better price.<sup>217</sup> According to one panelist, under such a commitment, a hospital that buys an unauthorized product not only loses its better price on the complying product, but

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existing dominant suppliers” by blocking entrants from serving the medical market); Elhauge (public cmt), *supra* note 212, at 29-31.

<sup>215</sup> See, e.g., GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 1 (noting that “[s]ome manufacturers – especially small manufacturers of medical devices – allege that contracting practices of some large GPOs have blocked their access to hospitals’ purchasing decisionmakers [and that this] den[ies] patients access to innovative or superior medical devices”).

<sup>216</sup> See, e.g., GAO Senate Testimony, *Contracting*, *supra* note 180, at 6. A sole-source contract, according to the GAO, is one that “give[s] one of several manufacturers of comparable products an exclusive right to sell a particular product through a GPO.” *Id.* at 5. See also Nova (public cmt), *supra* note 206, at 4-5 (GPOs impede companies such as Nova from introducing new and innovative products into the GPO’s member hospitals).

<sup>217</sup> See GAO Senate Testimony, *Contracting*, *supra* note 180, at 5.

also must repay savings earned from having enjoyed that better price for years.<sup>218</sup> Critics also challenge contracts that offer bundled price discounts to purchasers of particular product groups, and contracts of five years or more that “can direct business to manufacturers for an extended period.”<sup>219</sup>

The economic literature on tying, bundling, and exclusive dealing practices indicates that they can be efficient, although under certain circumstances they may be harmful to competition.<sup>220</sup> Scholarly legal commentary in recent years also has called into question the anticompetitive explanations for these practices and has focused on efficiencies and the potential welfare-enhancing aspects of these business arrangements.<sup>221</sup> Thus, courts typically engage in a fact-intensive inquiry to evaluate

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<sup>218</sup> See Holden 9/10/02 at 100-04; see also Elhauge (public cmt), *supra* note 212, at 34.

<sup>219</sup> See GAO Senate Testimony, *Contracting*, *supra* note 180, at 6; see also Everard 9/26 at 166 (citing “some of the GPO practices that block innovation and ... lower costs,” such as “supplier paid fees, sole source contracts, high commitment levels, bundling of both products and companies.”); Sing 9/26 at 118-25 (summarizing GAO report on GPOs and noting that certain GPO “contracting strategies have the potential to reduce competition” if the GPO or vendor has “a large market share”).

<sup>220</sup> See, e.g., Keith N. Hylton & Michael Salinger, *Tying Law and Policy: A Decision-Theoretic Approach*, 69 ANTITRUST L.J. 469 (2001). But see Elhauge (public cmt), *supra* note 212, at 1-46 (arguing why GPO contracting practices can be anticompetitive).

<sup>221</sup> See, e.g., Richard A. Posner, ANTITRUST LAW, at 229-32 (exclusive dealing), 251-56 (exclusive dealing), 197-207 (tying), and 234-36 (bundling) (2<sup>nd</sup> ed. 2001).

the competitive effects of such tying, bundling, and exclusive dealing claims.

Courts reviewing tying claims generally require that “(1) two separate products or services are involved, (2) the sale or agreement to sell one is conditioned on the purchase of the other, (3) the seller has sufficient economic power in the market for the tying product to enable it to restrain trade in the market for the tied product, and (4) a not insubstantial amount of interstate commerce in the tied product is affected.”<sup>222</sup>

Courts reviewing the competitive consequences of exclusive dealing contracts typically analyze factors such as:

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<sup>222</sup> ANTITRUST LAW DEVELOPMENTS at 179 & n.998 (citing cases) (5th ed. 2002). The law of bundled discounts is both unsettled and beyond the scope of this report. Only one court of appeals has squarely addressed bundled discounts, most recently in *LePage’s, Inc. v. 3M*, 324 F. 3d 141 (3rd Cir. 2003) (en banc), *cert denied*, 2004 U.S. LEXIS 4768 (2004). The Supreme Court denied review after the United States suggested that LePage’s was not “a suitable vehicle for providing ... guidance” in this area. Brief for the United States as Amicus Curiae, 2004 WL 1205191, 8 (May. 28, 2004). In its brief, the United States stated that “the Third Circuit was unclear as to what aspect of bundled rebates constituted exclusionary conduct” and “provided few useful landmarks on how Section 2 should apply as a general matter in future cases involving bundled rebates.” *Id.* at 16. Although the Third Circuit “cited the general principles” set out in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 202 (1993) and other cases, it “failed to explain precisely why the evidence supported a jury verdict of liability in this case, including what precisely rendered 3M’s conduct unlawful.” *Id.* The brief further noted that “the court of appeals’ failure to identify the specific factors that made 3M’s bundled discount anticompetitive may lead to challenges to procompetitive programs and prospectively chill the adoption of such programs.” *Id.*

the degree of exclusion flowing from the restraint, its duration and terminability, the percentage of the market foreclosed and other indicia of the likely effect on competitors' ability to operate, the availability of alternative access routes to supplies or customers, rivals' ability to employ countermeasures to defeat the attempted exclusion, and, ultimately, the likely impact of raising rivals' costs on competition in a relevant market, including consideration of any procompetitive justifications.<sup>223</sup>

As a threshold matter, some panelists and commentators questioned whether allegations of exclusive dealing, tying, and bundling are true. For example, one panelist stated that "very few GPO contracts today are, in fact, exclusive," and unlike true exclusive dealing contracts, sole source contracts allow hospitals the freedom to buy

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<sup>223</sup> FTC STAFF REPORT, ENTERING THE 21<sup>ST</sup> CENTURY: COMPETITION POLICY IN THE WORLD OF B2B ELECTRONIC MARKETPLACES § 3, at 26 (2000) (citations omitted) at [www.ftc.gov/os/2000/10/b2breport.pdf](http://www.ftc.gov/os/2000/10/b2breport.pdf). As four Justices stated in a concurring opinion in *Tampa Electric Co. v. Nashville Coal Co.*, 365 U.S. 320, 329 (1961), courts are to weigh "the probable effect of the [exclusive dealing] contract on the relevant area of effective competition, taking into account the relative strength of the parties, the proportionate volume of commerce involved in relation to the total volume of commerce in the relevant market area and the probable immediate and future effects which preemption of that share of the market might have on effective competition therein." See also *Jefferson Parish Hosp. District v. Hyde*, 466 U.S. 2, 45 (1984) (O'Connor, J. concurring) (advocating an analysis focused on "the number of sellers and buyers in the market, the volume of their business, and the ease with which buyer and sellers can redirect their purchases or sales to others").

from others.<sup>224</sup> Another commentator noted that GPO loyalty rebate programs allow buyers to purchase from rivals offering lower prices.<sup>225</sup> Other panelists noted that many long-term contracts are qualified in that "almost all GPO contracts can be terminated on 60- to 90-days notice."<sup>226</sup>

Some panelists argued that, even if the GPOs were doing what their critics alleged, these contracting practices can actually increase, not decrease, consumer welfare.<sup>227</sup> For example, one source reported that GPOs use the challenged contracting practices "as incentives for

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<sup>224</sup> Bloch 9/26 at 132, 129-130; see also Strong 9/26 at 160 (noting that, given the lack of "noncompliance" penalties, GPO Consorta's member health care systems "decide who they want to deal with. It's not us that's out calling those shots."). Another panelist questioned the degree of freedom actually offered, see Everard 9/26 at 168-69. For a response to that point, see HOVENKAMP, *supra* note 183, at 12 (conceding that "purchases made outside of the GPO contracting process will not necessarily enjoy the quantity-generated cost reductions" of GPO purchasing, but "[i]f that were not the case, then the GPO would have no reason for existence"). See generally *id.* at 24-29, for further argument that GPO contract arrangements do not amount to anticompetitive exclusive dealing.

<sup>225</sup> See HOVENKAMP, *supra* note 192, at 8-10.

<sup>226</sup> Bloch 9/26 at 132; see also Strong 9/26 at 157 (GPO Consorta has "included new technology provisions in all our contracts on a go-forward basis since the inception of our Code of Conduct. It allows us to go outside a contract with a manufacturer for new technology. In virtually all of our contracts, with perhaps one or two exceptions, we have a 90-day termination provision. That allows us to cancel a contract if we can't come to terms and move forward and contract for that new technology.").

<sup>227</sup> Strong 9/26 at 156-57.

manufacturers to provide deeper discounts and for hospital members to concentrate purchasing volume to obtain better prices.”<sup>228</sup>

Some researchers and industry representatives claim that providers who make purchases pursuant to GPO contracts generally save 10 to 15 percent of the price they would otherwise pay.<sup>229</sup> Also, GPO contracts that bundle products can be “simply ways of making products more attractive, effectively cutting price, or reducing costs by disposing of excess inventory.”<sup>230</sup>

One panelist asserted that programs that allow suppliers to “reward [buyers’] higher levels of compliance” can be procompetitive “because they’re offering increased dividends in exchange for volume,” and because they standardize the buyers’ products, which “leads to lower inventory costs [and] the ability to standardize patient care, leading to better quality, better staff education and improved safety.”<sup>231</sup> This same panelist explained that

long-term contracts are sometimes necessary in light of the costs of “large clinical evaluations.” He explained the process involved for clinically evaluating a particular product:

The evaluation took 18 months. Our direct costs were over \$150,000 . . . . We looked at product utilization in over 8,500 surgical cases in 60 of our facilities with over 2,100 surgeons participating. At the end of that evaluation process, our owners said this was too much work to award just a three-year contract . . . [and] they decided to award a five-year contract.<sup>232</sup>

He further stated that “strong” GPO programs are needed to counter the growing market power of suppliers that have consolidated in recent years.<sup>233</sup> Finally, he also questioned whether the challenged practices could really be injuring the upstream supplier market, citing evidence that the medical device market is flourishing.<sup>234</sup>

Others, however, question GPOs’

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<sup>228</sup> GAO Senate Testimony, *Contracting*, *supra* note 180, at 5.

<sup>229</sup> HIGPA (public cmt), *supra* note 183, at 7; MUSE & ASSOCIATES, *supra* note 198.

<sup>230</sup> HOVENKAMP, *supra* note 183, at 22.

<sup>231</sup> Strong 9/26 at 160; *see also* HOVENKAMP, *supra* note 183, at 18 (noting importance of “scale economies”); Strong 9/26 at 153 (arguing that the administrative fees that suppliers pay to GPOs are not to buy monopoly power but to “allow[] the supplier to have one contract in the market [and not] hundreds [to make with] individual health care facilities . . . [and to generate] marketing and contract visibility . . . contract implementation support [and] contract evaluation”).

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<sup>232</sup> Strong 9/26 at 158-59.

<sup>233</sup> *Id.* at 163.

<sup>234</sup> Strong 9/26 at 164; *but see* Weatherman 9/26 at 182 (challenging such assertions and noting that “the influence of supplier fees running directly from medical product’s vendors to the manager of the GPO buyers completely confounds any such analysis and creates such an appearance of unfairness and corruption as to deter many venture capitalists from funding new innovators in these markets”).

claimed efficiencies.<sup>235</sup> For example, after a pilot study, the General Accounting Office reported that “GPOs’ prices were not always lower and were often higher than prices paid by hospitals negotiating with vendors directly.”<sup>236</sup>

According to the GPO industry, GPOs provide additional benefits to their members, including reduced overhead costs for purchasing departments. In addition, GPOs claim to provide “assistance with product-comparison analysis and standardization of products.”<sup>237</sup> Through GPOs, members may be able to

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<sup>235</sup> See, e.g., Hilal 9/26 at 139 (questioning GPOs’ claimed efficiencies); GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 3; Everard 9/26 at 173.

<sup>236</sup> GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 3 (concluding that some hospitals saved as much as 26 percent by purchasing via a GPO contract, and others paid prices as much as 39 percent higher using the GPO contract. The GAO pilot study also found that hospitals with more than 500 beds often obtained better prices on their own, but “small and medium-sized hospitals were more likely to obtain price savings using a GPO contract.” *Id.* See also Lynn James Everard, *Health Policy Statement Number Seven And Marketplace Competition In the Health Care Supply Chain: A Market-Based Analysis* 4 (9/26) (“There is no valid proof of the cost savings claims of GPOs.”), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030926everardadd.pdf>. But see Bloch (stmt), *supra* note 184, at 6 (asserting that the GAO looked at only two products in one city and broad conclusions about cost savings cannot be drawn from such a small sample and that GAO study “failed to consider the fact that hospitals that obtain better pricing outside their GPO often use the GPO contract as a starting point for their negotiations with vendors”).

<sup>237</sup> See GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 6-7 (citing to GPO officials and a GPO trade organization).

reduce their supply costs via group purchasing, rebates, and surplus dividend payments.<sup>238</sup>

As one panelist stated, GPOs can not only “eliminate wasteful administrative duplication[,] ... they increase competition between rival GPOs, manufacturers and their member hospitals, all of which can translate into lower prices and higher quality for consumers.”<sup>239</sup> Moreover, “GPOs assist members in product selection, an activity that would otherwise use up large amounts of member staff time.”<sup>240</sup> One estimate suggested that hospitals would spend on average \$155,000 per hospital to duplicate the administrative and other functions GPOs provide.<sup>241</sup>

The structure and incentives of individual GPOs may play an important role in determining the level of efficiencies they

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<sup>238</sup> Strong 9/26 at 151-52; see also GAO Senate Testimony, *Contracting*, *supra* note 180, at 1 (“By pooling the purchases of these products for their hospital customers, GPOs may negotiate lower prices from vendors (manufacturers, distributors, and other suppliers), which can benefit hospitals and, ultimately, consumers and payers of hospital care (such as insurers and employers).”).

<sup>239</sup> Bloch 9/26 at 127; see also Heiman 9/26 at 189-92 (citing variety of efficiencies offered by GPOs); HOVENKAMP, *supra* note 183, at 1-2 (noting savings due to GPOs).

<sup>240</sup> HOVENKAMP, *supra* note 183, at 3.

<sup>241</sup> Eugene S. Schneller, *The Value of Group Purchasing in the Health Care Supply Chain* 6 (2000), at [http://wpcarey.asu.edu/hap/hap\\_novation.cfm](http://wpcarey.asu.edu/hap/hap_novation.cfm); See also Bloch (stmt), *supra* note 184, at 7 and n.24. See also Novation (public cmt), *supra* note 213, at 2 (“[S]tudies show that if GPOs did not exist, the average hospital would pay \$353,000 to replicate those purchasing functions.”).

obtain. For example, GPOs acting on their members' behalf may strive to achieve efficiencies for the members.<sup>242</sup> Thus, some noted that when the challenged contracting practices are arranged not by one rival manufacturer seeking to foreclose others, but by "a buyer or its agent" – *i.e.*, the buyers or their GPO – "in order to get lower prices from the manufacture[r]," the practices are likely to be pro-competitive.<sup>243</sup>

One panelist suggested this circumstance distinguishes the challenged practices from typical tying and bundling cases.<sup>244</sup> Indeed, another panelist believed that a GPO's refusal to carry a given manufacturer's product likely reflects buyers' skepticism about the manufacturer's claims about its product, not any competitive injury.<sup>245</sup>

By contrast, some commentators suggest that if suppliers control a GPO, the

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<sup>242</sup> See, e.g., *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 487-88 (1st Cir. 1988) (Breyer, J.) (noting lack of evidence that a standard-setting organization misled "reasonably sophisticated" buyers).

<sup>243</sup> Bloch 9/26 at 134-35; see also *id.* at 129 (distinguishing between "contracts and bundling programs" that buyers initiate, and those that sellers initiate, and noting that the former pose fewer competitive concerns because they are "driven by the economic interest of GPO member hospitals in obtaining lower prices and quality products").

<sup>244</sup> *Id.* at 134-35.

<sup>245</sup> Strong 9/26 at 157-58 (questioning manufacturers' claims that their excluded products are innovative, and trusting "the clinicians and the other product users" to decide that question for themselves); see also Goodman 9/10/02 at 85 (noting GPOs' "evidence-based decision making" with respect to new technologies).

organization may lack the incentive to promote efficiencies for its members. Some panelists suggested that such GPOs may have an incentive to collude with suppliers aiming to injure rival suppliers in a bid to acquire market power over the market for providing goods and services to the buyers.<sup>246</sup> Under this theory, the GPOs agree to raise barriers against rival suppliers through contract terms imposing tying, bundling, or exclusive dealing arrangements on the buyers.<sup>247</sup> These terms seek to "exclude rival manufacturers from competing for hospital sales even when the rival products are better or cheaper."<sup>248</sup>

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<sup>246</sup> See, e.g., ELHAUGE, *supra* note 206, at 30 n. 86 (challenging assumption that because GPOs are buyers' agents, they act as "an ordinary" buyer would, citing literature on agency costs showing that "agents generally always have some incentive to deviate from the interests of their principals").

The buyers themselves also may have an incentive to reach such agreements with suppliers, in exchange for "side payments that split the seller's supracompetitive profits, or special discounts that give the participating buyers market advantages over other buyers and thus enhance the participating buyers' downstream market power." ELHAUGE, *supra* note 206, at 28; see also Hilal 9/26 at 147-48 ("GPOs are not really collective bargainers .... [T]hey are, rather, franchisers .... Why would hospitals allow franchisers ... [to] make [their] li[v]es harder? Well, perhaps if they're part-owners of the franchising operation, or if the income is excluded from reimbursement computation ....").

<sup>247</sup> See, e.g., ELHAUGE, *supra* note 206, at 9-10; Hilal 9/26 at 143 (arguing that once a GPO grants monopoly power to a supplier, a "newcomer" supplier has difficulty entering because "for the new [product] to be offered ... the customers would have to be familiar with that product. For them to be familiar with that product, that newcomer must have access to the market," which he argues is impossible because of the GPOs).

<sup>248</sup> ELHAUGE, *supra* note 206, at 1.



Although suppliers do not need GPO support to attempt to exclude their rivals from the downstream market,<sup>249</sup> one panelist suggested that the GPOs can streamline the efforts to exclude.<sup>250</sup>

GPO members may also find it difficult to pursue other means of procuring goods for a variety of reasons. For example, member hospitals may be contractually bound to purchase certain supplies through a given GPO; the efficiencies that GPOs afford may outweigh their anticompetitive costs; member hospitals may enjoy “side-payments or special discounts” that give them private incentives to stay; a race-to-the-bottom effect may persuade a hospital to maintain its special GPO discount so that it does not suffer *vis-a-vis* its rivals; or agency problems that reward hospital administrators for winning short-term price cuts regardless of long-term harms may prevent hospitals from taking action against these

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<sup>249</sup> See Everard 9/26 at 168-69 (“For example, a multi-line supplier might be able to go to a hospital who is considering buying a product from a small company like Applied and say, you know, you might be able to buy that product and you’re right, you’re free to do it. However, if you choose to buy from that supplier, you’re going to lose significant discounts on all the other products that we sell to you. So ... the hospital is not really as free as one might think.”).

<sup>250</sup> See Weatherman 9/26 at 181-82 (“[T]he existence of GPOs makes anticompetitive contracting incredibly easy and efficient for these large manufacturers who would have to negotiate separate contracts with thousands of individual hospitals instead of with three or four large GPOs. So, the GPOs provide a very efficient vehicle for the large manufacturers to throw their weight around in the market.”).

anticompetitive practices.<sup>251</sup>

Others counter that GPOs are unlikely to collude with suppliers in this way for long, because buyers unhappy with the anticompetitive results can always leave the GPO for other means of purchasing supplies.<sup>252</sup> One panelist noted that GPOs must compete for hospitals’ business and that hospitals “are free to select GPOs that best represent their interests.”<sup>253</sup>

#### ***E. Statement 7 Does Not Protect Anticompetitive Contracting Practices***

*Health Care Statement 7* addresses the formation of a GPO. See Box 7-1. Some have proposed altering *Statement 7*, citing to concerns about alleged anticompetitive contracting practices.<sup>254</sup> The

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<sup>251</sup> See ELHAUGE, *supra* note 206, at 36-42.

<sup>252</sup> HOVENKAMP, *supra* note 183, at 23 (arguing that GPOs lack incentives to accept such a “bribe” from suppliers, in part because it risks having GPO members defect to other means of purchasing supplies).

<sup>253</sup> Clark 9/10/02 at 63; *see also* Burns 9/10/02 at 74 (noting existence of competition among GPOs for hospitals’ business); Betz 9/10/02 at 108 (same).

<sup>254</sup> See, e.g., Everard 9/26 at 165-66 (stating that *Health Care Statement 7* does not “protect patients and caregivers” and that “it must be revised to address the economic realities of the current medical product marketplace”); GAO Senate Testimony, *Pilot Study*, *supra* note 180, at 1 (noting that new concerns “have spurred calls for reexamining federal antitrust guidelines regarding GPOs” and stating that the antitrust guidelines “afford[] GPOs considerable latitude to merge and grow [and] has permitted the creation and growth of the largest GPOs”). *But see* Bloch 9/26 at 219-23.

Agencies, however, do not believe that it is appropriate or wise to amend *Statement 7*, because the statement and its safety zone thresholds do not prevent and should not be appropriately read as preventing antitrust challenges to any of the alleged anticompetitive contracting practices about which panelists and others have raised concerns.

*Statement 7* and its safety zone thresholds aim to address monopsony and oligopoly concerns with the formation of a GPO.<sup>255</sup> This statement reflects concerns that a particular GPO could (1) create monopsony power, injuring competition in the supplier market or (2) facilitate collusion in the sale of hospital products or services, injuring competition in the downstream market.

*Statement 7* does not address all potential issues that GPOs may raise. For example, it is silent on alleged exclusive dealing, tying, and bundling concerns that many panelists discussed in the Hearings. It is also silent on other potential competitive concerns, such as price-fixing, market allocation, mergers, etc. No statement is

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(defending *Health Care Statement 7*).

<sup>255</sup> One panelist noted this point and “urg[ed] the FTC to revisit the structure of the guidelines” to make the point clear. Latham 9/10/02 at 93. It is hardly atypical for Agency guidelines to address only a certain class of competitive issues. The Competitor Collaboration Guidelines also address only a limited set of anticompetitive concerns; they were not designed to address all possible anticompetitive conduct associated with competitor collaborations. See *Antitrust Guidelines for Collaborations Among Competitors*, 2 n.5 (2000) at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

**Box 4-1: Health Care Statement 7.** This statement provides in part: “The Agencies will not challenge, absent extraordinary circumstances, any joint purchasing arrangement among health care providers where two conditions are present: (1) the purchases account for less than 35 percent of the total sales of the purchased product or service in the relevant market; and (2) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.”

likely to cover every issue that could arise. The Agencies believe amending the statement to address some, but not all potential issues, is likely to be counterproductive. For example, some might argue that because certain issues were discussed, *Statement 7* implicitly endorses as legal whatever conduct is not specifically addressed. If a supplier coordinates with the buyers, or with GPOs that have turned on their buyers, to exclude rival suppliers, *Statement 7* would not protect such conduct from antitrust challenge.

In sum, *Statement 7* governs Agency actions examining monopsony and oligopoly issues in connection with a GPO’s formation. It does not preclude Agency action challenging anticompetitive conduct – such as anticompetitive contracting practices – that happens to occur in connection with GPOs. The Agencies will examine, on a case-by-case basis, the facts of any alleged anticompetitive contracting practices to determine whether the practice violates the antitrust laws.

## VIII. TIERING AND PAY-FOR-PERFORMANCE

Commentators and panelists noted that some providers have resisted tiering and pay-for-performance programs, and refused to provide information regarding the quality of care they provide.<sup>256</sup> When providers collectively refuse to enter into such arrangements or provide information to purchasers, the Agencies will carefully examine such conduct. As appropriate, the Agencies will bring cases against providers who collusively refuse to enter into such arrangements or provide such information. The Agencies also will challenge unilateral conduct or bundled contracting practices, where appropriate.

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<sup>256</sup> See *supra* Chapters 1 & 3.

**CHAPTER 5:           INDUSTRY SNAPSHOT: INSURANCE AND OTHER THIRD  
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## CHAPTER 5: INDUSTRY SNAPSHOT: INSURANCE AND OTHER THIRD PARTY PAYMENT PROGRAMS

### I. OVERVIEW

Chapter 5 provides an introduction to health insurance, including the applicable regulatory framework and sources of health care coverage. Chapter 6 summarizes competition law as it applies to the health insurance industry and then analyzes current controversies, including most favored nation clauses, mandated benefits, and consumer directed health plans.

Representatives from insurance groups and organizations, as well as legal, economic, and academic experts, spoke at the Hearings on insurance-related panels, including: Health Insurance: Payor/Provider Issues (September 9, 2002); Health Insurance Monopoly Issues: Market Definition (April 23); Health Insurance Monopoly Issues: Competitive Effects (April 23); Health Insurance Monopoly Issues: Entry and Efficiencies (April 24); Health Insurance Monopsony: Market Definition (April 24); Health Insurance Monopsony: Competitive Effects (April 25); Health Insurance/Providers: Countervailing Market Power (May 7); Most Favored Nation Clauses (May 7); Financing Design/Consumer Information Issues (June 12); Mandated Benefits (June 25); and Medicare and Medicaid (September 30).<sup>1</sup>

### II. INTRODUCTION

In 2002, the Census Bureau estimated that approximately 85 percent of

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<sup>1</sup> Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf>.

the United States' population had health insurance coverage.<sup>2</sup> Most Americans under the age of 65 obtain health insurance through their employer or a family member's employer. Many obtain coverage through a government program or purchase an individual insurance policy. Medicare covers most Americans aged 65 and over. Many individuals also purchase additional insurance to cover Medicare co-payments and those health care goods and services for which Medicare does not pay.

Health insurance and other third party payment programs pay for a substantial majority of health care services. As Chapter 1 notes, in 2002, national health expenditures were approximately \$1.6 trillion. Private health insurance paid for \$549.6 billion (35 percent), other private funds paid for \$77.5 billion (five percent), and public funds paid for \$713.4 billion (46 percent).<sup>3</sup> Consumer out-of-pocket expenses accounted for an additional \$212.5 billion in private expenditures (14 percent).<sup>4</sup>

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<sup>2</sup> ROBERT J. MILLS & SHAILESH BHANDARI, U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2002, at 1 (2003), available at <http://www.census.gov/prod/2003pubs/p60-223.pdf>. For more detail on the uninsured, see *infra* Chapter 5, Section VIII.

<sup>3</sup> Stephen Heffler et al., *Health Spending Projections Through 2013*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-79, 83 ex.4, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.79v1?ck=nck>. Consumer contributions to private health insurance premiums are included in the amount for private health insurance expenditures, not in the amount for consumers' out-of-pocket payments. *Id.* at 86.

<sup>4</sup> *Id.* at 83 ex.4.

Health insurance generally covers hospitalization, emergency care, and a range of clinical services. Coverage for pharmaceuticals is more variable, but still fairly common.<sup>5</sup> Hospitalization accounted for only 6.9 percent of consumers' out-of-pocket health-related expenses in 2002, while prescription drugs accounted for 22.9 percent.<sup>6</sup> Prescription drugs are projected to account for 32.5 percent of consumers' out-of-pocket health care expenses by 2013.<sup>7</sup>

Health insurance is subject to extensive federal and state laws and regulations. As noted previously, Americans obtain insurance coverage from various sources, including employment-based insurance, individual insurance, and Federal and State public sources, such as Medicare and Medicaid. These sources provide health care coverage through several types of health plans, including traditional indemnity (or fee-for-service (FFS)) plans, as well as managed care plans, which include health maintenance organizations (HMOs), preferred provider organizations (PPOs), and point of service plans (POSs).

This chapter first summarizes the state and federal laws and regulations that affect the health insurance industry. Next, this chapter describes employment-based, individually-purchased, and government-funded health care coverage, and considers the impact of public purchasing on the overall health care system. This chapter then considers in more detail the PPO. This chapter also discusses some issues

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<sup>5</sup> *Id.* at 80 ex.1.

<sup>6</sup> *Id.* at 87 ex.5.

<sup>7</sup> *Id.*

concerning the approximately 15 percent of the American population that is without health insurance at some point during the year. Finally, this chapter discusses consumer-driven health care initiatives and proposals.

### III. REGULATORY FRAMEWORK

The regulatory framework for health insurance varies, depending on whether coverage is individually-purchased, employment-based, or government-sponsored. The applicable regulatory framework for employment-based health insurance also may vary depending on whether the employer purchases coverage from a commercial insurer, self-insures the health plan, or uses a combination of approaches.

#### A. *McCarran-Ferguson Act*

The McCarran-Ferguson Act was adopted in 1945 to resolve a dispute over the authority of state and federal governments to regulate the business of insurance.<sup>8</sup> The McCarran-Ferguson Act clarified that the states had the authority to tax, license, and regulate insurance companies regardless of

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<sup>8</sup> McCarran-Ferguson Act, 15 U.S.C. §§ 1012-1014 (1945). The Act was a response to the Supreme Court's decision in *United States v. South-Eastern Underwriters Ass'n*, 322 U.S. 533 (1944), in which the Supreme Court held that insurance is commerce, and when transacted across state lines, is interstate commerce and subject to federal law, including the antitrust laws. This opinion reversed the Supreme Court's decision in *Paul v. Virginia*, 75 U.S. 168 (1869) and similar cases, in which the Court had held insurance was not commerce within the meaning of the Commerce Clause and was accordingly not subject to federal regulation. See *South-Eastern Underwriters*, 322 U.S. at 543-45.

the insurance company's state of incorporation, as well as the authority to allow insurance companies to engage in cooperative rate-making.<sup>9</sup> Section 2(b) of the McCarran-Ferguson Act specifically reserved authority for Congress to enact laws superceding state insurance laws and regulations, as long as the federal law specifically relates to the business of insurance.<sup>10</sup>

The McCarran-Ferguson Act exempts the "business of insurance" from the antitrust laws to the extent the states regulate such business.<sup>11</sup> Every state has adopted a framework for regulating insurance.<sup>12</sup> Section 3(b) of the McCarran-Ferguson Act provides that "[n]othing contained in this chapter shall render the said Sherman Act inapplicable to any agreement to boycott, coerce, or intimidate, or act of boycott, coercion, or intimidation."<sup>13</sup> Thus, the antitrust laws

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<sup>9</sup> McCarran-Ferguson Act § 1012; *Group Life & Health Ins. Co. v. Royal Drug Co.*, 440 U.S. 205, 221, 224 (1979) ("[T]he primary concern of both representatives of the insurance industry and the Congress was that cooperative ratemaking efforts be exempt from the antitrust laws" as long as they were regulated by the state.).

<sup>10</sup> McCarran-Ferguson Act § 1012(b).

<sup>11</sup> *Id.* §§ 1012(b).

<sup>12</sup> *See, e.g.*, NAT'L ASS'N OF INSURANCE COMMISSIONERS (NAIC), ANNUAL REPORT 1 (2003), at [http://www.naic.org/about/docs/03\\_annual\\_report.pdf](http://www.naic.org/about/docs/03_annual_report.pdf).

<sup>13</sup> McCarran-Ferguson Act § 1013(b). *But see* American Chiropractic Ass'n, *Comments Regarding Health Care and Competition Law and Policy* (Sept. 9, 2003) 1 (Public Comment) (arguing certain anticompetitive conduct is protected by the McCarran-Ferguson Act and this puts individual

generally apply to insurance company mergers, monopolization, and other conduct not constituting the "business of insurance," as well as to the specific forms of anticompetitive conduct listed in the McCarran-Ferguson Act.<sup>14</sup> Chapter 6 discusses antitrust enforcement in this area.

## **B. State Laws and Regulations**

Each state has its own laws and regulations governing health insurance.<sup>15</sup> Although these state rules vary greatly, each

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health care providers "at a distinct disadvantage" vis-a-vis insurers).

<sup>14</sup> McCarran-Ferguson Act § 1013. In a trilogy of cases decided between 1978 and 1982, the Supreme Court clarified that the McCarran-Ferguson Act exempted the business of insurance, not the business of insurance companies. The court "identified three criteria relevant in determining whether a particular practice is part of the 'business of insurance' exempted from the antitrust laws by § 2(b): *first*, whether the practice has the effect of transferring or spreading a policyholder's risk; *second*, whether the practice is an integral part of the policy relationship between the insurer and the insured; and *third*, whether the practice is limited to entities within the insurance industry." *Union Labor Life Ins. Co. v. Pireno*, 458 U.S. 119, 129 (1982). *See also Royal Drug*, 440 U.S. at 221-24, 229-30 n.36 & 37; *St. Paul Fire & Marine Ins. Co. v. Barry*, 438 U.S. 531, 546, 551 (1978); American Bar Ass'n, Section of Antitrust Law, *Comments Regarding The Federal Trade Commission's Workshop on Health Care and Competition Law and Policy* (Oct. 2002) 7-8 (Public Comment).

<sup>15</sup> *See, e.g.*, KAREN POLLITZ ET AL., GEORGETOWN UNIV. INSTITUTE FOR HEALTH CARE RESEARCH & POLICY, A CONSUMER'S GUIDE TO GETTING AND KEEPING HEALTH INSURANCE IN THE DISTRICT OF COLUMBIA (2002), available at <http://www.healthinsuranceinfo.net/dc.pdf>. This website has consumer guides for all 50 states and the District of Columbia.



state has an insurance commissioner charged with ensuring that insurers are solvent and do not engage in unfair or deceptive practices.<sup>16</sup>

### C. ERISA

The Employee Retirement Income Security Act of 1974 (ERISA) broadly preempts state law to establish and preserve uniform and exclusive federal regulation of covered employee benefit plans.<sup>17</sup> ERISA regulates any plan, fund, or program maintained for the purpose of providing retirement benefits, as well as medical or other health benefits for employees or their beneficiaries.<sup>18</sup> ERISA expressly permits states to continue to enforce all state laws that regulate the business of insurance, but it prohibits states from declaring an employee benefit plan that is covered by ERISA to be an insurance company or engaged in the business of insurance.<sup>19</sup> A state law

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<sup>16</sup> NAIC, *supra* note 12, at 1. Many states also have procedures for appealing coverage denials.

<sup>17</sup> Employee Retirement Income Security Act (ERISA) of 1974, 29 U.S.C. § 1001.

<sup>18</sup> See James C. Dechene, *Preferred Provider Organizations*, in HEALTH CARE CORPORATE LAW: MANAGED CARE § 2.12.7, at 2-50 n.21 (Mark A. Hall & William S. Brewbaker III eds., 1999 & Supp. 1999) (“ERISA requirements include, for example, broad reporting and disclosure requirements (29 U.S.C. §§ 1021 et seq.); participation and vesting requirements (29 U.S.C. §§ 1051 et seq.); funding requirements (29 U.S.C. §§ 1081 et seq.); and fiduciary responsibilities (29 U.S.C. §§ 1101 et seq.).”)

<sup>19</sup> 29 U.S.C. § 1144(a), (b)(2)(A), (b)(2)(B). The “savings clause” allows for state regulation of insurance, and the “deemer” clause prevents employee benefit plans from being deemed to be insurers.

regulates insurance if it is “specifically directed toward entities engaged in insurance” and “substantially affect[s] the risk-pooling arrangement between the insurer and the insured.”<sup>20</sup>

### D. HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which amended ERISA, the Public Health Service Act, and the Internal Revenue Code, establishes minimum federal standards and requirements concerning guaranteed issue and renewability of health coverage, limits exclusions for preexisting medical conditions, provides for credit against maximum preexisting condition exclusion periods for prior health coverage, prohibits individual discrimination based on health factors, and limits disclosure of personal health information.<sup>21</sup> HIPAA applies to both employee benefit plans and state-regulated insurers.<sup>22</sup>

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<sup>20</sup> Ky. Ass’n of Health Plans, Inc. v. Miller, 538 U.S. 329, 123 S. Ct. 1471, 1479 (2003) (internal citations omitted).

<sup>21</sup> Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936. See also U.S. Dept. of Labor, *Fact Sheet: HIPAA*, at <http://www.dol.gov/ebsa/newsroom/fshipaa.html> (last visited June 23, 2004); U.S. Dep’t of Labor, *Frequently Asked Questions About Portability of Health Coverage and HIPAA*, at [http://www.dol.gov/ebsa/faqs/faq\\_consumer\\_hipaa.html](http://www.dol.gov/ebsa/faqs/faq_consumer_hipaa.html) (last visited June 23, 2004). HIPAA also contains a number of provisions relating to fraud and abuse enforcement, which are not addressed in this Report.

<sup>22</sup> See *supra* note 21. See also 29 U.S.C. §§ 1181-1183 (ERISA); 42 U.S.C. §§ 300gg et seq. (Public Health Service Act).

## **E. COBRA**

The Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) provides for continuation of group health coverage that would otherwise be terminated.<sup>23</sup> Former employees and their dependents who lose coverage may temporarily continue their health coverage at group rates if they are willing to pay up to 102 percent of those rates, and they qualify under the terms of the statute. COBRA generally applies to group health plans maintained by employers with 20 or more employees in the prior year. It applies to plans in the private sector and those sponsored by state and local governments.<sup>24</sup>

## **F. Mandated Benefits**

State and federal laws mandate numerous health insurance benefits. Mandated benefits fall into three general categories: (1) *provider mandates*, which require health insurers to cover services provided by certain providers or categories of providers (*e.g.*, any-willing provider laws, freedom of choice, and laws mandating coverage of services provided by a select group of providers (*e.g.*, massage therapists or naturopaths)); (2) *coverage mandates*, which require health insurers to cover particular classes of individual patients and

conditions (*e.g.*, mental health parity); and (3) *benefit mandates*, which require health insurers to provide a specified minimum level of benefits (*e.g.*, 48 hour post-partum hospitalization, direct access to specialists).<sup>25</sup> Some states rarely mandate benefits, while other states do so routinely.<sup>26</sup> Federal law mandates a few benefits.<sup>27</sup>

## **G. Federal Tax Code**

The tax code subsidizes employment-based health insurance. Employer contributions for employees' health insurance coverage are deductible to employers, but are not considered taxable

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<sup>25</sup> Although there are three categories of mandated benefits, this Report focuses primarily on "provider mandates." *See infra* Chapter 6.

<sup>26</sup> Gitterman 6/25 at 8-9 (noting that Idaho has only ten mandated benefits, but Maryland has 52).

<sup>27</sup> The federal Newborns' and Mothers' Health Protection Act requires group health plans and insurers that provide benefits for hospital lengths of stay in connection with childbirth to provide coverage for a 48-hour hospital stay following a normal delivery and a 96-hour hospital stay following a cesarean delivery. The Mental Health Parity Act generally requires group health plans and insurers to provide for parity in lifetime and annual dollar limits on mental health benefits with dollar limits on medical and surgical benefits. The Women's Health and Cancer Rights Act requires plans and insurers to provide coverage for post-mastectomy benefits, including benefits for all stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction to produce a symmetrical appearance, prostheses and treatment of physical complications of the mastectomy, including lymphedemas. *See infra* Chapter 6.

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<sup>23</sup> The Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986, Pub. L. No. 99-509, 100 Stat. 1874. *See also* PENSION & WELFARE BENEFITS ADMIN., U.S. DEPT OF LABOR, HEALTH BENEFITS UNDER THE CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT (2001), at <http://www.labor.gov/ebsa/pdf/cobra99.pdf>.

<sup>24</sup> PENSION & WELFARE BENEFITS ADMIN., *supra* note 23, at 1-2.

income to employees.<sup>28</sup> Thus, employees obtain health care coverage through their employer with pre-tax dollars, which results in a tax subsidy for employment-based health insurance of more than \$100 billion per year.<sup>29</sup>

#### IV. EMPLOYMENT-BASED COVERAGE

The number of people with employment-based insurance fluctuated during the 1990s, but is currently stabilized at approximately 61 percent of the population.<sup>30</sup> The significance of

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<sup>28</sup> David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 YALE J. HEALTH POL'Y L. & ETHICS 23, 25 (2001).

<sup>29</sup> *Id.* (noting that exclusion from income in a progressive tax system means that subsidy varies with income, with greater subsidies going to those with higher incomes). See also OFFICE OF MGMT. & BUDGET, BUDGET OF THE U.S. GOVERNMENT: ANALYTICAL PERSPECTIVES, FISCAL YEAR 2004 (2003) (estimating personal income tax expenditure for health care at \$130.2 billion), available at <http://www.whitehouse.gov/omb/budget/fy2004/pdf/pec.pdf>; John Sheils & Randall Haught, *The Cost of Tax-Exempt Health Benefits In 2004*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-106, 110 (estimating personal income tax expenditure for health care at \$122.1 billion), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.106v1.pdf>. See also Stuart Butler, *A New Policy Framework for Health Care Markets*, 23 HEALTH AFFAIRS 22, 23 (Mar./Apr. 2004) (suggested that families receive more than \$140 billion in federal and state tax relief “if they hand over the control of health insurance to their employers.”). One panelist also noted the “huge distortions created by the tax system.” Francis 9/30 at 129.

<sup>30</sup> See MILLS & BHANDARI, *supra* note 2, at 1; John Holahan & Marie Wang, *Changes In Health Insurance Coverage: 1994-2000*, 2002 HEALTH AFFAIRS (Web Exclusive) W162, 163, at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w2.162v1/DC1>.

employment-based health insurance varies by industry. In some sectors of the economy (e.g., construction, service industries, and retail), employment-based health insurance is less common than in other sectors of the economy (e.g., finance and manufacturing).<sup>31</sup> Employer size matters as well; the larger the firm, the more likely it is that employees will be offered employment-based health insurance.<sup>32</sup> Not all employees take advantage of employment-based health insurance, and some employees obtain coverage for themselves, but not for their beneficiaries.<sup>33</sup> Although it is common parlance to speak of “employer contributions” to the cost of health care coverage, employees ultimately bear these costs, in the form of lower salaries and fringe benefits.<sup>34</sup>

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w2.162v1/DC1. See also Hyman & Hall, *supra* note 28, at 26 (stating that approximately 177 million Americans obtain health insurance coverage through their employers); INSTITUTE OF MEDICINE (IOM), COVERAGE MATTERS: INSURANCE AND HEALTH CARE 8 (2001) (noting that in 2000, approximately 66 percent of the population under age 65 receive employment-based health care insurance; most Americans older than 65 years of age receive health care coverage under the Medicare program).

<sup>31</sup> John Holahan & Marie Wang, *Changes In Health Insurance Coverage During The Economic Downturn: 2000-2002*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-31, 40, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.31v1?ck=nck>.

<sup>32</sup> MILLS & BHANDARI, *supra* note 2, at 7-8 & fig.3; Holahan & Wang, *supra* note 31, at 39-40 ex.8.

<sup>33</sup> Hyman & Hall, *supra* note 28, at 26.

<sup>34</sup> See Darling 6/12 at 100-102 (“[A]ll [health] benefits are foregone wages or other benefits paid for by the worker”); Jonathan Gruber, *Health Insurance and the Labor Market*, in 1A HANDBOOK OF HEALTH ECONOMICS 645, 699 (Anthony J. Culyer

**A. Sources and Regulation of Employment-Based Coverage**

Employers offer health coverage to their employees through various sources, including commercial insurance companies, employers' self-insured plans, and various combinations of the two.<sup>35</sup> The applicability of federal and state laws and regulations varies, depending on the source of health care coverage an employer makes available to employees.

Employers who offer health insurance through commercial insurers usually negotiate on behalf of their employees for specific benefits at a specified monthly premium per person or family.<sup>36</sup> Historically, most employers paid a percentage of the employees' monthly premium, but some employers are now shifting to a fixed dollar contribution in an

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& Joseph P. Newhouse eds., 2000) (“[I]ncreases in health insurance costs appear to be fully reflected in worker wages ...”).

<sup>35</sup> See *Am. Med. Sec. v. Bartlett*, 915 F. Supp. 740, 742 (D. Md. 1996), *aff'd*, 111 F.3d 358 (4th Cir. 1997). See also S. Allen 4/25 at 105-06 (in Arkansas, commercial insurance products are provided by three national plans, two large local plans, and 64 in-state and out-of state third party administrators, as well as self-insured plans providing health coverage to 45 to 50 percent of the covered population).

<sup>36</sup> Commercial insurance companies include both for-profit and not-for-profit entities. For-profit companies include, among others, Aetna, Cigna, and UnitedHealthCare. Although Blue Cross and Blue Shield Plans traditionally have been nonprofit companies, some have converted, or attempted to convert, to for-profit status in recent years. See, e.g., S. Allen 4/25 at 105-06; Ginsburg 4/23 at 19.

effort to contain costs.<sup>37</sup> Commercially insured plans are generally subject to state laws and regulations, and federal law.<sup>38</sup>

Some employers choose to self-insure their employees' health insurance plans by assuming 100 percent of the risk.<sup>39</sup> If the employer fully self-insures the health benefit plan, then it falls within the scope of ERISA and the state cannot regulate it.<sup>40</sup> The larger the firm, the more likely it is self-insured.<sup>41</sup>

Some employers create self-insured

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<sup>37</sup> See Alain Enthoven, *Employment-Based Health Insurance is Failing: Now What?*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-237, 242-43 (stating that paying a fixed percentage of employees' premiums rewards those that choose the most expensive plan), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.237v1.pdf>.

According to one report, employee contributions in 1996 accounted for approximately 30 percent of total health insurance premiums. Robert Kuttner, *The American Health Care System: Employer-Sponsored Health Coverage*, 340 NEW ENG. J. MED. 248, 250 (1999).

<sup>38</sup> For example, the Public Health Service Act (PHSA) and ERISA, as amended by HIPAA, impose certain federal requirements on insurers. See *supra* notes 21-22 and accompanying text. Employer-sponsored plans must also comply with ERISA, even if they are fully insured.

<sup>39</sup> *Am. Med. Sec.*, 915 F. Supp. at 742, 746.

<sup>40</sup> See *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724 (1985); *Am. Med. Sec.*, 915 F. Supp. at 742. See also Greg Kelly, *Financing Design / Consumer Information Issues 2* (6/12) [hereinafter G. Kelly (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030611gregkelly.pdf>; G. Kelly 6/12 at 114.

<sup>41</sup> See, e.g., Gingrich 6/12 at 15-16; Holahan & Wang, *supra* note 31, at 40; NEWT GINGRICH ET AL., *SAVING LIVES & SAVING MONEY* 84 (2003).

plans, but contract with commercial insurance companies to act as a third-party administrator (TPA) for claims processing, or for access to a provider network. ERISA preemption of state law varies, depending on the contractual relationship between the self-insured plan and the commercial insurer.<sup>42</sup>

Some employers self-insure their health plan up to a certain amount and purchase an insurance policy to cover costs that exceed that pre-determined, agreed upon amount.<sup>43</sup> This is often called “stop-loss” coverage.<sup>44</sup> For example, an employer may choose to self-insure its employees’ aggregate health care expenditures up to a maximum of \$1 million per year, and contract with a traditional insurance company to cover any health care costs in excess of that \$1 million. ERISA generally preempts state laws that apply to self-insured plans, including plans that purchase such stop loss insurance coverage.<sup>45</sup> In *American*

*Medical Security v. Bartlett*, the Fourth Circuit held that ERISA preempted a state regulation that was designed to subject to the state’s insurance laws self-insured plans carrying stop-loss insurance below state-specified minimum levels.<sup>46</sup>

Most cases have held “that ERISA preempts application of state insurance laws to self-insured plans that have arrangements with TPAs” to provide administration and claims processing services.<sup>47</sup> The case law is mixed whether ERISA preempts state laws if a self-insured plan contracts with an insurer to provide access to a provider network. For example, some courts have held that a state’s any willing provider laws will apply to PPOs established by an insurance company, even if the insurer is developing the PPO for use by an ERISA plan.<sup>48</sup> Others have held such laws are

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<sup>42</sup> See generally Dechene, *supra* note 18, § 2.12.7, at 2-52.

<sup>43</sup> *Am. Med. Sec.*, 915 F. Supp. at 742. The agreed upon amount is called the “attachment” point. There are two types of attachment points – specific (or individual) and aggregate. The specific attachment point is the amount above which the insurer must reimburse the employer for eligible claims made by an *individual* plan participant. The aggregate attachment point is the amount above which the insurer must reimburse the employer for eligible claims made by *all* plan participants. *Id.* at 742.

<sup>44</sup> *Id.* at 742.

<sup>45</sup> See *Am. Med. Sec.*, 111 F.3d at 362. See also *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724 (1985); Dechene, *supra* note 18, § 2.12.7, at 2-52 n.29. The Supreme Court considered the boundaries of ERISA preemption in four recent cases: *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488 (2004);

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*Kentucky Ass’n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002); *Pegram v. Herdrich*, 530 U.S. 211 (2000).

<sup>46</sup> *Am. Med. Sec.*, 111 F.3d at 362 (state regulation was designed to force self-insured plans to provide state mandated benefits if the employer was reimbursed for employees’ eligible claims below \$10,000 per beneficiary).

<sup>47</sup> Dechene, *supra* note 18, § 2.12.7, at 2-51 to 2-52 n.28 (citing to *Children’s Hosp. v. Whitcomb*, 778 F.2d 239 (5th Cir. 1985), *Moore v. Provident Life & Accident Ins. Co.*, 786 F.2d 922 (9th Cir. 1986), *Ins. Bd. of Bethlehem Steel Corp. v. Muir*, 819 F.2d 408 (3rd Cir. 1987), *State Farm Mut. Auto. Ins. Co. v. C.A. Muer Corp.*, 397 N.W.2d 299 (Mich. Ct. App. 1986)).

<sup>48</sup> See, e.g., *Stuart Circle Hosp. Corp. v. Aetna Health Mgmt.*, 995 F.2d 500 (4th Cir. 1993); *Blue Cross & Blue Shield v. St. Mary’s Hosp., Inc.*, 426 S.E.2d 117 (Va. 1993).

preempted by ERISA.<sup>49</sup> The Supreme Court's recent decision in *Kentucky Ass'n of Health Plans, Inc. v. Miller* does not settle this area of the law.<sup>50</sup>

## **B. Issues and Priorities**

One speaker provided an overview of the priorities of employees and employers in dealing with health insurance coverage.<sup>51</sup> Employees want good coverage at a reasonable price that is administratively simple, covers alternative treatments, and continues into retirement.<sup>52</sup> Employees also

are concerned about costs.<sup>53</sup> A 2002 study reported that 43 percent of employees feared that their employment-based coverage would be cut back within the next year, 21 percent feared they would not be able to afford the increases in out-of-pocket expenses, and 8 percent feared they would lose their employment-based benefits within one year.<sup>54</sup> From an employee perspective, if premium increases are larger than salary increases, take-home pay declines.<sup>55</sup>

Surveys reveal that choice is important to many employees, but employers vary greatly in the number of

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<sup>49</sup> See, e.g., *BPS Clinical Lab. v. Blue Cross & Blue Shield*, 522 N.W.2d 902 (Mich. Ct. App. 1994). The Supreme Court held that ERISA does not preempt a New York state law that required hospitals to impose varying surcharges on health insurers, including self-insured ERISA plans. *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995). The Supreme Court did note, however, that a state law that attempted to force ERISA plans to adopt certain benefits might be preempted. *Id.* at 668. The case does not clarify whether state laws governing TPAs or PPOs are preempted when contracting with ERISA plans. See *Dechene*, *supra* note 18, § 2.12.7, at 2-54 to 2-55.

<sup>50</sup> *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 123 S. Ct. 1471, 1476 n.1 (2003) (noting that Kentucky's law was specifically limited to "employee benefit plans 'not exempt from state regulation by ERISA.'"). For a discussion of any willing provider laws see *infra* Chapter 6.

<sup>51</sup> See M. Young 6/12 at 91-96; Michael Young, *Financing Design/Consumer Information Issues 2-3, 7* (6/12) (slides) [hereinafter M. Young Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030612young.pdf>.

<sup>52</sup> M. Young 6/12 at 91-94. The same panelist noted that although some administrative hassles have been eliminated as electronic claims processing becomes more prevalent, electronic databases are not universal and many employees still face administrative difficulties as they navigate the

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health care system. *Id.* at 93. Many insurance companies, on which employers rely to set the standards concerning what treatments are covered, also are slow to adopt coverage for alternative treatments. Finally, he noted that the percentage of large employers providing health benefits for retirees appears to be dwindling quickly. *Id.* at 93-94. See also THE KAISER FAMILY FOUND., EMPLOYER HEALTH BENEFITS 2003 ANNUAL SURVEY § 11, at 132 (in 2003, 38 percent of large employers (200 or more employees) offered health benefits to retirees versus 66 percent in 1988; since 1991, the range has fluctuated from a high of 46 percent in 1991 to a low of 35 percent in 2000; in 2003, 10 percent of small employers (less than 200 employees) offered such benefits), available at <http://www.kff.org/insurance/ehbs2003-abstract.cfm>.

<sup>53</sup> M. Young 6/12 at 92.

<sup>54</sup> M. Young 6/12 at 94-95; M. Young Presentation, *supra* note 51, at 3 (citing a "Robert Wood Johnson Foundation survey of 800 registered voters, January 2002").

<sup>55</sup> See, e.g., M. Young 6/12 at 92 ("[A] lot of our clients will have employees whose payroll deduction for health care will be greater than their increase in their salary. And what happens is their take-home pay becomes less"). Darling 6/12 at 101 ("[A]ll [health] benefits are foregone wages or other benefits paid for by the worker").

insurance plan options they offer their employees.<sup>56</sup> The larger the employer, the more likely there will be more than one coverage option, but the health plan options can change from year-to-year.<sup>57</sup>

According to several panelists, employers are questioning whether they should be providing health insurance coverage.<sup>58</sup> One speaker cautioned that employers cannot maintain the health care financing structure the way it is and, without changes, many employers will be forced to take more drastic measures with respect to providing employment-based health care coverage.<sup>59</sup> Another speaker suggested that employers were likely to continue providing health coverage, but the amount of money they contribute will not keep pace with the

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<sup>56</sup> See, e.g., M. Young 6/12 at 91, 95; KAISER FAMILY FOUND., *supra* note 52, § 4, at 62 (in 2003, 62 percent of covered workers had more than one health plan option, and this percent has been relatively stable since 1996).

<sup>57</sup> M. Young 6/12 at 91-92; M. Young Presentation, *supra* note 51, at 2. See also KAISER FAMILY FOUND., *supra* note 52, § 4, at 64 (38 percent of covered workers have just one plan option; 74 percent of large employers offered employees a choice between at least two health plans versus 26 percent of small employers (less than 200 employees) that offered a choice).

<sup>58</sup> Darling 6/12 at 107; M. Young 6/12 at 99.

<sup>59</sup> M. Young 6/12 at 99; M. Young Presentation, *supra* note 51, at 7 (structure of employment-based health insurance has changed in recent years: less tightly managed HMOs, more cost sharing with employees, more choices of plans; more drastic changes possible in future: consideration of dropping coverage, consideration of consumer-driven health plans).

cost of health care.<sup>60</sup> Some panelists asserted that small employers face greater challenges than large employers.<sup>61</sup>

Some commentators criticize employment-based insurance coverage because it reflects the coverage preferences of employers instead of employees.<sup>62</sup> Others argue that the existence of employment-based health insurance impedes achieving universal coverage.<sup>63</sup> Some panelists suggest that the regulatory environment favors large employers over small employers and those that purchase individual policies.<sup>64</sup>

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<sup>60</sup> Darling 6/12 at 107 (“[T]he amount of money they [employers] pay will grow more slowly than the cost of health care will, and therefore the employees and their retirees will be spending a lot more money”).

<sup>61</sup> See, e.g., M. Young 6/12 at 95-96; Gingrich 6/12 at 15-16.

<sup>62</sup> See, e.g., EMPOWERING HEALTH CARE CONSUMERS THROUGH TAX REFORM (Grace-Marie Arnett ed., 1999); Butler, *supra* note 29, at 23; Stuart Butler & David B. Kendall, *Expanding Access and Choice for Health Care Consumers Through Tax Reform*, 18 HEALTH AFFAIRS 45, 46 (Nov./Dec. 1999); SHARON SILOW-CARROLLET AL., IN SICKNESS AND IN HEALTH? THE MARRIAGE BETWEEN EMPLOYERS AND HEALTH CARE (1995); Uwe E. Reinhardt, *Employer-Based Health Insurance: A Balance Sheet*, 18 HEALTH AFFAIRS 124, 127 (Nov./Dec. 1999). See also Hyman & Hall, *supra* note 28, at 26-27 (“[D]ifficulties with employment-based insurance stem from the fact that someone other than the ultimate consumer of health care is making most of the decisions about what coverage to purchase and how much to pay”); M. Young Presentation, *supra* note 51, at 4.

<sup>63</sup> See, e.g., SILOW-CARROLLET AL., *supra* note 62; Reinhardt, *supra* note 62, at 127.

<sup>64</sup> M. Young 6/12 at 95-96; G. Kelly 6/12 at 114-16; Gingrich 6/12 at 15-16.

Despite these employee and employer misgivings, as well as commentator criticisms, one benefits consultant stated that there is a continuing role for employment-based coverage.<sup>65</sup> He noted that employers can devote greater resources to understanding the various insurance product offerings and can represent a larger purchasing group than individual employees. Employers generally have greater negotiating power with insurance companies than individuals.<sup>66</sup> Group underwriting spreads the risks and provides lower administrative costs.<sup>67</sup> Moreover, group policies generally provide more benefits, such as prescription drug coverage.<sup>68</sup> Others note that employment-based insurance coverage provides a stable and effective source of coverage that is valued by employees.<sup>69</sup>

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<sup>65</sup> M. Young 6/12 at 99; Darling 6/12 at 107. *But see* Gingrich 6/12 at 15. In fact, the tax preferences for employment-based coverage likely confers the most significant advantage. *See* Hyman & Hall, *supra* note 28, at 25

<sup>66</sup> *See* M. Young 6/12 at 98; M. Young Presentation, *supra* note 51, at 5. *But see* Gingrich 6/12 at 15 (“[W]e artificially constrain and raise the cost of insurance for the self-employed, the unemployed, small businesses, and family farms. There is no inherent reason we can’t have a nationwide market based on something like eBay, where people can go online with very little intermediation cost and buy into a national risk pool .... You should individually be able to buy group insurance.”).

<sup>67</sup> M. Young 6/12 at 98; M. Young Presentation, *supra* note 51, at 10.

<sup>68</sup> M. Young Presentation, *supra* note 51, at 10.

<sup>69</sup> *See* Darling 6/12 at 100 (referencing employee surveys). This panelist emphasized the importance employees place on health benefits,

One panelist argued that the tax preference for employment-based health insurance should be eliminated.<sup>70</sup> He suggested that an individual-based health insurance system would be more conducive to quality and price competition.<sup>71</sup> He explained that between 12 and 16 percent of the U.S. workforce changes jobs each year, and as a result, employers have little incentive to offer health insurance plans that invest in quality health care up-front because they may be more costly in the short-run.<sup>72</sup> He concluded that a system that enables individuals to purchase a portable health insurance plan, which they may keep for decades, will foster development of a market-based health care sector, including health plans that focus on quality of care and health for the long-term.<sup>73</sup>

Several commentators also have suggested eliminating the tax bias in favor of

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stating that some large employers suspended their contributions to employees’ 401(k) plans, but were very modest with decreases in health benefits. She noted that employees went on strike against Hershey Corporation over an increase from 3 percent to 5 percent in employees’ contributions to health coverage. *Id.* at 101-102. *See also* Hyman & Hall, *supra* note 28, at 42-43.

<sup>70</sup> *See* Greenberg 6/12 at 63.

<sup>71</sup> *Id.* at 64.

<sup>72</sup> *Id.* at 64-65 (the investment up-front would render the plans less-costly in the long-run).

<sup>73</sup> *Id.* at 64-69. *See also infra* notes 200-209, and accompanying text (discussing consumer-driven health care), and *supra* Chapter 1 (discussing quality).



employment-based health insurance.<sup>74</sup> One commentator stated that as consumers begin making their own decisions about health insurance and care, market forces will encourage the private sector to create more information resources to enable consumers to make more informed choices.<sup>75</sup> Another commentator stated that market forces in health care “are badly distorted or blocked by employers’ failure to offer employees responsible choices; by the tax treatment of ‘employer-paid’ health insurance; by providers’ resistance to the collection and publication of quality-related information; by provider monopolies; and by laws and regulations that block the development of high-quality, cost-effective alternatives to fee-for-service (FFS) indemnity insurance.”<sup>76</sup> He suggested that these problems are not insurmountable and that market forces could be strengthened by a

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<sup>74</sup> Butler, *supra* note 29, at 23 (suggesting government “expand tax credits and other tax relief for non-employer-sponsored coverage and for consumers’ direct expenditures, preferably in combination with a phased-in ceiling on the tax exclusion”); Scott Harrington & Tom Miller, *Perspective: Competitive Markets for Individual Health Insurance*, 2002 HEALTH AFFAIRS (Web Exclusive) W359, 360 (suggesting more comparable tax treatment for all health insurance consumers), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.359v1.pdf>. See also Gingrich 6/12 at 6-21.

<sup>75</sup> Butler, *supra* note 29, at 23-24. See *infra* notes 200-209, and accompanying text, for a discussion of consumer-driven health care.

<sup>76</sup> Alain Enthoven, *Market Forces And Efficient Health Care Systems*, 23 HEALTH AFFAIRS 25, 25 (Mar./Apr. 2004) (stating that market forces in this context “meet certain fundamental conditions, including that the buyers are (reasonably well) informed, are using their own money (at least at the margin), and face a choice among competing alternative suppliers”).

number of steps, including providing consumers with information, economic incentives, and the ability to choose among health plans.<sup>77</sup>

One speaker described his company’s actions to address rising health care costs and to make employees more cost-conscious. In 2003, the company provided a fixed subsidy of \$220 per month to employees for health care coverage, regardless of the health care plan they chose. His company also increased copayments for office and emergency room visits, introduced hospital deductibles, and carved out the pharmacy benefit and introduced a three-tier formulary.<sup>78</sup> This panelist explained that given his company’s “defined contribution strategy, [the] employees are well aware of the accelerating cost of health care. Their response has been to move to lower cost plans, even if it means more hassles to access specialists.”<sup>79</sup>

One panelist argued that state and federal regulations have undermined the

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<sup>77</sup> *Id.* at 25-26 (suggesting that a fixed dollar amount, rather than a fixed percentage of the premium, as well as allowing employees to share in the savings if they choose a lower-cost health plan, is one way to provide incentives for employees to seek greater value for their money). See also Enthoven, *supra* note 37, at 242-43; Kelly Hunt et al., *Paying More Twice: When Employers Subsidize Higher-Cost Health Plans*, 16 HEALTH AFFAIRS 150, 154 (Nov./Dec. 1997) (research findings, although not definitive, suggested that between 1994-1995, “firms that did not subsidize more expensive health plans had lower price increases or greater price decreases than those that did subsidize”).

<sup>78</sup> Meyer 4/11 at 24-27. See also *infra* Chapter 7.

<sup>79</sup> Meyer 4/11 at 27-28.

performance of the health insurance market.<sup>80</sup> According to this panelist, HIPAA and follow-on state regulations requiring guaranteed issue and limiting the prices that can be charged in the small-group insurance market have had disastrous consequences.<sup>81</sup> Guaranteed issue requires insurers that sell coverage to employers in the small group market to offer and sell that coverage to all small employers in the market. This panelist suggested that with guaranteed issue, a small employer may choose to remain uninsured until one of its employees needs extensive medical care, knowing that regulations require the insurance companies to issue coverage and some state laws restrict the price and type of coverage.<sup>82</sup> This panelist stated that such regulation causes “healthier groups to leave the market, prices to skyrocket, and insurers to stop offering coverage.”<sup>83</sup> Another panelist identified a number of regulations that restrict

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<sup>80</sup> See G. Kelly 6/12 at 118; G. Kelly (stmt), *supra* note 40, at 3, 5-6.

<sup>81</sup> See G. Kelly 6/12 at 115-16; G. Kelly (stmt), *supra* note 40, at 3.

<sup>82</sup> G. Kelly 6/12 at 115-18 (“Under [state] guaranteed issue, an individual who becomes ill may apply for private insurance coverage and must be accepted. This is comparable to allowing a person to purchase auto insurance for a car wreck after its happened.”); G. Kelly (stmt), *supra* note 40, at 5-6.

<sup>83</sup> G. Kelly 6/12 at 118; G. Kelly (stmt), *supra* note 40, at 5-6. This speaker indicated that guaranteed issue resulted in a minimum monthly premium for family coverage of \$1,176 in Portland, Maine, \$3,576 in Trenton, New Jersey, and \$1,113 in Ithaca, New York. Conversely, in three states without such laws, the monthly premium for comparable family coverage was \$355 in Madison, Wisconsin, \$410 in Arlington, Virginia, and \$461 in Pittsburgh, Pennsylvania. G. Kelly 6/12 at 116-17; G. Kelly (stmt), *supra* note 40, at 4.

competition – sometimes by design, and other times unintentionally.<sup>84</sup>

## V. INDIVIDUAL INSURANCE

In 1999, approximately 16 million working-age adults and children – almost seven percent of the population under the age of 65 – obtained health insurance coverage through individually issued, non-group policies.<sup>85</sup> One set of commentators suggest the small market share for individual health insurance is due, at least in part, to the tax-subsidies provided for employment-based coverage.<sup>86</sup> Individual insurance policies generally are more expensive than group policies because there is no spreading of underwriting risk, and adverse selection and marketing and administrative expenses are greater than with group policies.<sup>87</sup>

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<sup>84</sup> Francis 9/30 at 129-30.

<sup>85</sup> IOM, *supra* note 30, at 41.

<sup>86</sup> See Harrington & Miller, *supra* note 74, at 360 (suggesting “[b]roader access to more comparable tax treatment for all health insurance consumers, regardless of where or how they purchase insurance, is needed to provide a deeper, more diversified pool of potential customers and move the individual market beyond a narrow niche role.”).

<sup>87</sup> See GREG SCANDLEN, DEFINED CONTRIBUTION HEALTH INSURANCE 17 (Nat’l Center for Policy Analysis, Policy Backgrounder No. 154, 2000) (stating that expenses are higher because insurance companies use agents to screen individuals for the highest risks, “people in the individual market are older, sicker and poorer than those in the group market ... [and that] they are also unsubsidized by either their employers or by the government ... [and] lapse rates are high as people acquire coverage when they have the money, and drop it when they run out of funds”). See also G. Kelly (stmt), *supra* note 40, at 5; Gingrich 6/12 at 15; Harrington & Miller, *supra* note 74, at 359.

Nonetheless, according to two panelists, regulation has altered this situation in some states, making small group coverage more expensive than individual insurance.<sup>88</sup> Consumers can obtain guidance about purchasing individual policies from various sources, including insurers, government, industry associations, and independent groups.<sup>89</sup>

## VI. PUBLICLY-FUNDED PROGRAMS

Medicare and Medicaid pay for approximately \$500 billion in health care expenses each year. Medicare provides coverage for approximately 40 million elderly and disabled Americans, and Medicaid provides coverage for approximately 50 million low-income

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<sup>88</sup> See G. Kelly 6/12 at 115-16; G. Kelly (stmt), *supra* note 40, at 7 (noting that “the small group market is, on average, much more expensive than the individual market” and small business members paid approximately 25 percent more than individuals for insurance policies available on the Internet); M. Young Presentation, *supra* note 51, at 10; M. Young 6/12 at 92. Individual policies, however, often do not provide coverage as comprehensive as that available in the group market, and such pricing comparisons may not be based on similar coverage. See also SCANDLEN, *supra* note 87, at 17 (HIPAA requirements and other cost-increasing regulations more prevalent in the small group market).

<sup>89</sup> See, e.g., KAREN POLLITZ ET AL., *supra* note 15, at 12; Agency for Healthcare Research & Quality (AHRQ), *Pub. No. 93-0018, Checkup on Health Insurance Choices* (Dec. 1992), at <http://www.ahrq.gov/consumer/insuranc.htm> (last visited June 28, 2004); American Health Insurance Plans (AHIP), *Guide to Health Insurance*, at <http://www.ahip.org/content/default.aspx?bc=41329351> (last visited June 28, 2004).

Americans.<sup>90</sup> Although the programs are not directly subject to the antitrust or consumer protection laws enforced by the Agencies, one panelist observed that these programs “are dominant realities of the American health care system. They influence the nature of competition. They influence the areas in which competition can exist, and the rules under which it has to exist, and the risks and rewards, and the institutional framework within which all of those things take place.”<sup>91</sup> This section focuses on two key government-funded programs: Medicare and Medicaid.

### A. Medicare

In 1965 the Medicare Program was created.<sup>92</sup> Medicare initially provided certain health care coverage to eligible individuals age 65 or older, but was expanded in 1972 to cover individuals under age 65 with End-Stage Renal Disease (ESRD) and some other disabilities.<sup>93</sup> Most

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<sup>90</sup> See, e.g., Antos 9/30 at 114 (there is some overlap of coverage for the two programs, resulting in approximately 80 million people being covered by these two programs); Joseph Antos, *Can Medicare and Medicaid Promote More Efficient Health Care?* 1 (9/30), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030930josephantos.pdf>.

<sup>91</sup> Hyman 9/30 at 112-13.

<sup>92</sup> 42 U.S.C. § 1395 *et. seq.* See also Centers for Medicare & Medicaid Services (CMS), *Medicare Information Resource*, at <http://www.cms.hhs.gov/medicare> (last modified Sept. 12, 2003).

<sup>93</sup> ESRD is chronic, irreversible kidney disease. Patients with ESRD require dialysis, usually 3 times per week, to cleanse the blood of toxins, which, if not removed through dialysis, will kill the patient. There are approximately 400,000 people in

individuals who are eligible for either Social Security Old-Age Benefits or Railroad Retirement Benefits also are eligible for Medicare.<sup>94</sup>

Medicare has multiple parts. Part A provides hospital insurance coverage. Most people are eligible for Medicare Part A because they or a spouse paid into the program through payroll tax deductions while they were employed.<sup>95</sup> Part A helps pay for inpatient hospital stays, skilled nursing facility care, some home health care, hospice care, and blood provided while in a hospital or skilled nursing care facility.<sup>96</sup>

Medicare Part B is optional supplementary medical insurance, covering,

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the U.S. with ESRD, of whom 300,000 must receive dialysis every other day. Cashia 9/30 at 164; Joseph Cashia, *National Renal Alliance: Success Starts with Choosing the Right Partner* 9 (9/30) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030930cashia.pdf>. Medicare pays for over 70 percent of all dialysis treatments. One speaker testified about several problems with the Medicare ESRD program: Medicare pays dialysis treatment centers only 30 percent of what it paid in 1984 (after accounting for inflation); there is inconsistent state regulatory oversight and credentialing; and there are payment differentials between urban and rural treatment centers. Cashia 9/30 at 167, 169-172.

<sup>94</sup> 42 U.S.C. § 1395 *et. seq.*

<sup>95</sup> 42 U.S.C. § 1395c. *See also* U.S. DEP'T OF HEALTH & HUMAN SERVICES (HHS), *MEDICARE & YOU: 2004 (2004)*, available at <http://www.medicare.gov/publications/pubs/pdf/10050.pdf>. Because Medicare is financed on a "pay-as-you-go" basis, the expenses of current beneficiaries are paid with contributions from payroll taxes imposed on those currently working. Individuals who did not pay into Medicare through payroll taxes can participate in Part A by paying a premium.

<sup>96</sup> HHS, *supra* note 95.

among other things, doctors' visits, outpatient medical and surgical services and supplies, diagnostic tests, and durable medical equipment (*e.g.*, wheelchairs, hospital beds, and oxygen). Individuals must pay a premium – \$66.60 per month in 2004 – to participate in Part B.<sup>97</sup> Premiums cover approximately 25 percent of the expenditures for Part B services.<sup>98</sup>

Medicare does not pay for all hospital or other medical expenses.<sup>99</sup> Many Medicare beneficiaries also purchase private Medicare Supplemental Insurance Policies

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<sup>97</sup> *See Id.* The premium can be changed annually. The monthly premium is usually taken out of the recipient's monthly Social Security, Railroad Retirement, or Office of Personnel Management Retirement payment. Other covered services include: ambulatory surgery center facility fees for approved procedures, part-time or intermittent home health care services, certain outpatient medical and mental health therapies, and blood provided as an outpatient or as part of a Part B covered service.

<sup>98</sup> The remaining 75 percent comes from general revenues.

<sup>99</sup> For example, in 2003, Medicare beneficiaries were responsible for the following costs of hospital and medical care: (1) hospital stays – \$840 per day for the first 60 days, \$210 per day for days 61-90, and \$420 per day for days 91-150; (2) skilled nursing facilities – up to \$105 per day for days 21-100; (3) blood – cost of the first three pints; (4) Medicare Part B yearly deductible – \$100 per year; and (5) Coinsurance and copayments – 20 percent of Medicare-approved amount for most covered services, 50 percent of Medicare-approved amount for outpatient mental health treatment, and copayments for outpatient hospital services. *See generally*, U.S. DEP'T OF HEALTH & HUMAN SERVICES (HHS), *CHOOSING A MEDIGAP POLICY: A GUIDE TO HEALTH INSURANCE FOR PEOPLE WITH MEDICARE*, at <http://www.medicare.gov/Publications/Pubs/pdf/02110.pdf>.

known as Medigap policies.<sup>100</sup> Medigap policies are federally regulated and must use one of ten standardized policies. Some of these standardized Medigap policies also pay for some routine services and prescription drugs.<sup>101</sup>

In 1997, Congress enacted Medicare + Choice (M+C) as Part C of Medicare. M+C was renamed Medicare Advantage (MA) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).<sup>102</sup> MA allows Medicare beneficiaries to join privately operated managed care plans.<sup>103</sup> The plans are paid an administratively determined rate by Medicare and plans also may charge an additional premium and offer additional benefits.<sup>104</sup> Medicare beneficiaries who joined MA plans often received greater

benefits (*e.g.*, prescription drug coverage) in exchange for accepting limits on their choice of providers.<sup>105</sup> In 2002, MA plans were providing health care to 5 million Medicare beneficiaries, down from 6.35 million enrollees in December 1999.<sup>106</sup> Congress added a new Part D to Medicare as part of the MMA. Part D will provide some coverage for prescription drugs for certain eligible enrollees.<sup>107</sup>

According to the 2004 Medicare trustees report, the program is unsustainable in its current form.<sup>108</sup> The unfunded obligations of the program currently exceed \$6 trillion, and the Part A trust fund is projected to be exhausted in 2019.<sup>109</sup> The trustees report indicates that the Part A trust fund can be restored to actuarial balance “by an immediate 108 percent increase in program income or an immediate 48 percent reduction in program outlays (or some combination of the two),” with far greater

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<sup>100</sup> See HHS, *supra* note 95, § 8, at 63-68 (entitled “Other Insurance and Ways to Pay Health Care Costs”). Some Medicare beneficiaries receive additional health insurance through employer provided retirement programs. By statute, Medicare is a secondary payor to such benefits. See generally, KAISER FAMILY FOUND., *supra* note 52.

<sup>101</sup> See HHS, *supra* note 99.

<sup>102</sup> Pub. L. No. 108-173, 117 Stat. 2066 (2003). Pursuant to Implementation of Medicare Advantage Program, 42 U.S.C. § 1395w-21, any legislative reference to Medicare + Choice is deemed a reference to Medicare Advantage and MA.

<sup>103</sup> See HHS, *supra* note 95, § 6, at 43-54 (entitled “Medicare + Choice Plans”).

<sup>104</sup> Pizer 4/23at 146-47; Steven Pizer, *Competition in the Medicare+Choice Program 5* (4/23) (slides) [hereinafter Pizer Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/pizer.pdf>; Steven Pizer & Austin Frakt, *Payment Policy and Competition in the Medicare+Choice Program*, 24 HEALTH CARE FIN. REV. 83 (Fall 2002).

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<sup>105</sup> See HHS, *supra* note 95, § 6, at 43-54 (entitled “Medicare + Choice Plans”); Pizer 4/23 at 144; Pizer Presentation, *supra* note 104, at 2; Pizer & Frakt, *supra* note 104, at 83.

<sup>106</sup> Pizer & Frakt, *supra* note 104, at 83 & n.1.

<sup>107</sup> Pub. L. No. 108-173.

<sup>108</sup> 39 BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE & FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS ANN. REP. 1-21 (2004) (§ I, Overview) [hereinafter 2004 MEDICARE TRUSTEES REPORT], at <http://www.cms.hhs.gov/publications/trusteesreport/2004/tr.pdf>.

<sup>109</sup> 2004 MEDICARE TRUSTEES REPORT, *supra* note 108, at 2 (“The financial status of the fund has deteriorated significantly, with asset exhaustion projected to occur in 2019 under current law compared to 2026 in last year’s report.”).

adjustments necessary if changes are delayed or phased in.<sup>110</sup>

MA plans also have had difficulties.<sup>111</sup> One speaker stated that the program was a failure because of pricing problems and “incredible inflexibilities in the administration of the program.”<sup>112</sup> Another speaker disagreed that Medicare Plus Choice was a complete failure, but noted that it is far from what it could have been.<sup>113</sup> One panelist testified that although the Medicare program has attempted to introduce competitive pricing to set the rates the government pays to MA plans, to date none of those efforts has been successful.<sup>114</sup> As a result, Medicare continues to establish the payment rates administratively. According to this speaker, to the extent plans compete, it typically has been on the benefits they provide.<sup>115</sup> This speaker discussed some of his empirical research findings, which show that in counties with multiple MA plans competing for beneficiaries, the plans competed based upon premiums paid by Medicare

beneficiaries and extra benefits.<sup>116</sup>

The Medicare program has a significant effect on the overall U.S. health care market. As one panelist remarked, “Medicare’s administrative requirements shape the business environment for everybody in the health care sector ... and changes to the Medicare program have spillover effects on the rest of the market.”<sup>117</sup> He stated that some Medicare policies, such as hospital prospective payment, have improved the health care system and benefitted consumers.<sup>118</sup> Nonetheless, he argued that Medicare policy more often than not fails “to promote innovation and efficiency in the health care sector.”<sup>119</sup> As he explained, “Medicare and Medicaid continue to rely on regulation and micro-management rather than competition and consumer choice,” undermining both the ability and willingness of providers to compete.<sup>120</sup> Another speaker noted that because hospitals have to abide by Medicare’s rules for their Medicare patients, those rules end up governing how hospitals do business in the private sector as well.<sup>121</sup>

Most panelists noted that there are good aspects to the Medicare program, but

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<sup>110</sup> Social Security & Medicare Trustees, *Status of the Social Security and Medicare Programs: A Summary of the 2004 Annual Reports*, <http://www.ssa.gov/OACT/TRSUM/trsummary.html> (last visited July 15, 2004).

<sup>111</sup> Antos 9/30 at 121.

<sup>112</sup> *Id.* at 122.

<sup>113</sup> Francis 9/30 at 128.

<sup>114</sup> Pizer 4/23 at 147.

<sup>115</sup> *Id.* at 147.

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<sup>116</sup> *Id.* at 158 (noting that the amount of competition in any given county also affected new entry; *i.e.*, the more competing plans, the less likely entry would occur).

<sup>117</sup> Antos 9/30 at 115.

<sup>118</sup> *Id.* at 115. *See also* Crippen 9/30 at 155.

<sup>119</sup> Antos 9/30 at 115, 124.

<sup>120</sup> *Id.* at 116, 122.

<sup>121</sup> Francis 9/30 at 131.

suggested that it should be significantly reformed.<sup>122</sup> Several speakers stated that Medicare impedes innovation in health care.<sup>123</sup> For example, one speaker explained that Medicare regulations prohibit paying for a physician visit unless the physician physically sees the patient. This rule has an important anti-fraud rationale, but it creates difficulties when services are more efficiently delivered without this requirement. For example, a consultation between a rural general practitioner and an urban specialist might be beneficial to the patient, but it is less likely to occur if the urban specialist cannot bill for his services unless the patient travels to his office.<sup>124</sup>

Several speakers noted that the Medicare prescription drug benefit will be helpful to beneficiaries, because it will help in the management of chronic illness, and fills an obvious gap in the benefit package.<sup>125</sup> Some expressed concern, however, about the risks for innovation if the Centers for Medicare & Medicaid Service (CMS) start setting pharmaceutical prices.<sup>126</sup>

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<sup>122</sup> See, e.g., Antos 9/30 at 116, 121-23; Francis 9/30 at 132-37, 141-42; Lemieux 9/30 at 144, 146-47.

<sup>123</sup> Francis 9/30 at 135-36; Antos 9/30 at 115, 124; Lemieux 9/30 at 147-53.

<sup>124</sup> Francis 9/30 at 135.

<sup>125</sup> Lemieux 9/30 at 145-46, 150; Francis 9/30 at 136-37.

<sup>126</sup> Antos 9/30 at 125-26 (cautioning that short-term low prices are “seductive if you’re looking at big budget deficits,” but could discourage long-term investment and innovation); Lemieux 9/30 at 151. See also *infra* Chapter 7. But see CENTERS FOR MEDICARE & MEDICAID SERVICES, PUB. NO. CMS-

One speaker suggested that the federal government should reform Medicare to look more like the Federal Employees Health Benefits Program (FEHBP), which would empower consumers and have positive spillover effects on the broader health care market.<sup>127</sup> He and others claim such an approach would rely on “consumer choice in a sensible way, with good, solid federal oversight” to protect consumers.<sup>128</sup> Another speaker agreed that there were profound differences between FEHBP and Medicare because the government relied on competition in FEHBP and on administratively designed benefits and delivery arrangements in Medicare, with the result that FEHBP beneficiaries have had catastrophic and prescription drug coverage for many years, while Medicare beneficiaries only recently got both.<sup>129</sup> According to this speaker, Medicare’s legislative and regulatory requirements make it extremely difficult for CMS to adapt the program to changes in health care delivery and standards.<sup>130</sup>

## **B. Medicaid**

In 1965, the Medicaid program was established to provide health care coverage

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11054, THE FACTS ABOUT UPCOMING NEW BENEFITS IN MEDICARE (2004), available at <http://www.medicare.gov/Publications/Pubs/pdf/11054.pdf> (noting that the MMA specifically bars CMS from negotiating drug prices).

<sup>127</sup> Antos 9/30 at 122-23.

<sup>128</sup> *Id.* at 122-23.

<sup>129</sup> Francis 9/30 at 185-87.

<sup>130</sup> *Id.* at 128-37, 186-87. See also Antos 9/30 at 121-22; Lemieux 9/30 at 144-47.

for certain low-income families, as well as certain low-income aged, blind, and disabled individuals.<sup>131</sup> The federal government sets eligibility and service parameters for the Medicaid program, and the states specify the services they will offer and the eligibility requirements for enrollees, and administer the program.<sup>132</sup> As a result, Medicaid programs vary from state to state. Costs are shared between the federal and state governments, with federal contributions varying based on the wealth of the state and the amounts the state contributes toward the program.<sup>133</sup>

Medicaid programs generally cover young children and pregnant women whose family income is at or below 133 percent of the Federal poverty level, as well as some low-income elderly and disabled adults.<sup>134</sup>

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<sup>131</sup> 42 U.S.C. § 1396 *et. seq.* See also CMS, *supra* note 92.

<sup>132</sup> CMS, *supra* note 92.

<sup>133</sup> See CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS), MEDICAID: A BRIEF SUMMARY, at <http://www.cms.hhs.gov/publications/overview-medicare-medicaid/default4.asp> (last modified Jan. 28, 2004).

<sup>134</sup> See *Id.* Generally, programs will cover those who meet one of the following criteria: (1) meeting the requirements for the Aid to Families with Dependent Children (AFDC) program that were in effect in the state on July 16, 1996; (2) children under age 6 whose family is at or below 133 percent of the Federal poverty level; (3) pregnant women whose family income is below 133 percent of the federal poverty level; (4) Supplemental Security Income (SSI) recipients in most states; (5) recipients of adoption or foster care assistance; (6) certain protected groups who are permitted to keep Medicaid benefits for a limited period of time (*e.g.*, individuals who are disqualified for cash assistance due to worker income from other sources); and (7) all children born

A recipient's resources also must be limited. The scope of services provided to Medicaid recipients includes: inpatient and outpatient hospital services, prenatal care, childhood vaccines, physician services, and nursing facilities services for persons aged 21 or older.<sup>135</sup>

In 2002, total Medicaid enrollment was 50.8 million, up from 44.2 million in 2000. Of the 50.8 million enrollees, 25.5 million were non-disabled children, 12.9 million were non-disabled, non-aged adults, 7.9 million were disabled, and 4.5 million were aged.<sup>136</sup> Children and adults who are not disabled or aged accounted for the greatest enrollment increases.<sup>137</sup> Total Medicaid spending increased 25 percent, from \$205.8 billion in 2000 to \$257.6 billion in 2002.<sup>138</sup> Increased spending for aged and disabled individuals accounts for almost 60 percent of this spending increase, and these

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after September 30, 1983, under age 19, whose families' income is at or below the federal poverty level. *Id.*

<sup>135</sup> See *Id.* Other Medicaid services may include family planning services and supplies, rural health clinic services, home health care for persons eligible for skilled-nursing service, laboratory and x-ray services, pediatric and family nurse practitioner services and nurse-midwife services, and early and periodic screening, diagnostic, and treatment services for children under age 21. *Id.*

<sup>136</sup> JOHN HOLAHAN & BRIAN BRUEN, MEDICAID SPENDING: WHAT FACTORS CONTRIBUTED TO THE GROWTH BETWEEN 2000 AND 2002? 4 (Kaiser Comm'n on Medicaid & the Uninsured, Issue Paper Pub. No. 4139, 2003), available at <http://www.kff.org/medicaid/loader.cfm?url=/commo/spot/security/getfile.cfm&PageID=22135>.

<sup>137</sup> *Id.* at 4.

<sup>138</sup> *Id.* at 3.



individuals account for over 70 percent of all Medicaid spending and 85 percent of spending for prescription drugs.<sup>139</sup>

Most states have enrolled a substantial majority of their Medicaid population in some form of managed care.<sup>140</sup> Many states have obtained waivers from CMS, authorizing experimental demonstration projects to cover uninsured populations and to test new delivery systems.<sup>141</sup>

### C. *Other Public Programs*

In 1997, as part of the Balanced Budget Act, Congress created title XXI, the State Children's Health Insurance Program (SCHIP).<sup>142</sup> SCHIP "was designed as a Federal/State partnership, similar to Medicaid, with the goal of expanding health insurance to children whose families earn too much money to be eligible for Medicaid, but not enough money to purchase private insurance."<sup>143</sup> SCHIP gives grants to states to provide health insurance coverage for

uninsured children in families with income up to 200 percent of the federal poverty level.<sup>144</sup> In 2003, 5.8 million children were enrolled in SCHIP at some point during the fiscal year, up from 5.3 million children in 2002.<sup>145</sup>

Uninsured children who are not eligible for Medicaid, under age 19, and who are at or below 200 percent of the federal poverty level meet the federal eligibility criteria for SCHIP.<sup>146</sup> Although states are allowed to impose cost sharing provisions, such as premiums, deductibles, or fees for some services, states cannot impose cost-sharing for pediatric preventative care or immunizations, or in amounts that exceed 5 percent of a family's gross or net income.<sup>147</sup>

States have the option whether to participate in SCHIP, and if they do, they may provide coverage by expanding Medicaid, expanding or creating a state children's health insurance program, or some combination of both. As of September

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<sup>139</sup> *Id.* at 2, 8. In 2002, Medicaid paid approximately \$92.3 billion (out of \$257.6 billion in total spending) for long term care. *Id.* at 7.

<sup>140</sup> See CMS, *supra* note 133.

<sup>141</sup> *Id.* These waivers are authorized by the Social Security Act § 1115.

<sup>142</sup> See Centers for Medicare & Medicaid Services (CMS), *Welcome to the State Children's Health Insurance Program*, at <http://www.cms.hhs.gov/schip/about-SCHIP.asp> (last visited June 23, 2004). See also American Academy of Pediatrics, *The State Children's Health Insurance Program*, at <http://www.aap.org/advocacy/schipsun.htm> (last visited June 23, 2004).

<sup>143</sup> See CMS, *supra* note 142.

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<sup>144</sup> *Id.* News Release, U.S. Dep't of Health & Human Services (HHS), SCHIP Provided Health Coverage to 5.8 Million Children in 2003 (Feb. 12, 2004) ("The SCHIP law authorized \$40 billion in federal funds over 10 years to improve children's access to health coverage."), at <http://www.hhs.gov/news/press/2004pres/20040212.html>. SCHIP spending limits for fiscal years 1998 through 2007 are as follows: \$4,295 billion for FY 1998; \$4,275 billion for FY 1999 through FY 2001; \$3,150 billion for FY 2002 through FY 2004; \$4,050 billion for FY 2005 through FY 2006; and \$5 billion for FY 2007. CMS, *supra* note 142.

<sup>145</sup> HHS News Release, *supra* note 144.

<sup>146</sup> See American Academy of Pediatrics, *supra* note 142.

<sup>147</sup> See CMS, *supra* note 142; American Academy of Pediatrics, *supra* note 142.

30, 1999, all states and U.S. territories had an approved SCHIP plan.<sup>148</sup> States also can spend up to 10 percent of the funds to provide coverage through a community-based health delivery system or by purchasing family coverage.<sup>149</sup>

Like Medicaid, states have enrolled many of their SCHIP participants in managed care. The states administer SCHIP under Medicaid rules or by using alternative health insurance plans that meet the actuarial value of certain key health services.

There are a number of additional public programs that provide care to specific categories of individuals.<sup>150</sup> TRICARE/CHAMPUS is a military health care program for active duty and retired members of uniformed services, their families, and survivors. The Department of Veterans Affairs provides medical assistance to eligible veterans. The Indian Health Service (IHS) provides medical assistance to eligible American Indian and Alaska Native people at IHS facilities.

## VII. PPOS

More than 100 million Americans receive their health care benefits through a

PPO, whose structure and operation vary.<sup>151</sup> PPO health benefit options are “a configuration of benefit design features offered through a contracted network [that] may be assembled in a fully customized fashion by a self-funded employer or offered by an insurance carrier that develops network-based products that are sold to customers on an insured basis.”<sup>152</sup> Providers, independent companies, and hospital systems mostly own these networks, which they establish by contracting with a variety of providers, who typically are paid on a discounted FFS basis.<sup>153</sup> This section focuses on PPO health benefit options.<sup>154</sup>

### PPOs first emerged in the early

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<sup>151</sup> Robert E. Hurley et al., *The Puzzling Popularity of the PPO*, 23 HEALTH AFFAIRS 56, 58 (Mar./Apr. 2004); Andrew I. Batavia, *Preferred Provider Organizations: Antitrust Aspects and Implications for the Hospital Industry*, 10 AM. J.L. & MED. 169, 175 (1984). See also Eric R. Wagner, *Types of Managed Care Organizations*, in ESSENTIALS OF MANAGED HEALTH CARE 21 (Peter R. Kongstvedt ed., 4th ed. 2003); Dechene, *supra* note 18, § 2.1, at 2-3 to 2-5; Lerner 4/24 at 96-98 (listing many types of PPOs).

<sup>152</sup> Hurley et al., *supra* note 151, at 58.

<sup>153</sup> SHERMAN FOLLAND ET AL., THE ECONOMICS OF HEALTH AND HEALTH CARE 256 (2004); Stephen A. Norton & Stephen A. Zuckerman, *Reimbursement for Physician Services*, in INTEGRATING THE PRACTICE OF MEDICINE 78 (Ronald B. Connors ed., 1997) (“A recent study of 30 PPO plans indicates that the predominant payment method for PPO providers was discounted FFS and that none of the PPOs surveyed used capitation as a basic form of physician reimbursement.”). Providers who contract for inclusion in a PPO include IPAs, medical groups, individual physicians, hospitals, and other necessary facilities.

<sup>154</sup> For a discussion of physician network joint ventures, see *supra* Chapter 2.

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<sup>148</sup> See CMS, *supra* note 142.

<sup>149</sup> See *Id.* See also American Academy of Pediatrics, *supra* note 142.

<sup>150</sup> See generally U.S. Census Bureau, *Types of Health Insurance Coverage*, at [www.census.gov/hhes/hlthins/hlthinstypes.html](http://www.census.gov/hhes/hlthins/hlthinstypes.html) (last revised Apr. 21, 2004).

1980s and have grown significantly in the intervening decades. One survey found that the number of PPOs increased sevenfold between 1987 and 1994.<sup>155</sup> Another survey found that the number of employees enrolled in PPOs doubled between 1994 and 2002, and that in 2002, 50 percent of all employees enrolled in health insurance used PPO products.<sup>156</sup> It is difficult to obtain precise and reliable data on the number of PPOs and their exact enrollment.<sup>157</sup> Commentators attribute PPOs' rapid expansion to private insurers' attempts to control spiraling medical costs, providers' defensive reactions to the growth of HMOs, and consumer and employer preferences for greater choice in selecting primary care and specialized physicians than many HMOs offered.<sup>158</sup>

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<sup>155</sup> Norton & Zuckerman, *supra* note 153, at 78.

<sup>156</sup> Donald Crane, *Statement 4 (5/7)*, at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507doncrane.pdf>. See also S. Allen 4/25 at 105 (in Arkansas, BCBS has 71 percent of its business in PPOs).

<sup>157</sup> See Wu 4/23 at 128 (stating that it is hard to find accurate data on PPO enrollment because PPOs “lack many of the reporting and operating standards that [apply to] HMOs.”); Timothy Lake, *Literature Synthesis: How Health Plans Select and Pay Health Care Providers in their Managed Care Networks* 14-15, in TIMOTHY LAKE ET AL., *MEDICARE PAYMENT ADVISORY COMM'N*, MPR No. 8568-700, HEALTH PLANS' SELECTION AND PAYMENT OF HEALTH CARE PROVIDERS, 1999 app.C (2000) (final report) (“Analysis of PPO networks are made even more complex by the prevalent practice of renting rather than owning networks, as well as the existence of national and local independent PPOs that rent out each other's services.”).

<sup>158</sup> Dechene, *supra* note 18, § 2.1, at 2-3, § 2.2, at 2-5 (“Many [PPOs] were formed as a defensive alternative to the growth of HMOs. The initial physician-sponsored PPOs provided a vehicle

Some commentators believe PPOs have had considerable success in obtaining volume discounts from physician-participants.<sup>159</sup> One study found that two national insurers offered physicians payments that on average were approximately 11 to 20 percent lower for PPO products than for their indemnity plans.<sup>160</sup> Another commentator stated that PPOs began by paying physicians about 20 percent less than their average charge, but some “more aggressive” payors have asked providers to accept a fixed discounted-fee schedule for all services, often based on a Medicare fee schedule.<sup>161</sup>

Commentators state that most physicians are willing to accept the discounted fees that PPOs offer because they expect to obtain additional patients.<sup>162</sup> Many

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by which physicians could continue to practice traditional fee-for-service medicine in a structure that could compete with other managed care organizations.”); Desmarais 2/27 at 167; Kanwit 4/25 at 54-55.

<sup>159</sup> Norton & Zuckerman, *supra* note 153, at 78.

<sup>160</sup> Diana Verrilli & Stephen Zuckerman, *Preferred Provider Organizations and Physician Fees*, 17 HEALTH CARE FIN. REV. 3 (1996).

<sup>161</sup> Dechene, *supra* note 18, § 2.4.2.4, at 2-13. PPOs turn to external benchmarks such as the Medicare fee schedule because “[m]any providers have marked up their list prices [in recent years] so that the discounted prices do not represent much reduction at all.” *Id.* at § 2.1, at 2-3.

<sup>162</sup> See FOLLAND ET AL., *supra* note 153, at 257 (“[T]he provider may enjoy a large increase in patient care business by joining the network.”); Norton & Zuckerman, *supra* note 153, at 78. Physicians also may agree to contracts with discounted fees to avoid losing patients.

PPOs include a “rapid payment” clause for certain claims, which makes their plans more appealing to providers.<sup>163</sup> Two panelists noted that a consumer may end up paying higher prices if their physician ceases to participate in the PPO but the consumer continues to see that physician.<sup>164</sup> Some panelists noted that physicians typically participate in multiple PPO and HMO plans, which can increase contracting costs.<sup>165</sup>

Commentators question whether PPOs provide sufficient incentives for the delivery of cost-effective care.<sup>166</sup> A panelist observed that consumers enrolled in PPOs can easily refer themselves to specialists, which can lead to excess costs.<sup>167</sup>

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<sup>163</sup> FOLLAND ET AL., *supra* note 153, at 257; Wagner, *supra* note 151, at 21.

<sup>164</sup> See Crane 5/7 at 36; Feder 2/27 at 223.

<sup>165</sup> Each PPO has its own administrative and utilization requirements, and physicians must comply with all of the requirements to be paid. Edward B. Hirshfeld & Gail H. Thomanson, *Medical Necessity Determinations: The Need for a New Legal Structure*, 6 HEALTH MATRIX 3, 32-33 (1996); Casalino 9/25 at 16 (stating that it is difficult for physicians in solo or small group practice who contract with multiple HMOs to comply with each HMO’s utilization management process).

<sup>166</sup> Batavia, *supra* note 151, at 175-76; Dechene, *supra* note 18, § 2.4.2.4, at 2-13 (“While a discounted-fee schedule can be an important cost containment tool, it may be less effective than other payment mechanisms, especially capitation, used by HMOs.”); Burgess 4/9 at 107-108 (stating that FFS creates incentives to overprovide health care services).

<sup>167</sup> Crane 5/7 at 38 (observing that PPO “enrollees are allowed to directly refer to specialists. And, so, you can’t have precisely the same utilization controls.”).

Some commentators believe that PPOs can improve quality of care by implementing utilization review, creating clinical protocols, and using credentialing.<sup>168</sup> Although PPOs can undertake these steps on their own, payors are encouraging such strategies with economic incentives tied to various quality measures.<sup>169</sup> Others question whether PPOs can improve quality, contending that PPOs may not be able to encourage or compel changes in physician behavior.<sup>170</sup> They also argue that PPOs may not have sufficient access to quality-related data to implement certain care quality systems because “PPO participants are free to use out-of-network providers and no specific physician is responsible for all of their care.”<sup>171</sup>

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<sup>168</sup> Peter R. Kongstvedt, *Compensation of Primary Care Physicians*, in ESSENTIALS OF MANAGED HEALTH CARE, *supra* note 151, at 85, 92 (discussing credentialing) [hereinafter Kongstvedt, *Compensation*]; Peter R. Kongstvedt et al., *Using Data and Provider Profiling in Medical Management*, in ESSENTIALS OF MANAGED HEALTH CARE *supra* note 151, at 379.

<sup>169</sup> See Buxton 5/8 at 99 (stating that Blue Cross and other payors are working on the use of tiered fees for physicians to encourage higher quality outcomes and also stating that such incentives are “the wave of the future.”); Kongstvedt, *Compensation*, *supra* note 168, at 137; Burgess 4/9 at 107-108 (noting some economists argue that a mix of FFS and capitation helps balance incentives to under and over-use health care services). For further discussion of P4P programs, see *supra* Chapters 1 and 3.

<sup>170</sup> See Marren 5/8 at 79-80; Weis 5/8 at 74; Hurley et al., *supra* note 151, at 65-67.

<sup>171</sup> See Hurley et al., *supra* note 151, at 65; but see Dechene, *supra* note 18, § 2.4.2.3, at 2-12 (contending that provider-initiated PPOs may have greater access to performance related data).

## VIII. THE UNINSURED

Approximately 15 percent of the population, or 44 million Americans, were uninsured at some point during 2002.<sup>172</sup>

This section of the report describes the demographics of the uninsured, the impact of being uninsured, and the competitive implications of these facts.

There is no legal obligation to purchase health insurance. Some individuals can afford to purchase health insurance, but voluntarily elect to bear the risk of not doing so.<sup>173</sup> For many others,

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<sup>172</sup> MILLS & BHANDARI, *supra* note 2 at 1, 4. This figure is the Census Bureau's estimate of the number of Americans who are without health insurance *at some point during the year*. This estimated figure varies significantly, however, depending on the time period employed and the survey data that is used. See *Myths about the Uninsured: Hearing on the Uninsured Before the Health Subcomm., House Comm. On Ways and Means*, 108th Cong. (2004) (Statement of Len M. Nichols, Vice President, Center for Studying Health System Change) [hereinafter Nichols Statement], at <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=1226>; IOM, *supra* note 30, at 3 ("Estimates of the number of persons who lack insurance vary depending on the survey .... Surveys differ in their size and sampling methods, the ways in which questions are asked about insurance coverage, and the period over which insurance coverage or uninsurance is measured.").

<sup>173</sup> Uwe E. Reinhardt, *Is There Hope for the Uninsured?*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-376, 378-79 ("Not all 'uninsured' people, for example, represent a social problem in the sense that they are helpless victims of circumstance and require help from other members of society."), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.376v1.pdf>. See also Pauly 2/26 at 88 ("One fact is there are a lot of low-income people who have a lot better things to do with their money than spend it on health insurance, and ... [t]here are a lot of people who don't value insurance as much as it costs. So,

health insurance is prohibitively expensive when weighed against the cost of food, shelter, and basic necessities.<sup>174</sup>

The uninsured cut across a large swath of the United States: some are young and healthy, some are not; many are below the poverty line and others are reasonably wealthy. Those most likely to lack health insurance are young adults (18 to 24 years old), people with less education, and Hispanics.<sup>175</sup> In 2002, 23.5 percent of the uninsured were in households with annual incomes of less than \$25,000; 8.2 percent were in households with annual incomes of \$75,000 or more.<sup>176</sup> The uninsured population is large, but fluid. A substantial majority of those currently uninsured will not be uninsured a year from now; a

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they don't buy it for various reasons.").

<sup>174</sup> See INSTITUTE OF MEDICINE, HIDDEN COSTS, VALUE LOST: UNINSURANCE IN AMERICA 43 (2003) ("Food, shelter, transportation, and clothing account for 85 percent on average of the expenditures of families living without health insurance.").

<sup>175</sup> MILLS & BHANDARI, *supra* note 2; See also CONGRESSIONAL BUDGET OFFICE (CBO), HOW MANY PEOPLE LACK HEALTH INSURANCE AND FOR HOW LONG? 2 (2003), available at <ftp://ftp.cbo.gov/42xx/doc4210/05-12-Uninsured.pdf>.

<sup>176</sup> MILLS & BHANDARI, *supra* note 2, at 2 tbl.1, 6 fig.2, 7. Another way to look at the characteristics of the uninsured is as a percentage of the federal poverty level: 45 percent of the uninsured are within 100 to 300 percent of the federal poverty level, 36 percent are less than 100 percent of the federal poverty level, and 19 percent have incomes above 300 percent of the poverty level. In 2001, a family income of three hundred percent of poverty was \$42,384. Reinhardt, *supra* note 173, at 379-80. Cf. JOHN HOLAHAN ET AL., THE NEW MIDDLE-CLASS OF UNINSURED AMERICANS – IS IT REAL? 2 (Kaiser Comm'n on Medicaid & the Uninsured, Issue Paper Pub. No. 4090, 2003).

Congressional Budget Office study found that 45 percent of the uninsured were without coverage for four months or less and only 16 percent (or approximately 6.9 million Americans) remained uninsured for more than 2 years.<sup>177</sup> A second study suggests that approximately 12 percent of the uninsured remain so for more than four years.<sup>178</sup>

**A. What Is the Impact of Not Having Insurance?**

Being uninsured has significant health and financial consequences. Numerous studies indicate that being uninsured reduces consumption of health care services and products.<sup>179</sup> The uninsured are less likely to have a regular source of care, less likely to have had a recent physician visit, less likely to use preventive services, and more likely to delay seeking treatment.<sup>180</sup> One study indicates that those

who are uninsured for a full year receive about half as much care in dollar terms (\$1,253) per person as the privately insured (\$2,484).<sup>181</sup> A wide variety of adverse health consequences are associated with being uninsured.<sup>182</sup>

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*to obtain health care: recent estimates from the Robert Wood Johnson Foundation National Access to Care Survey*, 14 HEALTH AFFAIRS 139 (Fall 1995); Andrew B. Bindman et al., *Preventable Hospitalizations and Access to Care*, 274 JAMA 305 (1995); B. BLOOM ET AL., ACCESS TO HEALTH CARE PART 2: WORKING-AGE ADULTS (Nat'l Ctr. for Health Statistics, Vital Health Stat. Series 10, No. 197, Dep't of Health & Human Services Pub. No. (PHS) 97-1525, 1997); Helen R. Burstin et al., *The Effect of Change of Health Insurance on Access to Care*, 35 INQUIRY 389 (1998-99); John A. Ayanian et al., *Unmet Health Needs of Uninsured Adults in the United States*, 284 JAMA 2061 (2000)).

<sup>181</sup> See Jack Hadley & John Holahan, *How Much Medical Care Do The Uninsured Use, And Who Pays For It?*, 2003 HEALTH AFFAIRS (Web Exclusive) W3-66, 70, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.66v1.pdf>. The article notes that some of the difference is attributable to differences in age and health status between the insured and uninsured, but "research that takes these factors into account still finds about a 50 percent differential." *Id.* at 70.

<sup>182</sup> For example, the uninsured have worse medical outcomes and higher in-hospital mortality. See JACK HADLEY, THE KAISER COMM'N ON MEDICARE & THE UNINSURED, SICKER AND POORER: THE CONSEQUENCES OF BEING UNINSURED 4, fig.7 (2002) (finding that research published in the past 25 years suggests that having health insurance reduces mortality rates by 10 to 15 percent), at [http://www.kff.org/uninsured/upload/13970\\_1.pdf](http://www.kff.org/uninsured/upload/13970_1.pdf); IOM, WITHOUT COVERAGE, *supra* note 179, at 4-5; IOM, *supra* note 174, at 3 ("The relative mortality rate for the insured and uninsured reflect a 25 percent higher mortality rate within the uninsured population."); Colleen Berry & Julie Donohue, *The Uninsured in the U.S.: An Issue Brief*, 1 HARVARD HEALTH POL'Y REV. (Fall 2000), available at <http://hcs.harvard.edu/~epihc/currentissue/fall2000/ba>

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<sup>177</sup> Pamela Farley Short & Deborah R. Graefe, *Battery-Powered Health Insurance? Stability in Coverage of the Uninsured*, 22 HEALTH AFFAIRS 244, 247-48 (Nov./Dec. 2003); CBO, *supra* note 175, at viii fig.S2, 9 tbl.3.

<sup>178</sup> Short & Grafe, *supra* note 177, at 247.

<sup>179</sup> See IOM, *supra* note 30; INSTITUTE OF MEDICINE, CARE WITHOUT COVERAGE: TOO LITTLE, TOO LATE (2002) [hereinafter IOM, WITHOUT COVERAGE]; INSTITUTE OF MEDICINE, HEALTH INSURANCE IS A FAMILY MATTER (2002) [hereinafter IOM, FAMILY MATTER]. The IOM reports consolidate and critically appraise the evidence and research regarding the impact of uninsurance on individuals and communities.

<sup>180</sup> AMERICAN COLLEGE OF PHYSICIANS, NO HEALTH INSURANCE? IT'S ENOUGH TO MAKE YOU SICK: LIST OF REFERENCES AND ABSTRACTS 4-5 (1999), at <http://www.acponline.org/uninsured/lack-refs.pdf> (citing, e.g., Marc L. Berk et al., *Ability*

One study cautions that there is little evidence on whether the association between health insurance and health status is causal.<sup>183</sup> Research examining this point shows that health improvements have occurred for children and seniors under policies that expanded Medicaid, children's health, and Medicare coverage, but the evidence for non-elderly adults is less conclusive.<sup>184</sup>

Medical treatment for the uninsured is often more expensive than care of the insured because the uninsured are more likely to delay treatment and receive care in an emergency department.<sup>185</sup> Although one study suggested that the marginal cost of

providing care in an emergency department was not that much higher than in an outpatient setting,<sup>186</sup> hospitals have typically billed the uninsured full price for the services they received, instead of the discounted prices that hospitals offer insured patients.<sup>187</sup> Pursuant to Department of Health and Human Services (HHS) Secretary Tommy Thompson's direction, CMS and the Office of Inspector General of HHS issued guidance clarifying that hospitals can provide discounts to uninsured patients who cannot afford their hospital bills without violating Medicare payment rules.<sup>188</sup>

### **B. Who Pays for Health Care for the Uninsured?**

The uninsured and their families bear

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rry.html; John Billings et al., *Recent Findings on Preventable Hospitalizations*, 15 HEALTH AFFAIRS 239 (Fall 1996); A.B. Bindman et al., *Preventable Hospitalizations and Access to Health Care*, 274 JAMA 305 (1995); P.D. Sorlie et al., *Mortality in the Uninsured Compared with that in Persons with Public and Private Health Insurance*, 154 ARCH. INTERN. MED. 2409 (1994).

<sup>183</sup> HELEN LEVY & DAVID MELTZER, WHAT DO WE REALLY KNOW ABOUT WHETHER HEALTH INSURANCE AFFECTS HEALTH? 33 (Economic Research Initiative on the Uninsured, Working Paper No. 6, 2001), *reprinted in* HEALTH POLICY AND THE UNINSURED (Catherine McLaughlin ed. 2004), available at <http://www.umich.edu/~eriu/pdf/wp6.pdf>.

<sup>184</sup> LEVY & MELTZER, *supra* note 183, at 34. See also Economic Research Initiative on the Uninsured, *Research Highlight No. 2, Q&A with David Meltzer, M.D., Ph.D.* (Mar. 2003), at <http://www.umich.edu/~eriu/qa-meltzer.html>; Nichols Statement, *supra* note 172, at 4 ("What has not been proved by this standard is that universal coverage would improve the health of *all* of the uninsured.").

<sup>185</sup> Levy 9/26 at 39 (noting that when the uninsured do seek treatment, "acuity is greater and treatment is more complicated.")

<sup>186</sup> Robert M. Williams, *The Costs of Visits to Emergency Departments*, 334 NEW ENG. J. MED. 642 (1996).

<sup>187</sup> IOM, *supra* note 30, at 5. See also Milstein 5/29 at 272; Fraser 5/29 at 273 (discussing differences in hospital charges for the insured and uninsured as rack rates versus negotiated prices).

<sup>188</sup> The Office of the Inspector General, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills* (Feb. 2, 2004), at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf>; Centers for Medicare & Medicaid Services, *Questions On Charges For The Uninsured* (Feb. 17, 2004), at [http://www.cms.hhs.gov/FAQ\\_Uninsured.pdf](http://www.cms.hhs.gov/FAQ_Uninsured.pdf). See also News Release, U.S. Dep't of Health & Human Services, Text of Letter from Tommy G. Thompson Secretary of Health and Human Services to Richard J. Davidson President, American Hospital Association (Feb. 19, 2004) (responding to letter inquiry from hospital association indicating that hospitals have been billing uninsured patients full charges, instead of offering discounts), at <http://www.hhs.gov/news/press/2004pres/20040219.html>.

some of the costs for their health care. One study found that uninsured persons experiencing severe health problems had higher out-of-pocket spending (\$4,576 versus \$1,912) and higher total medical spending (\$42,166 versus \$26,957) than did the insured.<sup>189</sup>

In many instances, the uninsured cannot pay for the care they receive. The burden of providing this uncompensated care varies tremendously. Only 7.9 percent of the population is uninsured in Minnesota, while in Texas, almost 25 percent of the population is uninsured.<sup>190</sup> Hospitals bear the largest burden, because they must assess and stabilize all patients with an emergency medical condition, regardless of ability to pay.<sup>191</sup> Yet, even in the same geographic

area, the burden of providing uncompensated care varies significantly among hospitals.<sup>192</sup>

These costs are “absorbed by providers as free care, passed on to the insured via cost shifting and higher health premiums, or paid by taxpayers through higher taxes to finance public hospitals and public insurance programs.”<sup>193</sup> One study estimated that the uninsured received almost \$100 billion in care in 2001. Federal, state, and local governments paid for a majority of this amount, through a “maze of grants, direct provision programs, tax

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<sup>189</sup> James Smith, *Healthy Bodies and Thick Wallets: The Dual Relation between Health and Economic Status*, 13 J. ECON. PERSP. 145, 154 tbl.3 (1999). The study found no statistically significant difference in the wealth effects of the illness on the insured and uninsured. *Id.* Similarly, another study found non-statistically significant differences in the wealth impact on the insured and uninsured of being diagnosed with a serious illness (cancer, diabetes, heart attack, chronic lung disease, and stroke). *See* HELEN LEVY, THE ECONOMIC CONSEQUENCES OF BEING UNINSURED (Economic Research Initiative on the Uninsured, Working Paper No. 12, 2002), available at <http://www.umich.edu/~eriu/pdf/wp12.pdf>.

<sup>190</sup> MILLS & BHANDARI, *supra* note 2, at 9-10, tbl.4.

<sup>191</sup> *See, e.g.*, M. Ryan 3/26 at 32 (“[W]ith a high incidence of uninsured patients, we can find that we have a high incidence of patients who become inpatients for whom there is little or no reimbursement. It creates a substantial drain on the hospital resources. Yet, there is no way that we can avoid those responsibilities and so we provide care.”). This obligation is imposed by the Emergency Medical Treatment and Active Labor Act. *See supra* Chapter

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<sup>192</sup> *See* David A. Hyman, *Hospital Conversions: Fact, Fantasy, and Regulatory Follies*, 23 J. CORP. L. 741, 758-60 (1998). Many people believe that nonprofit hospitals obtain a tax exemption because they provide charity care to the uninsured. In fact, in most states, nonprofit hospitals are not required to provide a specific amount of charity care to receive a tax exemption. *See id.*; Kevin M. Wood, *Legislatively-Mandated Charity Care for Nonprofit Hospitals: Does Government Intervention Make any Difference?*, 20 REV. LITIG. 709 (2001); David A. Hyman, *The Conundrum of Charitability: Reassessing Tax Exemption for Hospitals*, 16 AM. J.L. & MED. 327, 332 (1990) (“A widely shared (but incorrect) position is that charitable equals charity.”)

Several class action lawsuits were recently filed against a large number of nonprofit hospitals, alleging that they “have distorted the extent of their charity care while using punishing tactics to obtain payments from uninsured patients.” *See* Holbrook Mohr, *Suit Alleges Lack of Charity at Nonprofit Hospitals*, WASH. POST, June 18, 2004, at E03.

<sup>193</sup> AMERICAN COLLEGE OF PHYSICIANS, *supra* note 180, at 1. *See also* Hadley & Holahan, *supra* note 181, at 79 n.1 (“‘Uncompensated care’ is defined as medical care the uninsured receive but do not pay for fully themselves. It includes reduced-fee care; charity care, for which the uninsured do not pay anything; and bad debts incurred by the uninsured.”).



appropriations, and Medicare and Medicaid payment add-ons.”<sup>194</sup> Yet, approximately \$35 billion in completely uncompensated care was still delivered in 2001.<sup>195</sup> Hospitals provided 60 percent of total uncompensated care (\$20.8 billion), and community health centers and physicians each provided 20 percent (\$7.1 billion and \$6.8 billion).<sup>196</sup> It is unclear how much of these costs are actually shifted to other payers.<sup>197</sup>

### C. *The Impact of Competition*

Our health care system relies on hospitals, physicians, and clinics to provide uncompensated care to the uninsured. Competition may help address some problems of the uninsured, for example, by lowering the price of insurance coverage and medical care.<sup>198</sup> Competition also may worsen the problems of the uninsured, however, by decreasing the ability of providers to cross-subsidize some products and services. Competition will not transfer resources to those who do not have them.<sup>199</sup> Proposals to address these matters should be carefully evaluated to ensure that the

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<sup>194</sup> Hadley & Holahan, *supra* note 181, at 78.

<sup>195</sup> *Id.* at 69 ex.2; IOM, *supra* note 174, at 5 tbl.ES1.

<sup>196</sup> Hadley & Holahan, *supra* note 181, at 70-71.

<sup>197</sup> IOM, *supra* note 174, at 55-58.

<sup>198</sup> See William M. Sage et al., *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35-36 (Mar./Apr. 2003).

<sup>199</sup> See Pauly 2/26 at 87 (“What competition alone can never do, it can’t get all or even most of the uninsured insured.”).

consequences of any reform are pro-competitive.

## IX. CONSUMER-DRIVEN HEALTH CARE

Panelists discussed the disadvantages of the current health care system, and the potential benefits of a more consumer-driven health care system. For example, Former Speaker of the House Newt Gingrich spoke at the Hearings and observed that “a third party payment model is inherently conflict-ridden because you have the person receiving the goods not responsible, the person [providing the] goods confused about who they’re responsible to, and the person who is paying the money irritated with both the provider and the patient.”<sup>200</sup>

Speaker Gingrich stated that there are four drivers, to transforming the U.S. health care system: the health care system must emphasize patient safety and outcome; embrace information technology (IT), computing, and communications; focus on quality and a culture of quality; and center on the individual consumer.<sup>201</sup> When consumers have information and knowledge, they will be empowered to make real choices about their care and take responsibility for their choices.<sup>202</sup> Other panelists agreed that we need a more

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<sup>200</sup> Gingrich 6/12 at 9.

<sup>201</sup> *Id.* at 10-13.

<sup>202</sup> *Id.* at 12-13. Speaker Gingrich noted that consumer choice also implies individual responsibility and accountability.

consumer-driven health care system,<sup>203</sup> and that there is considerable room for improvement in health care IT and consumer information.<sup>204</sup> Two panelists suggested that the government could play a role in creating an IT infrastructure.<sup>205</sup>

Consumer-driven health care relies on consumers to make their own decisions regarding the care they receive. Tax-advantaged savings accounts (Health Savings Accounts, Health Reimbursement Arrangements, and Flexible Spending Accounts) can be used to pay for out-of-pocket health care expenses with pre-tax dollars.<sup>206</sup> Commentators and panelists

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<sup>203</sup> See Lansky 6/12 at 70-72; David Lansky, *A person-centered view of consumer information in the health care marketplace* (6/12) (slides) [hereinafter Lansky Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030612lansky.pdf>; Comstock 6/12 at 111-13; Darling 6/12 at 103-04.

<sup>204</sup> See Lansky 6/12 at 70-89 (reporting on findings from studies and surveys conducted by the Foundation for Accountability (FACCT)); Lansky Presentation, *supra* note 203, at 4-16; Comstock 6/12 at 110-11; Gingrich 6/12 at 51-52 (“Everybody ought to have an electronic health record. It ought to be compatible across all the systems. All the major providers of these kind of systems should be part of an open systems architecture ...”).

<sup>205</sup> Lansky 6/12 at 87-88; Gingrich 6/12 at 56-60; Lansky Presentation, *supra* note 203, at 17-24. See also Antos 9/30 at 117-121 (noting that CMS has an enormous and potentially useful database of information, and although patient and provider privacy issues are important and need to be protected, CMS makes it extremely difficult for researchers, including consumer or business groups, to access it).

<sup>206</sup> NEWT GINGRICH ET AL., *SAVING LIVES & SAVING MONEY* 85 (2003). As of January 1, 2004, employees may contribute to health savings accounts that can earn tax free interest and be rolled over from

stated that when individuals are responsible for paying for their health care costs up to a certain amount, they are likely to become more health conscious and more value conscious about the health care products and services they are purchasing.<sup>207</sup> Panelists generally supported greater development of consumer-driven health care and individual health savings accounts, but agreed that

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year to year. The accounts, however, are only permitted in conjunction with eligible health insurance plans. Eligible plans must have an annual deductible of at least \$1,000 for an individual and at least \$2,000 for a family, but the sum of the annual deductible and the other annual out-of-pocket expenses (other than premiums) cannot exceed \$5,000 for an individual or \$10,000 for a family. See MMA § 1201; Health Savings Account, *Health Savings Account Learning Center*, at <http://www.ehealthinsurance.com/ehi/Welcome.ds> (last visited July 15, 2004).

<sup>207</sup> See Dwight McNeill, *Do Consumer-Directed Health Benefits Favor The Young And Healthy?*, 23 HEALTH AFFAIRS 186, 186, 191 (Jan./Feb. 2004) (noting that “[t]he espoused active ingredient of consumer-directed benefits is increased financial exposure to medical expenses to motivate consumers to be more prudent purchasers as they make price-sensitive choices” but that current limitations on such issues as investment and portability may limit their effectiveness); Jon R. Gabel et al., *Consumer-Driven Health Plans: Are They More Than Talk Now?*, 2002 HEALTH AFFAIRS (Web Exclusive) W395, 396 (“At its heart, the consumer-driven health care movement seeks to combine incentives with information to enable consumers to make informed choices about non-life-threatening health care.”), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.395v1.pdf>; G. Kelly 6/12 at 36 (noting that “what is going to be important going forward is for the consumer to have value, which is the equation of both price and quality .... [W]hen you spend your own money, you do it wisely ... I know, since it’s money out of my own pocket, what is the best mixture of both price and quality. I’m not going to buy the most expensive thing out there, but at the same time I’m going to get the best deal for my money.”).

clear, accurate, and easily accessible information will be necessary for consumers to make informed choices.<sup>208</sup> Panelists noted a number of other barriers to a consumer-driven health care system, including provider culture and misaligned financial incentives.<sup>209</sup>

lower costs, increase quality, and enhance consumer welfare.

In general, panelists agreed that the health care system has been designed around the preferences of payers, providers, and employers, and not consumers.<sup>210</sup> A more consumer-driven system has the potential to

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<sup>208</sup> Comstock 6/12 at 108-10; Lansky 6/12 at 70-71, 73-79 (providing three examples (one personal, two based on his organization's focus group studies) of how consumers take control or express the desire for more control by having access to more information); Lansky Presentation, *supra* note 203, at 3, 5-21; National Women's Law Center, *Comments Regarding Health Care and Competition Law and Policy* (Nov. 25, 2003) 8 (Public Comment) (noting importance of consumer information, especially in connection with women's reproductive health services, including treatment options); Shoptaw 4/11 at 59 (suggesting there will be a shift toward new consumer-directed health care, including defined contribution and medical savings accounts); *but see* M. Young 6/12 at 97-98 (noting that "many employers will embrace consumer-driven plans . . . not because they philosophically believe it's the right thing, but quite frankly because they have no other options and they are desperate").

<sup>209</sup> *See* Comstock 6/12 at 108, 111-13. *See also* Jon R. Gabel et al., *Employers' Contradictory Views About Consumer-Driven Health Care: Results from a National Survey*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-210, 214, 217 & 218 n.13 (noting the first evaluations of employers' views about consumer-driven health care's impact are ambiguous), at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.210v1/DC1>; MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS AND ECONOMICS OF RATIONING MECHANISMS (1996).

<sup>210</sup> *See* Lemieux 9/30 at 145-146; Francis 9/30 at 177, 180.

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## CHAPTER 6: COMPETITION LAW: INSURERS

### I. INTRODUCTION

In the health insurance industry, health insurers are both sellers of insurance to consumers and buyers of medical services. As a result, mergers and other conduct involving health insurers potentially can raise issues related to both monopoly and monopsony power. Chapter 6 discusses some of these issues.

### II. MERGERS OF HEALTH CARE INSURERS

As discussed in Chapter 4, the Agencies use the framework provided by the *1992 Horizontal Merger Guidelines (Merger Guidelines)*<sup>1</sup> to evaluate whether a merger or acquisition will likely “create or enhance market power or ... facilitate its exercise.”<sup>2</sup> Market power “is the ability profitably to maintain prices above competitive levels for a significant period of time.”<sup>3</sup> As in Chapter 4’s discussion of hospital mergers, this Chapter uses the framework of the *Merger Guidelines* to discuss issues that arise in connection with mergers or acquisitions involving health care insurers.

#### A. *Product and Geographic Market Definition*

Merger analysis can begin either with an assessment of direct evidence of

anticompetitive effects,<sup>4</sup> or the identification of relevant product and geographic markets and the calculation of the shares of market participants and concentration ratios.<sup>5</sup> A relevant market typically is defined as a product or group of products and a geographic area in which the product or groups of products is produced or sold such that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future producer or seller of those products in that area likely would impose at least a “small but significant and non-transitory” increase in price above the competitive level, assuming the terms of sale of all other products are held constant. A relevant market is a group of products and a

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<sup>1</sup> U.S. DEP’T OF JUSTICE & FEDERAL TRADE COMM’N, HORIZONTAL MERGER GUIDELINES § 0.1 (1992) [hereinafter MERGER GUIDELINES], available at <http://www.ftc.gov/bc/docs/horizmer.htm>.

<sup>2</sup> *Id.* When a group of sellers combines to exercise market power it is called oligopoly power.

<sup>3</sup> *Id.*

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<sup>4</sup> *E.g.*, *In re Schering-Plough Corp.*, No. 9297, at 16-17 (Dec. 18, 2003) (opinion) (discussing *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447, 460-61 (1986), in which the Supreme Court said that “the finding of actual, sustained adverse effects on competition ... is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis.”), available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>. A number of lower court decisions have followed this principle. *See, e.g.*, *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) (evidence of “an actual adverse effect on competition ... arguably is more direct evidence of market power than calculations of elusive market share figures”); *Toys R’ Us v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (market power can be proved “through direct evidence of anticompetitive effects”); *United States v. Baker Hughes Inc.*, 908 F.2d 981, 992 (D.C. Cir. 1990) (“[m]arket share is just a way of estimating market power, which is the ultimate consideration,” and ... “[w]hen there are better ways to estimate market power, the court should use them” (quoting *Ball Memorial Hospital v. Mutual Hospital Insurance*, 784 F.2d 1325, 1336 (7th Cir. 1986))).

<sup>5</sup> *See, e.g.*, *FTC v. H.J. Heinz Co.*, 246 F.3d 708 (D.C. Cir. 2001); MERGER GUIDELINES, *supra* note 1, § 0.2.

geographic area that is no bigger than necessary to satisfy this test.<sup>6</sup> Analysis typically starts with a narrow market, which is broadened until demand-side substitution is sufficient to make the price increase unprofitable.<sup>7</sup>

## 1. Product Market

In health insurance markets, considerable attention has focused on the definition of the relevant product market.<sup>8</sup> One threshold issue is whether health maintenance organizations (HMOs), point of service plans (POs), preferred provider organizations (PPOs), and indemnity plans are separate product markets or all part of a single product market.<sup>9</sup> A second issue is whether self-insured employer plans are in the same product market as commercial insurers and health plans.<sup>10</sup>

The first issue arises in deciding whether HMOs and PPOs are separate product markets, either from each other or from a market consisting of all health insurance financing.<sup>11</sup> Until recently, a prominent and common characteristic of many HMOs was the use of a closed panel of physicians with a primary care physician acting as a “gatekeeper,” but several panelists noted a pronounced trend toward less restrictive forms of managed care.<sup>12</sup> As a result, several panelists suggested that the relevant product market should be defined broadly.<sup>13</sup>

Two Seventh Circuit cases, *Blue Cross & Blue Shield v. Marshfield Clinic*<sup>14</sup> and *Ball Memorial Hospital v. Mutual*

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<sup>6</sup> MERGER GUIDELINES, *supra* note 1, § 1.0.

<sup>7</sup> *Id.* §§ 1.11, 1.21; Seth Sacher & Louis Silvia, *Antitrust Issues in Defining the Product Market for Hospital Services*, 5 INT’L J. ECON. BUS. 181, 182 (1998).

<sup>8</sup> *See, e.g.*, Monk 4/23 at 38-49; Ginsburg 4/23 at 24-26; Desmarais 4/23 at 36-38.

<sup>9</sup> *See, e.g.*, Monk 4/23 at 43-49; Ginsburg 4/23 at 25; Desmarais 4/23 at 36-38; Lerner 4/23 at 66; Feldman 4/23 at 52-64.

<sup>10</sup> *See, e.g.*, Monk 4/23 at 39-40 (until DOJ’s 1999 consent in *United States v. Aetna Inc.*, 1999-2 Trade Cas. (CCH) ¶ 72,730 (N.D. Tex. 1999), the definition of the relevant product and geographic markets for health insurance did not provoke controversy; usually, the relevant geographic market was at least statewide, and the relevant product market included self- and fully-insured products, as well as HMOs, PPOs, and indemnity plans); Ginsburg 4/23 at 26; Desmarais 4/23 at 42; Feldman 4/23 at 61-64.

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<sup>11</sup> The following analysis deals with group comprehensive medical insurance and may not be applicable to assessing transactions or practices involving individual comprehensive medical insurance, worker’s compensation, disability, long-term care, or dental insurance. *See, e.g.*, Desmarais 4/23 at 32 (“From our perspective, it’s important to realize that there’s really two distinct markets. There’s a group market for health insurance, as well as an individual market. The two markets vary considerably in terms of the economic, business and regulatory considerations and we need to keep that in mind.”); Feldman 4/23 at 56-57 (medicare health plan market may be distinct from employer health plan market).

<sup>12</sup> Ginsburg 4/23 at 21; 25-26; Desmarais 4/23 at 36-37; Monk 4/23 at 43-45; Lerner 4/23 at 67-68, 70-73. *See also supra* Chapter 1.

<sup>13</sup> *See, e.g.*, Lerner 4/23 at 66-73; Monk 4/23 at 42-44, 48.

<sup>14</sup> 65 F.3d 1406 (7th Cir. 1995) (Posner, C.J.).

*Hospital Ins., Inc.*,<sup>15</sup> suggest that HMOs and PPOs are not, and cannot be, separate markets. The Seventh Circuit indicated in both cases that HMOs and PPOs are instead part of a larger health insurance financing market.

In *Marshfield Clinic*, Blue Cross & Blue Shield (Blue Cross) and their subsidiary HMO alleged that the Marshfield Clinic, a physician-owned clinic, and its HMO had monopoly power in the HMO market that they had acquired and maintained through improper practices.<sup>16</sup> The Seventh Circuit rejected the argument that HMOs constituted a relevant product market separate from other forms of health care coverage. The court stated that “[a]n HMO is basically a method of pricing medical services,” and not a distinctive organizational form or group of skills.<sup>17</sup> The court noted that Blue Cross’s ability to contract with enough physicians to form a PPO network in the same geographic area in which it alleged the Marshfield Clinic had a monopoly implies that Blue Cross also had the ability to form an HMO.<sup>18</sup> The court concluded that “services offered by HMOs and by various fee-for-service plans are both provided by the same physicians, who can easily shift from one type of service to another if a change in relative prices makes one type more lucrative than others.”<sup>19</sup>

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<sup>15</sup> 784 F.2d 1325 (7th Cir. 1986) (Easterbrook, J.).

<sup>16</sup> *Marshfield Clinic*, 65 F.3d at 1407.

<sup>17</sup> *Id.* at 1409.

<sup>18</sup> *Id.* at 1410.

<sup>19</sup> *Id.* at 1411.

In *Ball Memorial Hosp. Inc. v. Mutual Hospital Insurance*, eighty acute care hospitals alleged that Blue Cross’s attempt to offer a PPO plan violated the antitrust laws because Blue Cross had market power and abused it.<sup>20</sup> The hospitals were concerned that if Blue Cross entered the PPO market, it would exercise monopsony power by lowering the prices it paid to participating hospitals.<sup>21</sup> The hospitals also were concerned that once Blue Cross lowered the prices it paid for their services, the hospitals would be forced to charge higher prices to other PPOs, including their own, which would allow Blue Cross to raise the costs of, and take business away from, competing PPO plans.<sup>22</sup>

The Seventh Circuit held that market power was a prerequisite to any finding that Blue Cross violated the antitrust laws and upheld the district court’s finding that Blue Cross did not have market power. Blue Cross’s lack of market power was based in large part on the district court’s finding that the product was health care financing, and that the “Blues, other insurance companies, hospitals offering PPOs, HMOs, and self-insuring employers all offer methods of financing health care.”<sup>23</sup>

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<sup>20</sup> *Ball Mem’l Hosp.*, 784 F.2d at 1330-31.

<sup>21</sup> *Id.* at 1331, 1339-40.

<sup>22</sup> *Id.* at 1331, 1338-40 (the hospitals raised issues about cost-shifting and cross-subsidization in this context). See *supra* Chapter 3 for further discussion of this issue.

<sup>23</sup> *Ball Mem’l Hosp.*, 784 F.2d at 1331, 1340. The court also stated that the “insurance industry is not like the steel industry, in which a firm must take years to build a costly plant before having anything to sell. The ‘productive asset’ of the

As in all industries, the specific facts of each matter must be carefully evaluated to determine the parameters of health insurance markets.<sup>24</sup> One panelist explained that “it’s important to keep an eye on the ball and remember that the question is not, is there a price difference between HMO products and PPO products and ... whether there are attribute differences between the products. The question is, assuming a competitive equilibrium in both and then the competitive equilibrium disappeared in one of them so that then somebody tried to raise price, would the change in relative price drive

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insurance business is money, which may be supplied on a moment’s notice, plus the ability to spread risk, which many firms possess and which has no geographic boundary.” *Id.* at 1335.

<sup>24</sup> In *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598-99 (1st Cir. 1993), the First Circuit affirmed the trial court’s rejection of an HMO-only market in favor of one that includes all forms of health care financing. As the court explained:

The problem with U.S. Healthcare’s argument is that differences in cost and quality between products create the possibility of a separate market, not the certainty .... [T]he issue ... would be whether a sole supplier of HMO services ... could raise price far enough over cost, and for a long enough period, to enjoy monopoly profits. Usage patterns, customer surveys, actual profit levels, comparison of features, ease of entry, and many other facts are pertinent in answering the question.

See also *Cont’l Orthopedic Applicances, Inc. v. Health Ins. Plan of Greater N.Y., Inc.*, 40 F. Supp. 2d 109, 119 (E.D.N.Y. 1999) (“[N]either of those cases [*Marshfield Clinic* and *U.S. Healthcare*], or for that matter, any of the cases cited in the defendants’ briefs, stand for the proposition that HMOs can never be a separate viable product market.”)

consumer response back and forth between the segments.”<sup>25</sup>

In *Aetna*, the Division concluded that “[b]y virtue of the benefit design differences, pricing differentials, and other factors, PPOs and indemnity plans are not reasonable substitutes for HMO and HMO-POS products. Neither employers nor employees view[ed] HMOs and PPOs as the same product, and enrollees who le[ft] an HMO disproportionately select[ed] another HMO, rather than a PPO, for their next plan.” The Division also concluded that a “small but significant increase in the price of HMO and HMO-POS products would not cause a sufficient number of customers to shift to other health insurance products to make such a price increase unprofitable [and, therefore,] HMO and HMO-POS plans ... are an appropriate relevant product market within which to assess the likely effects of the proposed acquisition.”<sup>26</sup>

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<sup>25</sup> Lerner 4/23 at 67, 73 (noting that all of the litigated cases have defined the market broadly, but that the analysis in many of the cases “is either thin or wrong-headed”). See also Arthur Lerner, *Health Insurance Monopoly Issues – Market Definition* 13 (4/23) (slides), at <http://www.ftc.gov/opp/hc/030423arthurlerner.pdf>; Feldman 4/23 at 50-51 (suggesting that the main problem with decision in *Marshfield Clinic* is it defines a product market using both supply and demand substitution, whereas the Guidelines suggest only demand substitution should be considered in defining a relevant product market), 52 (noting that although supply substitution is relevant to antitrust analysis, its use should be limited to identifying firms that participate in the relevant market and to the analysis of entry); MERGER GUIDELINES, *supra* note 1, §§ 1.32, 3.

<sup>26</sup> *United States v. Aetna Inc.*, No. 3-99CV 1398-H ¶¶ 17-18 (June 21, 1999) (complaint) [hereinafter *Aetna Complaint*], available at <http://www.usdoj.gov/atr/cases/f2500/2501.pdf>; see also *United States v. Aetna Inc.*, No. 3-99



In other investigations conducted both before and after *Aetna*, the Division concluded that the relevant product market was all managed care products, and not HMOs or PPOs separately. As one panelist stated, “[w]e need to study the reactions of health plans, employers and employees as the marketplace evolves. And ... any analysis that takes place from here on out needs to factor in the changing marketplace that is emerging due to the managed care backlash.”<sup>27</sup>

Another panelist stated that “we should look at the effect of macroeconomic conditions on how to define product markets. There’s soft empirical evidence which demonstrates that the price elasticity of demand for HMOs depends on macroeconomic conditions .... It suggests ... that the state of the macroeconomic economy might compress the price elasticity during good times, pushing the products possibly into the same market and then pulling them back apart again.”<sup>28</sup> This same panelist stated, however, that at this time “[t]here are distinct product markets for different types of health insurance plans, characterized by enrollees’ ability to “choose their own doctor,” including the ability to see specialist physicians without a referral

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CV1398-H, at 5-6 (Aug. 3, 1999) (revised competitive impact statement) [hereinafter *Aetna Impact Statement*], available at <http://www.usdoj.gov/atr/cases/f2600/2648.pdf>.

<sup>27</sup> Monk 4/23 at 49; *see also id.* (“[F]rom the evidence that I’ve been able to analyze ... HMOs and PPOs generally do compete in the same relevant market”).

<sup>28</sup> Feldman 4/23 at 60-61.

and to use any hospital recommended by a physician.”<sup>29</sup>

The second issue is whether self-insurance should be included as part of the relevant product market.<sup>30</sup> This issue is highly fact-specific, and will turn on the particulars of any given case. One panelist suggested that analyzing “win-loss reports from insurers and switching reports from employers can tease out the level of competition” that self-insurance provides, and stated his conclusion “that both funding types are in the same market.”<sup>31</sup> Such

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<sup>29</sup> Roger Feldman, *Health Insurance Monopoly Issues – Market Definition 7* (4/23) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030423feldman.pdf>; Feldman 4/23 at 52, 53-64 (discussing studies and demand elasticities that support his belief that there are separate product markets and noting that consumer price sensitivity appears to be significant among comparable plans, *i.e.*, is across plans where non-price attributes such as provider network and utilization controls are held constant).

<sup>30</sup> *See, e.g.*, Desmarais 4/23 at 37 (“Obviously, if I’m an insurer and I have an employer customer, I have to be mindful of the fact that that customer, at any time, can decide to become self-insured and to assume the responsibility and hire a TPA, not necessarily my insurance company, and that certainly has to color the relationships between the employer customers and the insurers and TPAs in which they do business.”).

<sup>31</sup> Monk 4/23 at 42-43. *See also id.* at 45 (noting that bidding documents and broker spreadsheets also provided useful insights); Feldman 4/23 at 96 (citing Portland, Oregon as an example of why the assessment of self-insurance in the product market has to be geographically specific: “[W]e found that even large employers in the Portland market just don’t want anything to do with self-insurance. It’s virtually a fully-insured city for reasons that are not entirely obvious to me.”). *But see* Lerner 4/23 at 98 (suggesting that although employers

reports might also provide insight on product market definition, geographic market definition, and ease of entry.<sup>32</sup>

## 2. Geographic Market

The Agencies begin geographic market analysis for mergers in this industry with the location of each firm to determine whether the merging firms sell in the same areas.<sup>33</sup> The Agencies then analyze the available facts to assess whether the relevant geographic market is larger or smaller than the candidate market.<sup>34</sup>

For example, in *Aetna* the Division alleged that “[t]he relevant geographic markets in which HMO and HMO-POS health plans compete are ... no larger than

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in Portland do not self-insure now, they might change their minds if the price of other insurance products went up); Monk 4/23 at 98-99 (noting that perhaps employers in Portland do not self-insure because the other available products are great, but if that were to change, employers might choose to self-insure).

<sup>32</sup> See Monk 4/23 at 42, 43 (noting that perhaps self-insurance should not be included in the relevant product market for small employers because such employers may not find it “advantageous to switch to a self-insured plan”). Obviously self-insurance can only be part of the relevant product market if employers view it as a substitute for products offered by commercial insurers.

<sup>33</sup> MERGER GUIDELINES, *supra* note 1, § 1.21. The Division, in some recent cases, has used the United States Department of Commerce Metropolitan Statistical Areas (MSAs) as a starting point for defining geographic markets for insurance company mergers.

<sup>34</sup> *Id.* See also Feldman 4/23 at 90 (“[I]f an HMO ... raises its price, would buyers switch to products produced outside the region? ... [T]he answer is quite clear, geography matters.”).

the local areas within which managed care companies market their respective HMO and HMO-POS plans ... [because] [p]atients seeking medical care generally prefer to receive treatment close to where they work or live, and many employers require managed care companies to offer a network that contains a certain number of health care providers within a specified distance of each employee’s home.”<sup>35</sup> The relevant geographic markets in that case were the MSAs “in and around Houston and Dallas, Texas.”<sup>36</sup>

## B. Competitive Effects

The *Merger Guidelines* describe two main theories of competitive harm: unilateral effects and coordinated interaction.<sup>37</sup> When mergers or acquisitions involving health care insurers have threatened competitive harm, it has more typically been through alleged unilateral

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<sup>35</sup> *Aetna Complaint, supra* note 26, ¶ 19. *But see* Monk 4/23 at 41 (arguing that although the *Merger Guidelines* do not use supply substitution to define markets, in his view “the ease and speed with which these [health] plans can move from one part of a state to another make insurance markets an exception”).

<sup>36</sup> *Aetna Complaint, supra* note 26, ¶ 20; *Aetna Impact Statement, supra* note 26, at 7. See also Monk 4/23 at 40 (“[M]y experience on more recent mergers suggests that an MSA-based, fully insured HMO market is still the Department of Justice’s starting point.”); News Release, Dep’t of Justice Antitrust Division, Statement on the Closing of its Investigation of Anthem, Inc.’s Acquisition of Wellpoint Health Networks, Inc. (Mar. 9, 2004), at [http://www.usdoj.gov/atr/public/press\\_releases/2004/202738.pdf](http://www.usdoj.gov/atr/public/press_releases/2004/202738.pdf).

<sup>37</sup> See MERGER GUIDELINES, *supra* note 1, §§ 2.1, 2.2.

effects than through coordinated effects. The likelihood of adverse unilateral effects usually is connected to whether each of the merging firms' products are each others' best substitute.<sup>38</sup> For example, in the *Aetna* case, the Division alleged that "Aetna and Prudential are among each other's principal competitors in the HMO and HMO-POS markets in Houston and Dallas, and are considered by employers to be close substitutes in their product attributes and quality."<sup>39</sup>

Several panelists suggested that the more similar the merging companies are, the more likely the entity could exercise market power post-merger. One panelist presented the results of an empirical study he conducted, in which he compared mergers involving locally-based health plans with those involving national HMOs. He found that these two types of HMOs are very different and that the entry of a national HMO is unlikely to impact significantly the profits or competitiveness of a local HMO, and *vice-versa*.<sup>40</sup> Thus, according to this panelist, in a market with three local HMOs and two national HMOs, the merger of the two national HMOs might result in

significant market power because its effects would be similar to a two to one merger.<sup>41</sup>

Many hearing participants testified that health insurance markets in most geographic areas enjoy robust competition, with "multiple health insurer competitors and several product options, including HMO, PPO, POS, and consumer directed health plans."<sup>42</sup> One panelist explained that "competitors within specific markets vary, including regional and local plans serving specific needs and geographies. There is a wealth of competition for employers'

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<sup>38</sup> *Id.* § 2.21 ("Substantial unilateral price elevation in a market for differentiated products requires that there be a significant share of sales in the market accounted for by consumers who regard the products of the merging firms as their first and second choices, and that repositioning of the non-parties' product lines to replace the localized competition lost through the merger be unlikely.")

<sup>39</sup> *Aetna Complaint*, *supra* note 26, ¶ 21; *Aetna Impact Statement*, *supra* note 26, at 8.

<sup>40</sup> Mazzeo 4/23 at 133-34, 139-42.

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<sup>41</sup> *Id.* at 142-143. Of course, a health plan merger does not necessarily have adverse unilateral effects just because it is "big." In the Division's recent investigation of the Anthem/WellPoint merger, for instance, the Division learned from employers and other market participants that, in addition to one of the merging parties' market shares being very small in each of the nine states in which they competed, neither of the WellPoint products was a close competitor to Anthem in any of these states. Given these facts, the Division concluded that this transaction would not enhance Anthem's ability to increase prices, reduce quality, or otherwise reduce consumer welfare in any of these markets. Dep't of Justice Antitrust Division, *supra* note 36.

<sup>42</sup> Fred Dodson, *Health Insurance Monopoly Issues – Competitive Effects 3* (4/23) [hereinafter Dodson (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030423freddodson.pdf>. See also Dodson 4/23 at 172; Darling 4/23 at 183-84; Helen Darling, *Health Insurance Monopoly Issues – Competitive Effects 1* (4/23) [hereinafter Darling (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030423darling.pdf>; Wu 4/23 at 117; Lawrence Wu, *Economic Issues in Analyzing Competitive Effects in Health Insurance Markets 4-14* (4/23) (slides) [hereinafter Wu Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030423wucompetitive.pdf>.

business. Additionally, employers can opt to self-fund their insurance.”<sup>43</sup>

Another panelist stated that, although large employers believe that health care markets could be more competitive in quality, service, innovation, and price, they “are generally satisfied with the level of competition among health plans and insurers.”<sup>44</sup> She noted that large employers usually can choose from both national health plans and smaller, regional plans to serve their health insurance needs, and that most insurers offer three to four products from which employees may choose.<sup>45</sup> Employers also will conduct periodic assessments and audits and will re-bid or re-negotiate their health insurance contracts if not satisfied.<sup>46</sup> Moreover, “[l]arge employers also have the option to self-fund their benefits, use a carrier or third party administrator to pay claims, [or] contract with networks to get appropriate discounts.”<sup>47</sup>

Other panelists stated that health insurance markets are not sufficiently competitive. One panelist presented data indicating substantial insurer and hospital concentration in numerous markets throughout the United States, and stated that this development has had serious implications for premium levels and

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<sup>43</sup> Dodson (stmt), *supra* note 42, at 3. *See also* Dodson 4/23 at 172; Darling 4/23 at 186.

<sup>44</sup> Darling (stmt), *supra* note 42, at 1. *See also* Darling 4/23 at 183-86.

<sup>45</sup> Darling 4/23 at 183, 185; Darling (stmt), *supra* note 42, at 1.

<sup>46</sup> Darling (stmt), *supra* note 42, at 1.

<sup>47</sup> *Id.*; *see also* Darling 4/23 at 185-87.

payments to other providers (*e.g.*, physicians).<sup>48</sup>

### C. *Entry*

The *Merger Guidelines* provide that entry should be considered if it is likely to occur within two years and be sufficient to deter or counteract the anticompetitive effects of the proposed merger.<sup>49</sup> Entry barriers to the health insurance industry may include: state laws and regulations, economies of scale, and firm reputation.

According to an ongoing study of health care markets in 12 geographic areas, the studied markets fall into three categories: (1) locales with a dominant Blue Cross plan, (2) locales with three or four major plans, typically one of which is a long-standing local plan, and (3) markets that are more fragmented, often lacking strong local plans. According to this study, in recent years national plans have been unsuccessful entering some of the Blue Cross dominant markets, but have been important players in some of the fragmented markets.<sup>50</sup>

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<sup>48</sup> Stephen Foreman & Dennis Olmstead, *Written Comments of the Pennsylvania Medical Society* 3 (9/9/02), at <http://www.ftc.gov/ogc/healthcare/pms.pdf>. *See also* Gabel 4/23 at 159 (in last few years, “the insurance industry has become less competitive”); Foreman 4/24 at 69-70; Hall 4/25 at 74-75, 78 (stating that Blue Cross is dominant in Alabama).

<sup>49</sup> MERGER GUIDELINES, *supra* note 1, § 3.

<sup>50</sup> Ginsburg 4/23 at 10-12; Paul Ginsburg, *Competition in Health Insurance* 6-7 (4/23) (slides) (noting that the underwriting cycle was leading to wider margins but that “exits from unprofitable markets” continued) [hereinafter Ginsburg Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030423ginsburg.pdf>.

The cost of establishing a network of providers may delay entry, depending on the type of insurance product. For example, in *Aetna* the Division alleged that “[e]ffective entry – entry and growth to minimum viable scale – for an HMO or HMO-POS plan in either Houston or Dallas typically takes two to three years and costs up to \$50 million.”<sup>51</sup> Several panelists agreed that entry barriers into health insurance markets appear to exist. One panelist presented research data suggesting that the health insurance industry has become less competitive over the last few years.<sup>52</sup> This panelist pointed out that recent premium increases usually would have spurred increased HMO entry.<sup>53</sup> HMO

entry is not occurring in most markets, however, because many insurers and HMOs were hurt during fierce price competition in the mid-1990’s, Wall Street is wary of HMOs with aggressive entry strategies, and the cost of entry is greater now than in previous periods.<sup>54</sup>

Other panelists acknowledged that, at least in some cases, state laws and regulations can create entry barriers.<sup>55</sup> One panelist stated that the need to create a provider panel is usually not a significant barrier to market entry because existing,

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<sup>51</sup> *Aetna Complaint*, *supra* note 26, ¶ 23. *See also Aetna Impact Statement*, *supra* note 26, at 8 n.4 (“Indeed, Aetna has acknowledged that on average it costs between \$600 and \$1000 per enrollee to build membership in a HMO.”); *Aetna Complaint*, *supra* note 26, ¶ 23 (further noting that these costs are substantially higher than those required for setting up a PPO or indemnity plan).

On the other hand, the Division also noted in Congressional testimony that “there has been new entry into various local [health plan] markets” and that “[b]etween 1994 and 1997 over 150 new HMOs were licensed across the country.” *Statement: Hearing on H.R. 1304, The Quality Health-Care Coalition Act of 1999, Before the House Comm. on the Judiciary*, 106th Cong. 8 (1999) (Statement of Joel I. Klein, Assistant Attorney General, Department of Justice Antitrust Division), *available at* <http://www.usdoj.gov/atr/public/testimony/2502.pdf>.

<sup>52</sup> Gabel 4/23 at 159.

<sup>53</sup> Gabel 4/23 at 163-64; Jon Gabel, *Competition Among Health Plans* 11 (4/23) (slides) [hereinafter Gabel Presentation], *at* <http://www.ftc.gov/opp/hc/030423jongabel.pdf> (suggesting that entry should have begun to increase for at least three reasons: (1) four years of underwriting profits, (2) growing profitability among publicly traded managed care companies, and (3) a limited number of competitors in many local

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markets). *See also* Ginsburg 4/23 at 20 (noting that “during the stage of the underwriting cycle when premium trends are exceeding cost trends, you expect to see exits from markets rather than entry, and from our on-the-ground sense at 12 sites, we are still seeing some exits, we’re not seeing any entry”); Ginsburg Presentation, *supra* note 50, at 13.

<sup>54</sup> Gabel 4/23 at 168-69; Gabel Presentation, *supra* note 53, at 15.

<sup>55</sup> *See, e.g.*, Desmarais 4/23 at 33, 35 (suggesting that in order “[t]o understand the current insurance marketplace, it’s important to recognize that insurers are subject to intense government scrutiny of their business practices” and that state policies sometimes reduce the number of insurers willing to do business in a particular state); Stephen Foreman, *Competition Among Health Plans* 11 (4/24) [hereinafter Foreman (stmt)], *at* <http://www.ftc.gov/opp/hc/030423forman.pdf> (noting that entry barriers include costs of regulatory approval, including capitalization). *See also*, Senkewicz 4/24 at 8-17 (outlining state regulatory procedures for insurers, but noting that state regulators do not view the requirements as barriers, but as good, sound regulation of an industry where the transactions are not at arms-length).

commercially-attractive provider networks may be rented.<sup>56</sup>

A former insurance commissioner for Missouri discussed several HMO mergers that his office reviewed during his tenure.<sup>57</sup> His office approved three of the four mergers because they were persuaded by the parties' arguments that entry was easy, that there were no capacity constraints on existing competitors (there were at least ten HMO competitors), and that any of the 320 insurers in the state could easily enter the HMO market.<sup>58</sup> Over the past eight years, however, the St. Louis HMO market has become very concentrated, and there has been no entry since the mid-1990s, he reported.<sup>59</sup>

This panelist suggested that entrants face a Catch 22 – they need a large provider network to attract customers, but they also need a large number of customers to obtain sufficient price discounts from providers to be competitive with the incumbents. Second, he noted the possibility that there is a first mover, or early mover, advantage in the HMO industry, possibly resulting in later entrants having a worse risk pool from

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<sup>56</sup> See Lerner 4/23 at 106-107 (suggesting employer community could set up own HMO if monopolist managed care plan unreasonably raised rates, absent the monopolist “tying up the provider community with exclusive contracts or something”); Wu 4/23 at 118-19. *But see* Foreman (stmt), *supra* note 55, at 9.

<sup>57</sup> Angoff 4/24 at 39-45.

<sup>58</sup> *Id.* See also American Bar Ass'n, *Comments Regarding the Federal Trade Commission's Workshop on Health Care and Competition Law and Policy* 8-9 (Public Comment).

<sup>59</sup> Angoff 4/24 at 43-45.

which to recruit members. Third, he noted that trade name recognition may inhibit entry.<sup>60</sup>

Other panelists agreed that the need for scale economies and a good reputation in the local market may create entry barriers. For example, historically, HMOs' scale economies were relatively low, requiring approximately 65,000 enrollees.<sup>61</sup> Recent information from investigations and the Hearings suggest this may no longer be the case.<sup>62</sup> One panelist noted that it is not uncommon for employers to ask for new or improved quality control and disease

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<sup>60</sup> *Id.* at 46-49. See also Foreman (stmt), *supra* note 55, at 7-8 (arguing that “mergers may have the effect of increasing brand name loyalty even though there has been no change in quality”); Angoff 4/24 at 52 (suggesting that perhaps the Guidelines should be revised to state that “even when a merger does not meet the Herfindahl thresholds, in a market, where entry is particularly difficult, and efficiencies are clearly not going to be created,” the merger should be challenged). *But see* Lerner 4/24 at 119-20 (noting that the antitrust laws should not be used to challenge inefficient mergers that do not raise competitive concerns).

<sup>61</sup> See Ruth S. Given, *Economies Of Scale And Scope As An Explanation Of Merger And Output Diversification Activities In The Health Maintenance Organization Industry*, 15 J. HEALTH ECON. 685 (1996); Douglas Wholey et al., *Scale And Scope Economies Among Health Maintenance Organizations*, 15 J. HEALTH ECON. 657 (1996).

<sup>62</sup> See, e.g., Ginsburg 4/23 at 19 (noting that one of the stated reasons for many of the recent health insurance mergers is “to achieve scale economies which presumably could come from the use of information technology and marketing and the same promotional programs and in-care management and how to do it”); Given 4/24 at 30-31, 33-37 (suggesting that the need for larger economies of scale and efficiencies, resulting in larger HMO size, also may create greater barriers to entry).

management programs from health plans seeking their business. Such programs often cost more and require larger patient populations than such programs did in the past.<sup>63</sup>

Moreover, some purchasers want to deal with firms that are already in the particular geographic market even if a firm with a national reputation is seeking to enter that market. For example, one panelist stated that in recent years “the only ... successful entry of national plans into markets has come from purchasing hospital-owned health plans, and now that the hospital-owned health plans are mostly gone, I would not be surprised if we wouldn’t – certainly, in the short term, I wouldn’t expect to see much national plan entry.”<sup>64</sup>

Conversely, other panelists suggested that expansion by existing firms is relatively easy. One panelist stated entry is easy because existing health plans do not face capacity constraints, the incremental cost of expansion is small, and regulatory requirements are generally minor.<sup>65</sup> This

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<sup>63</sup> See generally Ginsburg 4/23 at 18 (“Disease management and case management, these are new areas and some companies are pursuing it in a more sophisticated way.”); Given 4/24 at 33.

<sup>64</sup> Ginsburg 4/23 at 28-29. See also Foreman (stmt), *supra* note 55, at 8 (arguing that “developing credibility with employer-purchasers” is an entry barrier).

<sup>65</sup> Wu 4/23 at 119; Wu Presentation, *supra* note 42, at 5; Wu 4/24 at 53-62 (discussing studies of entry, expansion, and customer switching between health plans), 62 (concluding that, based on the studies he has reviewed, entry and expansion have been sufficient to take share away from the leading firm and have reduced HMO concentration over time,

panelist explained that informed and sophisticated employers and consultants help to keep the markets competitive by using competitive bidding to choose a health plan, and switching readily based on price.<sup>66</sup> Moreover, large employers often choose to be self-insured, bypassing traditional insurance plans altogether.<sup>67</sup> This panelist offered the Atlantic City, New Jersey, market as an example of entry creating effective competition.<sup>68</sup> Another panelist stated that “all that is required for a plan already licensed in a state to expand to another area of that state is to contract with an existing provider network and then market their new product.”<sup>69</sup>

#### D. *Efficiencies*

The *Merger Guidelines* make clear

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and that this evidence, along with facts about the percentage of employees who have a choice of plans, suggest that although there are switching costs, they do not rise to the level of being a barrier to entry).

<sup>66</sup> Wu 4/23 at 120-23; Wu Presentation, *supra* note 42, at 6-11; Wu 4/24 at 57-62.

<sup>67</sup> Wu 4/23 at 118.

<sup>68</sup> *Id.* at 123-24; Wu Presentation, *supra* note 42, at 11 (showing that from January 1994 through December 1998, new entrants captured 47 percent of the HMO/POS market from six incumbent firms and that the largest incumbent, Blue Cross & Blue Shield of New Jersey, went from having 38 percent of the market to 21 percent). *But see* Foreman 4/24 at 69 (arguing that more recent data suggests that there are only two insurers left in the Atlantic City, New Jersey market).

<sup>69</sup> *Id.* at 41. See also *Id.* (“In the late 1990s, there were many examples in many states where insurers rapidly expanded services from one part of the state to the next and the data showed that this expansion came at a very low price.”).

that efficiencies should be evaluated before determining whether a proposed merger is likely to be pro- or anti-competitive.<sup>70</sup> The *Merger Guidelines* provide that the Agencies “will not challenge a merger if cognizable efficiencies are of a character and magnitude such that the merger is not likely to be anticompetitive in any relevant market.”<sup>71</sup> Efficiencies are cognizable when they are merger-specific, have been verified, and do not arise from anticompetitive reductions in output or service.<sup>72</sup>

A merger may generate efficiencies for the merged HMO or other health plan that reduce the costs of hospitals, physicians, or other providers that deal with it. For example, one panelist discussed how HMOs might achieve economies of scale.<sup>73</sup> She noted that HMOs might lower supply-side costs by negotiating better prices with local

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<sup>70</sup> MERGER GUIDELINES, *supra* note 1, § 4 (as revised Apr. 8, 1997).

<sup>71</sup> *Id.* § 4.

<sup>72</sup> Merger-specific efficiencies are “only those efficiencies likely to be accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects.” *Id.* Cognizable efficiencies are assessed “net of costs produced by the merger or incurred in achieving those efficiencies.” *Id.*

<sup>73</sup> Given 4/24 at 27-34; Ruth Given, *National HMO Trends 6* (4/24) (slides) [hereinafter Given Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/0304given.pdf>. *See also* Given at 4/24 at 111-12 (“[J]ust because you have economies of scale doesn’t mean you have merger-specific efficiencies”).

physician and hospital networks.<sup>74</sup> Moreover, economies of scale may create lower costs for complying with state regulations, administering the HMO, or implementing disease and utilization management, she noted.<sup>75</sup> She maintained that these real cost savings are akin to a technological innovation that lowers input costs.<sup>76</sup>

Another panelist suggested that because the lower input price reflects genuine cost savings in the supply chain, overall welfare increases.<sup>77</sup> The first panelist discussed demand-side efficiencies (including broader provider networks, more financially stable and better managed organizations, and a larger patient population to provide a critical mass for population health and disease management programs) that may improve or increase the value of the HMO to the customer.<sup>78</sup>

Several panelists discussed the number of enrollees an HMO needs to achieve economies of scale. One panelist stated that HMOs reach maximum efficiencies with between 30,000 and 50,000

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<sup>74</sup> Given 4/24 at 33 (noting that plans may need to be bigger to negotiate with providers who also have gained greater market concentration); Given Presentation, *supra* note 73, at 6.

<sup>75</sup> Given 4/24 at 32-36; Given Presentation, *supra* note 73, at 6.

<sup>76</sup> Given Presentation, *supra* note 73, at 6; Given 4/24 at 32-37; *see also* Schwartz 4/25 at 9.

<sup>77</sup> Schwartz 4/25 at 9. *See also* Given 4/24 at 34-37; Given Presentation, *supra* note 73, at 6.

<sup>78</sup> Given 4/24 at 34-37; Given Presentation, *supra* note 73, at 6.



enrollees.<sup>79</sup> Another panelist suggested a similar range to have economies of scale, and observed that these efficiencies generally apply up to 115,000 enrollees.<sup>80</sup> A third panelist observed that in very small markets these scale economies may be difficult to achieve, and some markets probably cannot support large numbers of health plans.<sup>81</sup>

Several panelists suggested that researchers or the Agencies examine whether consummated health insurance mergers realized the efficiencies they claimed premerger.<sup>82</sup> To date, the Division has reviewed very few health insurance mergers where the parties claimed that the merger would result in efficiencies that can reasonably be accomplished only by the proposed merger or other means having comparable anticompetitive effects.

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<sup>79</sup> Given 4/24 at 32 -33 (noting that an article she wrote discussed maximizing efficiencies at about 115,000 enrollees, but in that case she was discussing the “whole state of California, and it’s about 30- to 40,000 when you adjust for” the number of geographic markets in which HMOs compete in the state; further noting, however, that these numbers may be biased low for current market conditions).

<sup>80</sup> Gabel 4/23 at 165-66; Gabel Presentation, *supra* note 53, at 9 (summarizing the literature about HMO market structure and performance and noting that local market competition increased between 1994 and 1997 despite national mergers, and that local markets determine the level of competition).

<sup>81</sup> Senkewicz 4/24 at 65-66.

<sup>82</sup> See Foreman 4/24 at 117; Angoff 4/24 at 117-118. See also *id.* at 122; Lerner 4/24 at 120, 123. Both panelists suggested that the Agencies work more closely with state insurance regulators with respect to health plan mergers.

## **E. Conclusion**

The Agencies will continue to follow the *Merger Guidelines* in health insurance mergers and conduct a factually intensive, case-specific assessment of whether a particular transaction under review will allow health plans to exercise market power with regard to their customers.<sup>83</sup>

## **III. MONOPSONY POWER**

Conceptually, monopsony power is the mirror image of monopoly power. A buyer has monopsony power when it can profitably reduce prices in a market below competitive levels by curtailing purchases of the relevant product or services.<sup>84</sup> The exercise of monopsony power causes competitive harm because the monopsonist will reduce purchases of the input, shift some purchases to a less efficient source, supply too little output in the downstream market, or do all three. When a monopsonist reduces purchases of inputs to

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<sup>83</sup> See, e.g., Feldman 4/23 at 96 (“Unfortunately, I think antitrust cases have to be done one at a time”); Lerner 4/23 at 97-98 (“So, I think a lot of these things, I agree, you have to look at the case you’re dealing with and figure out what makes sense”); Monk 4/23 at 98 (“[W]hen you’re looking at a specific market, you do have to factor in what the characteristics that are in that market at that time and whether the characteristics changed because there was a change in - either the market was currently in balance or out of balance”). See also Ginsburg 04/24 at 7 (“The key to performance by health insurers is really the direction that they get from employers, and I think the problems we have now often stem from the type of directions or absence of it that insurers are getting from employers, their customers”).

<sup>84</sup> Schwartz 4/25 at 8-9; see also Dick 4/25 at 4. When a group of buyers combines to exercise market power it is called oligopsony power.

reduce input prices, society foregoes the production of output whose value to consumers exceeds the resource costs of associated inputs, thereby creating a welfare loss to society.<sup>85</sup> To be sure, a buyer's post-merger ability to lower the cost of inputs is not necessarily an exercise of monopsony power.<sup>86</sup>

The Agencies have brought several cases that challenged the actual or potential exercise of monopsony power.<sup>87</sup> Two relatively recent Division cases, both settled by consent decree, alleged that the mergers would have led to monopsony power in

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<sup>85</sup> Schwartz 4/25 at 9-11; Marius Schwartz, Buyer Power Concerns and the *Aetna-Prudential* Merger, Address Before the 5th Annual Health Care Antitrust Forum at Northwestern University School of Law 4-6 (October 20, 1999) (noting that anticompetitive effects can occur even if the conduct does not adversely affect the ultimate consumers who purchase the end-product), available at <http://www.usdoj.gov/atr/public/speeches/3924.wpd>.

<sup>86</sup> Schwartz, *supra* note 85, at 5; see also Schwartz 4/25 at 9 ("If, for example, a merger enables the now bigger buyer to get a lower price because of efficiencies, for example, [when] it buys in bulk, and that saves resources, and that's what enables a lower wholesale price, then that's a good thing. That is likely to also increase the amount of the input that's purchased and, therefore, is a good thing for overall economic performance.").

<sup>87</sup> The Division defined monopsony markets in both *Aetna/Prudential* and *Cargill/Continental Grain*. *Aetna Complaint*, *supra* note 26, ¶ 27; *Aetna Impact Statement*, *supra* note 26, at 9; *United States v. Cargill, Inc.*, No. 1:99CV01875 ¶¶ 17-19 (July 8, 1999) (complaint), available at <http://www.usdoj.gov/atr/cases/f2500/2552.pdf>. See also Schwartz 4/25 at 8-22. The Commission defined monopsony markets in several cases, including *In re BP Amoco, PLC*, Dkt. No. 3938 (Aug. 25, 2000), complaint at ¶¶ 43-48 (complaint alleged that merger would lessen competition in bidding for rights to explore the Alaska North Slope).

some markets. *United States v. Cargill, Inc.*<sup>88</sup> involved a challenge to a merger of grain purchasers, and *United States v. Aetna, Inc.*<sup>89</sup> involved a challenge to the merger of two health care insurers, Aetna and Prudential.

Monopsony concerns can arise in health insurer mergers,<sup>90</sup> as well as in other contexts, including market allocation agreements among competing purchasers, most favored nation (MFN) clauses, and exclusive or quasi-exclusive dealing contracts.<sup>91</sup> Some of the Agencies' MFN cases can be seen as monopsony-related matters, as they dealt with the power of purchasers of services (such as dental, vision, or hospital care services) to impose contract terms on sellers of those services (such as dentists, optometrists, or hospitals).<sup>92</sup>

#### A. *Product and Geographic Market Definition*

As with monopoly analysis, an important aspect of monopsony analysis is market definition. One panelist noted that there are not many monopsony cases that

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<sup>88</sup> *United States v. Cargill, Inc.*, 2000-2 Trade Cas. (CCH) ¶ 72,966 (D.D.C. 2000).

<sup>89</sup> *United States v. Aetna, Inc.*, 1999-2 Trade Cas. (CCH) ¶ 72,730 (N.D. Tex. 1999).

<sup>90</sup> See also *supra* Chapter 1.

<sup>91</sup> See Miles 4/25 at 44.

<sup>92</sup> See *United States v. Med. Mut. of Ohio*, 1999-1 Trade Cas. (CCH) ¶ 72,465 (N.D. Ohio 1999); *United States v. Delta Dental of R.I.*, 943 F. Supp. 172 (D.R.I. 1996); *United States v. Vision Serv. Plan*, 1996-1 Trade Cas. (CCH) ¶ 71,404 (D.D.C. 1996).

clearly analyze market definition.<sup>93</sup> Buyer-side product market definition, in particular, is an active area of academic and legal inquiry, and is an area in which additional research is desirable.

Defining a buyer-side market involves reversing the standard seller-side formula to ask about the extent to which at-risk suppliers will substitute other outlets for their products or services in response to a small but significant and non-transitory *decrease* in price. The crucial consideration in defining monopsony product and geographic markets, therefore, is whether the buyers of the input in the putative market successfully would be able to lower the price they pay for the input or whether, instead, the sellers have sufficient realistic alternatives to allow them to circumvent the price decrease.

Several additional monopsony market definition-related points are worth noting. First, purchasers of the input need not compete in the output market to be

included in the relevant market for the purchase of the input.<sup>94</sup> Thus, it is possible that public payors (*e.g.*, Medicare and Medicaid) and private payors (*e.g.*, health care insurers) do not compete in output markets, but do compete in the market for the purchase of services from health care providers. Thus, purchasers of services might be differentiated in their competitive effectiveness just as sellers are differentiated in some downstream markets.<sup>95</sup>

Second, the same analytical tools used in defining markets to assess seller power can be applied when assessing buyer power.<sup>96</sup> Third, a firm need not have seller-side market power in order to have buyer-side monopsony power.<sup>97</sup> Fourth, while the Division previously treated the product market in *Aetna* as physicians' services, rather than defining separate product markets by physician specialty, monopsony antitrust markets might be appropriately defined in other circumstances for physician specialties, hospitals, or other provider

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<sup>93</sup> See Miles 4/24 at 130-31. This panelist said that the cases that do address monopsony power have not done a good job of analyzing market definition issues, defining the market in terms of the output market rather than the input market. *Id.* He noted, however, that the Second Circuit's decision in *Todd v. Exxon*, 275 F.3d 191 (2d Cir. 2001), which defined the product market by focusing on the interchangeability, from the perspective of plaintiff-employees, of job opportunities in the oil industry and job opportunities in other industries, handled monopsony market definition in a sound manner. *Id.* at 131-32. He also observed that *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940) and *Mandeville Island Farms v. American Crystal Sugar Co.*, 334 U.S. 219 (1948), both involved monopsony power issues in the form of naked price-fixing agreements among buyers with market power. *Id.* at 127-28.

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<sup>94</sup> See *id.* at 134; Schwartz 4/25 at 11-12.

<sup>95</sup> See McCarthy 4/24 at 202; Blair 4/24 at 204 (noting that when patients need medical services, "whether they're represented by a commercial health insurer or a government health insurer ... [they] contribute to the demand that's placed on the physician's time"); *but see* Foreman 4/24 at 204 (stating that it is a "non-answer" to tell physicians that their "response to a monopsony reduction in prices [should be] to expand your Medicare and Medicaid patient list").

<sup>96</sup> See Miles 4/24 at 134.

<sup>97</sup> See discussion of *Cargill*, *infra* notes 124-128, and accompanying text.

groupings.<sup>98</sup> Finally, as in other areas of antitrust analysis,<sup>99</sup> the presence or absence of price discrimination can, at times, play an important role in monopsony power analysis.<sup>100</sup>

### **B. Seller Switching Costs**

Seller switching costs are an important part of monopsony analysis. Seller switching costs are the costs faced by suppliers (*e.g.*, health care providers) in switching to different outlets (*e.g.*, health care insurers) for their services. High seller switching costs make it more difficult for a provider, when faced with lower reimbursement from a monopsonist health care insurer, to switch business to another health care insurer. Consequently, high seller switching costs make it more likely that monopsonist health care insurers could exercise market power against health care

providers. Although such switching costs may vary depending on the specifics of a market, they can be significant for health care providers.<sup>101</sup>

Seller switching costs for physicians can be significant because: (1) a physician's time is perishable and (2) it can be difficult for a physician to quickly replace lost patients.<sup>102</sup> Some have offered other reasons that physician switching costs can be significant. First, some have noted that such switching costs may be greater when a seller has invested in specialized assets and have suggested that the training undergone by physicians may be such an investment.<sup>103</sup> Second, some have noted that seller switching costs can be higher if the sellers are not mobile and have suggested that health care providers may not be geographically mobile.<sup>104</sup>

Other panelists disagreed with the notion that the seller switching costs faced by providers are substantial, and argued that some physicians are both geographically mobile and are able to serve other health

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<sup>98</sup> *Aetna Complaint*, *supra* note 26, ¶ 27; *Aetna Impact Statement*, *supra* note 26, at 9; *see also* McCarthy 4/24 at 166-67 (indicating that physician product market definition, in the context of monopsony, should be “basically specialty-specific”).

<sup>99</sup> *See, e.g.*, *United States v. Dairy Farmers of Am., Inc.*, No. 6:03-206 (Apr. 24, 2003) (complaint), *available at* <http://www.usdoj.gov/atr/cases/f200900/200972.pdf>.

<sup>100</sup> There was some disagreement among Hearings participants about the extent of price discrimination that actually occurs with respect to physician services. *Compare* Schwartz 4/25 at 16 (noting that there was a good deal of evidence in *Aetna* that “Aetna and other payors did not set their prices to physicians uniformly on a market wide basis, but rather, negotiated prices separately with individual physicians or individual physician groups”), *with* Frech 4/24 at 221 (stating that, once one looks past large physician groups, health care insurers do not engage in much price discrimination with respect to physicians).

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<sup>101</sup> *See* Foreman 4/24 at 175-77.

<sup>102</sup> *See* Schwartz 4/25 at 17; Foreman 4/24 at 175-77. This panelist added that the different billing, quality assurance, and other systems that insurers use can make it difficult for physicians to switch to serving patients covered by another health care insurer. *Id.* at 176-77.

<sup>103</sup> *See* Foreman 4/24 at 175-76; Frech 4/24 at 190.

<sup>104</sup> *See* Foreman 4/24 at 175-76. A related question to the issue of physician mobility is how quickly must provider migration remedy a monopsony situation to make an antitrust remedy inappropriate. *See* Frech 4/24 at 190.

care insurers locally.<sup>105</sup> These panelists also suggested that physicians facing a monopsonist may be able to respond by filling their practices with cash paying patients, closing their practices (*i.e.*, not taking on new patients from a health care insurer), or encouraging existing patients enrolled in the monopsonist health care insurer to change to other health care insurers.<sup>106</sup> The Agencies believe these competing claims are fact-specific empirical propositions that can only be resolved in the context of a particular matter.

### C. *Competitive Effects*

#### 1. **Insurer Market Share and the Cost of Provider Withdrawal**

Two recognized analyses of market share in the context of health care insurer monopsony are: (1) the health care insurer's locality-wide share, which is the health care insurer's market share of patients or patient dollars in a local market and (2) the health care insurer's share of each physician's business.<sup>107</sup> The locality-wide share indicates the size of the pool of patients available to the provider, if that provider were no longer to treat the monopsonist health care insurer's patients.<sup>108</sup>

The share of each provider's business, which matters only because there are switching costs, shows the number of

patients a provider would have to replace, if the provider were no longer to treat the health care insurer's patients.<sup>109</sup> If either type of market share is high, a provider faces high per-patient replacement costs if the provider no longer treats the health care insurer's patients.<sup>110</sup> If both market shares are high (and other factors are present) then a health care insurer merger or health care insurer monopsony conduct could allow the insurer to impose significant price reductions on a nontrivial number of providers.<sup>111</sup>

It is difficult, in the abstract, to state market share thresholds for such monopsony concerns. In part, this is because determining the existence of monopsony power requires the Agencies and courts to look at other factors in addition to the health care insurer's market share. The classic elements of monopsony power have been described as: (1) a large market share on the part of the purchaser; (2) an upward sloping or somewhat inelastic supply curve in the input market; and (3) an inability or unwillingness for new purchasers to enter the market or current purchasers to expand the amount of their purchases in the market.<sup>112</sup>

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<sup>109</sup> *See id.* at 19.

<sup>110</sup> *See id.* at 18-20.

<sup>111</sup> *See id.* at 21-22.

<sup>112</sup> *See Miles 4/25 at 35-36.* Some disagree on whether the physician supply curve is upward sloping or inelastic in many markets. *Compare McCarthy 4/24 at 217* (indicating that the physician supply curve may be flat in many areas due to excess capacity), *with Foreman 4/24 at 218* (stating that there is not "evidence of excess supply" and "depending on the specialty ... [there are] some intermediate term concerns about supply.").

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<sup>105</sup> *See McCarthy 4/24 at 163-64, 189.*

<sup>106</sup> *See id.* at 213-214; *McCarthy 4/25 at 135; Miles 4/24 at 213.*

<sup>107</sup> *See Schwartz 4/25 at 17-19.*

<sup>108</sup> *See id.* at 18.

## 2. Distinguishing Lawful From Unlawful Behavior

Of course, even if a health care insurer has monopsony power, the issue for antitrust purposes is whether the health care insurer has obtained or maintained that power through improper means.<sup>113</sup> If reimbursement levels are low due to lawfully obtained and exercised health care insurer market power, then there is no antitrust violation.

One area of health care insurer activity that may sometimes be confused with unlawful monopsony behavior is lawful managed care contracting. Managed care plans and other health care insurers can legitimately lower health care provider prices by increasing competition among health care providers or engaging in other activities that lower the costs of provider services. Indeed, because one of the purposes of managed care is to lower prices closer to a competitive level, it can be difficult to determine when a managed care purchaser is exercising monopsony power.<sup>114</sup>

The First Circuit dealt with this issue in *Kartell v. Blue Shield of Massachusetts*.<sup>115</sup>

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<sup>113</sup> See Miles 4/25 at 43-44.

<sup>114</sup> See Frech 4/25 at 24-25. See also *id.* at 24-25 (noting that HMOs and PPOs can “improve competition and lower prices” because they “perform search[es] for consumers and they provide stronger incentives for choice of the low-priced sellers”), 28 (also noting that “reducing prices towards the competitive level is one of the general purposes of managed care and ... – to the extent it happens – one of the competitive benefits of managed care and efficient health plans”).

<sup>115</sup> 749 F.2d 922 (1st Cir. 1984).

In *Kartell*, physicians sued Blue Shield, alleging that its prohibition on “balance billing” was an unreasonable restraint of trade or an act of monopolization or attempted monopolization.<sup>116</sup> The First Circuit, in rejecting this antitrust challenge, assumed for purposes of its analysis that Blue Shield had market power and that it used the market “power to obtain ‘lower than competitive’ prices.”<sup>117</sup> The court said that as long as the prices were not predatory, or below anyone’s incremental cost, “a legitimate buyer is entitled to use its market power to keep prices down.”<sup>118</sup>

One way to distinguish monopsony conduct from other market situations is to look for indicia of such conduct.<sup>119</sup> One

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<sup>116</sup> *Id.* at 923. Balance billing refers to the practice whereby a provider bills patients for the difference between what the insurer pays to the provider and the provider’s billed charge for the service. The prohibition on balance billing prohibits the provider from collecting money, other than copayments or deductibles, directly from the patient and requires providers who sign a participating provider agreement with Blue Shield “to accept as payment in full an amount determined by Blue Shield’s ‘usual and customary charge’ method of compensation.” *Id.*

<sup>117</sup> *Id.* at 927.

<sup>118</sup> *Id.* at 927-28, 929. The court also cited to three additional circumstances that argued “against any effort by an antitrust court to supervise the Blue Shield/physician price bargain .... First, the prices at issue are low prices, not high prices .... Second, the subject matter of the present agreement – medical costs – is an area of great complexity where more than solely economic values are at stake .... Third, the price system here at issue is one supervised by state regulators.” *Id.* at 930-31.

<sup>119</sup> See Brewbaker 9/26 at 50-53 (listing variety of factors indicating that payors lack monopsony power). See also Timothy J. Muris,

panelist suggested possible indicia including: (1) a decline in market output; (2) a pattern of provider exit because of low rates; (3) a large share of total market-wide reimbursements from the alleged monopsonist; (4) single rates for specialties rather than contract negotiations; (5) low reimbursement levels to providers; (6) limited opportunities to treat noncommercial patients; (7) low incomes for physicians and low profit margins for efficient providers; (8) no systematic excess capacity by providers market-wide; (9) few rival health care insurers; (10) low rates paid by rival health care insurers; and (11) difficulty of entry into the health care insurance market.<sup>120</sup> It is important to note that these indicia are not, individually or collectively, items that must be proven to show monopsony conduct.

### 3. Lowering Prices Below the Competitive Level

Some have said that the Agencies should be concerned whenever a transaction or practice leads to a lowering of prices.<sup>121</sup> A more appropriate way of framing this

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Everything Old is New Again: Health Care and Competition in the 21st Century, Speech Before the 7th Annual Competition in Health Care Forum 16-18 (Nov. 7, 2002), available at <http://www.ftc.gov/speeches/muris/murishhealthcarespeech0211.pdf> (noting that physicians who entered into consent agreements to settle FTC allegations of anticompetitive conduct were not located in areas with high payor concentration – indicating that the driving force behind such conduct was not an attempt to offset monopsony power).

<sup>120</sup> See McCarthy 4/25 at 65-69. See also discussion of entry, *supra* notes 49-69, and accompanying text.

<sup>121</sup> See Foreman 4/25 at 122-23.

issue is that the Agencies should be concerned only if the transaction or practice leads to prices below competitive levels. Of course, this requires a determination of the “competitive pricing level,” which is a daunting task.<sup>122</sup> Health care prices can be defined in a number of different ways, and even with an agreed-upon benchmark for competitive reimbursement, it can be difficult to know whether the price paid to health care providers has changed.<sup>123</sup>

### 4. Monopsony Power Absent Downstream Market Power

Finally, it should be noted that payors need not have monopoly power in downstream markets to have monopsony power in upstream markets.<sup>124</sup> Thus, in cases such as *Cargill*, a monopsony may affect suppliers but not consumers.<sup>125</sup> In *Cargill*, the Division challenged a merger that would have created a monopsony purchaser of grain in some local markets.<sup>126</sup> The merging companies, however, sold grain in world markets, in which they faced competition from many other grain sellers.<sup>127</sup> Thus, even if the merged firms imposed a loss on farmers by cutting back the quantity

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<sup>122</sup> See Frech at 25. See also *Kartell*, 749 F.2d at 927-28 (noting the difficulty of determining what is a reasonable or competitive price) and *infra* Chapter 7 (discussing the difficulties of using price controls to reflect competitive prices).

<sup>123</sup> See Frech 4/25 at 25-27.

<sup>124</sup> See Schwartz 4/25 at 11-12; Frech 4/25 at 29-30.

<sup>125</sup> See Schwartz 4/25 at 11-12.

<sup>126</sup> See *id.*

<sup>127</sup> See *id.*

of grain they bought from them, consumers of the merging companies would not be harmed because they had numerous other sources of supply.<sup>128</sup> The harm in the upstream market, however, was sufficient to prompt the Division to challenge the merger.

#### **D. Conclusion**

The Hearings confirmed two important, interrelated points with respect to monopsony power in the health insurance sector. First, under the right circumstances, monopsony power can be created or exercised in this industry. The Agencies consequently need to remain vigilant in monitoring the market for such situations. Second, properly ascertaining whether monopsony power has in fact been created or exercised in this industry typically will involve a case-specific, factually-intense assessment. As panelists pointed out, “‘low prices’ by themselves are not an indication or certainly not proof of monopsony power,”<sup>129</sup> and correctly determining the presence of monopsony power is “tricky.”<sup>130</sup>

### **IV. CURRENT CONTROVERSIES**

#### **A. Most Favored Nation Clauses**

An MFN clause is a contractual agreement between a supplier and a customer that requires the supplier to sell to the customer on pricing terms at least as favorable as the pricing terms on which that supplier sells to any other customer. In health care markets, large insurance plans

impose these contractual agreements in contracts with hospitals, physicians, and other health care providers. MFNs are sometimes also referred to as “most favored customer clauses,” “prudent buyer clauses,” or “nondiscrimination clauses.”

According to panelists at the Hearings, MFNs may be anticompetitive or procompetitive, depending on the circumstances.<sup>131</sup> Proponents of MFNs argue that they allow an insurer to be confident that the reimbursement it pays a provider is no greater than the rates paid by the insurer’s competitors. In certain situations, however, an MFN clause may harm competition either by substantially raising the costs of the insurer’s rivals, or reducing provider discounting in the particular market.<sup>132</sup>

Under either theory, any savings in provider costs to the firm imposing the MFN must be weighed against any higher provider costs incurred by that firm’s rivals.<sup>133</sup> The

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<sup>128</sup> See *id.* at 12.

<sup>129</sup> Miles 4/25 at 35.

<sup>130</sup> Frech 4/24 at 31-32.

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<sup>131</sup> Overstreet 5/7 at 146 (noting that “[t]here’s a fair consensus among economists that have looked at these things that they can be pro-competitive or anticompetitive depending on the factual circumstances”); Kopit 5/7 at 126, 132-35; Baker 5/7 at 139-43; Snow 5/7 at 154-55.

<sup>132</sup> As discussed *infra* notes 148-?, and accompanying text, MFNs are typically used to eliminate provider discounting if the insurer is controlled by providers.

<sup>133</sup> See Kopit 5/7 at 135-38 (suggesting that MFNs imposed by insurers with market power are likely anticompetitive unless they can be shown to reduce cost, similar to the the Robinson-Patman Act’s requirement that volume discounts be cost-justified). See also Overstreet 5/7 at 148, 190-92 (noting importance of determining actual impact of MFN in weighing theoretical claims that lower costs to the firm imposing the MFN are offset by higher costs to



Agencies consider economic justifications for MFNs when weighing their potential competitive effects.

According to some panelists, justifications for MFN clauses in other industries are not applicable when applied to the health care industry.<sup>134</sup> For example, MFNs can facilitate long-term contracts in industries such as natural gas, where it is difficult to predict future price changes and industry conditions. They also can be used as a substitute “low-cost seller” signal in industries in which it is difficult and costly for consumers to search for price information.<sup>135</sup>

These justifications for MFNs likely are not applicable to the use of MFNs in health care markets. The “equitable” argument in favor of MFNs that the largest buyer in the market is entitled to a quantity discount and to the best price is not supported by antitrust economics, but it is likely to be advanced by large buyers. In any case, there is no need for a counterintuitive blanket rule against MFNs. There may be situations, however, where an MFN has an anticompetitive effect and as noted above, in any investigation, the agencies would weigh the cost savings to the largest buyer against higher costs that may be incurred by that firm’s rivals.<sup>136</sup>

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competing firms).

<sup>134</sup> Baker 5/7 at 141-43.

<sup>135</sup> See *id.* at 142-43.

<sup>136</sup> See generally Snow 5/7 at 156-57 (arguing “that in most cases, the largest buyer is entitled to a quantity discount and to the best price”). See also discussion *infra* note 153; Kopit 5/7 at 136-37 (suggesting some providers may have the incentive

## 1. Prior Cases

The Agencies have brought several cases involving MFNs.<sup>137</sup> Only a few of those cases have resulted in judicial opinions, and they provide little guidance other than that MFNs are not per se lawful.<sup>138</sup> *Delta Dental Of Arizona* and *RxCare* involved provider-controlled insurers that imposed an MFN in order to eliminate provider discounting. *Vision Service Plan* and *Medical Mutual Of Ohio* involved insurers that were not provider-controlled and used their monopsony power to raise their rivals’ costs. In *Delta Dental of Rhode Island* the federal district court issued an opinion that held that MFNs are not per se lawful.<sup>139</sup>

Private litigation has had mixed results. In both *Ocean State* and *Kitsap v. Washington Dental*, courts found that the MFN clauses at issue did not violate the

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to offer smaller insurers lower rates in order to fill their remaining beds).

<sup>137</sup> United States v. Delta Dental Plan of Ariz., 1995-1 Trade Cas. (CCH) ¶ 71,048 (D. Ariz. 1995); United States v. Or. Dental Ser. 1995-2 Trade Cas. (CCH) ¶ 71,062 (N.D. Cal. 1995); United States v. Vision Serv. Plan, 1996-1 Trade Cas. (CCH) ¶ 71,404 (D.D.C. 1996); United States v. Delta Dental of R.I., 943 F. Supp. 172 (D.R.I. 1996); United States v. Med. Mut. of Ohio, 1999-1 Trade Cas. (CCH) ¶ 72,465 (N.D. Ohio 1999); *In re RxCare of Tenn., Inc.*, 121 F.T.C. 762 (1996).

<sup>138</sup> *e.g.*, Baker 5/7 at 143-45.

<sup>139</sup> *Delta Dental of R.I.*, 943 F. Supp. at 176. In a case involving enforcement of an administrative subpoena, the 6<sup>th</sup> Circuit made a similar observation. *Blue Cross & Blue Shield of Ohio v. Klein*, 117 F.3d 1420 (6th Cir. 1997) (unpublished opinion). See also Kopit 5/7 at 127-31; Overstreet 5/7 at 153.

antitrust laws.<sup>140</sup> In *Ocean State*, the First Circuit concluded, as a matter of law, that a prudent buyer policy, essentially identical to the MFN clauses in other antitrust cases, did not constitute monopolization in violation of Section 2 of the Sherman Act.<sup>141</sup> In *Marshfield Clinic*, the Seventh Circuit stated that the suggestion that the MFN established a price-floor for physicians' prices is an "ingenious but perverse argument."<sup>142</sup> The court acknowledged that an MFN might be misused to anticompetitive ends, but concluded there was no evidence of such conduct in that case.<sup>143</sup>

Other courts have recognized the anticompetitive potential of MFN clauses. In *United States v. Eli Lilly*, the court found that the MFN clause explained the existence of prices higher than the competitive price,

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<sup>140</sup> *Ocean State Physicians Health Plan, Inc. v. Blue Cross & Blue Shield of R.I.*, 883 F.2d 1101 (1st Cir. 1989); *Kitsap Physician Serv. v. Wash. Dental Serv.*, 671 F. Supp. 1267 (W.D. Wash. 1987). For a discussion of *Ocean State*, see *Kopit 5/7* at 124-27, 129-30, 134-35 and *Snow 5/7* at 154-57.

<sup>141</sup> *Ocean State*, 883 F.2d 1101 (1989). See also *Kopit 5/7* at 125-27. But see *Independence Blue Cross, July 23, 2003, Letter re: FTC/DOJ Hearings on Health Care and Competition Law and Policy 1* (Public Comment) (arguing that *Independence Blue Cross's* "Prudent Buyer" clause is not an MFN clause).

<sup>142</sup> *Marshfield Clinic*, 65 F.3d at 1415.

<sup>143</sup> *Id.* See also *Baker 5/7/03* at 144; Jonathan Baker, *Competitive Effects of Most Favored Nation Clauses in Health Care Markets 12 (5/7)* (slides) [hereinafter *Baker Presentation*], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030507baker.pdf>; *Kopit 5/7* at 119-21 ("One of the interesting things about that is there was no MFN in the case .... So, to say it was gratuitous, I'd say that's a fair statement.").

although there was no evidence of conspiracy.<sup>144</sup> In *Reazin v. Blue Cross & Blue Shield*, the court found that the MFN provided evidence of Blue Cross's market power, and the Tenth Circuit explicitly stated that the *Ocean State* decision did not alter its conclusion with respect to Blue Cross's possession of monopoly power.<sup>145</sup> Several other cases also have discussed the anticompetitive potential of MFN clauses.<sup>146</sup>

## 2. Competitive Concerns

MFNs, as used in health care markets, may result in competitive harm based upon two different theories.<sup>147</sup> First, MFNs can facilitate coordination among health care providers in certain instances where the insurer imposing the MFN is provider-controlled.<sup>148</sup> Under these circumstances, the MFN can make cheating on a cartel price more transparent and provide an enforcement mechanism that can

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<sup>144</sup> *United States v. Eli Lilly*, 24 F.R.D. 285 (D.N.J. 1959).

<sup>145</sup> *Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, 899 F.2d 951, 971 n.30 (10th Cir. 1990). The Tenth Circuit noted that it did not need to reach the question addressed in *Ocean State* of whether an MFN clause could itself violate Section 2. *Id.* at 971 n.30.

<sup>146</sup> *Williamette Dental Group v. Oregon Dental Serv. Corp.*, 882 P.2d 637 (Or. App. 1994); *In re Brand Name Prescription Drugs*, 288 F.3d 1028, 1033 (7th Cir. 2002); *Baker 5/7* at 141-45; *Baker Presentation*, *supra* note 143, at 8-12.

<sup>147</sup> See, e.g., *Baker 5/7* at 139-40.

<sup>148</sup> See *Baker 5/7* at 139-40; *Overstreet 5/7* at 146-47

be used against a price-cutting provider.<sup>149</sup>

For example, according to the allegations in *RxCare*, the Tennessee Pharmacists Association organized most of the pharmacies in Tennessee into a single provider network that used an MFN clause to discourage discounting and effectively create a price floor. One of *RxCare*'s stated goals was to "define and promote appropriate compensation to pharmacists for patient care."<sup>150</sup> The Commission's complaint alleged that *RxCare* and the association used the MFN clause to restrain "rivalry in the provision of pharmacy benefit prescription services among Tennessee pharmacies ... [and harm] consumers by limiting price competition and entry into pharmacy network services."<sup>151</sup>

Second, insurers that are not controlled by providers may impose MFNs to deter hospitals or other providers from granting discounts to competing health insurers. Under this theory, the MFN may create a barrier to entry or expansion by the insurer's rivals or may raise its rivals' costs, thereby making them less effective competitors.<sup>152</sup> Some panelists noted that providers have less incentive than they otherwise would to accept lower prices from another health plan because they will have to

give the lower price to the dominant plan with which they have the MFN agreement. Absent the MFN, panelists noted, some health insurers may offer new or different products, such as more restricted provider panels or tiered co-payments. These alternative insurers may have a greater ability to bargain for lower prices because, unlike many plans, they may have more flexibility in excluding providers or creating incentives for patients to choose low cost providers, panelists explained. Providers may favor the creation of these plans because, panelists observed, they may expand the size of the insured population by making insurance options available to people who otherwise could not afford them.<sup>153</sup>

Under this theory, the inability of the incumbent health plan's rivals to obtain discounts may result in the outright exclusion of rival health plans or new entrants into the market and allow the incumbent health plan to maintain or achieve prices above the competitive

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<sup>149</sup> See *United States v. Delta Dental Plan of Ariz.*, 1995-1 Trade Cas. (CCH) ¶ 71,048 (D. Ariz. 1995); *United States v. Oregon Dental Serv.*, 1995-2 Trade Cas. (CCH) ¶ 71,062 (N.D. Cal. 1995); *In re RxCare of Tenn., Inc.*, 121 F.T.C. 762 (1996).

<sup>150</sup> 121 F.T.C. at 763 ¶ 2 (complaint).

<sup>151</sup> *Id.* at 764 ¶ 8.

<sup>152</sup> *Baker 5/7* at 140; *Overstreet 5/7* at 147-48.

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<sup>153</sup> Hospitals, in order to fill their beds, may compete with each other at the margin for the additional patients that smaller insurers can provide them. A hospital, similar to an airline seeking to fill the seats on a flight, may be willing to serve those few additional patients at rates closer to its marginal cost than it would the bulk of its business. *Kopit 5/7* at 136-37. The airline analogy may not capture the full implications of this competition among hospitals over incremental sales, however, because passengers on an airplane do not compete with each other in a downstream market, whereas insurers compete with each other in the sale of health care insurance. The disparity in hospital rates among competing plans may affect that competition to a significant degree. *See Snow 5/7* at 156-57.

level.<sup>154</sup> In *Reazin v. Blue Cross & Blue Shield*, for instance, the court noted there was testimony that alternative delivery systems, such as HMOs, “were the first real challenge to our traditional system of delivering financing of care ... [and] that Blue Cross’s most favored nations clause hindered the development of alternative delivery systems, thereby interfering with the introduction of competition.”<sup>155</sup> The Tenth Circuit observed that, at least in the Kansas market, there were significant barriers to entry and Blue Cross’s actions were designed to maintain those barriers.<sup>156</sup>

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<sup>154</sup> Baker 5/7 at 140; Baker Presentation, *supra* note 143, at 6.

<sup>155</sup> 899 F.2d 951, 970 (10th Cir. 1990). For example, Blue Cross had terminated its contract with one hospital that was participating in an HMO. Moreover, it sent a letter to all other hospitals in its service area warning that if they decided to pursue vertical integration arrangements with insurers, Blue Cross would be forced to reassess its relationship with the hospital, and “[h]ospitals that wish to continue their current relationship with Blue Cross and Blue Shield, that do not seek to enroll subscribers in other programs, and that wish to cooperate with Blue Cross and Blue Shield as a major marketing arm of the hospital, will experience no change in the contractual relationship that has historically served Kansans well.” *Id.* at 959 n.8.

<sup>156</sup> *Id.* at 972 & n.32 (rejecting Blue Cross’s attempt to rely on *Ball Memorial Hosp. Inc. v. Mutual Hospital Insurance*, 784 F.2d 1325 (7th Cir. 1986), for the proposition that entry barriers in the health care financing market were always low). The 10<sup>th</sup> Circuit noted that entry barriers might be low in Indiana, where Blue Cross only had 27 percent of the market and there were 500 insurers currently doing business in the state, but they were not low in Kansas.

Interestingly, the plaintiff hospitals in *Ball Memorial* were attempting to prevent Blue Cross from entering the market with a PPO product that competed with many of their own. 784 F.2d at 1339. In *Reazin*, Blue Cross was attempting to prevent the

Under either of these theories, market power is an important part of the analysis. Panelists noted that there is no absolute market share threshold above which a firm may be able to employ an MFN anticompetitively.<sup>157</sup> Indeed, the relevant source of market power (and thus the relevant market share inquiry) depends on whether the theory of harm focuses on seller-side or buyer-side imposition of the MFN. For example, where the theory of harm focuses on the first theory (facilitation of provider coordination), the collective market power of the participating providers is an important consideration.

Conversely, where the theory of harm focuses on the second theory (raising rivals’ costs or abuse of health insurer monopsony power), the insurer’s market power upstream is a relevant inquiry.<sup>158</sup> Indeed, most of the cases finding MFN clauses anticompetitive involved plans with a dominant market share requiring providers to agree to an MFN clause or a dominant provider network requiring providers to agree to the MFN clause.<sup>159</sup>

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hospitals from participating in alternative delivery systems like HMOs and PPOs that might compete with Blue Cross’s traditional indemnity plans. 899 F.2d at 964-65.

<sup>157</sup> See Kopit 5/7 at 132-33, 194-95; Overstreet 5/7 at 147-48.

<sup>158</sup> See Kopit 5/7 at 132-3; Overstreet 5/7 at 147-48.

<sup>159</sup> See, e.g., *RxCare of Tenn.*, 121 F.T.C. 762 (1996); *Reazin*, 899 F.2d at 971 n.30 (“[T]he most favored nation clause here is not itself challenged as unlawful monopolization. Rather, it is only considered as evidence of, or as contributing to, Blue Cross’ market or monopoly power”). See also Baker 5/7 at 139 (noting that the cases in which

Panelists stated that, if the entity requiring the MFN clause has market power, it is more likely that the MFN clause will have anticompetitive effects.<sup>160</sup>

According to one panelist, MFN clauses may facilitate coordination among providers, and dampen competition. Coordination is facilitated because providers have less incentive to cheat on a price agreement by accepting lower prices from another health plan because they will have to give the lower price to the dominant plan with which they have the MFN agreement. Moreover, rival health plans may have less incentive to bargain with providers, because they know they cannot obtain a competitive advantage.<sup>161</sup>

*Conclusion.* The Agencies will continue to challenge the use of MFN clauses when the evidence suggests that such terms violate antitrust law.

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MFNs receive antitrust scrutiny usually involve a dominant health plan); Kopit 5/7 at 131.

<sup>160</sup> See Overstreet 5/7 at 147 (noting that the “concern in the upstream market is most likely to be a competitive one when that market is concentrated, is subject to oligopoly coordination; in the downstream market, the concern is most likely to be a real issue when the firm imposing the MFN has a large share of the market”); Baker 5/7 at 139-140. *But see* Snow 5/7 at 156 (arguing that an MFN is “primarily a device to prevent price discrimination. . . [and] that in most cases, the largest buyer is entitled to a quantity discount and to the best price”).

<sup>161</sup> Baker 5/7 at 139-41; Baker Presentation, *supra* note 143, at 5. See also *RxCare of Tenn.*, 121 F.T.C. 762.

## **B. Mandated Benefits**

### **1. Claimed Benefits of Mandates**

Proponents view mandates as a way of providing access to benefits valued by beneficiaries but withheld by employers or insurers. Proponents see health care as a “merit good,” “the provision of which should not be limited to those who are able to pay for medical care and who see the wisdom in doing so.”<sup>162</sup> Proponents also argue that mandates correct for insurance market failures, and that the required inclusion of some benefits in all health insurance plans can be welfare enhancing.<sup>163</sup>

More concretely, one commentator has suggested that plans have an incentive to offer inefficiently inadequate benefits because health insurance contracts are, by necessity, incompletely specified, and mandates prevent post-contractual opportunism and the exploitation of informational asymmetries.<sup>164</sup> The same commentator stated that mandates may also help compensate for the bounded rationality of consumers in choosing among health insurance plans.<sup>165</sup>

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<sup>162</sup> Russell Korobkin, *The Efficiency of Managed Care “Patient Protection” Laws: Incomplete Contracts, Bounded Rationality, and Market Failure*, 85 CORNELL L. REV. 1, 8 (1999). See also Lawrence H. Summers, *Some Simple Economics of Mandated Benefits*, 79 AM. ECON. REV. 177, 178 (May 1989).

<sup>163</sup> Korobkin, *supra* note 162, at 87-88.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.* See also Summers, *supra* note 162, at 178 (suggesting that individuals may “irrationally underestimate the probability of catastrophic health expenses, or of a child’s illness that would require a

Commentators have also suggested that mandates can help solve the problem of adverse selection.<sup>166</sup> According to these commentators, if employees have more information about whether they will face high medical bills than employers do, employers that provide generous fringe benefits may end up attracting employees who are disproportionately likely to make expensive claims. This dynamic might discourage employers from offering comprehensive benefits to employees.

Two panelists noted that many insurers and employers might be reluctant to offer a benefit that attracts high cost employees or beneficiaries.<sup>167</sup> By requiring all insurance plans to cover certain costly illnesses, the risk is spread across a large number of employers/health insurers.

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sustained leave”); Frank A. Sloan & Mark A. Hall, *Market Failures and the Evolution of State Regulation of Managed Care*, 65 LAW & CONTEMP. PROBS. 169, 173 (Fall 2002) (“[T]he complexity of the contract may make it very costly for the ordinary consumer to make comparisons among the few alternative plans most consumers have.”).

In such situations, consumers are likely to adopt choice strategies that have various weaknesses. Herbert A. Simon, *Rational Choice and the Structure of the Environment*, 63 PSYCHOL. REV. 129 (1956); James G. March, *Bounded Rationality, Ambiguity, and the Engineering of Choice*, 9 BELL J. ECON. 587, 590 (1978). For example, the greater the number of plan attributes that must be compared and weighed, the more likely it is that consumers will simply focus on the price of the plan. Korobkin, *supra* note 162, at 88.

<sup>166</sup> See Gitterman 6/25 at 19; Hyman 6/25 at 85. See also Summers, *supra* note 162, at 179.

<sup>167</sup> Hyman 6/25 at 85; Greenberg 9/9/02 at 179-180 (noting risk selection problems in the health care market). Cf. Herzlinger 5/27 at 92 (suggesting that providers who treat sicker patients should receive higher payments).

Finally, one panelist asserted that mandates may be necessary to prevent discrimination against particular conditions.<sup>168</sup> In this view, mandates ensure parity of access to treatment.<sup>169</sup>

Proponents of mandates generally argue that the costs of an individual proposed mandate are low. For example, one panelist stated that mental health parity laws would, on average, result in premium increases of less than one percent.<sup>170</sup> Proponents of mandates also suggest that any analysis of the cost of the mandated benefit must consider the consequences of failing to provide the mandated coverage.<sup>171</sup>

## 2. Claimed Disadvantages/ Inefficiencies of Mandates

Opponents of mandated benefits argue that forced inclusion of insurance benefits raises premium costs, and may lead employers to opt out of providing health

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<sup>168</sup> Ibson 6/25 at 19 (noting employers often single out “mental health disorders and impose restrictive limits on care”).

<sup>169</sup> See *id.* at 22-24.

<sup>170</sup> See *id.* at 23 (referring to studies performed by PricewaterhouseCoopers and the National Advisory Mental Health Council). But see Knettel 6/25 at 78-79 (arguing that flexible interpretations of parity laws and carve out arrangements have made impact of parity requirements “tolerable”).

<sup>171</sup> Ibson 6/25 at 24 (arguing that untreated depression costs the economy \$44 billion per year in lost productivity); Laser 6/25 at 47-48 (noting that “there was no cost increase due to contraceptive coverage ... and the savings of contraceptive coverage outweigh the costs” including savings from “fewer pregnancies, fewer deliveries, and healthier newborns”).

insurance and employees to drop their coverage.<sup>172</sup> Opponents generally argue that the market is likely to do a more efficient job allocating resources between health insurance and other consumer goods than the alternatives.<sup>173</sup> As one article states, “if plans compete on price, choice, and quality, they have incentives to cover services that yield expected health benefits that are worth their costs to consumers. Patients who want comprehensive coverage can choose high premium plans.”<sup>174</sup>

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<sup>172</sup> See Kanwit 6/25 at 37-39; Gitterman 6/25 at 8 (“[W]hy mandate Cadillac coverage when purchasers just want a Chevy.”); MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS AND ECONOMICS OF RATIONING MECHANISMS 22, 24 (1997) (identifying mandates as an important source of inefficiency, and observing that “[e]conomists explain that it usually makes no sense to mandate or encourage insurance that many consumers are unwilling to buy.”).

Studies suggest twenty to twenty-five percent of uninsured Americans lack coverage because of benefit mandates. GAIL JENSEN & MICHAEL MORRISEY, MANDATED BENEFIT LAWS AND EMPLOYER-SPONSORED HEALTH INSURANCE 1 (1999) (prepared for Health Insurance Ass’n of America), available at <http://www.insureusa.org/research/jensen.htm>; Frank A. Sloan & Christopher J. Conover, *Effects of State Reforms on Health Insurance Coverage of Adults*, 35 INQUIRY 280 (1998). See also Kanwit 6/25 at 38-39; T. Miller 6/25 at 63.

<sup>173</sup> RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE? 429 (1997).

<sup>174</sup> Patricia M. Danzon, *Tort Liability: A Minefield for Managed Care?*, 26 J. LEGAL STUD. 491, 509 (1997). See also David A. Hyman, *Consumer Protection in a Managed Care World: Should Consumers Call 911?*, 43 VILL. L. REV. 409, 437 (1998) (“Policy sellers must weigh whether broadening coverage ... [is] worth doing if [it] price[s] the policy out of the market – or result[s] in a shift in the nature of coverage from that which is most

Some assert that mandating benefits takes away the option of lower-priced insurance and forces consumers to pay for insurance they may not want or to go without coverage at all.<sup>175</sup> As one panelist noted, with mandates “you are banning what are in effect the low cost health insurance contractual alternatives ... that should, in theory, begin to decrease insurance coverage at least on the margin particularly for price sensitive buyers.”<sup>176</sup>

Panelists and commentators noted that it appears that legislative enthusiasm for a particular mandate may be based on an isolated anecdote, with little or no analysis of costs and benefits.<sup>177</sup> Mandates, as one panelist observed, may create an illusion of

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appealing to the covered pool as a whole.”).

<sup>175</sup> Korobkin, *supra* note 162, at 22. See also Kanwit 6/25 at 28 (arguing that mandates “drive up the costs for employers and consumers”, “may restrict consumer choice”, “discourage competition among providers”, and “stifle innovative medical advances in treatment and diagnosis because they freeze current practice.”).

<sup>176</sup> T. Miller 6/25 at 57.

<sup>177</sup> See, e.g., Kanwit 6/25 at 40 (describing the New England Journal of Medicine study that suggested that the mandated 48 hour maternity stay mandate did not help infant health); Hyman 6/25 at 87 (noting use of “horror stories” to set regulatory agenda); Clark Havighurst, *American Health Care and the Law: We Need to Talk!*, 19 HEALTH AFFAIRS 84, 105 n.7 (July/Aug. 2000) (“Nothing could be clearer, however, than that the signals that voters (consumers wearing a different hat and having less reason to think rationally or fully inform themselves) send to their representatives do not invite rational consideration of difficult trade-offs.”); David A. Hyman, *Regulating Managed Care: What’s Wrong With A Patient Bill of Rights*, 73 S. Cal. L. Rev. 221, 237-41 (2000).

getting benefits for free.<sup>178</sup> Legislators may be motivated to pass mandates because they can deliver a benefit to consumers but not incur an on-budget cost. In general, tax revenues are not required to pay for the mandate, but the mandate is still a tax on consumers.<sup>179</sup>

Others note the need for many mandates may be questionable; health insurers have obvious economic incentives to offer the benefits that consumers desire and are willing to pay for – facts which cast doubt on whether most mandates are cost-justified.<sup>180</sup> Finally, according to some panelists and commentators, providers of the mandated benefit are usually the most vigorous proponents of legislation, making it more likely that the mandated benefit constitutes “provider protection” and not

“consumer protection.”<sup>181</sup>

One panelist noted compliance with mandates is difficult for employers and insurers operating in multiple states. When a carrier or employer wants to provide uniform benefits across its workforce, it must adopt an aggregation of the most restrictive provisions to ensure the offering complies with all states simultaneously.<sup>182</sup> Alternatively, the employer can create a self-funded employee benefit plan, which is not subject to state mandated benefits laws.<sup>183</sup>

Commentators and panelists stated that mandates also limit employers’ ability to offer health insurance coverage.<sup>184</sup> One panelist described the employer as having a pie that has a limited number of dollars for health care coverage. Employers will eliminate other benefits to offset the cost of

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<sup>178</sup> Gitterman 6/25 at 9 (“It’s hard for any voter, consumer or worker to know for sure how he or she is being affected by what ends up being a confusing tax. This helps policymakers foster the illusion that benefits can be provided and no one bears the cost.”).

<sup>179</sup> Uwe E. Reinhardt, *Health Insurance for the Nation’s Poor*, 6 HEALTH AFFAIRS 101, 106 (Spring 1987) (“A pseudo-tax is a government-mandated fiscal transfer among private individuals, institutions, or business firms that can be referred to by a name other than tax and that does not flow through a public budget for which politicians can be held accountable.”); DANIEL P. GITTERMAN & ROBERT NORDYKE, PROVIDING CREDIBLE INFORMATION AND IMPROVING HEALTH INSURANCE REGULATORY IMPACT ANALYSIS IN CALIFORNIA: A REPORT TO THE CALIFORNIA HEALTH CARE FOUNDATION 2 (1999).

<sup>180</sup> Jensen & Morrisey, *supra* note 172, at 5. See also *supra* note 174, and accompanying text.

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<sup>181</sup> See, e.g., Kanwit 6/25 at 39-40 (describing the mandates for autologous bone marrow transplant (ABMT), a breast cancer treatment for women for which there were no clinical trials, many women died from the treatment, and ABMT was no more effective than the standard treatment); T. Miller 6/25 at 66; Jensen & Morrisey, *supra* note 172, at 5; Hyman, *supra* note 177, at 223.

<sup>182</sup> Knettel 6/25 at 76. Of course, these are the very employers that may be best able to avoid the state mandates by self-insuring.

<sup>183</sup> The Employee Retirement Income Security Act (ERISA) largely preempts self-insured plans from state mandates. Thus, an employer may avoid state regulation by providing its own insurance. See *supra* Chapter 5.

<sup>184</sup> Jensen & Morrisey, *supra* note 172, at 9-10.



any mandated benefits.<sup>185</sup> According to several panelists, mandates increase premiums and decrease wages and other benefits employers might otherwise offer.<sup>186</sup>

Other commentators assert that state-imposed mandated benefits disproportionately affect small businesses because they are less able to avoid the costs of such mandates by self-insuring.<sup>187</sup> Although determining the actual cost of an individual mandated benefit can be difficult, the aggregate cost of such mandates appears to account for a substantial percentage of premium cost.<sup>188</sup>

Finally, some commentators have noted the behavioral economic arguments in favor of mandated benefits are theoretical, and not based on empirical evidence

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<sup>185</sup> Knettel 6/25 at 73-75 (noting that each time a benefit is mandated that mandate “is going to be offset by a benefit reduction of equal or greater cost in some other area”). *See also* Sloan & Conover, *supra* note 172.

<sup>186</sup> *See* T. Miller 6/25 at 64 (noting that mandates “can also have offsetting effects in terms of lower wages, decreased employment, reduced generosity of fringe benefits as well”). *See also* Gitterman 6/25 at 18; T. Miller 6/25 at 57.

<sup>187</sup> As the costs of mandates rise, more firms seek to self-insure to avoid the added expense of state mandates, but some smaller businesses do not have the necessary capital to do so. *See* Jensen & Morrissey, *supra* note 172, at 10. As stop-loss insurance with low attachment points has made self-insurance available on a broader basis, this problem has become less significant.

<sup>188</sup> *See* Kanwit 6/25 at 37; Gitterman 6/25 at 15 (“One of the things that you have seen in the 1996 mental health parity debate is the incredible wide range of estimates from each of these different consulting groups. I think the costs were somewhere between zero and 8 percent.”).

regarding the performance of the health insurance market.<sup>189</sup> Mandate proponents presented no evidence that consumers demand insufficient health insurance, and there is some evidence that many consumers actually demand excessive health insurance.<sup>190</sup> Mandate proponents presented no evidence that government intervention is likely to improve the efficiency of health insurance benefit design, and there is some evidence to the contrary.<sup>191</sup>

### 3. Any Willing Provider and Freedom of Choice Legislation: A Case Study of Mandates

Any willing provider (AWP) laws require managed care companies to include in their networks any provider that is willing to participate in the plan in accordance with the plan’s terms.<sup>192</sup> Freedom of choice (FOC) laws are similar to AWP laws, but are directed at consumers instead of providers.<sup>193</sup> Many states have adopted AWP and/or FOC laws for at least some

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<sup>189</sup> *See generally* 6/26 at 6-105; Hyman, *supra* note 177, at 234-36.

<sup>190</sup> The substantial tax subsidy for employment-based health insurance encourages broader and deeper insurance coverage than would otherwise be the case. Pauly 2/26 at 98; Clark Havighurst, *How the Health Care Revolution Fell Short*, 65 LAW & CONTEMP. PROBS. 55, 69-71 (2002).

<sup>191</sup> *See generally* Hyman, *supra* note 177.

<sup>192</sup> Michael Vita, *Regulatory Restrictions on Selective Contracting: An Empirical Analysis of ‘Any Willing Provider’ Regulations*, 20 J. HEALTH ECON. 955, 956 (2001).

<sup>193</sup> *See, e.g., id.* (“[F]reedom of choice (FOC) laws . . . obligate plans to reimburse for care obtained from a qualified provider even if the provider is not a member of the network”)

health care providers.<sup>194</sup>

Commission staff has expressed concerns about AWP and FOC laws, noting that they could have anticompetitive effects and harm consumers.<sup>195</sup> These laws can make it more difficult for health insurers to negotiate discounts from providers in exchange for the higher patient volume that likely would result from restricted provider networks.<sup>196</sup> They can also limit competition, by restricting the ability of insurance companies to structure different plans with varying levels of choice in

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<sup>194</sup> See, e.g., *id.* (“By one count, 34 states had enacted some form of FOC or AWP law by 1996”).

<sup>195</sup> See FTC staff comments on proposed legislation that incorporated any willing provider or “freedom of choice” provisions in the following states: Rhode Island (Letter from Office of Policy Planning et al., to Patrick C. Lynch, Attorney General (Apr. 8, 2004)), at <http://www.ftc.gov/os/2004/04/ribills.pdf>; Massachusetts (Letter from Bureau of Competition, to John C. Bartley, Representative (May 30, 1989)); New Hampshire (Letter from Office of Consumer & Competition Advocacy, to Paul J. Alfano (Mar. 17, 1992)); California (Letter from Office of Consumer & Competition Advocacy, to Patrick Johnston, Senator (June 26, 1992)), at <http://www.ftc.gov/opa/predawn/F93/calpharm.htm>; Montana (Letter from Office of Consumer and Competition Advocacy, to Joseph P. Mazurek, Attorney General (Feb. 4, 1993)); New Jersey (Letter from Office of Consumer and Competition Advocacy, to E. Scott Garrett, Assemblyman (Mar. 29, 1993)); Pennsylvania (Letter from Office of Consumer and Competition Advocacy, to Roger Madigan, Senator (Apr. 19, 1993)); South Carolina (Letter from Office of Consumer and Competition Advocacy, to Thomas C. Alexander, Representative (May 10, 1993)); and Nevada (Letter from Bureau of Competition, to David A. Gates, Commissioner of Insurance (Nov. 5, 1986)).

<sup>196</sup> See, e.g., FTC Staff letter to Rhode Island, *supra* note 195, at 6; Greenberg 6/12 at 68-69.

response to consumer demand.<sup>197</sup> These restrictions on competition may result in insurance companies paying higher fees to providers, which in turn generally results in higher premiums, and may increase the number of uninsured Americans.

As Commission staff explained in its most recent advocacy letter on this issue,

Empirical evaluations of any willing provider and “freedom of choice” provisions indicate that these policies result in higher health care expenditures. One study found that states with highly restrictive any willing provider/freedom of choice laws spent approximately 2% more on healthcare than did states without such policies. This finding likely reflects the fact that these laws reduce the ability of insurers to offer less expensive plans with limited provider panels. This interpretation is supported by another study that found that metropolitan areas with a high intensity of any willing provider/freedom of choice regulation had HMO market shares approximately 7% lower than comparable areas without these provisions. “Freedom of choice” provisions reduced HMO market share more than any willing provider laws.<sup>198</sup>

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<sup>197</sup> See *supra* note 196.

<sup>198</sup> FTC Staff letter to Rhode Island, *supra* note 195. See also Michael A. Morrissey & Robert L. Ohsfeldt, *Do State ‘Any Willing Provider’ and ‘Freedom of Choice’ Laws Affect HMO Market Share?*, 40 INQUIRY 362 (2003/2004).

Many provider groups support AWP and FOC legislation.<sup>199</sup> Commission staff observed in its most recent advocacy letter that “several scholars have noted that any willing provider and ‘freedom of choice’ laws are more likely to appear in states with limited managed care penetration, and suggested that these provisions are actually intended to preempt competition among providers [provider protection], instead of protecting the interest of patients.”<sup>200</sup>

#### 4. Potential Responses to the Demand for Mandated Benefits

As the number of mandated benefits has risen, sensitivity to their cost ramifications has increased. The Unfunded Mandates Reform Act discourages Congress from imposing unfunded mandates on other

governmental entities.<sup>201</sup> The states have developed a variety of strategies to weigh the costs of mandated benefits, with varying degrees of success.<sup>202</sup>

There are four basic models for mandatory review processes: (1) use of an independent standing health care commission or legislative advisory commission/interim committee; (2) use of an administrative agency; (3) use of legislative research or fiscal staff; and (4) use of proponent prepared and submitted assessments to the legislative committee.<sup>203</sup> Each model has procedural variations in the review process including how the bills are referred for evaluation and the specific requirements of the impact analysis. Some of the models may be more credible and provide more objective information than others.

*Conclusion.* For mandates to improve the efficiency of the health insurance market, state and federal legislators must be able to identify services the insurance market is not currently covering for which consumers are willing to pay marginal cost. This task is challenging under the best of circumstances – and

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<sup>199</sup> See, e.g., Gene A. Blumenreich, *United States Supreme Court upholds “any willing provider” statutes*, 71 AANA J. 259 (Aug. 2003) (Legal Brief of American Ass’n of Nurse Anesthetists), at <http://www.aana.com/legal/legbrfs/2003/pdfs/p259-262.pdf>; American Medical Ass’n, *H-285.984 Any Willing Provider Provisions and Laws* (AMA policy re: “Any Willing Provider” laws, including opposing federal preemption of state AWP laws), at [http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=browse&doc=policyfiles/HnE/H-285.984.htm](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-285.984.htm) (last visited June 25, 2004); National Community Pharmacists Ass’n, *High Court Upholds State Any Willing Provider Laws* (from AMERICA’S PHARMACIST, May 2003), at [http://www.ncpanet.org/leg\\_gov/notes\\_from\\_capitol\\_hill/2003/may.shtml](http://www.ncpanet.org/leg_gov/notes_from_capitol_hill/2003/may.shtml)

<sup>200</sup> FTC Staff letter to Rhode Island, *supra* note 195. *But see* Blumenreich, *supra* note 199 (noting that the American Association of Nurse Anesthetists (AANA) supports AWP legislation, arguing that these laws prohibit insurance companies from discriminating against them).

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<sup>201</sup> CONGRESSIONAL BUDGET OFFICE, CBO’S ACTIVITIES UNDER THE UNFUNDED MANDATES REFORM ACT, 1996-2000 (2001), available at <ftp://ftp.cbo.gov/28xx/doc2843/UMRA-Paper.pdf>; Unfunded Mandates Reform Act (UMRA) of 1995, Pub. L. No. 104-4, 109 Stat. 48. The UMRA requires the Congressional Budget Office (CBO) to prepare an analysis of the direct costs of any mandates and an assessment of whether the bill authorizes or otherwise provides funding to cover the costs of the mandate.

<sup>202</sup> Gitterman & Nordyke, *supra* note 179.

<sup>203</sup> Gitterman 6/25 at 12-13.

benefits are not mandated under the best of circumstances. In practice, mandates may limit consumer choice, eliminate product diversity, and raise the cost of health insurance. Mandates may also increase the number of uninsured Americans, as employers and employees opt out of the market.

State and federal policy makers should consider expressly factoring these risks into their decision making process, and develop ways of insulating the process of mandating benefits from their effects. Governments should reconsider whether current mandates, including AWP and FOC laws, best serve their citizens' health care needs.

**CHAPTER 7:           INDUSTRY SNAPSHOT AND COMPETITION LAW:  
                                  PHARMACEUTICALS**

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## CHAPTER 7: INDUSTRY SNAPSHOT AND COMPETITION LAW: PHARMACEUTICALS

### I. OVERVIEW

The Hearings examined the impact of competition law and policy on cost, innovation, and access to drug products in the pharmaceutical industry. After reviewing the importance of patent protection and competition in spurring pharmaceutical innovation, the Hearings focused on the role of pharmacy benefit managers (PBMs) and the effects of direct-to-consumer (DTC) advertising on consumer demand for, and pricing of, pharmaceutical products.

Representatives from the pharmaceutical industry and legal, economic, and academic experts spoke at the Hearings on pharmaceutical topic panels, including: Generics and Branded Pharmaceuticals (September 10, 2002); Advertising and Pharmaceuticals: DTC Advertising and Promotion (September 10, 2002); and Pharmaceuticals: Formulary Issues (June 26).<sup>1</sup> This chapter provides a brief overview of the drivers of competition for pharmaceutical products, discusses Commission initiatives in the pharmaceutical industry and highlights the contentious public issues surrounding PBMs and DTC advertising.

To date, most empirical evidence suggests that PBMs have lowered costs for health plan sponsors. Nonetheless, the use of PBMs as intermediaries between pharmaceutical manufacturers and health plan sponsors has raised public concern about whether PBMs increase pharmacy benefit costs for health plan sponsors and their enrollees. Pursuant to a legislative directive, the Commission is examining one particular aspect of these allegations – whether it costs more for a health plan sponsor to use mail order pharmacy services integrated with a PBM than to use non-integrated mail order or retail pharmacies.

Similarly, the effects of DTC advertising have been subject to debate. Currently available empirical evidence does not support the allegations that DTC advertising increases inappropriate prescription of, or prices for, pharmaceutical products. Indeed, research shows that truthful and non-misleading advertising generally benefits consumers by providing them with useful information about their health care and treatment options.<sup>2</sup> Nevertheless, definitive conclusions await the development of better empirical

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<sup>1</sup> A complete list of participants on these and other panels is available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcare/hearings/completeagenda.pdf>. These issues were also considered at a workshop held by the Commission on September 10, 2002. A complete list of participants in the workshop is available *infra* Appendix A and at <http://www.ftc.gov/ogc/healthcare/>.

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<sup>2</sup> See, e.g., PAULINE M. IPPOLITO & JANIS K. PAPPALARDO, FEDERAL TRADE COMM’N, ADVERTISING NUTRITION & HEALTH: EVIDENCE FROM FOOD ADVERTISING 1977-1997 (2002), available at <http://www.ftc.gov/opa/2002/10/advertisingfinal.pdf>; PAULINE M. IPPOLITO & ALAN D. MATHIOS, FEDERAL TRADE COMM’N, INFORMATION AND ADVERTISING POLICY: A STUDY OF FAT AND CHOLESTEROL CONSUMPTION IN THE UNITED STATES, 1977-1990 (1996).

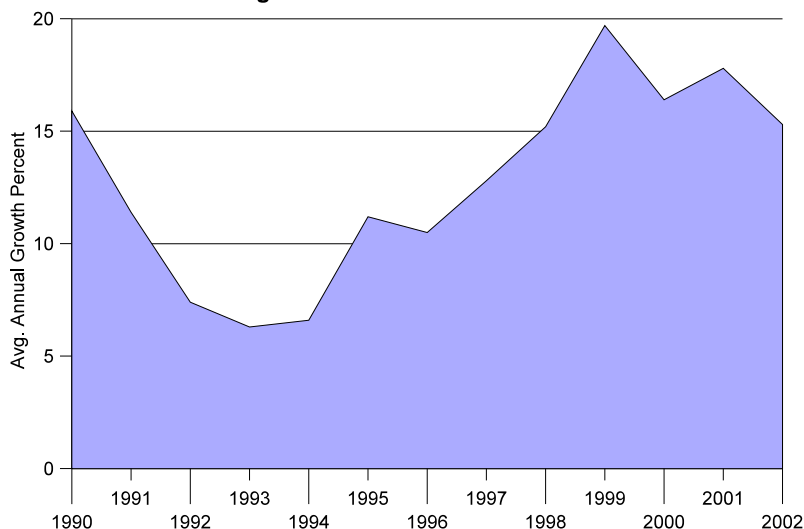
evidence about the effects of DTC advertising of prescription drugs.

## II. BACKGROUND ON INNOVATION IN THE PHARMACEUTICAL INDUSTRY

The role of prescription pharmaceutical drugs has changed significantly over the last 25 years. Medicines now exist to treat conditions that previously had no treatment or required lengthy hospital stays and/or surgery, allowing health care providers to employ less invasive treatments.<sup>3</sup> Advances in science and technology have given researchers more sophisticated knowledge of the root causes of diseases. Scientists can more effectively design medicines to attack specific diseases, resulting in the invention of new medicines.<sup>4</sup>

U.S. spending on pharmaceutical products mirrors this changing role. U.S. spending on pharmaceuticals increased to \$140.6 billion in 2001, more than triple the amount in 1990.<sup>5</sup> Total U.S. spending for drug products accounts for approximately 11

Figure 1: National Prescription Health Expenditures  
Average Annual Growth from Prior Year



percent of personal health care spending.<sup>6</sup> Figure 1 shows the annual rate of increase in spending on prescription pharmaceuticals during the last decade.<sup>7</sup> One report estimates that approximately half of the increase in spending is due to increased utilization, and that the remainder of the increase is split evenly between increases in retail prices and increases in the use of more expensive drugs.<sup>8</sup>

This increase in spending for pharmaceutical products has been coupled with an increase in research and development (R&D) spending to develop and bring to market new pharmaceutical

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<sup>3</sup> PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA (PHRMA), INSIGHTS 2003: HIGHLIGHTS FROM THE PHARMACEUTICAL INDUSTRY PROFILE 3 (2003), available at <http://www.phrma.org/publications/publications//2003-10-07.892.pdf>.

<sup>4</sup> *Id.*

<sup>5</sup> Kaiser Family Found., *Prescription Drug Trends* 1 (May 2003), at <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14267>.

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<sup>6</sup> *Id.*

<sup>7</sup> Centers for Medicare & Medicaid Services, *Health Accounts: National Health Expenditures 1965-2013, History and Projections by Type of Service and Source of Funds: Calendar Years 1965-2013*, at <http://www.cms.hhs.gov/statistics/nhe/default.asp#download> (last modified Mar. 24, 2004).

<sup>8</sup> Kaiser Family Found., *supra* note 5, at 2. See also Bhattacharjya 9/10/02 at 173.

products. From 1990 to 2001, annual R&D spending in the pharmaceutical industry increased from \$8 billion to \$30 billion.<sup>9</sup>

The Commission examined extensively the drivers behind this increased R&D spending and pharmaceutical innovation in its October 2003 Report, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (FTC Patent Report)*.<sup>10</sup> The *FTC Patent Report* found both patents and competition play an essential role in spurring innovation in the pharmaceutical industry. Patents spur innovation in several different ways. First, patents create incentives for brand-name companies to innovate by excluding others from making, using, or selling a claimed invention for a specific period of time.

Second, patents disclose to the public information that might otherwise remain a trade secret. Such disclosure encourages innovation by giving generic companies an opportunity to design around brand-name patents.<sup>11</sup> Panelists at the Health Care

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<sup>9</sup> PHRMA, *supra* note 3, at 6 (these expenditures are not adjusted for inflation).

<sup>10</sup> See FEDERAL TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) [hereinafter *FTC PATENT REPORT*], available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. The report also described the regulatory process used by the Food and Drug Administration to ensure pharmaceutical products are safe and effective. *Id.* § 3, at 6-9.

<sup>11</sup> *Id.* § 3, at 9 (“Panelists reported that patent protection promotes innovation in the pharmaceutical industry by creating incentives for brand-name companies to innovate, and by disclosing inventions, thereby encouraging generic companies to innovate by designing around brand-name company

Hearings supported the *FTC Patent Report*'s conclusion that patent protection is essential to innovation in the pharmaceutical industry.<sup>12</sup> Innovation in this industry is costly and unpredictable as it requires significant amounts of pioneering research to discover and test new drug products. Patent protection allows pharmaceutical firms to recoup the substantial capital investments made to discover, test, and obtain regulatory approval of these new drug products. Box 7-1 references some of the empirical studies of the role of patents in spurring innovation in the pharmaceutical industry.

#### A. *Types of Innovation in the Pharmaceutical Industry*

The *FTC Patent Report* describes two main types of innovation: (i) discrete innovation; and (ii) incremental innovation.<sup>13</sup> Innovation can occur at many points along the continuum, from discrete to incremental, but these categories help classify innovation in the pharmaceutical industry.

#### 1. Discrete Innovation

Discrete innovation focuses on the “discovery and development of new chemical or molecular entities to make small

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patents.”).

<sup>12</sup> Bhattacharjya 9/10/02 at 177; Glover 9/10/02 at 182-83; Schultz 9/10/02 at 211; Lock 9/10/02 at 220-21; McCluskey 9/10/02 at 221.

<sup>13</sup> Although these are the two main categories, innovation may occur somewhere between these two types. *FTC PATENT REPORT*, *supra* note 10, at 4.



**Box 7-1 Empirical Studies on the Role of Patents in Spurring Innovation in the Pharmaceutical Industry**

Empirical studies have shown that patents play an essential role in spurring innovation in the pharmaceutical industry. One study conducted by Edwin Mansfield analyzed a random sample of 100 firms, excluding very small firms, from twelve broadly defined industries. The study found patents to be essential for the pharmaceutical and chemical industries in developing or introducing thirty percent or more of their inventions. See Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCIENCE 173, 174-75 (1986); see also FTC, PATENT REPORT § 2, at 11 (citing Mansfield study). The pharmaceutical industry participants reported that “60% of inventions would not have been developed and 65% would not have been commercially introduced absent patent protection.” FTC, PATENT REPORT § 2, at 11 (citing Mansfield study); Mansfield, *supra*, at 175.

Another study by Richard C. Levin, Alvin K Klevorick, Richard R. Nelson and Sidney G. Winter analyzed survey responses from 650 R&D managers representing 130 lines of business. This study found patents were especially important in the pharmaceutical drug industry to prevent duplication. See Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, in BROOKINGS PAPERS ON ECONOMIC ACTIVITY 795-96 (1987); see also FTC, PATENT REPORT § 2, at 11 (citing Levin, Klevorick, Nelson and Winter study).

A more recent study by Wesley M. Cohen, Richard R. Nelson and John P. Walsh found that in the pharmaceutical industry patents were effective appropriability mechanisms for more than 50% of all product innovations. WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) 32 tbl.1 (Nat’l Bureau of Econ. Research, Working Paper No. 7552, 2000), at <http://papers.nber.org/papers/w7552.pdf>; see also FTC, PATENT REPORT § 2, at 11-12 (citing Cohen, Nelson and Walsh study).

molecule drug products.”<sup>14</sup> The benefits of investing large amounts of time and money into such discoveries can be very high. For example, “[t]he discovery of a chemical molecule that is both efficacious and safe for human usage can result in a totally new drug product.”<sup>15</sup> The benefits of discrete innovation, however, do not come without high fixed costs and risks that the effort will not produce a marketable product. Brand-name companies can spend 10-15 years on development for a new drug before the

product enters the market.<sup>16</sup> During this time brand-name companies incur significant costs at a high risk that their product may not make it out of clinical trials.<sup>17</sup>

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<sup>16</sup> *Id.* at 5; see Gregory J. Glover, *Competition in the Pharmaceutical Marketplace* 3 (3/19/02) (stating that the average cost to develop a new drug is \$802 million) [hereinafter Glover (stmt)], at <http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf>.

<sup>17</sup> See Glover (stmt), *supra* note 16, at 3 (“On average, economists estimate that it takes 10-15 years to develop a new drug. Most drugs do not survive the rigorous development process – only 20 in 5,000 compounds that are screened enter

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<sup>14</sup> *Id.* at 4-5.

<sup>15</sup> *Id.* at 5.

## 2. *Incremental Innovation*

Incremental innovation “consists of enhancing known chemical entities by formulating new dosage forms or additional methods of use for existing chemical entities.”<sup>18</sup> The term “incremental” generally refers to advances in technology that are built on the features or elements of existing technology.<sup>19</sup> Drugs formed this way are referred to as incrementally modified drugs (IMDs).<sup>20</sup>

The *FTC Patent Report* describes three ways incremental innovation is achieved. One is through new formulations, which include such things as changes in dosage forms or new ways of administering approved drugs. The second method is combining two previously approved active ingredients to form a new product. The third is the use of derivatives of previously approved drugs to form a new product.<sup>21</sup> There are a variety of views about the benefits of these modified drugs, ranging from the view that IMDs bring significant health enhancements to consumers to the view that IMDs only serve to extend a

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preclinical testing, and only 1 drug in 5 that enters human clinical trials is approved by the FDA as being both safe and effective.”).

<sup>18</sup> FTC PATENT REPORT, *supra* note 10, at 8.

<sup>19</sup> *Id.* at 8; see also THE NAT’L INSTITUTE FOR HEALTH CARE MGMT., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 5 (2002) [hereinafter NIHCM, INNOVATION REPORT], available at <http://www.nihcm.org/innovations.pdf>.

<sup>20</sup> NIHCM, INNOVATION REPORT, *supra* note 19, at 5.

<sup>21</sup> *Id.* at 5, 8.

brand-name company’s “patent monopolies beyond the patent expiry of the new chemical entity ... by a matter of years, not days or weeks or months.”<sup>22</sup>

## B. *The Role of Competition in Spurring Pharmaceutical Innovation*

Several panelists at the health care hearings highlighted the importance of competition to spur innovation. For example, some panelists suggested that the incentives to innovate provided by patent rights should be balanced against the competition provided by generic drugs.<sup>23</sup> The *FTC Patent Report* has articulated how competition spurs pharmaceutical innovation. First, brand-name companies with patented drugs are increasingly competing with one another, particularly within the same therapeutic class. Second, provisions in the Hatch-Waxman Amendments have fostered competition from generics by streamlining the generic drug approval process.<sup>24</sup>

*Competition Among Brand-Name Companies.* The *FTC Patent Report* indicated that brand-name pharmaceutical companies believe that competition among brand-name companies continues to increase because the period of market-exclusivity between the introduction of a breakthrough

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<sup>22</sup> FTC PATENT REPORT, *supra* note 10, at 9.

<sup>23</sup> Lock 9/10/02 at 220-21; McCluskey 9/10/02 at 221.

<sup>24</sup> FTC PATENT REPORT, *supra* note 10, at 10-12. Another form of competition that may affect innovation is the competition among generic firms for the same brand-name product.

medicine and the introduction of a competing therapeutic agent has been consistently shrinking.<sup>25</sup> Although brand-to-brand competition may have increased in those therapeutic areas in which demand for the drugs is likely to increase, one commentator has suggested that price competition among several drug products in a therapeutic class can be limited.<sup>26</sup>

*Competition From Generic Drug Products.* The Hatch-Waxman Amendments govern the generic drug approval process and have played a major role in spurring additional competition in the pharmaceutical industry. The Amendments “established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers.”<sup>27</sup> The Amendments also streamlined procedures for allowing generic drug applicants an opportunity to gain FDA approval prior to patent expiration.<sup>28</sup> Since enactment of

Hatch-Waxman in 1984, barriers to competition have been lowered, and price competition in those markets with generic entry has increased significantly.<sup>29</sup>

Competition from generic drugs can deliver large price savings to consumers, because generic drugs are typically far less expensive than their corresponding brand-name versions. A Congressional Budget Office (CBO) study attempted to quantify the magnitude of this effect by analyzing retail pharmacy data from 1993 and 1994. The study found that the average price of a generic prescription was approximately half of the average price of a brand-name prescription.<sup>30</sup> The CBO estimated that the availability of generic drugs saved purchasers between \$8 billion and \$10 billion in 1994 alone.<sup>31</sup>

Other empirical economics literature also finds procompetitive effects associated

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<sup>25</sup> *Id.* at 10-11. See also Thomas H. Lee, ‘Me-Too’ Products: Friend or Foe?, 350 NEW ENG. J. MED. 211 (2004).

<sup>26</sup> FTC PATENT REPORT, *supra* note 10, at 10 n.46 (citing NIHCM, INNOVATION REPORT, *supra* note 19, at 3).

<sup>27</sup> FEDERAL TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at i (2002) [hereinafter FTC GENERIC DRUG STUDY], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>; see also FTC PATENT REPORT, *supra* note 10, at 11.

<sup>28</sup> FTC PATENT REPORT, *supra* note 10, at 11. Brand-name companies must provide the FDA with information regarding patents that cover their drug products, which the FDA then lists in a publication commonly known as the “Orange Book.”

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For an overview of Orange Book procedures, see DuPont 9/10/02 at 162-68. See also 21 U.S.C. § 355(j)(7)(A); FTC GENERIC DRUG STUDY, *supra* note 27, at 25-37 (Chapter 3: “Settlements Related to Paragraph IV Certifications”). Generic drug companies that seek FDA approval prior to patent expiration must give notice to brand-name companies stating that the listed patents are invalid or not infringed by the generic product.

<sup>29</sup> FTC PATENT REPORT, *supra* note 10, § 3, at 11 n.50-51.

<sup>30</sup> CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 28 (1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>.

<sup>31</sup> *Id.* at 31. See also McCloskey 9/10/02 at 197-98 (discussing how seniors benefit from generic drug usage).

with the introduction of generic drugs.<sup>32</sup> This literature points to significant short-run competitive impacts of generic entry that can lead to substantial benefits for consumers of prescription drugs.<sup>33</sup>

The *FTC Patent Report* highlights two provisions of Hatch-Waxman that have played a significant role in spurring increases in generic competition: the 180-day exclusivity provision and the 30-month stay provision. Under the 180-day provision, the first generic firm to file an application for a new drug is granted 180 days of marketing exclusivity if the generic firm certifies that its product does not infringe any of the brand-name company's patents on the drug product or if the generic firm challenges the validity of the brand-name company's patent. During this 180-day exclusivity period the FDA may not approve subsequent generic applications for the same drug.<sup>34</sup> The 180-day exclusivity provision has provided increased incentives for a generic firm to be the first to file an application to market its product. As the first to file, a generic has the potential to

“reap the reward” of being the only generic product in the market for a set period of time.<sup>35</sup> The provision also provides more incentives for companies to challenge patents and develop alternatives to patented drugs.<sup>36</sup>

A brand-name company may receive a 30-month stay of FDA approval of a generic applicant if the brand-name company has received notice of the filing of such a generic application and files suit for patent infringement within 45 days of that notice.<sup>37</sup> According to the legislative history, the stay allows for the commencement of a lawsuit and takes into account the patent owner's rights while still encouraging generic entry.<sup>38</sup>

### ***C. Policy Choices That Could Undermine Innovation and Competition in the Pharmaceutical Industry***

Both patent protection and competition have led to substantial investment and innovation in the pharmaceutical industry. Certain policy choices currently being debated, however, have the potential to undercut certain aspects of patent protection and competition. These

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<sup>32</sup> See, e.g., DAVID REIFFEN & MICHAEL R. WARD, *GENERIC DRUG INDUSTRY DYNAMICS* (Bureau of Econ. of the Federal Trade Commission, Working Paper No. 248, 2002), available at <http://www.ftc.gov/bc/workpapers/industrydynamicsreiffenwp.pdf>; see also Reiffen 9/10/02 at 204-10; Henry Grabowski & John M. Vernon, *Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331 (1992).

<sup>33</sup> FTC PATENT REPORT, *supra* note 10, at 11 n.52 (an additional benefit is that generic competition has forced brand-name companies to develop new products to replenish their revenue stream).

<sup>34</sup> FTC GENERIC DRUG STUDY, *supra* note 27, at vi.

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<sup>35</sup> FTC PATENT REPORT, *supra* note 10, at 12.

<sup>36</sup> *Id.* at 12; see also *Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

<sup>37</sup> FTC PATENT REPORT, *supra* note 10, at 12; FTC GENERIC DRUG STUDY, *supra* note 27, at ii; H.R. REP. NO. 98-857, at 27 (1984), reprinted in 1984 U.S.C.C.A.N. 2647.

<sup>38</sup> FTC PATENT REPORT, *supra* note 10, at 12.

new policy choices warrant serious discussion and debate.

One policy choice involves price regulation or price controls to lower prescription drug prices. Levels of prescription drug spending have increased in recent years due to increases in both the number of prescriptions and prices. Many consumers face hardships in keeping up with these escalating prices.<sup>39</sup> Thus, the impetus to consider price regulation or price controls is understandable.

Before any move in this direction, however, it is important to review the history of attempts to solve public problems through price controls. Price controls have typically led to significant market place distortions that harmed consumers.<sup>40</sup> Price controls are also difficult to administer.<sup>41</sup> Price controls that reduce prices too low reduce output and capacity, lower the quality of the services that are provided, and diminish the incentives for innovation,

including ongoing R&D.<sup>42</sup> Thus, price controls on pharmaceuticals have a significant potential to harm consumers.<sup>43</sup>

Another policy choice surrounds whether government should use its purchasing power to purchase drugs on behalf of consumers and thereby lower prices. One risk of this approach is the potential for the government to become a “monopsonist.” As Chapter 6 reflects, monopsony is “market power exercised by buyers rather than sellers” that lets the buyer “reduce the purchase price by scaling back its purchases.”<sup>44</sup> The *1992 Horizontal Merger Guidelines (Merger Guidelines)* provide that market power encompasses the ability of a single buyer “to depress the price paid for a product to a level that is below the competitive price and thereby depress output. The exercise of market power by buyers (‘monopsony power’) has adverse effects comparable to those associated with

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<sup>39</sup> Lock 9/10/02 at 191-92 (describing how many seniors cannot afford their prescription drugs and how they sacrifice their financial savings to pay for necessary medication).

<sup>40</sup> See, e.g., Stuart M. Butler, *The Fatal Attraction of Price Controls*, in HEALTH POLICY REFORM: COMPETITION AND CONTROLS (Robert B. Helms, ed. 1993). See also W. Duncan Reekie, *How Competition Lowers the Costs of Medicines*, 14 PHARMOECONOMICS 107, 112 (1998); PATRICIA M. DANZON ET AL., THE IMPACT OF PRICE REGULATION ON THE LAUNCH DELAY OF NEW DRUGS – EVIDENCE FROM TWENTY-FIVE MAJOR MARKETS IN THE 1990S (Nat’l Bureau of Econ. Research, Working Paper No. 9874, 2003).

<sup>41</sup> Butler, *supra* note 40.

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<sup>42</sup> A study by the U.S. Department of Health and Human Services warns that “[g]overnment controls on drug access and pricing may result in decreased revenues, which reduce monies available for research and development” and thus lead to slowed or delayed development and introduction of new drugs into the marketplace. OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING & EVALUATION, U.S. DEP’T. OF HEALTH & HUMAN SERVICES, SECURING THE BENEFITS OF MEDICAL INNOVATION FOR SENIORS: THE ROLE OF PRESCRIPTION DRUGS AND DRUG COVERAGE 11 (2002).

<sup>43</sup> John E. Calfee, *Pharmaceutical Price Controls and Patient Welfare*, 134 ANN. INTERN. MED. 1060 (2001).

<sup>44</sup> IIA PHILLIP E. AREEDA ET AL., ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 575, at 363 (2d ed. 2002).

the exercise of market power by sellers.<sup>45</sup> A likely market effect of government-based monopsony power would be not only lower prices for pharmaceutical products, but also reduced investment in R&D. Subsequently, less innovation in the pharmaceutical industry might result over the longer term. Once again, such a marketplace distortion could lead to significant consumer harm.

### III. COMMISSION INITIATIVES TO ENSURE CONSUMERS RECEIVE THE BENEFITS OF PHARMACEUTICAL COMPETITION

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers to ensure that consumers receive the benefits of generic drug competition. One type of conduct involves allegedly anticompetitive agreements between brand-name and generic companies.<sup>46</sup>

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<sup>45</sup> U.S. DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 0.1 (1992), available at <http://www.ftc.gov/bc/docs/horizontal.htm>.

<sup>46</sup> See, e.g., *In re Bristol-Myers Squibb Co.*, No. C-4076 (Apr. 14, 2003) (decision and order), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>; *In re Abbott Laboratories*, No. C-3945 (May 22, 2000) (decision and order), available at <http://www.ftc.gov/os/2000/05/c3945.do.htm>; *In re Geneva Pharmaceuticals, Inc.*, No. C-3946 (May 22, 2000) (decision and order), available at <http://www.ftc.gov/os/2000/05/c3946.do.htm>; *In re Hoechst Marion Roussel, Inc.*, No. 9293 (May 8, 2001) (decision and order), available at <http://www.ftc.gov/os/2001/05/hoechstdo.htm>; *FTC v. Mylan Laboratories, Inc.*, 62 F. Supp. 2d 25 (D.D.C. 1999), available at <http://www.ftc.gov/os/1999/07/mylan.pdf>.

In a recent opinion, the Commission ruled that Schering-Plough Corporation (Schering), Upsher-Smith Laboratories, Inc. (Upsher), and American Home Products (AHP) entered into illegal agreements in 1997 and 1998 to delay the entry of lower-cost generic competition for Schering's prescription drug K-Dur 20.<sup>47</sup> Schering and its potential generic competitors, Upsher and AHP, settled patent litigation on terms that included substantial payments by Schering to those potential rivals in return for agreement to defer introduction of the generic products. The Commission held that these provisions were unfair methods of competition and entered an order that would bar similar conduct in the future.<sup>48</sup>

The Commission also has taken antitrust enforcement action against other types of improper conduct. These actions charged abuse of FDA regulations governing patent listings<sup>49</sup> and potentially anticompetitive agreements between rival generic manufacturers.<sup>50</sup> For example, the Commission alleged a decade-long pattern of anticompetitive acts by Bristol-Myers

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<sup>47</sup> *In re Schering-Plough Corp. et al.*, No. 9297 (Dec. 8, 2003) (final order), available at <http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf>, appeal docketed, No. 04-10688-AA (11th Cir. filed Feb. 13, 2004). K-Dur is used to treat people with low potassium.

<sup>48</sup> *Id.*

<sup>49</sup> See, e.g., *Bristol-Myers*, No. C-4076 (decision and order); *In re Biovail Corp.*, No. C-4060 (Oct. 2, 2002) (decision and order), available at <http://www.ftc.gov/os/2002/10/biovaildo.pdf>.

<sup>50</sup> *In re Biovail Corp. & Elan Corp. PLC*, No. C-4057 (Aug. 15, 2002) (decision and order), available at <http://www.ftc.gov/os/2002/08/biovaildo.pdf>.

Squibb (BMS) to obstruct the entry of low-price generic competition for three of its widely-used pharmaceutical products: two anti-cancer drugs, Taxol and Platinol, and the anti-anxiety agent BuSpar. BMS allegedly abused FDA regulations to block generic entry, misled the U.S. Patent and Trademark Office to obtain unwarranted patent protection, and filed baseless patent infringement lawsuits to deter entry by generics.

According to the FTC's complaint, BMS' illegal conduct protected nearly \$2 billion in annual sales at a high cost to cancer patients and other consumers, who – being denied access to lower-cost alternatives – were forced to overpay by hundreds of millions of dollars for important and often life-saving medications.<sup>51</sup>

In addition, the Commission issued its comprehensive study of this industry, *Generic Drug Entry Prior to Patent Expiration*, in 2002.<sup>52</sup> That study examined whether the conduct that the FTC had challenged represented isolated instances or

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<sup>51</sup> The Commission cooperated in its investigation of BMS with various state attorneys general that had filed their own antitrust suits in federal court. By agreement, the States deferred to the Commission whereby the FTC assumed the lead in negotiating the conduct limitation provisions contained in the proposed order. The states entered essentially the same injunctive terms in their orders. In addition to the injunctive relief, the states will recover substantial monetary relief. See News Release, Federal Trade Comm'n, FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition (Mar. 7, 2003), at <http://www.ftc.gov/opa/2003/03/bms.htm>.

<sup>52</sup> FTC GENERIC DRUG STUDY, *supra* note 27.

was more typical of pharmaceutical industry business practices and whether certain provisions of the Hatch-Waxman Act, which govern generic drug entry, were susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products.<sup>53</sup> This study found that if left unchecked, certain provisions of the Hatch-Waxman Act had the potential to be abused, thereby preventing generic drugs from becoming timely available.<sup>54</sup>

To combat this potential for abuse and resultant delays in generic drug competition, the Commission recommended two major changes to the Hatch-Waxman Act. These recommendations were to provide only one 30-month stay per brand-name drug product and to require notification to the Commission of certain types of pharmaceutical company agreements.<sup>55</sup> The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) includes these two significant recommendations.<sup>56</sup> The Commission will continue to protect consumers from anticompetitive practices that inflate drug prices.

#### IV. PBMS: OVERVIEW AND POLICY QUESTIONS

##### The growth of pharmacy benefit

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<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at ii.

<sup>55</sup> See *Id.* at ii-vi.

<sup>56</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, 117 Stat. 2066 (2003).

managers (PBMs) is an important development in providing consumer access to prescription drugs. This section describes PBMs' role in administering pharmacy benefit services on behalf of their clients (*i.e.*, health plan sponsors such as large employers or health insurance carriers), provides overview information about the industry, and highlights the important public policy issues that panelists discussed. Public scrutiny has increased recently over PBMs' role in administering pharmacy benefit services. To date, the empirical evidence suggests that consumers with prescription drug insurance administered by a PBM save substantially on their drug costs as compared to cash-paying customers.<sup>57</sup> At the behest of Congress, the Commission is examining one aspect of the PBM industry – whether PBMs' mail order pharmacies save money for health plan sponsors and consumers as compared to retail pharmacies and mail order pharmacies not owned by PBMs. Congress has required the Commission to complete this study by June 2005.

**A. What is a PBM?**

PBMs manage the pharmacy benefit of group health plan sponsors, such as HMO plans, self-insured employers, indemnity plans, labor union plans, and plans covering public employees.<sup>58</sup> When an enrollee in

one of these plans purchases a drug at a retail pharmacy, he or she presents a health plan card identifying the source of insurance coverage. The pharmacy will transmit the insurance coverage information to the PBM, which verifies coverage and determines if the plan covers the prescribed drug, what the plan owes as direct payment to the pharmacy, and what the enrollee's co-payment will be (if any). The PBM transmits this information back to the pharmacy, logs the payment information on its system, and transmits the billing information to health insurers. These insurers then remit payment to the PBM, which forwards payment to the retailer. This process, known as claims adjudication, is handled electronically. Ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.<sup>59</sup>

In the words of one panelist, PBMs are the “middlemen” between pharmaceutical manufacturers and health plans or employers.<sup>60</sup> PBMs contract with pharmaceutical manufacturers on behalf of the plan sponsors to obtain brand-name and generic drugs. One panelist noted that a large customer base enables the largest PBMs with the most covered lives to drive the market share of any one pharmaceutical drug product and, therefore, obtain the lowest prices from pharmaceutical manufacturers.<sup>61</sup> PBMs use mail order pharmacies or contract with retail pharmacies to establish networks of nearby pharmacies through which enrollees can

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<sup>57</sup> See, e.g., GENERAL ACCOUNTING OFFICE (GAO), EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES (2003), available at <http://www.gao.gov/cgi-bin/getrpt?GAO-03-196>. One weakness of the GAO study, however, is the lack of a baseline for comparing cost savings among customers with prescription drug insurance coverage.

<sup>58</sup> Richardson 6/26 at 7.

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<sup>59</sup> *Id.* at 8.

<sup>60</sup> Calfee 6/26 at 46.

<sup>61</sup> See Boudreau 6/26 at 57.



have their prescriptions filled. Most PBMs contract with 90 percent of the retail pharmacies in the region they serve.<sup>62</sup> National PBMs have established networks that include nearly all retail chain pharmacies. In these contracts, the parties agree to the dispensing fees that the PBM will pay the retail pharmacy.

### **B. The PBM Formulary**

The main tool that PBMs use to manage pharmacy benefits is the formulary, which is a list of PBM-approved drugs for treating various diseases and conditions.<sup>63</sup> Through a formulary, the PBM controls the price that health plans and enrollees pay and may influence the use of various drugs and the mix of drugs dispensed.<sup>64</sup> Panelists reported that although PBMs design formularies, plan sponsors often demand a customized formulary that addresses various needs of their enrollees (*e.g.*, cost containment, access to certain medicines, high generic substitution, etc.).<sup>65</sup>

One panelist described generally how a formulary decision is made in a single therapy class for its preferred national

formulary.<sup>66</sup> The panelist stated that an independent pharmacy and therapeutics (P&T) committee first evaluates the drugs in the particular class for clinical effectiveness and safety. Each drug is then classified for formulary purposes as “include on the formulary,” “exclude from the formulary,” or “optional.” The next step for drugs classified as “optional” is that the P&T committee ranks them on clinical effectiveness, and then again by cost. The “optional” drugs also are examined for their market share and likely customer reaction if the PBM were to prefer certain drugs over others. After the rankings are complete, the PBM decides which drugs to include on its national formulary. As noted above, group health plans may negotiate certain aspects of a PBM’s preferred national formulary.

In deciding which drugs to include in the formulary (and their placement within various tiers on the formulary), two practices come into play: (i) generic substitution; and (ii) therapeutic interchange. Generic substitution is the dispensing of a bio-equivalent generic drug product that contains the same active ingredient(s) as the brand-name drug and is, among other things, chemically identical in strength, concentration, dosage form, and route of administration as the substituted brand-name product. Generic substitution generally occurs when a consumer presents a prescription for a brand-name drug and the pharmacist fills the prescription with a generic version of the drug product without the need for prior physician authorization. Because generic drugs are substantially less expensive than their brand-name

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<sup>62</sup> Richardson 6/26 at 9.

<sup>63</sup> Barreuta 6/26 at 87.

<sup>64</sup> Richardson 6/26 at 16; *see also* Academy of Managed Care Pharmacy (AMCP), *Comments Regarding the June 26, 2003 Joint FTC-DOJ Hearings on Health Care and Competition Law and Policy (Pharmaceuticals: Formulary)* (Aug. 5, 2003) 2 (Public Comment) (“[A] well-desired, properly administered formulary will assist in the effective management of a patient’s overall health care.”).

<sup>65</sup> Boudreau 6/26 at 65.

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<sup>66</sup> *Id.* at 60-64. *See also* Barreuta 6/26 at 92.

counterparts, generic substitution lowers prescription drug costs.<sup>67</sup>

Therapeutic interchange involves a pharmacist substituting a therapeutically equivalent, but distinct, drug product for the drug product referred to on the consumer's prescription (*e.g.*, two brand-name drug products that treat the same ailment). Prior physician authorization is required before a pharmacist is allowed to interchange one brand-name drug for another.

The co-pays that enrollees must pay are determined with all of these variables in mind. Co-pays significantly influence drug utilization. Most group health plan sponsors negotiate a three-tiered co-pay arrangement with the PBM, with the lowest co-pay for generic drugs, the middle tier for brand-name drugs with no generic equivalent, and the highest co-pay for brand-name drugs with a generic equivalent.<sup>68</sup> Some plan sponsors negotiate a fourth tier for drugs not included on the PBM formulary, and so-called lifestyle drugs, *e.g.*, drugs to combat hair loss.<sup>69</sup> The ascending rates of the co-pays are designed to create an incentive for the enrollee to prefer the lowest cost, yet clinically effective, alternative.

Greater formulary compliance allows the PBMs to negotiate with the pharmaceutical manufacturer for better prices, because formulary compliance is an indication of the ability of the PBM to steer enrollees to various drugs. Thus, formulary compliance allows the PBM to negotiate

what it can deliver for the manufacturers in terms of growth of their market share or avoidance of the manufacturer losing market share.<sup>70</sup>

Plan sponsors may negotiate with PBMs to provide enrollees incentives to use the PBM network pharmacies so that the PBM has greater control of reimbursement and adherence to formulary drugs. Those incentives range from differential co-pays to denial of coverage for out-of-network purchases. Plan sponsors and PBMs also negotiate over incentives for enrollees to use mail order distribution for maintenance medications.<sup>71</sup> Mail order distribution typically is handled through the PBMs' own internal mail order pharmacies or through mail order pharmacies under contract with another PBM.

### ***C. Flow of Payments for Drug Benefits and PBM Services***

To perform its services, a PBM enters contracts with healthcare plans, retail pharmacies, and drug manufacturers. When a PBM establishes retail networks, it contracts with retail pharmacies on reimbursement amounts for drugs dispensed by the pharmacy. For a given drug, the price that the PBM will reimburse a retail pharmacy is stated as a discount from a measure of wholesale price plus a dispensing fee for the pharmacy. For brand-name drugs, the "average wholesale price" (AWP) as stated by the manufacturer is used as a basis for the discount, so the price

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<sup>67</sup> See Dicken 6/26 at 32.

<sup>68</sup> Richardson 6/26 at 19.

<sup>69</sup> *Id.* at 19.

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<sup>70</sup> Barreuta 6/26 at 91.

<sup>71</sup> Maintenance drugs are those used for treatment of chronic conditions, *e.g.*, hypertension, diabetes, etc.

formula would be, for example, “AWP - 10% + \$2.00.” For generic drugs, the average price used is the “maximum allowable cost” (MAC) as specified by the PBM, so the formula might be “MAC - 10% + \$2.00.” Retail pharmacies are willing to offer discounts from the reference price (AWP or MAC) depending on the type of plan sponsors covered by the PBM and the exclusivity of the retail pharmacy network. The more exclusive the network, the larger the discount retail pharmacies will offer, believing that greater exclusivity is likely to bring them more customers.

The PBM’s contract with a plan sponsor covers the amount that the plan sponsor will pay the retail pharmacy per prescription of each drug, as well as separate charges for the variety of PBM services that the plan sponsor may utilize. The PBM’s charge to the plan sponsor per script is similar in form to the retail pharmacy contract. For brand-name drugs, it is a discount off AWP plus an administration charge per script, *e.g.*, “AWP - 5% + \$0.10.” For generic drugs, the charge has the same form except the discount will be from the MAC as specified by the PBM.

Finally, the contract negotiated with the pharmaceutical manufacturer may provide a rebate off the fees owed by the PBM based on (a) a percentage of AWP or some other wholesale benchmark, (b) achieving certain specified sales or market share targets, (c) preferred placement of certain drug products on the PBMs’ formulary, or (d) a combination of items (a) - (c). In addition, the manufacturer may pay the PBM an administration fee and a fee for the PBM providing promotional services.

PBMs also may be paid for providing services such as drug utilization reviews, which analyze physician prescribing patterns to identify physicians who prescribe high cost drugs when lower cost alternatives are available; disease management services, which offer treatment information to, and monitoring of, patients with certain chronic diseases; or drug interaction reviews to determine what other drugs patients may be taking so that the pharmacist can ensure against adverse reactions.<sup>72</sup> In addition, PBMs may offer specialty pharmacy services, including the provision of certain high cost, low utilization drugs that retail pharmacies normally do not carry and that may require special means of distribution (*e.g.*, refrigeration) or professional administration.

#### **D. Industry Overview**

It is estimated that there are 60 PBMs operating in the United States today. There are three independent, full-service PBMs with national scope: Medco Health Solutions, Inc. (Medco) (formerly Merck-Medco), Express Scripts, Inc., and Caremark, Inc..<sup>73</sup> Some PBMs are owned by significant retail supermarket/pharmacy chains, *e.g.*, CVS’s PharmaCare, Kroger’s Prescription Plans, and Walgreen’s Health Initiatives. Many large insurers such as

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<sup>72</sup> Richardson 6/26 at 21-22.

<sup>73</sup> The Commission announced that it had closed its antitrust investigation into Caremark Rx, Inc.’s proposed acquisition of Advance PCS on February 11, 2004 without taking any further action. *See* Statement, Federal Trade Comm’n, Caremark Rx, Inc./Advance PCS (Feb. 12, 2004), *available at* <http://www.ftc.gov/os/caselist/0310239/040211ftcstatemnt0310239.pdf>.

Aetna and Cigna offer in-house PBM functions. In addition, there are many smaller, privately-held PBMs. The relative size and ranking of these companies varies according to the measure used, such as annual prescription expenditures, prescriptions per year, or covered lives.<sup>74</sup> Each measure has its own shortcomings. Overall, however, the market share figures present an industry in which three national PBMs are major players; a large share, anywhere from one-third to one-half, includes health plans and retail pharmacy chains offering PBM services; and local and regional PBMs have a significant presence.<sup>75</sup>

***E. Competition Between PBMs: The Bidding Process***

Group health plan sponsors generally procure PBM services through a bidding process. They typically issue requests for proposals to several PBMs and then evaluate the proposals based on costs and the package of services offered by each bidder. Plan sponsors, or their consultants, conduct these bid processes. Smaller employers or health plans with limited geographic scope likely will have many choices among PBMs, because smaller and more regionally oriented PBMs can meet their needs. Larger employers or health plans often turn to the largest PBMs because of their experience in serving large clients and their nationwide network of pharmacies, although several health plans and retail pharmacy chains offering PBM services also could meet their needs.

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<sup>74</sup> Richardson 6/26 at 11.

<sup>75</sup> *Id.* at 13.

PBMs appear to compete on price and non-price dimensions. One survey of plan sponsors using PBM services showed the financial terms of the bid (such as the reimbursement rate and dispensing fee paid to pharmacies, the rebates paid to plan sponsors based on formulary drugs utilized, mail order pricing, and administrative fees) often were the key determinants in the selection of the winning bid.<sup>76</sup> This study also found that plan sponsors were concerned about non-price dimensions of service, such as plan design, the extent of the retail network, and mail order components. Each term or feature is balanced against each other and is driven by the needs of the plan sponsor. For example, some want to maximize generic substitution, whereas others want to maximize rebates from manufacturers.<sup>77</sup>

***F. Benefits of PBMs: The Evidence to Date***

The General Accounting Office released a study in January 2003 that examined the effects of PBMs on the Federal Employees Health Benefits Program, enrollees, and pharmacies.<sup>78</sup> The report considered the prescription benefits programs offered within three health plans available to federal government employees. These three plans covered about 4.5 million

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<sup>76</sup> See PRICEWATERHOUSECOOPERS LLP, HEALTH CARE FINANCING ADMINISTRATION, STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT (2001), available at <http://www.cms.gov/researchers/reports/2001/cms.pdf>.

<sup>77</sup> Boudreau 6/26 at 65; see also Barrueta 6/26 at 105.

<sup>78</sup> See GAO, *supra* note 57.

lives. The largest of these plans, BCBS, held contracts with two PBMs: AdvancePCS, which handled their retail network; and Medco, which supplied their mail order pharmacy benefits. Another plan, GEHA, contracted solely with Medco. The third plan, PacifiCare, used a PBM called Prescription Solutions, which is a subsidiary of PacifiCare, which also sells independent PBM services.

**Table 1: Discounts Relative to Cash Prices**

	Generic Drugs	Brand-Name Drugs
Retail Pharmacy	47%	18%
PBM's Mail Order Pharmacy	53%	27%

The study compared prices that three types of customers paid for 14 brand name drugs and four generic drugs: (1) cash-paying customers, who buy at retail pharmacies; (2) health plan sponsors and their enrollees, who buy at retail pharmacies; and (3) health plan sponsors and their enrollees, who buy from a PBM's mail order facility. Table 1 shows the results of the study. The study found that the lowest average prices for 30-day supplies were obtained when the drug was purchased through the PBM's mail order pharmacy.<sup>79</sup>

<sup>79</sup> Similar relative cost saving for PBM clients have also been documented. See Cindy Parks Thomas et al., *Impact of Health Plan Design And Management On Retirees' Prescription Drug Use And Spending 2001, 2002* HEALTH AFFAIRS (Web Exclusive) W408, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.408v1>.

For generic drugs purchased through a retail pharmacy, enrollees in health plans paid an average 47 percent less than cash customers.

## G. *Issues Facing the PBM Industry*

### 1. Transparency

Panelists discussed the significance of rebate transparency in the PBM market, including whether a PBM should be required to disclose to plan sponsors the rebates that pharmaceutical manufacturers pay PBMs for meeting certain market share targets. One panelist stated that armed with information about rebates, plan sponsors can encourage PBMs to compete more aggressively so that the plan sponsor obtains lower prices.<sup>80</sup> By contrast, other panelists suggested that rebate transparency can be handled through private contracts, because there is no barrier to a plan sponsor negotiating an arrangement providing it with access to the PBMs' rebate information.<sup>81</sup> Another panelist suggested that many plan sponsors have placed a greater emphasis on paying lower administrative fees as a trade-off for allowing PBMs to keep pharmaceutical

<sup>80</sup> Balto 6/26 at 78. In addition to price, plan sponsors may be concerned about other PBM services such as network availability or access to a wide variety of drug products. As Section D, *supra* reflects, the current structure of the PBM industry does not suggest the potential for a PBM to exercise monopsony power over pharmaceutical manufacturers.

<sup>81</sup> Calfee 6/26 at 99; Balto 6/26 at 99. See also Hewitt Associations, LLC, *Hewitt's 2004 Future Health Care Expectations Survey: An Overview*, at <http://was4.hewitt.com/hewitt/resource/spkrsconf/subspkrsconf/teleconferences/tapes/10-08-03.pdf> (last visited June 22, 2004).

manufacturer rebates.<sup>82</sup>

Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms. Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health care services, either as lower premiums for health insurance, lower out-of-pocket costs (for that portion of health care expenditures borne directly by consumers through deductibles and co-payments), or improved services. Negotiated limitations on transparency are unlikely to be so severe that health plan sponsors cannot assess the price and quality of the services they are receiving. Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract.

## 2. Regulation and Litigation

The American Federation of State County & Municipal Employees filed a lawsuit in 2003 alleging that the largest PBMs have engaged in unfair and deceptive practices under California state law.<sup>83</sup> The complaint alleges that PBMs engage in various forms of conduct designed to

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<sup>82</sup> Barrueta 6/26 at 105.

<sup>83</sup> *AFSCME v. AdvancePCS*, No. BC 292227, at ¶ 4 (Cal. Super. Ct., Los Angeles Cty. filed Apr. 4, 2003) (first amended representative action and complaint), *available at* <http://www.hagens-berman.com/files/PBM%20Complaint%20-%20Amended%20-%20NP1049738021600.pdf>.

increase their profits, instead of benefitting employers and consumers. The case is currently pending.

In April 2004, the United States along with 20 states announced a settlement of claims for injunctive relief and state unfair trade practices against Medco.<sup>84</sup> The United States and the states alleged that Medco encouraged physicians to switch patients to different prescription drugs that earned Medco higher rebates from pharmaceutical manufacturers, but that Medco failed to pass on these savings to patients or their health plan sponsors. Both the United States and the states alleged that the drug switches resulted in increased costs to health plans and patients, primarily in follow-up doctor visits and tests. Medco claims, however, that its plans and services saved money for patients and health plans. The consent order requires Medco to pay \$29 million to states for damages, fees, and restitution. Other federal allegations, however, were not settled, and that case will continue.

Two states and the District of Columbia have enacted legislation regulating PBM practices, and other states are considering such legislation.<sup>85</sup> Maine's

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<sup>84</sup> *See* News Release, U.S. Dep't of Justice, The United States Settles Its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions (Apr. 26, 2004), *at* <http://www.usdoj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf>.

<sup>85</sup> Rx Access Act of 2004, Act 15-410, 2004 Council of the Dist. of Columbia (D.C. 2004); Act to Provide for the Regulation of Pharmacy Benefits Management, H.B. 1311, 79th Leg. Assem., Reg. Sess. (S.D. 2004); Act to Protect Against Unfair

statute was challenged on the basis of ERISA preemption, and the District Court issued a preliminary injunction enjoining enforcement of the law.<sup>86</sup>

### 3. Integrated Mail Order Pharmacies

As noted above, mail order has grown in importance and, for maintenance medications, can be an efficient and low-cost distribution channel. A recent study funded by the retail pharmacy industry identifies possible actions that PBMs could employ to inflate their revenues.<sup>87</sup> The two main actions alleged include: steering enrollees to higher priced products on which the PBM earns larger rebates, regardless of the overall cost of the drug to the health plan; and artificially inflating AWP on prescriptions filled by a PBM-owned mail order pharmacy through the use of re-labeled drugs. The authors refer to both of these practices collectively as PBM self-dealing. Though no direct evidence of self-dealing is given, the paper assumes that self-dealing could result in higher profits for PBMs and higher costs for plan sponsors.

Congress has required the Commission to study these allegations. In particular, Section 110 of the MMA requires

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Prescription Drug Practices, S.B. 194, 121st Leg., 1st Reg. Sess. (Me. 2003). See *supra* Chapter 6 for a broader discussion of the competitive implications of such mandates.

<sup>86</sup> Pharm. Care Mgmt. Ass'n v. Rowe, Civ. No. 03-153-B-W (D.Me. Mar. 9, 2004).

<sup>87</sup> JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT (2003), available at [http://www.mpaginc.com/news/pbm\\_report.pdf](http://www.mpaginc.com/news/pbm_report.pdf).

the Commission to conduct a "Conflict of Interest Study" that includes the following:

1. An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to mail-order pharmacies not owned by PBMs and community pharmacies.
2. Whether such group health plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

The statute requires the Commission to make any necessary recommendations concerning these allegations and to report its findings in a study by June 2005. The Commission expects that the results of this study will inform the debate about the role of PBMs in the industry.

### V. DIRECT TO CONSUMER ADVERTISING

The impact of direct to consumer (DTC) advertising of prescription drugs on demand for, and the prices of, prescription drug prices has generated considerable debate. This debate has grown louder as DTC advertising has grown from \$791 million in 1996 to \$2.467 billion in 2000.<sup>88</sup> A basic tenet of competition policy is that truthful and non-misleading advertising

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<sup>88</sup> Magazine Publishers of America (MPA), *Comments Regarding Competition Law and Policy & Health Care* (Sept. 30, 2002) 2 (Public Comment) [hereinafter MPA (public cmt)].

benefits consumers.<sup>89</sup> The available evidence suggests that, on balance, this is true of DTC advertising of prescription drugs. Commission staff have articulated the beneficial effects of DTC advertising — as well as evidence of potential costs — in recent comments (*DTC Comments*) to the Food and Drug Administration (FDA).<sup>90</sup> This section briefly summarizes these comments and provides insights gained from the panelists on DTC advertising of pharmaceutical products.

### A. *The Effects of DTC Advertising*

Panelists at the health care hearings agreed that advertising increases consumer

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<sup>89</sup> See, e.g., JOHN E. CALFEE & JANIS K. PAPPALARDO, FEDERAL TRADE COMM'N, HOW SHOULD HEALTH CLAIMS FOR FOODS BE REGULATED? AN ECONOMIC PERSPECTIVE (1989); ALISON MASSON & ROBERT L. STEINER, FEDERAL TRADE COMM'N, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS (1985).

<sup>90</sup> See Staff of the Federal Trade Commission, In the Matter of Request for Comments on Consumer-Directed Promotion, Public Hearing Dkt. No. 2003N-0344, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. 3 (Dec. 1, 2003) [hereinafter *Comments at Dec. 2003 FDA Pub. Hearing*], available at <http://www.ftc.gov/be/v040002text.pdf>.

Commission staff have also filed other comments with the FDA on related issues. See Staff of the Federal Trade Commission, In the Matter of Request for Comment on First Amendment Issues, Public Hearing Dkt. No. 02N-0209, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. (Sept. 13, 2002), available at <http://www.ftc.gov/os/2002/09/fdatextverson.pdf>; Staff of the Federal Trade Commission, In the Matter of Direct-to-Consumer Promotion, Public Hearing Docket No. 95N-0227, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. (Jan. 11, 1996), available at [www.ftc.gov/be/v960001.htm](http://www.ftc.gov/be/v960001.htm).

and physician awareness of the potential benefits of pharmaceuticals and helps close the information gaps among pharmaceutical manufacturers, doctors, and consumers.<sup>91</sup> Panelists also presented evidence that shows some patients have been prompted by DTC advertising to talk to a doctor about a condition that they had not discussed previously.<sup>92</sup> One panelist stated that DTC advertising can increase compliance with pharmaceutical usage regimes and can assist in educating patients and health professionals about the risks, diagnosis, and treatment of a particular medical condition.<sup>93</sup>

The *DTC Comments* noted that a number of major surveys have been conducted to assess the effect of DTC advertising on consumer attitudes, experiences, and behavior. The general consensus from these and other surveys is that DTC advertising provides consumers with useful information, stimulates productive discussions between doctors and patients, and encourages consumers to learn more about previously undiagnosed conditions.<sup>94</sup>

### Physician attitudes toward DTC

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<sup>91</sup> Calfee 9/10/02 at 258, 262; Raymond 9/10/02 at 279; Samp 9/10/02 at 292; Burkholder 9/10/02 at 245; see also MPA (public cmt), *supra* note 88, at 2-4.

<sup>92</sup> Calfee 9/10/02 at 262; Raymond 9/10/02 at 279.

<sup>93</sup> Raymond 9/10/02 at 279-81.

<sup>94</sup> *Comments at Dec. 2003 FDA Pub. Hearing*, *supra* note 90, at 6. This comment summarizes the major consumer surveys relating to DTC advertising of prescription drugs and is not repeated here.



advertising are mixed. An FDA survey reported that 40 percent of the physicians surveyed felt that DTC advertising had a positive effect on their patients and their practices, 30 percent felt it had a negative effect, and 30 percent felt it had no effect.<sup>95</sup> Another recent survey found that the most frequent complaints voiced by physicians were that DTC advertising did not provide information in a balanced manner, and that it encouraged patients to seek treatments they did not need (approximately 80 percent). On the other hand, the same survey found that more than 70 percent of physicians felt that DTC advertising helped educate patients about available treatments and 67 percent felt that it helped them have better discussions with their patients.<sup>96</sup>

The panelists also observed that pharmaceutical manufacturers advertise brand-name drugs to increase sales, to complement physician detailing and promotion, and to extend the blockbuster nature of the drug advertised.<sup>97</sup> They noted

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<sup>95</sup> Kathryn Aikin, *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, Direct-To-Consumer Promotion: Public Meeting, Before the U.S. Food & Drug Admin. Ctr. for Drug Evaluation & Research (Sept. 22, 2003) (presentation slides of FDA), available at <http://www.fda.gov/cder/ddmac/aikin/aikin.PPT>.

<sup>96</sup> Joel S. Weissman et al., *Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-219, 224, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.219v1>.

<sup>97</sup> Findlay 9/10/02 at 269-70; Calfee 9/10/02 at 293; Samp 9/10/02 at 287-88 (noting that manufacturers advertise direct to consumers because they believe DTC advertising can increase sales); Carabello 6/12/03 at 170-71 (discussing her view that

that there were no DTC advertisements for generic prescription drug products, because these products rapidly gain market share by virtue of their lower prices and state laws requiring pharmacists to employ generic substitution.<sup>98</sup>

There remains debate regarding the impact of DTC advertising on the price and quantity sold of prescription drugs, in part due to the difficulties inherent in estimating the empirical effects. Some panelists, for example, suggested it was difficult to draw conclusions about DTC on drug utilization alone because of other forces such as increased insurance coverage of drugs, an increase in FDA approval of drugs, an increase in the diagnosis of many chronic conditions, and an increase in physician detailing and the free samples provided to physicians.<sup>99</sup> In their survey of the research literature, Commission staff noted that empirical evidence on the effects of DTC advertising on sales is mixed, with some studies showing a positive effect, while others do not. They described a number of more recent studies showing a pattern where DTC advertising expands the overall demand for the relevant therapeutic class of drugs, while typically failing to increase the market share of the specific drug being

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advertising is “designed to spark the interest of the health care consumer and prompt the buyer, the patient, to access or purchase services”); see also Lurie 9/10/02 at 272 (purpose of advertising is to get someone to buy something).

<sup>98</sup> Findlay 9/10/02 at 269-70; Samp 9/10/02 at 291-92.

<sup>99</sup> Burkholder 9/10/02 at 250; Findlay 9/10/02 at 266-68.

advertised.<sup>100</sup>

In regard to the price effects of DTC advertising, Commission staff noted the absence of evidence that the costs of such advertising are passed on to consumers in the form of higher prices. They also pointed out that the low volume of DTC expenditures – 2.2 percent of total prescription drug sales and 16 percent of overall drug company promotion costs – reinforces the view that such advertising would have a limited effect (if any) on price.<sup>101</sup> Nevertheless, staff cautioned that

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<sup>100</sup> MARTHA WOSINSKA, JUST WHAT THE PATIENT ORDERED? DIRECT-TO-CONSUMER ADVERTISING AND THE DEMAND FOR PHARMACEUTICAL PRODUCTS (Harvard Bus. School, Marketing Research Paper No. 02-04, 2002) (while DTC advertising expands total therapeutic class sales, it only increases the sales of the particular brand if the brand has a preferred status on the health insurer's formulary), *available at* [http://ssrn.com/abstract\\_id=347005](http://ssrn.com/abstract_id=347005); T. IZUKA & G. JIN, THE EFFECT OF DTC ADVERTISING IN THE PRESCRIPTION DRUG MARKETS (Univ. of Md., Working Paper, Sept. 2003); MEREDITH B. ROSENTHAL ET AL., KAISER FAMILY FOUND., DEMAND EFFECTS OF RECENT CHANGES IN PRESCRIPTION DRUG PROMOTION (2003), *available at* <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14380>. For a useful review of these and other empirical investigations into the demand effects of DTC advertising, see GENERAL ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS (Report to Congressional Requesters, 2002), *available at* <http://www.gao.gov/new.items/d03177.pdf>.

<sup>101</sup> Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498 (Feb. 14, 2002). The authors also note the skewed distribution of DTC expenditures across drug classes, with the 20 largest drug classes accounting for over 60 percent of total expenditures. As a result, the relative size of DTC advertising

the issue of price effects remains unsettled because there have been no well-controlled tests designed to directly test the claim that DTC advertising raises price. Such studies are the best test of such a hypothesis.

**B. *DTC Advertising of Pharmaceuticals Must Not Be False and Misleading***

Panelists agreed that prescription drug promotion must be fair and balanced and include both benefit and risk information to educate and inform consumers about their health care decisions.<sup>102</sup> Panelists suggested that one of the contentious issues with DTC advertising of prescription drugs was whether benefits and risks were presented in an understandable manner.<sup>103</sup> Panelists did not claim that DTC advertisements were false and misleading.<sup>104</sup>

To address the concerns of conveying risks of prescription drugs in an understandable manner, the Food and Drug Administration (FDA) has sought public comment concerning whether and how it should alter its approach to regulating

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expenditures will vary significantly across drug classes.

<sup>102</sup> *See generally*, panel discussion 9/10/02 at 245-300. For an overview of the Food and Drug Administration's regulation of DTC advertisements, see Frank 9/10/02 at 231-42.

<sup>103</sup> Samp 9/10/02 at 290; *see also* Burkholder 9/10/02 at 252.

<sup>104</sup> Findlay 9/10/02 at 297.

prescription drug advertising.<sup>105</sup> In late 2003, the FTC staff filed a comment with the FDA suggesting that consumers and competition would benefit if the FDA adopted more consumer-friendly and less burdensome risk disclosure requirements.<sup>106</sup> In early 2004, the FDA issued and sought public comment on three draft guidance documents designed to improve communications to consumers and health care practitioners about health conditions and medical products.<sup>107</sup> In May 2004, FTC staff filed a comment generally supporting the changes reflected in these guidance documents, but also recommending that the FDA conduct consumer research concerning the risk disclosures they would require.<sup>108</sup> The FDA continues to work with industry and other interested parties to determine the best way to inform consumers on prescription drug issues.

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<sup>105</sup> For an economic analysis of the costs and benefits of drug advertising restrictions, including the effect of FDA's regulations on these costs and benefits, see J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 SETON HALL L.J. 1370 (1994).

<sup>106</sup> See *Comments at Dec. 2003 FDA Pub. Hearing*, *supra* note 90, at 3.

<sup>107</sup> See News Release, Food & Drug Admin., New FDA Draft Guidance Aim to Improve Health Information (Feb. 4, 2004), at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01016.html>.

<sup>108</sup> See Staff of the Federal Trade Commission, In the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion, Public Hearing Dkt. No. 2004D-0042, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. (May 10, 2004), *available at* <http://www.ftc.gov/os/2004/05/040512dtcdrugscomment.pdf>.

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## CHAPTER 8: MISCELLANEOUS SUBJECTS

### I. CERTIFICATES OF NEED

*Introduction.* State certificate of need (CON) programs generally prevent firms from entering certain areas of the health care market unless they can demonstrate to state authorities that there is an unmet need for their services. Upon making such a showing, prospective entrants receive from the state a CON allowing them to proceed.<sup>1</sup> Proving that unmet need to state authorities is sometimes expensive and time-consuming.<sup>2</sup> Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke on the subject of CON at the Hearings on a panel discussing Quality and Consumer Protection: Market Entry (June 10).<sup>3</sup>

Many CON programs trace their origin to a repealed federal mandate. The

National Health Planning and Resources Development Act of 1974<sup>4</sup> offered states powerful incentives to enact state laws implementing CON programs.<sup>5</sup> By 1980, all states except Louisiana had enacted CON programs.<sup>6</sup> Congress repealed the federal law in 1986, but a substantial number of states continue to maintain CON programs,<sup>7</sup> “although often in a loosened form compared to their predecessors.”<sup>8</sup>

The Agencies believe that CON programs can pose serious competitive concerns that generally outweigh CON

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<sup>1</sup> See JOHN MILES, 2 HEALTH CARE & ANTITRUST LAWS: PRINCIPLES AND PRACTICE § 16:1, at 16-2, 16-5 to 16-6 (2003) (noting that CONs under the federal Health Planning Act required providers to “obtain state approval – a ‘certificate of need’ – before spending set amounts on capital investments or adding new health care services”); James F. Blumstein & Frank A. Sloan, *Health Planning and Regulation Through Certificate of Need: An Overview*, 1978 UTAH L. REV. 3; Randall Bovbjerg, *The Importance of Incentives, Standards, and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83; Clark C. Havighurst, *Regulation of Health Facilities and Services by “Certificate of Need”*, 59 VA. L. REV. 1143 (1973).

<sup>2</sup> See Keith B. Anderson, *Certificate of Need Regulation of Health Care Facilities*, FTC Staff Prepared Statement Before North Carolina State Goals and Policy Board 7 n.17 (Mar. 6, 1989).

<sup>3</sup> Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf>.

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<sup>4</sup> Pub. L. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5), *repealed*, Pub. L. 99-660, § 701, 100 Stat. 3799 (1986).

<sup>5</sup> MILES, *supra* note 1, § 16:1, at 16-2.

<sup>6</sup> See, e.g., Morrisey 6/10 at 146; *On Certificate of Need Regulation: Hearing on H.B. 332 Before the Senate Comm. On Health and Human Services* (Ohio 1989) (Statement of Mark D. Kindt, FTC Regional Director) (noting that by 1980, all states except Louisiana had enacted CON legislation) [hereinafter Kindt].

<sup>7</sup> See Davenport-Ennis 5/29 at 113-14; Morrisey 6/10 at 146 (noting that by 2002, about 36 states and the District of Columbia retained CON programs in some form); MILES, *supra* note 1, § 16:2, at 16-9 (stating that “CON laws remain in many states and the District of Columbia”). Quite recently, Florida exempted from CON new adult open-heart surgery and angioplasty programs at general hospitals and the addition of beds to existing hospital structures. Fla. Bill SJ 01740 (effective July 1, 2004), *amending* FLA STAT. ch. 408.036, .0361 (2003).

<sup>8</sup> MILES, *supra* note 1, § 16:1, at 16-2 to 16-3. See also Len M. Nichols et al., *Are Market Forces Strong Enough to Deliver Efficient Health Care Systems? Confidence is Waning*, 23 HEALTH AFFAIRS 1, 11 (Mar./Apr. 2004) (noting that CON programs “eroded through the 1990s”).

programs’ purported economic benefits. Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns. The Report analyzes each of these points in turn below.

#### **A. Rationale Behind CON Programs**

CON programs had the major goal of controlling costs by restricting provider capital expenditures.<sup>9</sup> The forces of competition ordinarily limit excess supply, but, according to a panelist representing the American Health Planning Association, “[c]ompetition in health care is ... very different” than in other markets.<sup>10</sup> Congress appears to have shared this view in 1974; the passage of the Health Planning Act reflected a congressional belief that market failure plagued the health care market, resulting in

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<sup>9</sup> See Piper 6/10 at 53; Morrisey 6/10 at 146 (noting that CON programs “were established in the ‘70s to help control health care costs”). See also MILES, *supra* note 1, § 16:1, at 16-4 (“[The primary role of the Health Planning Act was to regulate the supply of health care resources, particularly institutional services, by requiring a CON from the state before certain levels of capital expenditures could be made or new services introduced.”); Kindt, *supra* note 6, at 2-3 (noting that a “key justification” for CON programs has been “the belief that health care providers, particularly hospitals, would undertake excessive investment in unregulated health care markets,” driving up health care costs); PUBLIC HEALTH RESOURCE GROUP, CERTIFICATE OF NEED PROJECT REPORT 17-18 (2001).

<sup>10</sup> Piper 6/10 at 53-54 (observing that the main aim of CON programs is to limit “excess supply generating excess demand”). See also PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 18.

“excess supply and needless duplication of some services.”<sup>11</sup>

The system of cost-based reimbursement may have driven the problem that Congress sought to solve.<sup>12</sup> When many CON programs were established, government or private insurance paid health care expenses “on a retrospective cost reimbursement basis.”<sup>13</sup> This, coupled with the general concern that patients would not be sufficiently price sensitive and would demand the perceived highest quality services, led to the fear that health care providers would expand their services – sometimes to the point of offering unnecessarily duplicative services – because they competed largely on only non-price grounds.<sup>14</sup>

Although cost-based reimbursement is much less common today, some contend that CON programs still have a role to play in the health care marketplace. Indeed, one panelist argued that in health care markets, “providers control the supply of services. Medical practitioners direct the flow of patients and therefore the demand for

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<sup>11</sup> MILES, *supra* note 1, § 16:1, at 16-4.

<sup>12</sup> See *id.*

<sup>13</sup> Anderson, *supra* note 2, at 6. See also Davenport-Ennis 5/29 at 114 (noting that at the time, the federal government reimbursed health care expenses on a “cost-plus basis, which did not provide the cost control capability of today’s prospective payment system”).

<sup>14</sup> Morrisey 6/10 at 147; see also Davenport-Ennis 5/29 at 114 (noting that government officials intended CON to “retain rising health care costs, to prevent unnecessary duplication of resources and services, and [to] expand consumer access to quality health care services”).

services.”<sup>15</sup> In health care markets, he stated, “supply generates demand[,] putting traditional economic theory on its head.”<sup>16</sup> Moreover, consumers lack the information to compare prices, he said.<sup>17</sup> Such problems can lead to an inefficient allocation of health care resources and higher health care costs, some state.<sup>18</sup>

Some commentators also suggest that CON programs can enhance health care quality and access.<sup>19</sup> One panelist, for example, stated that there are “few mechanisms” other than the CON process that promote “minimum patient volumes” that contribute, he stated, to better quality

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<sup>15</sup> Piper 6/10 at 55.

<sup>16</sup> *Id.* at 62.

<sup>17</sup> *Id.* at 55 (noting, however, that consumers do “suffer under the ultimate increased costs in premiums and their taxes”). The same panelist also cited empirical studies suggesting that CON programs reduce health care costs, studies that another panelist questioned. Compare Piper 6/10 at 57-61, and Thomas R. Piper, *Comments Regarding Hearings on Health Care and Competition Law and Policy* 5-13 (Public Comment) (discussing these and other studies) [hereinafter Piper (public cmt)], with Loeffler 6/10 at 127 (questioning those studies), and with Piper 6/10 at 127-28 (responding to such questions). See generally *infra* notes 37-42, and accompanying text.

<sup>18</sup> See, e.g., MILES, *supra* note 1, § 16:1, at 16-4 (describing Congress’ concerns); Piper 6/10 at 62 (asserting that “[a]reas with more hospitals and doctors spend more on health care services per person”); PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 11 (“Adding providers usually mean increases in costs.”); see also Piper 6/10 at 126 (noting that the fact that the public fisc is at stake adds importance to the concern).

<sup>19</sup> PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 5.

care.<sup>20</sup> CON regulation also can address cherry picking, preventing firms from, for example, converting cancer “medical practices to medical care facilities [that] divert well-insured patients [from] local hospital cancer programs” and “undermine[] the ability of essential community hospitals to provide a full array of oncology services to the entire community.”<sup>21</sup>

## **B. Competitive Concerns that CON Programs Raise**

Many have criticized CON programs for creating barriers to entry in the health care market.<sup>22</sup> As noted previously, CON

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<sup>20</sup> Piper (public cmt), *supra* note 17, at 12 (noting, for example, that in CON-free states, “the percentage of patients that had surgery in low volume programs was three times higher than in states with CON regulation”).

<sup>21</sup> Piper (public cmt), *supra* note 17, at 13-14; see also Piper 6/10 at 54 (noting that CON programs aim to overcome “market gaps and excesses like the avoidance of low-income populations and concentration of services in . . . affluent areas”); Nichols et al., *supra* note 8, at 11 (stating that today “some states are considering reinstating or reinvigorating [CON programs] in response to construction of physician-owned specialty facilities, which has posed a competitive threat to community hospitals”). But see Price 6/10 at 108 (would-be entrant denying allegation of “cherry picking”); Davenport-Ennis 5/29 at 115-16 (stating that CON programs restrict the supply of cancer treatment services such that “low-income, seriously ill, and rural patients” who do not live near a hospital or major medical center lose access to care).

<sup>22</sup> See Anderson, *supra* note 2, at 7; Hennessy 6/10 at 95, 99-100 (“CON protects incumbent providers . . . from competition” and is an “impediment to innovation [and] quality improvement” in health care); Blumstein & Sloan, *supra* note 1; Bovbjerg, *supra* note 1; Havighurst, *supra* note 1. The Commission has also noted the

regimes prevent new health care entrants from competing without a state-issued certificate of need, which is often difficult to obtain. This process has the effect of shielding incumbent health care providers from new entrants. As a result, CON programs may actually increase health care costs, as supply is depressed below competitive levels.<sup>23</sup>

Moreover, CON programs can retard entry of firms that could provide higher quality services than the incumbents.<sup>24</sup> By protecting incumbents, CON programs likewise can “delay[] the introduction and acceptance of innovative alternatives to costly treatment methods.”<sup>25</sup> Similarly, CON programs’ “[c]urtailing [of] services or facilities may force some consumers to resort to more expensive or less-desirable substitutes, thus increasing costs for patients or third-party payers. For example, if nursing home beds are not available, the discharge of patients from more expensive hospital beds may be delayed or patients may be forced to use nursing homes far from

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impact of CON programs on entry and firm behavior. *See In re Hosp. Corp. of Am.*, 106 F.T.C. 361, 489-501 (1985).

<sup>23</sup> *See* Anderson, *supra* note 2, at 7-8; Kindt, *supra* note 6, at 6-7.

<sup>24</sup> *See, e.g.*, Anderson, *supra* note 2, at 7-9; Kindt, *supra* note 6, at 6; *Hosp. Corp. of Am.*, 106 F.T.C. at 495 (opinion of the Commission) (stating that “CON laws pose a very substantial obstacle to both new entry and expansion of bed capacity in the Chattanooga market” and that “the very purpose of the CON laws is to restrict entry”).

<sup>25</sup> Anderson, *supra* note 2, at 9; Kindt, *supra* note 6, at 6.

home.”<sup>26</sup>

Empirical studies indicate that CON programs generally fail to control costs and can actually lead to increased prices.<sup>27</sup> Supporting this conclusion, some panelists offered examples of the anticompetitive effects of CON programs. One panelist, for example, noted that CON programs “artificially limit[]” access to cancer treatment, placing “vital therapies and technologies out of [consumers’] reach” in favor of “old technologies.”<sup>28</sup> He stated that his practice’s application to a state for a certificate of need to introduce improved cancer radiation technology faced opposition in June 2002 from all of the state’s operators of existing radiation therapy equipment. One year later, at the time of his testimony in the Hearings, he noted that the state still had not approved the CON application.<sup>29</sup> By contrast, in a bordering state without a CON program, his practice was able to introduce new cancer-fighting technologies rapidly.<sup>30</sup> Another panelist stated that incumbent home health service providers in her state have, for 23 years, successfully opposed the CON application of her nursing service, thereby barring its entry and “keep[ing] the oligopoly in place.”<sup>31</sup> The incumbents, she

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<sup>26</sup> Kindt, *supra* note 6, at 7.

<sup>27</sup> *See generally infra* notes 37-42, and accompanying text.

<sup>28</sup> Hennessy 6/10 at 92-93.

<sup>29</sup> *Id.* at 95-96; *see also id.* at 96-97 (noting similar opposition to application to introduce PET scanning to state with CON program).

<sup>30</sup> *Id.* at 95-98, 136.

<sup>31</sup> Price 6/10 at 101-10.



stated, charge more for comparable services than her service would.<sup>32</sup> The barrier to entry has likewise shielded incumbents from the need to offer improved and innovative services, she said.<sup>33</sup> As a result, some patients resort to services that “are not to their liking” or simply are not served at all.<sup>34</sup> Other panelists described how an incumbent used the CON process as a barrier to entry in a local surgical market,<sup>35</sup> and how a CON program restricted supply in a way that jeopardized patients’ care.<sup>36</sup>

### C. CON and Cost Control

Several panelists and commentators stated that CON programs generally fail to control costs.<sup>37</sup> Indeed, one panelist

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<sup>32</sup> *Id.* at 105.

<sup>33</sup> *Id.* at 106.

<sup>34</sup> *Id.* at 102, 104 (reporting that she has spoken to “young people who have been lying in their own waste for three days with no one to come take care of them”).

<sup>35</sup> Rex-Waller 3/27 at 58.

<sup>36</sup> Davenport-Ennis 5/29 at 115-21.

<sup>37</sup> *See* Hennessy 6/10 at 93-94 (stating that “CON is a failure as a cost containment tool” and that the premiums in Kansas and Missouri are generally the same, in spite of the fact that one state has a CON program and the other does not); Anderson, *supra* note 2, at 2-6 (summarizing empirical evidence and finding that CON fails to regulate costs); Kindt, *supra* note 6, at 3-5 (summarizing empirical studies on the economic effects of CON programs and concluding that “[t]here is near universal agreement among the authors [of studies on the economic effects of CON programs] and other health economists that CON has been unsuccessful in containing health care costs”); DANIEL SHERMAN, FEDERAL TRADE COMM’N, THE EFFECT OF STATE CERTIFICATE-OF-NEED LAWS ON HOSPITAL COSTS: AN ECONOMIC POLICY ANALYSIS

surveyed the empirical literature on the economic effects of CON programs and concluded that the “literature tends to conclude ... that CON has been ineffective in controlling hospital costs,” and that, to the contrary, “[i]t may have raised costs and restricted entry.”<sup>38</sup> Commentators stated that the reason that CON has been ineffective in controlling costs is that the programs do not put a stop to “supposedly unnecessary expenditures” but “merely redirect[] any such expenditures into other areas.”<sup>39</sup> Thus, a CON rule that restricts capital investment in new beds does nothing to prevent

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(1988) (concluding, after empirical study of CON programs’ effects on hospital costs using 1983-84 data, that strong CON programs do not lead to lower costs but may actually increase costs); MONICA NOETHER, FEDERAL TRADE COMM’N, COMPETITION AMONG HOSPITALS 82 (1987) (empirical study concluding that CON regulation led to higher prices and expenditures); KEITH B. ANDERSON & DAVID I. KASS, FEDERAL TRADE COMM’N, CERTIFICATE OF NEED REGULATION OF ENTRY INTO HOME HEALTH CARE: A MULTI-PRODUCT COST FUNCTION ANALYSIS (1986) (economic study finding that CON regulation led to higher costs, and that CON regulation did little to further economies of scale); *cf.* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 4 (noting that the “track record of the cost effectiveness of state CON programs is decidedly mixed,” and that “[i]n some states, the of effectiveness is at least partially attributable to deficiencies in program operations and to political environments in which legislative or high-level executive branch intervention alters or affects CON decision-making”). *See also* David S. Salkever, *Regulation of Prices and Investment in Hospitals in the United States*, in 1B HANDBOOK OF HEALTH ECONOMICS, 1489-90 (A.J. Culyer & J.P. Newhouse eds., 2000) (concluding that “there is little evidence that [1970s-era] investment controls reduced the rate of cost growth,” even though “inconsistent reports of constraining effects on numbers of beds and diffusion of some specialized services did appear”).

<sup>38</sup> Morrissey 6/10 at 148-49, 152-53.

<sup>39</sup> Kindt, *supra* note 6, at 5.

hospitals from “add[ing] other kinds of fancy equipment” and using that to compete for consumers.<sup>40</sup>

As one commentator noted, “[t]he regulation of supply through mechanisms such as CON may have made sense when most reimbursement was cost-based and thus there was incentive to expand regardless of demand but they make much less sense today when hospitals are paid a fixed amount for services and managed care forces them to compete both to participate in managed-care networks and then for the plans’ patients.”<sup>41</sup> The policy justification of CON programs is particularly questionable given the number of evolving supply and demand-side strategies for controlling costs, including those outlined in Chapter 1.<sup>42</sup>

*Conclusion.* The Agencies believe that CON programs are generally not successful in containing health care costs and that they can pose anticompetitive risks. As noted above, CON programs risk entrenching oligopolists and eroding consumer welfare. The aim of controlling costs is laudable, but there appear to be other, more effective means of achieving this goal that do not pose anticompetitive risks. A similar analysis applies to the use of CON programs to enhance health care

quality and access. For these reasons, the Agencies urge states with CON programs to reconsider whether they are best serving their citizens’ health care needs by allowing these programs to continue.

## II. STATE ACTION AND NOERR DOCTRINES

The state action and Noerr-Pennington doctrines curb competition law in order to promote important values, such as federalism and the right to petition the government for redress of grievances.<sup>43</sup> Inappropriately broad interpretations of these doctrines, however, can chill or limit competition in health care markets.<sup>44</sup> Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing Competition Law and Noerr Pennington/State Action issues on June 11.<sup>45</sup>

### A. State Action Doctrine

The state action doctrine precludes federal antitrust scrutiny of certain state (and state authorized) conduct. The state action doctrine is rooted in principles of federalism and respect for state sovereignty. As the Supreme Court stated in the seminal state

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<sup>40</sup> *Id.*

<sup>41</sup> MILES, *supra* note 1, § 16:1, at 16-3.

<sup>42</sup> *See, e.g.*, Kindt, *supra* note 6, at 8-11; Anderson, *supra* note 2, at 9-13 (same); Davenport-Ennis 5/29 at 121 (citing means other than CON programs “to regulate over-usage and over-referral”). *But see* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 11 (stating that “[m]anaged care companies have not created the competition and lower cost solutions originally expected of them”).

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<sup>43</sup> *See* Havighurst 6/11 at 30-32.

<sup>44</sup> *See, e.g.*, Robin E. Remis, *Health Care and the Federal Antitrust Laws: The Likelihood of a Harmonious Coexistence*, 13 J. CONTEMP. HEALTH L. & POL’Y 113, 123-25 (1996).

<sup>45</sup> Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcarehearings/completeaenda.pdf>.

action case, neither the Sherman Act nor its history suggests that Congress intended the antitrust laws to “restrain a state or its officers or agents from activities directed by the legislature.”<sup>46</sup>

The state action doctrine shields activities of the state when it is acting in its sovereign capacity, and actions of most other entities and individuals if they are acting in furtherance of a clearly articulated state policy and are actively supervised by the state.<sup>47</sup> The clear articulation requirement “ensures that these entities may use anticompetitive mechanisms only if those mechanisms operate because of a deliberate and intended state policy.”<sup>48</sup> Similarly, the active supervision requirement “ensures that the entities are acting pursuant to state policy, not their own private

interests ....”<sup>49</sup>

One panelist noted that antitrust law is unsettled as to whether state regulatory commissions and licensing boards must satisfy both of these requirements.<sup>50</sup> The issue is better formulated as whether regulatory commissions and licensing boards that are substantially controlled by incumbent providers are really state actors, rather than private entities, for purposes of assessing state action. When providers substantially control a regulatory commission or licensing board, there are good reasons to require satisfaction of both the clear articulation and active supervision requirements of the state action doctrine.<sup>51</sup>

The Agencies have long opposed improper extensions of the state action doctrine. Unfortunately, some courts have broadly interpreted the “clear articulation” and “active supervision” requirements in

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<sup>46</sup> *Parker v. Brown*, 317 U.S. 341, 350-51 (1943).

<sup>47</sup> *See, e.g.*, *Town of Hallie v. City of Eau Claire*, 471 U.S. 34, 40 (1985) (holding that a municipality engaging in activity pursuant to state policy qualifies as state action and no active supervision required); *Cal. Retail Liquor Dealers Ass’n v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980) (stating that “the challenged restraint must be one clearly articulated and affirmatively expressed as state policy [and that] the policy must be actively supervised by the State itself”) (internal quotation marks and citation omitted). *See also* discussion in OFFICE OF POLICY PLANNING, FEDERAL TRADE COMM’N, REPORT OF THE STATE ACTION TASK FORCE 1 (2003) [hereinafter *FTC, STATE ACTION REPORT*], available at <http://www.ftc.gov/os/2003/09/stateactionreport.pdf>; James F. Blumstein & Terry Calvani, *State Action as a Shield and a Sword in a Medical Services Antitrust Context: Parker v. Brown in Constitutional Perspective*, 1978 *Duke L.J.* 389.

<sup>48</sup> *FTC, STATE ACTION REPORT*, *supra* note 47, at 1.

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<sup>49</sup> *Id.* The active supervision requirement similarly ensures that there is actual (and not simply nominal) oversight by the state.

<sup>50</sup> *See* *Andrus 6/11* at 52 (“For licensing boards, the Midcal test – because licensing boards are quasi-state agencies or entities, it’s not absolutely clear whether they need to satisfy both prongs of Midcal ... We know that they have to satisfy the first prong of Midcal, that is, the clear articulation prong.”).

<sup>51</sup> *See* *FTC, STATE ACTION REPORT*, *supra* note 47, at 15 (“[T]he active supervision test is applied when the Court deems there to be an appreciable risk that the challenged conduct may be the product of parties pursuing their own interests rather than state policy.”); Einer Elhauge, *The Scope of Antitrust Process*, 104 *HARV. L. REV.* 668, 688 (1991) (“[F]inancially interested actors cannot be trusted to decide which restrictions on competition advance the public interest; politically accountable actors can.”).

ways that sweep more broadly than necessary to protect the interests of federalism.<sup>52</sup> Health care has not been immune to these overly broad interpretations.<sup>53</sup>

Panelists cited specific areas in which entities might improperly invoke the state action doctrine to shield anticompetitive conduct in health care markets, including: (1) efforts by the medical staff of public hospitals to withhold staff privileges from rival health care providers;<sup>54</sup> (2) state efforts to sanction hospital mergers without federal antitrust review;<sup>55</sup> and (3) private efforts to use state agencies' frequent reliance on private credentialing bodies to raise barriers to entry or otherwise limit competition.<sup>56</sup>

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<sup>52</sup> FTC, STATE ACTION REPORT, *supra* note 47, at 25-49; Delacourt 6/11 at 8, 134.

<sup>53</sup> See *Jackson v. W. Tennessee Healthcare, Inc.*, 2004 U.S. Dist. LEXIS 4571 (W.D. Tenn. 2004); *Crosby v. Hosp. Auth. of Valdosta*, 93 F.3d 1515, 1532 (11th Cir. 1996) (stating that “clear articulation” test requires “only that the anticompetitive conduct be reasonably anticipated, rather than the inevitable, ordinary, or routine outcome of a statute”) (quoting *FTC v. Hosp. Bd. of Dir. of Lee County*, 38 F.3d 1184 (11th Cir. 1994)); *Martin v. Mem’l Hosp. at Gulfport*, 86 F.3d 1391 (5<sup>th</sup> Cir. 1996). See also FTC, STATE ACTION REPORT, *supra* note 47, at 29-33.

<sup>54</sup> Havighurst 6/11 at 40.

<sup>55</sup> *Id.* at 44-45.

<sup>56</sup> *Id.* at 46-48 (asserting that “[t]he pharmacy profession has succeeded over the last ten years in raising the minimum training for pharmacists from five to six years,” resulting in “a huge shortage of pharmacists” and cost increases); Lyon 6/11 at 60-70 (arguing that a private, national nursing organization has persuaded state nursing boards to raise barriers to entry to the nursing profession by

The Commission has an ongoing advocacy role in encouraging states to consider the competitive implications of proposed legislation. For example, state legislators have asked the Commission to comment on draft legislation that would shield physicians from antitrust liability for collective bargaining. Commission staff have responded by noting that “an antitrust exemption (i) would authorize physician price fixing, which is likely to raise costs and reduce access to care; and (ii) would *not* improve the quality of care, which can be accomplished through less anticompetitive means.”<sup>57</sup> State reaction to Commission advocacy on this point has been “varied but, in large part, positive.”<sup>58</sup>

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adding certain certification or licensing requirements); McClure 6/11 at 91-94, 112-13 (arguing that the American Dental Association has persuaded some state dental boards to pursue disciplinary action against dentists who advise their patients to have fillings made with amalgam containing mercury removed).

<sup>57</sup> FTC, STATE ACTION REPORT, *supra* note 47, at 67, *citing* Letter from Richard A. Feinstein, Assistant Director, Federal Trade Commission, to Robert R. Rigsby, District of Columbia Office of Corporation Counsel (Oct. 29, 1999) (regarding Bill No. 13-333), at <http://www.ftc.gov/be/hilites/rigsby.htm>; *Prepared Statement Concerning the “Quality Health-Care Coalition Act of 1999”*: *Hearing on H.R. 1304 Before the House Comm. on the Judiciary*, 106th Cong. 5 (1999) (Statement of Robert Pitofsky, Chairman, Federal Trade Commission), at <http://www.ftc.gov/os/1999/06/healthcaretestimony.htm>; Letter from William J. Baer, Director, Federal Trade Commission, to Rene O. Oliveira, Texas House of Representatives (May 13, 1999) (regarding Senate Bill 1468), at <http://www.ftc.gov/be/v990009.htm>.

<sup>58</sup> FTC, STATE ACTION REPORT, *supra* note 47, at 67. One panelist explicitly supported the FTC’s competition advocacy on this issue.

Likewise, the Commission recently issued a report on competition in the market for online contact lens sales.<sup>59</sup> The report recommends that states considering regulating the sellers of replacement lenses assess the competitive effects of their actions. Specifically, it cautions that “requiring a professional license to sell replacement contact lenses over the Internet is likely to raise prices and/or reduce convenience to consumers without substantially increasing health protections.”<sup>60</sup>

The report noted that “consumers can often achieve significant savings by purchasing replacement lenses from sellers other than their eye care providers,” including from online vendors.<sup>61</sup> The report recognized, however, that patients could hurt their eyes by getting and wearing replacement contact lenses without a valid prescription, and that requiring patients to have valid prescriptions for their replacement lenses induces them to get regular eye exams.<sup>62</sup> Imposing a prescription requirement for contact lens sellers, the report noted, thus may make

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Havighurst 6/11 at 46.

<sup>59</sup> See FEDERAL TRADE COMM’N, POSSIBLE ANTICOMPETITIVE BARRIERS TO E-COMMERCE: CONTACT LENSES (2004), available at <http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf>. The report followed a 2002 public workshop on possible barriers to competition in e-commerce markets in contact lenses and nine other industries. *Id.* at 2-3.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* at 13.

<sup>62</sup> *Id.* at 9.

sense.<sup>63</sup>

The critical policy question is whether additional state regulation – particularly regulation requiring contact lens sellers to have a state professional license, such as an optician’s license – is likely to hurt, or help, consumer welfare. Although such a licensing requirement may afford some consumer benefits, those benefits may be available through other, less restrictive means, and the extra regulation may “induce Internet sellers to charge higher prices or exit the market entirely, harming consumers.”<sup>64</sup> Indeed, the resulting increase in price or curtailed convenience in ordering replacement lenses might lead some to “over-wear their lenses or forgo replacement lenses altogether.”<sup>65</sup> For these reasons, the report urged state decision-makers to carefully tailor their regulatory efforts in this area to promoting consumer welfare, without enacting unnecessary licensing requirements that could drive low-cost Internet sellers from the market.<sup>66</sup>

The Agencies have extensive experience with the state action doctrine in health care cases. As Chapter 2 reflects, a case implicating the state action doctrine is currently pending in administrative litigation.<sup>67</sup> As Chapter 1 similarly reflects,

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<sup>63</sup> *Id.* at 15-16.

<sup>64</sup> *Id.* at 22-23.

<sup>65</sup> *Id.* at 23.

<sup>66</sup> See also *supra* Chapter 2 (noting similar considerations apply to telemedicine).

<sup>67</sup> See *In re* S.C. State Bd. of Dentistry, No. 9311, <http://www.ftc.gov/os/adjpro/d9311/index.htm>.

the Agencies have jointly filed amicus briefs regarding the scope of the state action doctrine in several health care antitrust cases. Deciding one of these cases en banc, the Fifth Circuit made clear that courts should not “infer ... a policy to displace competition from naked grants of authority” that serve as “the enabling statutes by which myriad instruments of local government across the country gain basic corporate powers.”<sup>68</sup> To do otherwise would extend *Parker* “downward, contrary to the teaching that local instruments of government are subject to the Sherman Act.”<sup>69</sup>

### **B. Noerr-Pennington Doctrine**

The First Amendment protects the right to petition the government for redress of grievances. Informed by that Amendment, the *Noerr* doctrine immunizes petitioning from scrutiny under the Sherman Act, even when such petitioning is done “to restrain competition or gain advantage over competitors.”<sup>70</sup> By shielding individuals’ rights to petition the government for redress of grievances, *Noerr* acts as an “important limitation on the antitrust laws.”<sup>71</sup>

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<sup>68</sup> *Surgical Care Ctr. of Hammond v. Hosp. Serv. Dist. No. 1 of Tangipahoa Parish*, 171 F.3d 231, 236 (5<sup>th</sup> Cir. 1999).

<sup>69</sup> *Id.*

<sup>70</sup> *Andrx Pharm. v. Biovail*, 256 F.3d 799, 817 (D.C. Cir. 2001), *cert. denied*, 122 S. Ct. 1305 (2002). The doctrine is named for the seminal cases that treated it: *Eastern R.R. Presidents Conference v. Noerr*, 365 U.S. 127 (1961), and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

<sup>71</sup> *Prepared Statement: Hearing on Generic Pharmaceuticals Before the S. Comm. on Commerce, Sci., and Transp.*, 107th Cong. 5 (2002) (Statement of Timothy J. Muris, Chairman, Federal Trade

Some courts have read this doctrine too broadly. One important limitation on the *Noerr* doctrine relates to the definition of “petitioning the government.” The *Noerr* doctrine does not cover every communication to the government. Rather, *Noerr* properly shields conduct directed toward obtaining discretionary governmental action.

The Commission has urged this point in a case involving health care. As *amicus curiae* in *In re Buspirone*, the Commission successfully persuaded the court that a drug manufacturer’s listing of a patent in the Food and Drug Administration’s “Orange Book” involves no discretionary government decision or action for which a drug manufacturer “petitions,” and thus does not enjoy *Noerr* protection.<sup>72</sup> In that case, Bristol-Myers Squibb (BMS) had allegedly foreclosed competition on one of its drugs by improperly submitting patents for listing in the Food and Drug Administration’s (FDA) Orange Book. Under the Drug Price Competition and Patent Term Restoration Act,<sup>73</sup> known popularly as the Hatch-Waxman Amendments, innovator drug companies that list their drug patents in the FDA’s Orange Book could, under certain

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Commission), at <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; *see also* Delacourt 6/11 at 18 (noting that goal of *Noerr* doctrine is to “prevent antitrust enforcement from halting or even chilling legitimate political conduct”).

<sup>72</sup> *In re Buspirone Patent Litigation*, 185 F.Supp.2d 363, 369 (S.D.N.Y. 2002).

<sup>73</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)), amending the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 52-675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397)).

circumstances, automatically win a stay of FDA approval of any generic rival to that drug for up to 30 months.<sup>74</sup> BMS argued that its submission of patent information for listing in the Orange Book was a petitioning of the government and was thus immune from antitrust review under *Noerr*.<sup>75</sup> As the Commission noted in its *amicus* brief, however, a company's Orange Book filing constitutes the formulaic provision of data in a manner that is informational and mechanical. The FDA, in turn, lists the provided data in the Orange Book in a manner that is purely ministerial. The court thus found that Orange Book listings are as ministerial as tariff filings, which have routinely been held to fall outside the scope of *Noerr* immunity.<sup>76</sup>

Likewise, in the Commission's independent action against BMS, the Commission alleged *inter alia* that BMS "abus[ed] FDA regulations to block generic entry; ma[de] false statements to the FDA in connection with listing patents in the Orange Book; engag[ed] in inequitable conduct before the U.S. Patent and Trademark Office to obtain patents; and fil[ed] baseless patent infringement suits."<sup>77</sup> The Commission stated that BMS's conduct fell outside the

scope of *Noerr*. Among other reasons for this conclusion, the Commission noted that "just as the repeated filing of lawsuits brought without regard to the merits, and for the purpose of using the judicial process (as opposed to the outcome of the process), warrants rejection of *Noerr* immunity, so too do the alleged repeated filing of patents on the Orange Book without regard to their validity, enforceability, or listability; repeated filing of recklessly or deliberately false statements with government agencies; and filing of lawsuits brought with or without regard to the merits, also cause the actions challenged here to fall outside the scope of *Noerr*'s protection."<sup>78</sup>

*Conclusion.* The state action and *Noerr* doctrines play important roles in promoting such values as federalism and the right to petition the government for redress of grievances. Taken too far, these doctrines can impede efforts to maintain vigorous competition in the health care field. The Agencies will continue to advocate in all appropriate venues for interpretations of these doctrines that are consistent with the principles that justify the doctrines in the first place.

### III. LONG-TERM CARE

*Introduction.* Long-term care facilities play an important role in our health care system. Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing Competition Law and Long Term Care/Assisted Living Facilities issues on

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<sup>74</sup> See 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>75</sup> See *Buspirone*, 185 F.Supp.2d at 369.

<sup>76</sup> See *id.* at 371.

<sup>77</sup> See Federal Trade Comm'n, Analysis to Aid Public Comment: *In re Bristol-Myers Squibb Company*, at <http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm>. The matter was settled by consent decree. See *In re Bristol-Myers Squibb*, No. C-4076 (Mar. 7, 2003) (agreement containing consent order), available at <http://www.ftc.gov/os/2003/03/bristolmyersconsent.pdf>.

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<sup>78</sup> FTC, Analysis to Aid Public Comment, *supra* note 77.

June 11.<sup>79</sup>

Several forces drive the market for long-term care, including the aging of the population, growing consumer awareness, restrictions on entry imposed by CON, and changing consumer preferences.<sup>80</sup> Various long-term care options are available, including nursing homes, assisted living facilities, home care, and adult care.<sup>81</sup> Assisted living facilities are the most rapidly growing form of senior housing.<sup>82</sup> Panelists discussed several challenges in the market for long-term care, including consumer information and the role of competition.

#### A. *Consumer Information*

Long-term care facilities make varying degrees of information available to consumers. Marketing materials, contracts, websites and publications, tours of care facilities, and communications with residents and families are the principal

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<sup>79</sup> Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf>.

<sup>80</sup> Thayer 6/11 at 147-48; Jan Thayer, *Assisted Living* 19 (6/11) (slides) [Thayer Presentation], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030611thayer.pdf>; U.S. DEP'T OF HEALTH & HUMAN SERVICES, HIGH SERVICE OR HIGH PRIVACY ASSISTED LIVING FACILITIES, THEIR RESIDENTS AND STAFF: RESULTS FROM A NATIONAL SURVEY 1 (2000) [hereinafter HHS, ASSISTED LIVING SURVEY], available at <http://aspe.hhs.gov/daltcp/reports/hshpes.htm>.

<sup>81</sup> Thayer 6/11 at 141. Hospice care is also available to consumers with a terminal condition.

<sup>82</sup> HHS, ASSISTED LIVING SURVEY, *supra* note 80, at 1.

means for disclosure of information.<sup>83</sup> Information regarding nursing homes is also available from public sources, including state and federal agencies.<sup>84</sup> Although these sources provide a considerable volume of information to consumers of nursing home care, panelists stated that much work remains to develop “ways to collect and present accurate, meaningful information that consumers can use.”<sup>85</sup> One panelist observed that less information is available regarding assisted living facilities, and expressed concern about the reliability of the information that is disclosed.<sup>86</sup>

Panelists noted that it is difficult to provide consumer information regarding quality of long-term care because of difficulties defining and measuring “quality.”<sup>87</sup> One panelist noted that

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<sup>83</sup> Thayer 6/11 at 149; Thayer Presentation, *supra* note 80, at 22-24; Love 6/11 at 172; Keren Brown Wilson, *Assisted Living: Evolving Model for A New General of Elderly* 12-13 (6/11) [K. Wilson (stmt)], at <http://www.ftc.gov/ogc/healthcarehearings/docs/030611wilson.pdf>; Manard 6/11 at 175-76.

<sup>84</sup> See Centers for Medicare & Medicaid Services, Dep't of Health & Human Services, *Nursing Home Compare*, <http://www.medicare.gov/NHCompare/home.asp> (Page Last Updated Feb. 19, 2004).

<sup>85</sup> Manard 6/11 at 174-75; Edelman 6/11 at 188.

<sup>86</sup> Edelman 6/11 at 188; see also HHS, ASSISTED LIVING SURVEY, *supra* note 80, at 2.

<sup>87</sup> J. Lynn 5/30 at 178, 192-93; K. Wilson (stmt), *supra* note 83, at 15-16; Jan Thayer, *Written Statement of Jan Thayer On Behalf of The National Center for Assisted Living, Federal Trade Commission/Department of Justice, Hearing on Long Term Care/Assisted Living* 5 (6/11) [hereinafter Thayer (stmt)]; see also U.S. DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL,



consumers care about both quality of care and quality of life, but these terms mean different things to different people, and views on these subjects can change over time.<sup>88</sup> Panelists observed that consumer information must be usable, reliable, and relate to consumer values for it to have beneficial consequences.<sup>89</sup>

Several panelists stated that too much emphasis is currently placed on measures of quality that are prone to misinterpretation or that give an inaccurate picture of the quality of services provided.<sup>90</sup> One panelist pointed out that “almost every measure of quality in a care system will look better if the very sick die quickly.”<sup>91</sup> Providers and regulatory agencies may also focus on attributes of quality (*e.g.*, safety) that are less significant to consumers than other attributes of quality (*i.e.*, dignity).<sup>92</sup> Panelists agreed that more research is necessary to link the quality measures collected by providers and regulatory agencies to quality of care and quality of life

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NURSING HOME DEFICIENCY TRENDS AND SURVEY AND CERTIFICATION PROCESS CONSISTENCY (Mar. 2003).

<sup>88</sup> Thayer (stmt), *supra* note 87, at 5.

<sup>89</sup> *Id.* at 5-6; J. Lynn 5/30 at 176.

<sup>90</sup> K. Wilson (stmt), *supra* note 83, at 16; K. Wilson 6/11 at 163; Thayer (stmt), *supra* note 87, at 7; Manard 6/11 at 180.

<sup>91</sup> J. Lynn 5/30 at 196.

<sup>92</sup> K. Wilson (stmt), *supra* note 83, at 5-6, 16-17; K. Wilson 6/11 at 156-58; Thayer (stmt), *supra* note 87, at 7-8; Thayer 6/11 at 151-152.

as experienced by consumers.<sup>93</sup> Panelists expressed concern that regulations required them to collect and disseminate information that was irrelevant to what consumers cared about (quality of care and quality of life).<sup>94</sup>

Panelists suggested several ways to improve mandated disclosure of information, consumer information, including the development of standardized quality measures,<sup>95</sup> greater consideration of the accessibility and usability of the information,<sup>96</sup> and enlisting the assistance of family members.<sup>97</sup> There was less agreement on the use of formal contracts to communicate information and address provider liability concerns (“negotiated risk

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<sup>93</sup> Thayer (stmt), *supra* note 87, at 7; *see also* Thayer 6/11 at 151; Manard 6/11 at 180; K. Wilson 6/11 at 162-63.

<sup>94</sup> Thayer (stmt), *supra* note 87, at 8; K. Wilson (stmt), *supra* note 83, at 17.

<sup>95</sup> Thayer (stmt), *supra* note 87, at 6; Thayer 6/11 at 150; Manard 6/11 at 176, 178; J. Lynn 5/30 at 178-79; Joanne Lynn, *Care to Count on When You Need It Most - Reforming Health Care Policy For Fatal Chronic Illness* 16 (5/30) (slides), at <http://www.ftc.gov/ogc/healthcarehearings/docs/030530lynjjoanne.pdf>.

Several panelists stated that consumers want more information on staffing patterns. Edelman 6/11 at 192-93; Paul 6/11 at 206-07; Love 6/11 at 218-19. One panelist suggested that the measures might include the suitability of the long-term care facility for consumers with a particular medical condition.

<sup>96</sup> Paul 6/11 at 203; Manard 6/11 at 178; *see also* Edelman 6/11 at 194-96; K. Wilson (stmt), *supra* note 83, at 7.

<sup>97</sup> K. Wilson (stmt), *supra* note 83, at 9; Thayer (stmt), *supra* note 87, at 8.

agreements”),<sup>98</sup> and on the effects of increased compensation for workers.<sup>99</sup>

### ***B. Competition in the Market for Long-Term Care***

There are a number of impediments to competition in the market for long-term care.<sup>100</sup> Many consumers are too sick, lack the time, or have insufficient information to shop around for nursing home care.<sup>101</sup> Consumers interested in assisted living facilities are less subject to these impediments, but less information is available for them to use. Medicare and Medicaid are dominant purchasers in the nursing home market; Medicaid covers more than two-thirds of residents and Medicare covers an additional 10 percent.<sup>102</sup> Medicaid plays a very small role and Medicare plays no role in the market for assisted living facilities.<sup>103</sup> One panelist complained that

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<sup>98</sup> Assisted Living Federation of America, *ALFA Releases Negotiated Risk Manual* (Apr. 3, 2000), at <http://www.alfa.org/public/articles/details.cfm?id=119>; Eric Carlson, *In the Sheep's Clothing of Resident Rights: Behind the Rhetoric of "Negotiated Risk,"* NAELA QUARTERLY, Spring 2003, at 1-2, available at [http://www.nslc.org/articles/neg\\_risk\\_naela.pdf](http://www.nslc.org/articles/neg_risk_naela.pdf); K. Wilson (stmt), *supra* note 83, at 7; see also K. Wilson 6/11 at 159-160; Edelman 6/11 at 219-20.

<sup>99</sup> K. Wilson (stmt), *supra* note 83, at 18; Edelman 6/11 at 196-97; see also Manard 6/11 at 184.

<sup>100</sup> J. Lynn 5/30 at 199; see also Thayer (stmt), *supra* note 87, at 7.

<sup>101</sup> J. Lynn 5/30 at 199; Manard 6/11 at 176.

<sup>102</sup> Manard 6/11 at 173-74.

<sup>103</sup> Thayer (stmt), *supra* note 87, at 8; Manard 6/11 at 182.

Medicare and Medicaid payment levels are so low that nursing homes discriminate against program beneficiaries when deciding who to admit.<sup>104</sup> Panelists and commentators have complained that CON restricts entry and protects incumbent providers.<sup>105</sup>

The Agencies applaud the disclosure of information to consumers in the market for long-term care. The Agencies urge states with CON programs involving long-term care facilities to reconsider whether they are best serving their citizens' health care needs by allowing these programs to continue.<sup>106</sup>

## **IV. INTERNATIONAL PERSPECTIVES**

*Introduction.* All health care markets worldwide face the same triad of challenges: reducing health care costs, improving quality, and increasing access.<sup>107</sup>

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<sup>104</sup> Edelman 6/11 at 195-96 (“[D]iscrimination against Medicaid beneficiaries has been a common problem for decades.”).

<sup>105</sup> Price 6/10 at 103 (“[I]t is a Certificate of Need process in Vermont that keeps the oligopoly in place.”); see also *supra* notes 37-42, and accompanying text.

<sup>106</sup> See *supra* notes 37-42, and accompanying text.

<sup>107</sup> William M. Sage & Peter J. Hammer, *A Copernican View of Health Care Antitrust*, 65 LAW AND CONTEMP. PROB. 241, 248 (2002) (“[U]nderlying all health care systems are qualitatively similar problems, resources, and objectives.”); Peter S. Hussey et al., *How Does the Quality of Care Compare in Five Countries*, 23 HEALTH AFFAIRS 89 (May/June 2004) (identifying quality problems in health care delivery worldwide); ORGANIZATION FOR ECONOMIC COOPERATION & DEVELOPMENT (OECD), TOWARDS HIGH-

Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing International Perspectives on Health Care and Competition Law and Policy on September 30.<sup>108</sup>

Most countries employ a mix of public and private financing and delivery systems, coupled with substantial regulation and subsidies.<sup>109</sup> Panelists agreed that competition law and policy play important but constrained roles in their countries.<sup>110</sup> Panelists also considered the significance of market concentration and consumer information in their respective countries.

#### **A. *International Perspectives on Competition and Health Care***

In countries throughout the world, people regard health care as “special.”<sup>111</sup> This perception has led many to argue that health care should not be subject to standard antitrust principles, or that special

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PERFORMING HEALTH SYSTEMS (2004).

<sup>108</sup> Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcare/hearings/completeagenda.pdf>.

<sup>109</sup> M. Jacobs 9/30 at 79-80; Purcell 9/30 at 56; Bhojani 9/30 at 13, 101.

<sup>110</sup> See Purcell 9/30 at 74-75; Bhojani 9/30 at 16-17; M. Jacobs 9/30 at 87. Representatives of the competition agencies of Australia, Ireland and Taiwan testified at the Hearings.

<sup>111</sup> Purcell 9/30 at 74-75, 91-93.

exemptions should be created.<sup>112</sup> One panelist observed that many in the health care field are more concerned with *why* competition laws are applied to health care, and not with *how* such laws should be applied.<sup>113</sup> More generally, competition is often viewed as irrelevant or even destructive to health care quality.<sup>114</sup> Efforts by antitrust agencies to bridge this gap have focused on education and outreach, but such efforts have proven difficult.<sup>115</sup> Antitrust agencies need to engage in ongoing competition advocacy to meet this challenge.<sup>116</sup>

#### **B. *Concentration of Health Care Markets***

Health care markets worldwide are becoming increasingly concentrated.<sup>117</sup> Concentration can result in cost efficiencies and economies of scale, but more concentrated markets pose greater risks to

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<sup>112</sup> Bhojani 9/30 at 17, 25-28; B. Cooper 9/30 at 38-39.

<sup>113</sup> Bhojani 9/30 at 16-17.

<sup>114</sup> Purcell 9/30 at 67, 74-75; M. Jacobs 9/30 at 86.

<sup>115</sup> Bhojani 9/30 at 16-19; Purcell 9/30 at 56; M. Jacobs 9/30 at 87 (challenges to antitrust enforcement include “widespread professional and, to a lesser extent perhaps, social opposition”).

<sup>116</sup> M. Jacobs 9/30 at 85-88; Purcell 9/30 at 74-75.

<sup>117</sup> Liu 9/30 at 52-53 (noting concentration of hospital markets and medical groups in Taiwan); Purcell 9/30 at 61, 64-66 (noting concentration in health insurance markets in Ireland); M. Jacobs 9/30 at 81-82 (noting concentration in multiple health care financing and delivery markets in Australia and U.S.).

competition.<sup>118</sup> In addition, regulation can easily create barriers to entry, which is likely to worsen market concentration.<sup>119</sup>

### C. *Consumer Information in Health Care Markets*

Consumer information is a problem in health care markets worldwide. Lack of information is a significant problem for many consumers.<sup>120</sup> Restrictions on truthful advertising create further barriers to information flow.<sup>121</sup> In some instances, however, consumers also face an oversupply of information and a paucity of resources to compare such information.<sup>122</sup> Some countries have sought to address these problems with standardized disclosures and brochures.<sup>123</sup> Consumer information presents challenges for competition agencies, governments, providers, and

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<sup>118</sup> M. Jacobs 9/30 at 82. *See also supra* Chapter 3.

<sup>119</sup> Purcell 9/30 at 65-66 (“However necessary risk equalization might be, it undoubtedly represents a barrier to entry to the health insurance market, as, of course, does the uncertainty about how the whole scheme will operate.”).

<sup>120</sup> M. Jacobs 9/30 at 83 (“[I]n many markets, there is almost no information at all.”). *See also supra* Chapter 1.

<sup>121</sup> Purcell 9/30 at 107. *See also supra* Chapter 7.

<sup>122</sup> B. Cooper 9/30 at 32 (“There’s actually a lot of information out there. So consumers actually have to deal with perhaps an oversupply of information, but it’s very difficult to compare the products of different funds the way the information is presented. They’re comparing apples with oranges and it makes life very hard.”); M. Jacobs 9/30 at 83.

<sup>123</sup> B. Cooper 9/30 at 32; Purcell 9/30 at 75.

individual consumers throughout the world.

## V. REMEDIES

*Introduction.* Competition law is only as good as the remedies it imposes. An effective remedy must resolve the anticompetitive harm, restore competition, and prevent future anticompetitive conduct.<sup>124</sup> Optimal enforcement must steer between over-deterrence and under-deterrence. Over-deterrence may occur if conduct that is not, in fact, anticompetitive is challenged, or if excessive sanctions are imposed on anticompetitive conduct.<sup>125</sup>

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<sup>124</sup> *See* Robert Pitofsky, *Antitrust at the Turn of the Twenty-First Century: The Matter of Remedies*, 91 GEORGETOWN L.J. 169, 170 (2002) (“Broadly speaking, the principal goals of antitrust should be first, to deter anticompetitive conduct, adjusting for the fact that much illegal conduct is not detected; and second, to take illegal gains away from the law violators and restore those monies to the victims.”) *See also* Kursh 10/1 at 5-6 (“First and foremost, the remedy must resolve the competitive problem. The only legitimate goal of a civil antitrust remedy, whether in a merger or a civil non-merger context, is to restore competition to the marketplace . . . . A second guiding principle [is that] [t]here must be a close, logical nexus between the remedy and the alleged violation . . . . The third guiding principle is . . . that the remedy should promote competition and not competitors . . . . And finally, but very importantly, the remedy must be enforceable.”).

<sup>125</sup> *See* X PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* ¶ 1741c, at 160 (2d ed. 2004) (“[F]urther inquiry may be inadvisable because its expense or high error rate would significantly deter desirable business behavior without significantly deterring anticompetitive behavior . . . This screening rationale applies . . . to rule of reason inquiry because the litigation costs and risks of error under that approach may exceed the benefits of inquiry for many categories of cases.”); Roxane C. Busey, *American Bar Ass’n, Commission’s Request for Comment on Remedial*

Under-deterrence may occur if anticompetitive conduct is not identified and addressed, or if inadequate remedies are imposed in response to such conduct.<sup>126</sup> The Agencies must avoid both of these extremes to effect optimal deterrence, while recognizing that bringing cases helps create a “compliance norm.”<sup>127</sup> As noted previously, the Agencies have brought almost twenty cases in the past two years against providers allegedly engaged in anticompetitive conduct.

Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing Competition Law and Remedies: Civil/Criminal on October 1.<sup>128</sup> Panelists disagreed on whether the Agencies are over-detering or under-detering anticompetitive conduct in the health care marketplace.<sup>129</sup>

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*Use of Disgorgement* (Public Comment) (noting concern with duplicative liabilities and recoveries).

<sup>126</sup> See, e.g., *Pfizer, Inc. v. Government of India*, 434 U.S. 308, 315 (1978) (If plaintiffs are “not permitted to seek remedy for their antitrust injuries, persons doing business both in this country and abroad might be tempted to enter into anticompetitive conspiracies . . .”). See HERBERT HOVENKAMP, *FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE* §17 (2d ed. 1999); WILLIAM BREIT & KENNETH G. ELZINGA, *ANTITRUST PENALTY REFORM: AN ECONOMIC ANALYSIS* (1986).

<sup>127</sup> See generally TOM R. TYLER, *WHY PEOPLE OBEY THE LAW* (1990).

<sup>128</sup> Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, at <http://www.ftc.gov/ogc/healthcare/hearings/completeagenda.pdf>.

<sup>129</sup> Compare Bierig 10/1 at 70-72 and 109-113, with Grady 10/1 at 56-60 and 116.

## A. *Civil Antitrust Remedies*

Civil remedies come in two basic types (structural and conduct) and are applied to two types of cases (merger and non-merger). Enforcement officials must assess whether the remedy should change the structure of the industry, regulate the conduct of the affected firms, or do both.<sup>130</sup>

Structural remedies, which require the divestiture of some assets to preserve competition, are more common in merger cases.<sup>131</sup> There is typically little need for post-divestiture oversight because the divestiture generally restores competition to the pre-merger level.<sup>132</sup> Because conduct remedies can be difficult to formulate, require ongoing oversight, and may be difficult to modify in response to changed circumstances, they are used less frequently in merger cases.<sup>133</sup>

The Agencies rarely seek dissolution.

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<sup>130</sup> O’Connor 10/1 at 24; Kursh 10/1 at 7.

<sup>131</sup> Federal and State enforcers must balance competing interests and concerns in arriving at the appropriate structural remedy. See, e.g., Donahue 10/1 at 34-44. The enjoining of a proposed merger also constitutes a structural remedy.

<sup>132</sup> O’Connor 10/1 at 26 (“The economists, of course, tell us that structural remedies change the incentive structure of the firms, and that compliance is more likely with structural remedy than with conduct remedies that require substantially more judicial oversight.”); Kursh 10/1 at 7-8.

<sup>133</sup> An injunction barring some behavior may put a firm at a disadvantage in reacting to unforeseen changes in the market. Kursh 10/1 at 7-9; O’Connor 10/1 at 26 (“For example, there is general agreement that divestiture is preferred in merger cases.”).

As the Commission wrote in its decision in *Indiana Federation of Dentists*, dissolution is appropriate “only in circumstances where there is no significant function remaining for an organization other than to repeat the antitrust violations or in which a conduct order would not reasonably be expected to prevent repeating such violations.”<sup>134</sup> Both Agencies have settled a number of cases by requiring the dissolution of the entity that facilitated alleged anticompetitive conduct.<sup>135</sup>

Civil non-merger cases involve a far broader range of settings and conduct.<sup>136</sup> The Agencies have typically focused on enjoining the conduct in question – a strategy described by panelists and commentators as “go and sin no more.”<sup>137</sup> In

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<sup>134</sup> *FTC v. Indiana Fed’n of Dentists*, 101 F.T.C. 57 (1986). See also III PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶ 653c, at 100 (2d ed. 2002) (“The strongest arguments for dissolution, divestiture, or other structural relief dissipating the monopolist’s power are deterrence-based. Such remedies are intended to prevent a recurrence of § 2 violations by making the defendant unable to engage in them.”).

<sup>135</sup> *United States v. Mountain Health Care*, P.A. 2003-2 Trade Cas. (CCH) P74,162, *appeal dismissed* 2004 U.S. App. LEXIS 8641 (4th Cir. 2004); *In re Carlsbad Physician Ass’n*, No. C-4081 (May 2, 2003) (agreement containing consent order to cease and desist), *available at* <http://www.ftc.gov/os/2003/05/carlsbadagree.pdf>; *In re Obstetrics and Gynecology Med. Corp. of Napa Valley*, No. C-4048 (May 14, 2002) (decision and order), *available at* <http://www.ftc.gov/os/2002/05/obgyndo.pdf>.

<sup>136</sup> Kursh 10/1 at 9 (“[C]ivil non-merger antitrust violations appear in infinite variety.”).

<sup>137</sup> O’Connor 10/1 at 31; David Marx Jr., *Messenger Models: What Can the Agencies do to Prevent Provider Networks from Violating the Antitrust Laws?*, HEALTH LAW NEWS, April 2004, at

some instances, relief is also sought against consultants and other parties who planned or enabled the anticompetitive conduct.<sup>138</sup> “Fencing-in provisions” are sometimes used to prevent recurrence.<sup>139</sup> The Agencies have also required parties to terminate or modify contracts,<sup>140</sup> and generate written reports regarding compliance efforts.<sup>141</sup>

On rare occasions, disgorgement is sought as well.<sup>142</sup> Disgorgement is an equitable remedy, designed to deprive the wrongdoer of his unjust enrichment and to deter others from future violations. The Commission’s policy statement on

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25. See also Singer 10/1 at 49 (“The core remedies have been the typical cease and desist, don’t do it any more remedies ....”).

<sup>138</sup> See *In re Me. Health Alliance*, No. C-4095 (Aug. 27, 2003) (decision and order), *available at* <http://www.ftc.gov/os/2003/08/mainehalthdo.pdf>; *In re Physician Network Consulting*, No. C-4094 (Aug. 27, 2003) (decision and order), *available at* <http://www.ftc.gov/os/2003/08/physnetworkdo.pdf>; *In re Aurora Assoc’d Primary Care Physicians*, No. 011 0174 (May 9, 2002) (complaint), *available at* <http://www.ftc.gov/os/2002/05/auroracmp.pdf>; Press Release, U.S. Dep’t of Justice, Florida Physicians Agree to Stop Illegal Joint Negotiations in Response to Justice Department Lawsuit (Jan. 26, 1999), *at* [http://www.usdoj.gov/atr/public/press\\_releases/1999/2196.htm](http://www.usdoj.gov/atr/public/press_releases/1999/2196.htm).

<sup>139</sup> Kursh 10/1 at 10; Singer 10/1 at 49. Such provisions may prohibit even lawful conduct, depending on the facts of the case and nature of the harm and the market.

<sup>140</sup> Kursh 10/1 at 11.

<sup>141</sup> Kursh 10/1 at 11.

<sup>142</sup> Federal Trade Comm’n, *Policy Statement on Monetary Equitable Remedies in Competition Cases*, 68 FR 45820, 45821 (2003) [hereinafter FTC, *Monetary Equitable Remedies*].

disgorgement outlines three factors that it will consider when evaluating use of this remedy.<sup>143</sup> Three years ago, the Commission pursued disgorgement in a monopolization case in the healthcare industry, and secured a settlement with Mylan Labs, Inc., of \$100 million.<sup>144</sup>

Panelists debated the propriety of disgorgement in health care cases. One panelist stated that disgorgement will be difficult to obtain because financial harm to consumers often cannot be quantified.<sup>145</sup> Another panelist believed disgorgement should be employed more frequently to deter anticompetitive conduct.<sup>146</sup> One panelist and commentators stated that the frequency of alleged physician price fixing cases indicates that physicians are insufficiently deterred by existing remedies.<sup>147</sup> Another panelist observed, however, that the Commission is unlikely to seek disgorgement unless there

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<sup>143</sup> FTC, *Monetary Equitable Remedies*, *supra* note 142. The three factors are that: (1) the underlying violation must be clear; (2) there must be a reasonable basis for calculating the amount of remedial payment; and (3) the value of seeking disgorgement will be considered in light of other remedies available in the matter, including private actions and criminal proceedings. *Id.*

<sup>144</sup> *FTC v. Mylan Labs, Inc.*, Civ. 98-3114 (TFH) (D.D.C. Feb. 9, 2001) (alleged monopolization; stipulated judgment included \$100 million restitution); *see* Mem. Opinion, 62 F. Supp. 2d 25, 36-37 (D.D.C. 1999), *revised and reaffirmed in pertinent part*, 99 F. Supp. 2d 1, 4-5 (D.D.C. 1999).

<sup>145</sup> Bierig 10/1 at 118.

<sup>146</sup> Grady 10/1 at 115-16.

<sup>147</sup> *Id.* at 116 (“[T]he reason they haven’t gotten the message is I don’t think they’re frankly scared enough.”); Marx, *supra* note 137, at 28.

was a clear violation of the law that was “on all fours with existing precedent.”<sup>148</sup> The Agencies will carefully consider whether disgorgement is appropriate in all future cases.

Remedies may also have significant consequences in other markets. Commentators have found that the announcement of a Commission enforcement action against an advertiser has a significant impact on the advertiser’s share price.<sup>149</sup> Being the target of an enforcement action is unlikely to enhance a provider’s reputation.<sup>150</sup>

## **B. Criminal Antitrust Remedies**

Some antitrust violations can give rise to criminal sanctions. As noted previously, the Division has exclusive jurisdiction over enforcement of federal criminal antitrust statutes. There have been only a few criminal health care antitrust cases.<sup>151</sup> One panelist suggested that criminal enforcement is inappropriate because physicians do not understand the antitrust laws, and do not intend to violate

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<sup>148</sup> Orlans 10/1 at 116-117.

<sup>149</sup> *See* Sam Peltzman, *The Effects of FTC Advertising Regulation*, 24 J.L. & ECON. 403 (1981); Alan Mathios & Mark Plummer, *The Regulation of Advertising by the Federal Trade Commission: Capital Market Effects*, 12 RES. L. & ECON. 77 (1989).

<sup>150</sup> Health care providers are greatly concerned with their reputations. *See* William M. Sage, *Reputation, Malpractice Liability, and Medical Error*, in ACCOUNTABILITY: PATIENT SAFETY AND POLICY REFORM (Virginia A. Sharpe, ed., 2004).

<sup>151</sup> Grady 10/1 at 53-56; Greaney 9/10/02 at 313.

them.<sup>152</sup> Other panelists dismissed this claim, and stated that both physicians and their consultants should face criminal sanctions in appropriate cases.<sup>153</sup> The Division is continuing to consider carefully the appropriateness of criminal sanctions in particular health care cases.

*Conclusion.* Remedies are a critical issue in implementing an effective competition policy. If remedies are inadequate, they will not have a credible deterrent effect. If remedies are excessive, they will over-deter, and discourage conduct that is actually permissible. Balancing these considerations is a difficult task.

The Agencies view all anticompetitive conduct as serious, and will seek appropriate sanctions in light of the considerations outlined previously. In general, much more stringent measures are necessary against those who violate the antitrust laws repeatedly or flagrantly and those who facilitate anticompetitive conduct by multiple parties. The Division will also pursue criminal sanctions in appropriate cases. Disgorgement and/or dissolution will be sought in appropriate cases.

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<sup>152</sup> Bierig 10/1 at 68.

<sup>153</sup> Grady 10/1 at 54-55, 94-95; O'Connor 10/1 at 103-04.



**APPENDIX A:  
WORKSHOP AND HEARINGS PARTICIPANTS**

**PARTICIPANTS AT FTC WORKSHOP  
SEPTEMBER 9-10, 2002**

**Primary Source:** <http://www.ftc.gov/ogc/healthcare/agenda.htm>.

<b>NAME</b>	<b>AFFILIATION AS OF DATE OF TESTIMONY</b>	<b>DATE</b>
Sheila F. <b>Anthony</b>	Commissioner, Federal Trade Commission	9/9/02
JoAnne <b>Bailey</b>	U.S. General Accounting Office	9/10/02
J. Howard <b>Beales, III</b>	Director, Bureau of Consumer Protection, Federal Trade Commission	9/9/02
Robert <b>Betz</b>	President/Chief Executive Officer, Health Industry Group Purchasing Association	9/10/02
Ashoke <b>Bhattacharjya</b>	Senior Director, Business Information, Janssen Pharmaceutica	9/10/02
William <b>Brewbaker, III</b>	Professor of Law, University of Alabama School of Law	9/9/02
Ellen <b>Burkett</b>	Clinical Director, MedSouth IPA	9/9/02
Rebecca <b>Burkholder</b>	Director, Health Policy, National Consumer League	9/10/02
Lawton Robert <b>Burns</b>	James Joo-Jin Kim Professor/Professor of Health Care Systems and Management, Wharton School of Business, University of Pennsylvania; Director, Wharton Center for Health Management & Economics	9/10/02
John E. <b>Calfee</b>	Resident Scholar, American Enterprise Institute	9/10/02
Bruce <b>Clark</b>	Assistant Vice President, Shared Services, Intermountain Health Care	9/10/02
Ellen S. <b>Cooper</b>	Assistant Attorney General, Antitrust Division, Maryland Office of the Attorney General	9/9/02
Helen <b>Darling</b>	President, Washington Business Group on Health	9/9/02
Henry R. <b>Desmarais</b>	Senior Vice President, Policy and Information, Health Insurance Association of America	9/9/02
Jarilyn <b>Dupont</b>	Senior Legislative Counsel, Office of Policy, Food & Drug Administration	9/10/02

<b>Steven Findlay</b>	Director, Research and Policy, National Institute for Health Care Management Foundation	9/10/02
<b>Stuart Fine</b>	Chief Executive Officer, Grand View Hospital; representing American Hospital Association	9/9/02
<b>Stephen Foreman</b>	Director, Pennsylvania Medical Society Health Services Research Institute; representing American Medical Association	9/9/02
<b>Lesley R. Frank</b>	Senior Advisor – Regulatory Counsel, Center for Drug Evaluation and Research, U.S. Food & Drug Administration	9/10/02
<b>Gregory Glover</b>	Partner, Ropes & Gray	9/10/02
<b>Thomas L. Greaney</b>	Professor of Law/Co-Director, Center for Health Law Studies, Saint Louis University School of Law	9/10/02
<b>Warren Greenberg</b>	Professor of Health Economics and Health Care Sciences, George Washington University	9/9/02
<b>Clifford Goodman</b>	Senior Scientist, The Lewin Group	9/10/02
<b>Peter J. Hammer</b>	Assistant Professor of Law, University of Michigan Law School	9/10/02; 5/28/03
<b>Catherine I. Hanson</b>	Vice President/General Counsel, California Medical Association	9/9/02
<b>Larry Holden</b>	President, Medical Device Manufacturers of American	9/10/02
<b>Stephanie W. Kanwit</b>	General Counsel/Senior Vice President, Public Policy and Research, American Association of Health Plans	9/9/02
<b>William E. Kovacic</b>	General Counsel, Federal Trade Commission	9/10/02
<b>Stephen Latham</b>	Director, Center for Health Law & Policy, Quinnipiac University School of Law	9/10/02
<b>Thomas B. Leary</b>	Commissioner, Federal Trade Commission	9/10/02
<b>Cara S. Lesser</b>	Senior Health Researcher, Center for Studying Health System Change	9/9/02
<b>Sarah Lock</b>	Senior Attorney, AARP Foundation Litigation	9/10/02

<b>Peter Lurie</b>	Deputy Director, Health Research Group, Public Citizen	9/10/02
<b>Deborah P. Majoras</b>	Principal Deputy Assistant Attorney General, U.S. Department of Justice Antitrust Division	9/9/02
<b>Carl Manley</b>	Vice President, Materials Management, Sentara HealthCare	9/10/02
<b>Amanda McCloskey</b>	Director, Health Policy Analysis, Families USA	9/10/02
<b>Timothy J. Muris</b>	Chairman, Federal Trade Commission	9/9/02
<b>Donald J. Palmisano</b>	President Elect, American Medical Association	9/9/02
<b>Sandra Raymond</b>	President/Chief Executive Officer, Lupus Foundation of America	9/10/02
<b>David Reiffen</b>	Economist, Office of Economic Policy, U.S. Treasury Department	9/10/02
<b>Richard Samp</b>	Chief Counsel, Washington Legal Foundation	9/10/02
<b>David Scheffman</b>	Director, Bureau of Economics, Federal Trade Commission	9/9/02
<b>Bill Schultz</b>	Representing Generic Pharmaceutical Association	9/10/02
<b>Joseph Simons</b>	Director, Bureau of Competition, Federal Trade Commission	9/9/02
<b>Michael Wroblewski</b>	Assistant General Counsel, Office of Policy Studies, Federal Trade Commission	9/10/02
<b>William Vogt</b>	Assistant Professor of Economics and Public Policy, H. John Heinz III School of Public Policy and Management, Carnegie Mellon University	9/9/02; 5/28/03
<b>Lawrence Wu</b>	Vice President, National Economic Research Associates, Inc.	9/9/02

**PARTICIPANTS AT FTC/DOJ HEARINGS  
FEBRUARY TO SEPTEMBER 2003**

**Primary Source:** <http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf>.

<b>NAME</b>	<b>AFFILIATION AS OF DATE OF TESTIMONY</b>	<b>DATE</b>
<b>Edward Alexander</b>	President/Chief Executive Officer, Surgical Alliance Corporation	3/27/03
<b>Sharon Allen</b>	President/Chief Operating Officer, Arkansas Blue Cross and Blue Shield	4/25/03
<b>Stuart H. Altman</b>	Sol. C. Chaikin Professor of National Health Policy, The Heller School for Social Policy & Management, Brandeis University	2/28/03
<b>Carl Ameringer</b>	Associate Professor of Political Science/Director, Graduate Program in Public Administration, University of Wisconsin	9/26/03
<b>Ralph K. Andrew</b>	Director, Government Affairs, New York Eye and Ear Infirmary	3/26/03
<b>Meredyth Andrus</b>	Assistant Attorney General, Antitrust Division, Maryland Office of the Attorney General	6/11/03
<b>Jay Angoff</b>	Counsel, Roger G. Brown & Associates	4/24/03
<b>Sheila F. Anthony</b>	Commissioner, Federal Trade Commission	4/11/03
<b>Joseph Antos</b>	Wilson H. Taylor Scholar in Health Care and Retirement Policy, American Enterprise Institute; Adjunct Professor, School of Public Health, University of North Carolina, Chapel Hill	9/30/03
<b>Susan Apold</b>	President, American College of Nurse Practitioners; Dean of Nursing, College of Mount St. Vincent	6/10/03
<b>David A. Argue</b>	Corporate Vice President, Economists Incorporated	3/28/03; 4/11/03; 9/24/03
<b>Bartley Asner</b>	Chairman of the Board of Directors, California Association of Physician Groups	9/25/03
<b>Charles D. Baker</b>	President/Chief Executive Officer, Harvard Pilgrim Health Care, Inc.	2/28/03

Jonathan B. <b>Baker</b>	Professor of Law, American University Washington College of Law	5/7/03
David <b>Balto</b>	Partner, White & Case LLP	4/11/03; 6/26/03
Jonathan R. <b>Bates</b>	President/Chief Executive Officer, Arkansas Children's Hospital	4/11/03
Anthony <b>Barrueta</b>	Senior Counsel, Kaiser Foundation Health Plan, Inc.	6/26/03
Jeffrey C. <b>Bauer</b>	Senior Vice President, Superior Consultant Company, Inc.	6/10/03
Gloria <b>Bazzoli</b>	Professor of Health Administration, Medical College of Virginia, Virginia Commonwealth University	5/28/03; 5/29/03
Carol <b>Beeler</b>	Vice President, Operations, Health Inventures; representing Federated Ambulatory Surgery Association	3/26/03
Robert <b>Berenson</b>	Senior Consultant, AcademyHealth	5/30/03
Harris A. <b>Berman</b>	Chief Executive Officer, Tufts Health Plan	2/28/03
Sitesh <b>Bhojani</b>	Commissioner, Australian Competition and Consumer Commission	9/30/03
Jack <b>Bierig</b>	Partner, Sidley Austin Brown & Wood LLP	10/1/03
Gregory G. <b>Binford</b>	Partner, Benesch, Friedlander, Coplan & Aronoff LLP	9/24/03
Roger D. <b>Blair</b>	Huber Hurst Professor of Economics and Legal Studies, University of Florida	4/24/03
Robert E. <b>Bloch</b>	Senior Partner, Mayer, Brown, Rowe & Maw LLP	9/26/03
Maxwell Gregg <b>Bloche</b>	Professor of Law, Georgetown University School of Law; Co-Director, Georgetown-Johns Hopkins Joint Program in Law and Public Health	6/10/03
James F. <b>Blumstein</b>	Professor of Law, Vanderbilt Law School; Director, Health Policy Center, Vanderbilt Institute for Public Policy Studies	2/27/03
Thomas M. <b>Boudreau</b>	Senior Vice President/General Counsel/Corporate Secretary, Express Scripts	6/26/03

<b>Stuart Bondurant</b>	Senior Special Assistant to the President, Georgetown University for Medical Center Affairs; representing Association of American Medical Colleges	5/30/03
<b>Jeffrey Brennan</b>	Assistant Director, Bureau of Competition, Federal Trade Commission	6/26/03
<b>William Brewbaker</b>	Professor of Law, University of Alabama School of Law	9/26/03
<b>James F. Burgess, Jr.</b>	Associate Professor, Boston University School of Public Health	4/9/03
<b>Lawton Robert Burns</b>	James Joo-Jin Kim Professor/Professor of Health Care Systems, Wharton School of Business, University of Pennsylvania; Director, Wharton Center for Health Management & Economics	4/9/03
<b>Roxane Busey</b>	Partner, Gardner, Carton & Douglas	9/24/03
<b>Bradford Buxton</b>	Senior Vice President, Health Care Management Division, Blue Cross Blue Shield of Illinois	5/8/03
<b>Tammi O. Byrd</b>	President-Elect, American Dental Hygienists' Association	6/10/03
<b>John E. Calfee</b>	Resident Scholar, American Enterprise Institute	6/26/03
<b>Cory S. Capps</b>	Visiting Assistant Professor of Management & Strategy, Kellogg School of Management, Northwestern University	4/10/03
<b>Laura Carabello</b>	Chief Creative Officer, CPRi Communications	6/12/03
<b>Winifred Carson-Smith</b>	Counsel, American Nurses Association	2/27/03
<b>Lawrence Casalino</b>	Assistant Professor, University of Chicago	5/28/03; 9/25/03
<b>Joseph A. Cashia</b>	Chief Executive Officer/Co-Founder, National Renal Alliance, LLC	9/30/03
<b>Carolyn Clancy</b>	Director, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/27/03; 5/28/03
<b>William Cohen</b>	Assistant General Counsel, Office of Policy Studies, Federal Trade Commission	6/26/03

<b>Marcia L. Comstock</b>	Chief Operating Officer/Board of Directors, Wye River Group on Healthcare	6/12/03
<b>Paul Conlon</b>	Vice President, Clinical Quality and Patient Safety, Trinity Health; Clinical Assistant Professor of Pharmacy, University of Michigan	5/29/03
<b>Michael Connair</b>	Orthopedic Surgeon; Clinical Instructor, Yale- New Haven Hospital and the Hospital of St. Raphael	9/26/03
<b>Bruce Cooper</b>	Director, Professions Compliance Unit, Enforcement and Coordination Branch, Australian Competition and Consumer Commission	9/30/03
<b>Ellen S. Cooper</b>	Assistant Attorney General, Antitrust Division, Maryland Office of the Attorney General	6/26/03
<b>Donald Crane</b>	President/Chief Executive Officer, California Association of Physician Groups	5/7/03
<b>Christine Crofton</b>	Social Scientist, Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/30/03
<b>Dan L. Crippen</b>	Former Director, Congressional Budget Office	9/30/03
<b>Jon Christianson</b>	Professor, Healthcare Management, University of Minnesota	5/28/03
<b>Serdar Dalkir</b>	Industrial Organization Economist, Microeconomic Research Consulting Associates	5/8/03
<b>Bernie Dana</b>	Consultant for Long Term Care Management/Assistant Professor of Business, Evangel University; representing American Health Care Association	6/12/03
<b>Charles Darby</b>	Co-Project Officer on Consumer Assessment of Health Plans (CAHPS) Survey, Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/30/03
<b>Helen Darling</b>	President, Washington Business Group on Health	2/27/03; 4/23/03; 6/12/03

Jacqueline M. <b>Darrah</b>	Director, Health Law Division, American Medical Association	2/27/03
Nancy <b>Davenport-Ennis</b>	President/Chief Executive Officer, National Patient Advocate Foundation	5/29/03
John <b>Delacourt</b>	Assistant Director, Office of Policy Planning, Federal Trade Commission	6/11/03
Suzanne <b>Delbanco</b>	Executive Director, The Leapfrog Group	5/29/03
Henry R. <b>Desmarais</b>	Senior Vice President, Policy and Information, Health Insurance Association of America	2/27/03; 4/23/03
John <b>Dicken</b>	Assistant Director for Health Care Issues, U.S. General Accounting Office	6/26/03
Fred <b>Dodson</b>	Vice President, Network Management, PacifiCare of California	4/23/03
James A. <b>Donahue, III</b>	Chief Deputy Attorney General, Antitrust Section, Pennsylvania Office of Attorney General	10/1/03
Timothy F. <b>Doran</b>	Pediatrician; representing American Academy of Pediatrics	2/27/03
Claudia H. <b>Dulmage</b>	Attorney, U.S. Department of Justice Antitrust Division	6/26/03
Toby S. <b>Edelman</b>	Attorney, Center for Medicare Advocacy	6/11/03
David <b>Eisenstadt</b>	Co-Founder, Microeconomic Consulting and Research Associates, Inc.	3/28/03; 4/10/03
William <b>Encinosa</b>	Health Economist, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/28/03
Lynn James <b>Everard</b>	Co-Founder, The Foundation for Healthcare Integrity	9/26/03
Eugene Anthony <b>Fay</b>	Vice President, Government Affairs, Province Healthcare Co.	4/10/03
Judy <b>Feder</b>	Professor/Dean of Public Policy, Georgetown University	2/27/03
Roger <b>Feldman</b>	Blue Cross Professor of Health Insurance/Professor of Economics, University of Minnesota	4/23/03



Howard <b>Feller</b>	Partner, McGuire Woods LLP	9/24/03
Elliot <b>Fisher</b>	Professor of Medicine and Community and Family Medicine, Dartmouth Medical School and the Center for the Evaluative Clinical Studies	5/27/03
Mark <b>Flaherty</b>	Attorney	9/26/03
Stephen <b>Foreman</b>	Director, Pennsylvania Medical Society Health Services Research Institute; representing American Medical Association	4/24/03; 4/25/03; 5/7/03
Nancy <b>Foster</b>	Senior Associate Director, Health Policy, American Hospital Association	5/29/03
Walton <b>Francis</b>	Economist and Policy Analyst	9/30/03
Irene <b>Fraser</b>	Director, Center for Organization and Delivery Studies, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/28/03; 5/29/03
H.E. <b>Frech, III</b>	Professor of Economics, University of California, Santa Barbara	3/26/03; 3/27/03; 4/24/03; 4/25/03
Jon <b>Gabel</b>	Vice President, Health Systems Studies, Health Research and Educational Trust; representing American Hospital Association	4/23/03
Martin <b>Gaynor</b>	E.J. Barone Professor of Economics and Public Policy, H. John Heniz III School of Public Policy and Management, Carnegie Mellon University	2/26/03; 5/7/03; 5/27/03; 5/28/03
John E. <b>Gebhart, III</b>	Chairman/Chief Executive Officer, DoctorQuality, Inc.	6/12/03
Jeffrey <b>Geppert</b>	Senior Analyst, Center for Primary Care and Outcomes Research, Center for Health Policy, Stanford University	5/28/03
Newt <b>Gingrich</b>	Chief Executive Officer, The Gingrich Group	6/12/03
Paul B. <b>Ginsburg</b>	President, Center for Studying Health System Change	2/26/03; 4/23/03

<b>Daniel P. Gitterman</b>	Assistant Professor of Public Policy and Political Science, University of North Carolina, Chapel Hill	6/25/03
<b>Ruth Given</b>	Health Care Director, Deloitte Research, Deloitte Consulting and Deloitte & Touche	4/24/03
<b>Kevin Grady</b>	Partner, Alston & Bird LLP; Chair, American Bar Association Section of Antitrust Law	10/1/03
<b>Thomas L. Greaney</b>	Professor of Law/Co-Director of the Center for Health Law Studies, Saint Louis University School of Law	2/27/03
<b>Warren Greenberg</b>	Professor of Health Economics and Health Care Sciences, George Washington University	5/28/03; 6/12/03
<b>Warren Grimes</b>	Professor of Law, Southwestern University School of Law	6/26/03
<b>Margaret E. Guerin-Calvert</b>	Principal, Competition Policy Associates, Inc.	3/26/03; 3/27/03; 4/10/03; 5/8/03; 9/24/03
<b>Stuart Guterman</b>	Director, Office of Research, Development, and Information, Centers for Medicare and Medicaid Services	5/29/03
<b>Dennis A. Hall</b>	President, Baptist Health System, Inc.	4/25/03
<b>Peter J. Hammer</b>	Assistant Professor of Law, University of Michigan Law School	2/27/03
<b>Russell D. Harrington, Jr.</b>	President/Chief Executive Officer, Baptist Health	4/11/03
<b>Barry C. Harris</b>	Principal, Economists Incorporated	3/26/03; 4/23/03
<b>Clark Havighurst</b>	Professor of Law, Duke University Law School	6/11/03
<b>Curt Hawkinson</b>	Chair, Professional Practice Council, American Association of Physician Assistants	9/25/03
<b>Gary Heiman</b>	President/Chief Executive Officer, Standard Textile	9/26/03
<b>John Hennessy</b>	Executive Director, Kansas City Cancer Centers	6/10/03

<b>Regina Herzlinger</b>	Nancy R. McPherson Professor of Business Administration, Harvard Business School	5/27/03
<b>Judith Hibbard</b>	Professor of Health Policy, University of Oregon; Clinical Professor of Public Health and Preventative Medicine, Oregon Health & Sciences University	5/29/03
<b>Said Hilal</b>	President/Chief Executive Officer/Member of the Board of Directors, Applied Medical Resources Corporation	9/26/03
<b>J. Edward Hill</b>	Member, Board of Trustees, American Medical Association	9/25/03
<b>Albert Holloway, Jr.</b>	President/Chief Executive Officer/Founder, The IPA Association of America	9/25/03
<b>Debra Holt</b>	Economist, Bureau of Economics, Federal Trade Commission	3/27/03
<b>Jamie E. Hopping</b>	Chief Operating Officer, Ardent Health Services	4/11/03
<b>Robert L. Hubbard</b>	Director of Litigation/Assistant Attorney General, Antitrust Bureau, Office of New York State Attorney General	4/10/03
<b>Robert E. Hurley</b>	Associate Professor, Department of Health Administration, Virginia Commonwealth University; representing Center for Studying Health System Change	4/9/03
<b>David A. Hyman</b>	Professor of Law, University of Maryland School of Law; Special Counsel, Federal Trade Commission	6/25/03; 5/28/03
<b>Ralph Ibson</b>	Vice President, Government Affairs, National Mental Health Association	6/25/03
<b>Lisa Iezzoni</b>	Health Services Researcher, Division of General Medicine and Primary Care, Beth Israel Deaconess Medical Center	5/28/03
<b>Karen Ignagni</b>	President/Chief Executive Officer, American Association of Health Plans	5/27/03
<b>Harold N. Iselin</b>	Partner, Couch White, LLP	3/27/03
<b>Jon B. Jacobs</b>	Attorney, U.S. Department of Justice Antitrust Division	3/28/03

<b>Michael Jacobs</b>	Professor of Law, DePaul University College of Law	9/30/03
<b>Peter D. Jacobson</b>	Associate Professor, University of Michigan School of Public Health	4/10/03
<b>Brent James</b>	Executive Director, Institute for Health Care Delivery Research, Inter mountain Health Care	5/28/03
<b>Clifton E. Johnson</b>	Partner, Hall, Render, Killian, Heath & Lyman, P.S.C.	6/26/03
<b>Charles N. Kahn, III</b>	President, Federation of American Hospitals	2/27/03; 5/29/03
<b>James J. Kane, Jr.</b>	Cardiologist, Little Rock Cardiology Clinic, P.A.	4/11/03
<b>Stephanie W. Kanwit</b>	General Counsel/Senior Vice President, Public Policy and Research, American Association of Health Plans	2/27/03; 4/25/03; 6/25/03
<b>Dennis I. Kelly</b>	Executive Vice President, Development & Government Relations, MedCath Corporation	3/27/03
<b>Greg Kelly</b>	Executive Director, Coalition Against Guaranteed Issue	6/12/03
<b>Richard Kelly</b>	Attorney, Bureau of Consumer Protection, Federal Trade Commission	6/12/03
<b>Daniel Kessler</b>	Professor, Stanford Business School	5/28/03; 5/29/03
<b>Kenneth W. Kizer</b>	President/Chief Executive Officer, National Quality Forum	6/11/03
<b>Morris Kleiner</b>	Professor of Public Affairs and Industrial Relations, Humphrey Institute of Public Affairs and the Industrial Relations Center, University of Minnesota	6/10/03
<b>Anthony J. Knettel</b>	Vice President, Health Affairs, The ERISA Industry Committee	6/25/03
<b>Douglas D. Koch</b>	Professor/The Allen, Mosbacher, and Law Chair in Ophthalmology, Cullen Eye Institute, Baylor College of Medicine	6/12/03
<b>William G. Kopit</b>	Senior Member, Epstein Becker & Green, P.C.	4/10/03; 4/11/03; 5/7/03

<b>William E. Kovacic</b>	General Counsel, Federal Trade Commission	2/27/03
<b>Andrew Kumpuris</b>	Visiting Professor in Healthcare Policy, Washington and Lee University	5/30/03
<b>Gail Kursh</b>	Deputy Chief, Legal Policy Section/Special Counsel for Federal-State Cooperation, U.S. Department of Justice Antitrust Division	10/1/03
<b>James Langenfeld</b>	Director, LECG, L.C.C.; Adjunct Professor, Loyola University School of Law, Chicago	4/11/03; 5/7/03
<b>David Lansky</b>	President, Foundation for Accountability	6/12/03
<b>Rachel Laser</b>	Senior Counsel, National Women's Law Center	6/25/03
<b>Thomas B. Leary</b>	Commissioner, Federal Trade Commission	5/30/03
<b>Thomas H. Lee</b>	Internist/Cardiologist/Chief Medical Officer, Partners Community Healthcare, Inc.	6/12/03
<b>Robert F. Leibenluft</b>	Partner, Hogan & Hartson LLP; representing Antitrust Coalition for Consumer Choice in Health Care	3/28/03; 5/7/03; 9/24/03
<b>Jeff Lemieux</b>	Senior Economist, Progressive Policy Institute	9/30/03
<b>Arthur N. Lerner</b>	Partner, Crowell & Moring, LLP	3/27/03; 4/23/03; 4/24/03; 9/25/03
<b>Cara S. Lesser</b>	Senior Health Researcher, Center for Studying Health System Change	3/27/03
<b>Wendy Levinson</b>	Professor of Medicine/Vice-Chair, Department of Medicine, University of Toronto	5/30/03
<b>Mark Levy</b>	Executive Director, Committee of Interns and Residents	9/26/03
<b>Len-yu Liu</b>	Commissioner, Taiwan Fair Trade Commission	9/30/03
<b>Lynne Loeffler</b>	Representing American College of Nurse Midwives	6/10/03
<b>Steven Lomazow</b>	Neurologist; representing American Academy of Neurology	6/10/03
<b>Karen Love</b>	Founder/Chair, Consumer Consortium on Assisted Living	6/11/03

<b>William J. Lynk</b>	Senior Vice President/Senior Economist, Lexecon Inc.	4/10/03
<b>George F. Lynn</b>	President/Chief Executive Officer, AtlantiCare; representing American Hospital Association	3/27/03
<b>Joanne Lynn</b>	Director, The Washington Home Center for Palliative Care Studies	5/30/03
<b>Brenda Lyon</b>	Professor, Indiana University School of Nursing; representing National Association of Clinical Nurse Specialists	6/11/03
<b>Deborah P. Majoras</b>	Principal Deputy Assistant Attorney General, U.S. Department of Justice Antitrust Division	2/28/03
<b>Francis J. Mallon</b>	Chief Executive Officer, American Physical Therapy Association	6/10/03
<b>Barbara Manard</b>	Vice President, Long Term Care/Health Strategies, American Association of Homes and Services for the Aging	6/11/03
<b>Stephen Mansfield</b>	President/Chief Executive Officer, St. Vincent Health System	4/25/03
<b>John P. Marren</b>	Partner, Hogan Marren, Ltd.	5/8/03
<b>David Marx, Jr.</b>	Partner, McDermott, Will & Emery	9/25/03
<b>Robert E. Matthews</b>	Executive Director, PriMed Physicians	9/24/03
<b>Glen Mays</b>	Researcher, Center for Studying Health System Change	5/30/03
<b>Michael J. Mazzeo</b>	Assistant Professor, Kellogg School of Management, Northwestern University	4/23/03
<b>Thomas R. McCarthy</b>	Senior Vice President, National Economic Research Associates, Inc.	3/27/03; 4/24/03; 4/25/03
<b>Mark McClure</b>	Dentist, National Integrated Health Associates	6/11/03
<b>LaMar McGinnis</b>	Clinical Professor of Surgery, Emory University School of Medicine; Medical Director, Eberhart Cancer Center, DeKalb Medical Center; representing American College of Surgeons	5/30/03
<b>Robert M. McNair, Jr.</b>	Partner, Drinker Biddle & Reath LLP	5/7/03

<b>Peggy McNamara</b>	Policy Analyst, Center for Organization and Delivery Studies, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/28/03
<b>Astrid Meghriyan</b>	Counsel, California Medical Association	9/24/03
<b>Markus H. Meier</b>	Deputy Assistant Director, Bureau of Competition, Federal Trade Commission	9/25/03
<b>Joseph M. Meyer</b>	Director, Corporate Benefits Planning, ALLTEL Corporation	4/11/03
<b>John Jeff Miles</b>	Principal, Ober Kaler	4/10/03; 4/24/03; 4/25/03; 5/8/03; 6/26/03; 9/25/03
<b>Michael Millenson</b>	Mervin Shalowitz, M.D. Visiting Scholar, Kellogg School of Management, Northwestern University	5/27/03
<b>Frances H. Miller</b>	Professor of Law, Boston University School of Law	2/28/03
<b>Tom Miller</b>	Director, Health Policy Studies, Cato Institute	6/25/03
<b>Arnold Milstein</b>	Medical Director, Pacific Business Group on Health; National Health Care Thought Leader, Mercer Human Resource Consulting	2/27/03; 5/28/03; 5/29/03; 5/30/03
<b>Jerome H. Modell</b>	Professor Emeritus, University of Florida, College of Medicine; representing American Society of Anesthesiologists	6/10/03
<b>James J. Mongan</b>	President/Chief Executive Officer, Partners HealthCare	2/28/03
<b>David Monk</b>	Vice President, National Economic Research Associates, Inc.	4/23/03
<b>David Morehead</b>	Senior Vice President, Medical Affairs/Chief Medical Officer, OhioHealth	3/26/03; 3/27/03
<b>Michael Morrissey</b>	Professor, School of Public Health, University of Alabama, Birmingham	6/10/03

<b>Robert Moses</b>	Senior Vice President/Chief Counsel Health Care, Oxford Health Plans	4/10/03
<b>Dan Mulholland</b>	Senior Partner, Horty, Springer & Mattern, P.C.	3/27/03
<b>Timothy J. Muris</b>	Chairman, Federal Trade Commission	2/26/03
<b>Ryan Mutter</b>	Representing Center for Organization and Delivery Studies, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/28/03
<b>Woodrow Myers, Jr.</b>	Executive Vice President/Chief Medical Officer, WellPoint Health Networks	5/29/03
<b>Russ Newman</b>	Executive Director, Professional Practice, American Psychological Association	6/10/03
<b>Nancy Nielsen</b>	Vice Speaker, House of Delegates, American Medical Association	5/30/03
<b>Monica Noether</b>	Vice President, Charles River Associates	5/7/03; 9/24/03
<b>Kevin J. O'Connor</b>	Attorney, Godfrey & Kahn	10/1/03
<b>Margaret O'Kane</b>	President, National Committee for Quality Assurance	5/30/03
<b>Frank Opelka</b>	Chief, Division of Colon and Rectal Surgery, Beth Israel Deaconess Medical Center; representing American College of Surgeons	2/27/03
<b>Melvin H. Orlans</b>	Special Litigation Counsel, Office of the General Counsel, Federal Trade Commission	3/28/03; 10/1/03
<b>Thomas Overstreet</b>	Vice President, Charles River Associates	5/7/03
<b>R. Hewitt Pate</b>	Assistant Attorney General for Antitrust, U.S. Department of Justice	2/26/03
<b>Barbara Paul</b>	Director, Quality Measurement and Health Assessment Group, Center for Beneficiary Choices, Centers for Medicare and Medicaid Services	6/11/03
<b>Mark V. Pauly</b>	Bendheim Professor/Chair, Department of Health Care Systems, Wharton School of Business, University of Pennsylvania	2/26/03; 5/28/03



<b>Thomas R. Piper</b>	Board of Directors, American Health Planning Association; Director, Certificate of Need Program and State Health Planning and Department Agency, Missouri Department of Health	6/10/03
<b>Steven Pizer</b>	Assistant Professor of Health Services, Boston University School of Public Health; Health Economist, Department of Veterans Affairs	4/23/03
<b>Megan D. Price</b>	Director, Contracts & Communications, Professional Nurses Services, Inc.	6/10/03
<b>Louise Probst</b>	Executive Director, Gateway Purchasers for Health and St. Louis Area Business Health Coalition	5/29/03
<b>Declan Purcell</b>	Appointed Member, Irish Competition Authority	9/30/03
<b>Richard D. Raskin</b>	Partner, Sidley Austin Brown & Wood LLP	9/25/03
<b>John G. Rex-Waller</b>	Chairman/President/Chief Executive Officer, National Surgical Hospitals	3/27/03
<b>John Richardson</b>	Director of Medicare, The Health Strategies Consultancy	6/26/03
<b>Vicky Robinson</b>	Chief, Industry Guidance Branch, Office of Counsel to the Inspector General, U.S. Department of Health and Human Services	6/26/03
<b>Patrick Romano</b>	Associate Professor of Medicine and Pediatrics, University of California, Davis, School of Medicine	5/28/03; 5/29/03
<b>Meredith Rosenthal</b>	Health Economist, Harvard School of Public Health	5/28/03
<b>Douglas C. Ross</b>	Partner, Davis Wright Tremaine LLP	9/25/03
<b>Kevin W. Ryan</b>	Project Director, Arkansas Center for Health Improvement; Assistant Professor, College of Public Health, University of Arkansas for Medical Sciences	4/11/03
<b>Robert J. Ryan</b>	Senior Vice President/General Counsel, MedStar Health, Inc.	3/26/03
<b>Seth B. Sacher</b>	Principal, Charles River Associates	3/26/03; 4/11/03

<b>Lee B. Sacks</b>	Executive Vice President/Chief Medical Officer, Advocate Health Care	3/26/03
<b>William Sage</b>	Professor of Law, Columbia University School of Law	5/28/03; 5/29/03
<b>Marius Schwartz</b>	Professor of Economics, Georgetown University	4/25/03
<b>Vincent Scicchitano</b>	Senior Vice President, Business Operations, Vytra Health Plans	3/27/03
<b>Thomas A. Scully</b>	Administrator, Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services	2/26/03
<b>Mary Elizabeth Senkewicz</b>	Senior Counsel, Health Policy, National Association of Insurance Commissioners	4/24/03
<b>Peter M. Sfikas</b>	Chief Counsel/Associate Executive Director, American Dental Association	2/27/03; 6/12/03
<b>James D. Shelton</b>	Chairman/Chief Executive Officer, Triad Hospitals, Inc.	3/26/03
<b>Robert L. Shoptaw</b>	Chief Executive Officer, Arkansas Blue Cross and Blue Shield	4/11/03
<b>Merrile Sing</b>	Senior Analyst, U.S. General Accounting Office	9/26/03
<b>Toby G. Singer</b>	Partner, Jones Day	3/28/03; 10/1/03
<b>Frank Sloan</b>	J. Alexander McMahon Professor of Health Policy and Management/Professor of Economics, Duke University	4/10/03
<b>Kirby O. Smith</b>	President/Chief Executive Officer, Susquehanna Health System	4/11/03
<b>Steven E. Snow</b>	Partner, Partridge Snow & Hahn LLP	5/7/03
<b>Shoshana Sofaer</b>	Robert P. Luciano Professor of Health Care Policy, School of Public Affairs, Baruch College, City University of New York	5/30/03
<b>Cathy Stoddard</b>	Registered Nurse, Allegheny General Hospital; representing Service Employees International Union	5/29/03
<b>John W. Strong</b>	President/Chief Executive Officer, Consorta, Inc.	9/26/03

<b>Bradley C. Strunk</b>	Health Research Analyst, Center for Studying Health System Change	3/27/03
<b>Daniel Stryer</b>	General Internist, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/28/03
<b>Robert Taylor</b>	Managing Partner, Robert Taylor Associates	4/10/03; 411/03
<b>Jan Thayer</b>	Chair, National Center for Assisted Living	6/11/03
<b>Mozelle W. Thompson</b>	Commissioner, Federal Trade Commission	9/30/03
<b>Anthony Tirone</b>	Director, Federal Relations, Joint Commission on Accreditation of Healthcare Organizations	5/29/03
<b>Mark Tobey</b>	Chief, Antitrust Section, Consumer Protection Division, Office of the Attorney General, Texas	5/7/03
<b>Dawn M. Touzin</b>	Director, Community Health Assets Project, Community Catalyst	4/10/03
<b>Robert Town</b>	Assistant Professor, Department of Health Services Research and Policy, University of Minnesota	4/9/03; 5/28/03
<b>Reed Tuckson</b>	Senior Vice President, Consumer Health and Medical Care Advancement, UnitedHealth Group	5/30/03
<b>Christine A. Varney</b>	Partner, Hogan & Hartson LLP; representing American Hospital Association	2/27/03
<b>Gregory Vistnes</b>	Vice President, Charles River Associates	3/26/03; 10/1/03
<b>Michael Vita</b>	Assistant Director for Antitrust, Bureau of Economics, Federal Trade Commission	5/28/03
<b>J. Mark Waxman</b>	President/General Counsel, CareGroup, Inc.	2/28/03
<b>Elizabeth Weatherman</b>	Member, Healthcare Group, Warburg Pincus	9/26/03
<b>Ernest I. Weis</b>	Chief Executive, Advocate Health Partners; representing the American Hospital Association	5/8/03
<b>Charles A. Welch</b>	President, Massachusetts Medical Society	2/28/03
<b>Gregory J. Werden</b>	Senior Economic Counsel, U.S. Department of Justice Antitrust Division	3/26/03

<b>John Wiegand</b>	Attorney, Federal Trade Commission	9/24/03
<b>John Wilson</b>	Orthopedic Surgeon, OrthoArkansas, P.A.; President-Elect, Arkansas Medical Society	4/11/03
<b>Keren Brown Wilson</b>	President, Jessie F Richardson Foundation	6/11/03
<b>Robin Wilson</b>	Associate Professor of Law, University of South Carolina School of Law	6/10/03
<b>Herbert Wong</b>	Economist, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services	5/28/03
<b>Lawrence Wu</b>	Vice President, National Economic Research Associates, Inc.	4/11/03; 4/23/03; 4/24/03
<b>Gary J. Young</b>	Associate Professor of Health Services/Co- Director, Program on Health Policy and Management, Boston University School of Public Health	4/10/03; 5/28/03
<b>Michael Young</b>	Senior Vice President, Health & Welfare Practice, Aon Consulting	6/12/03
<b>Jack Zwanziger</b>	Director, Health Policy and Administration Division, School of Public Health, University of Illinois	3/26/03

**APPENDIX B:  
PUBLIC COMMENTS**

**FTC WORKSHOP ON HEALTH CARE AND COMPETITION LAW AND POLICY  
SEPTEMBER 9-10, 2002**

**Primary Source:** <http://www.ftc.gov/os/comments/healthcarecomments/index.htm>.

NAME	TITLE OF COMMENT
<b>American Bar Association, Section of Antitrust Law</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding The Federal Trade Commission's Workshop on Health Care and Competition Law and Policy (Oct. 2002)</i></li> </ul>
<b>American College of Surgeons (ACS)</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding the Federal Trade Commission (FTC) Workshop on Health Care Competition Law and Policy (Sept. 30, 2002) [Submitted by Thomas R. Russell]</i></li> </ul>
<b>American Medical Association (AMA)</b>	<ul style="list-style-type: none"> <li>• <i>On Integration, Physician Joint Contracting, and Quality: Taking a Fresh Look at Some "Settled" Questions (Sept. 9, 2002) [Presentation by Catherine Hanson]</i></li> </ul>
Carolyn <b>Buppert</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Competition Law and Policy &amp; Health Care (Aug. 30, 2002)</i></li> </ul>
George H. <b>Koenig</b>	<ul style="list-style-type: none"> <li>• <i>Additional Testimony Subsequent to FTC Workshop on Health Care and Competition Law and Policy (Sept. 16, 2002)</i></li> </ul>
Robert F. <b>Leibenluft</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Competition Law and Policy &amp; Health Care (Sept. 30, 2002) [On Behalf of The Antitrust Coalition for Consumer Choice in Health Care (ACCC-HC)]</i></li> <li>• <i>Letter to Member of Congress (Apr. 12, 2002) (The Antitrust Coalition For Consumer Choice in Health Care)</i></li> <li>• <i>Competition in Health Insurance and Physician Markets: A Review of "Competition in Health Insurance: A Comprehensive Study of US Markets" By the American Medical Association (Apr. 2002) (Prepared by Charles River Associates)</i></li> <li>• <i>"Why Physician Cartels Do Not Need a "Fresh Look" – a Response to the AMA's Testimony at the FTC Health Care Competition Workshop</i></li> </ul>

<b>Magazine Publishers of America (MPA)</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Competition Law and Policy &amp; Health Care (Sept. 30, 2002) [Submitted by James R. Cregan]</i></li> </ul>
<b>Roy J. Meidinger</b>	<ul style="list-style-type: none"> <li>• <i>Health Industry: Great Intentions Gone Bad</i></li> </ul>
<b>Novation</b>	<ul style="list-style-type: none"> <li>• <i>Comment Regarding Competition Law and Policy &amp; Health Care (Sept. 30, 2002) [Submitted by Jody Hatcher]</i></li> </ul>
<b>Pfizer Inc.</b>	<ul style="list-style-type: none"> <li>• <i>Comments of Pfizer Inc. in Response to FDA Request for Comments on First Amendment Issues, Docket No. 02N-0209 (Sept. 13, 2002) [George W. Evans &amp; Arnold I. Friede]</i></li> </ul>
<b>Prairie Health Purchasing Alliance (PHPA)</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Competition Law and Policy &amp; Health Care (Sept. 27, 2002) [Submitted by Benjamin Vander Kooi, Jr.]</i></li> </ul>

<p><b>David L. Redfern</b></p>	<ul style="list-style-type: none"> <li>• <i>Competition in Health Care Workshop (Oct. 8, 2002)</i></li> <li>• <i>Attachment 1 - Woman's Clinic, Inc. v. St. John's Health System, Inc., Cause No. 01-3245-CV-S AE-ECF (Dec. 21, 2001) (First Amended Complaint)</i></li> <li>• <i>Attachment 2 - Compromise and Settlement Agreement Between Sisters of Mercy Health System, St. Louis, Inc. and State of Missouri</i></li> <li>• <i>Attachment 3 - Executive Council of Greene County Medical Society Memo (July 12, 2001); Letter from Rosary Payne, Division Counsel, American Medical Association (AMA) (Sept. 12, 2001); Sandy Z. Poneleit, Doctors' Departures Worry Medical Society, SPRINGFIELD NEWS-LEADER (July 24, 2001)</i></li> <li>• <i>Attachment 4 - Claudette Riley, Premiums Eat Up Teachers' Raises, SPRINGFIELD NEWS-LEADER (Sept. 6, 2001); Claudette Riley, Focus Put on School Health Benefits, SPRINGFIELD NEWS - LEADER (Sept. 14, 2001); Sandy Z. Poneleit, Companies' Health Care Costs Soar, SPRINGFIELD NEWS -LEADER (Feb. 15, 2002); Jack Wang, Health Insurance Premiums Will Skyrocket for Some State Employees, KY3 NEWS (Aug. 21, 2002); Cheryl Capages, Economic Survey Reveals Local Optimism, SPRINGFIELD BUS. J. 3 (Oct. 29 - Nov. 4, 2001); Commerce Bank, 2002 Economic Survey Results</i></li> <li>• <i>Attachment 5 - American Medical Association, Competition in Health Insurance: A Comprehensive Study of U.S. Markets. (Nov. 2001)</i></li> </ul>
<p><b>Washington Business Group on Health (WBGH)</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Competition Law and Policy &amp; Health Care (Sept. 30, 2002) [Submitted by Helen Darling]</i></li> </ul>

**FTC/DOJ HEARINGS ON HEALTH CARE AND COMPETITION LAW AND POLICY  
FEBRUARY TO SEPTEMBER 2003**

**Primary Source:** <http://www.ftc.gov/os/comments/healthcarecomments2/index.htm>.

NAME	TITLE OF COMMENT
<b>Academy of Managed Care Pharmacy (AMCP)</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding the June 26, 2003 Joint FTC-DOJ Hearings on Health Care and Competition Law and Policy (Pharmaceuticals: Formulary) (Aug. 5, 2003)</i></li> <li>• <i>Principles of a Sound Drug Formulary System (Oct. 2000)</i></li> <li>• <i>Where We Stand: Regulation of Pharmacy Benefit Management Companies (Approved by the AMCP Board of Directors Apr. 3, 2002)</i></li> <li>• <i>Where We Stand: Formularies (Revised by the AMCP Board of Directors Feb. 2003)</i></li> <li>• <i>Concepts in Managed Care Pharmacy: Formulary Management (June 1998)</i></li> </ul>
<b>American Academy of Pediatrics</b>	<ul style="list-style-type: none"> <li>• <i>Testimony Before the Federal Trade Commission on Health Care and Competition Law and Policy (Feb. 27, 2003) [Presented by Tim Doran]</i></li> </ul>
<b>American Association of Health Plans (AAHP)</b>	<ul style="list-style-type: none"> <li>• <i>Perspectives on Competition Policy and the Health Care Marketplace (Feb. 27, 2003) [Statement of Stephanie Kanwit]</i></li> <li>• <i>Additional Talking Points in Response to AHA's Study on Hospital Costs (Feb. 27, 2003) [Submitted by Stephanie Kanwit]</i></li> <li>• <i>The Myth of Health Plan Monopsony Power (Apr. 25, 2003) [Presentation by Stephanie Kanwit]</i></li> <li>• <i>The Myth of Health Plan Monopsony Power (Apr. 25, 2003) [Statement of Stephanie Kanwit]</i></li> <li>• <i>Toward A More Accountable Regulatory System (June 25, 2003) [Presentation by Karen Ignagni]</i></li> </ul>



<p><b>American Association of Nurse Anesthetists (AANA)</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Health Care and Competition Law and Policy (Nov. 20, 2003) [Submitted by Frank Purcell]</i></li> <li>• <i>Selected Literature on Anesthesia Markets, Quality Outcomes, and Responses to Anti-competitive Behaviors</i></li> <li>• <i>New Economic Perspectives on the Market for Anesthesia Services: Achieving Desired Reforms Through Fair Competition (Nov. 2003) [Presented by Jeffrey C. Bauer]</i></li> <li>• <i>John D. Klein, When Will Managed Care Come to Anesthesia?, 23 J. HEALTH CARE FIN. 62 (1997)</i></li> <li>• <i>Ira P. Gunn, Health Educational Costs, Provider Mix, and Healthcare Reform: A Case in Point - Nurse Anesthetists and Anesthesiologists, 64 J. AM. ASS'N OF NURSE ANESTHETISTS 48 (1996)</i></li> <li>• <i>Michael Pine et al., Surgical Mortality and Type of Anesthesia Provider, 71 AANA J. 109 (2003)</i></li> <li>• <i>Jeffrey H. Silber et al., Anesthesiologist Direction and Patient Outcomes, 93 ANESTHESIOLOGY 152 (2000)</i></li> <li>• <i>Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 66 Fed. Reg. 4,674 (2001)</i></li> <li>• <i>Quality of Care in Anesthesia (Oct. 23, 2003), at <a href="http://www.aana.com/crna/prof/quality_silber2.asp">http://www.aana.com/crna/prof/quality_silber2.asp</a></i></li> <li>• <i>Jerry Cromwell, Health Professions Substitution: A Case Study of Anesthesia, in THE U.S. HEALTH WORKFORCE: POWER, POLITICS, AND POLICY 219 (MARIAN OSTERWEIS ET AL. ed., 1996)</i></li> <li>• <i>Testimony of Jan Stewart On Behalf of the American Association of Nurse Anesthetists, Before the House Judiciary Committee (June 22, 1999)</i></li> <li>• <i>Quality of Care in Anesthesia: Synopsis of Published Information Comparing Certified Registered Nurse Anesthetist and Anesthesiologist Patient Outcomes (2002)</i></li> </ul>
<p><b>American Bar Association, Section of Antitrust Law</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments on the Public Hearings on Health Care and Competition Law and Policy (Dec. 18, 2003)</i></li> </ul>

<p><b>American Chiropractic Association (ACA)</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Health Care and Competition Law and Policy (Sept. 9, 2003) [Submitted by Daryl D. Wills &amp; James D. Edwards]</i></li> <li>• <i>Comments Regarding Health Care and Competition Law and Policy (Nov. 25, 2003) [Submitted by Donald J. Krippendorf &amp; George B. McClelland]</i></li> <li>• <i>Brief of Appellants, American Chiropractic Association, Inc. v. Trigon Health Care Inc. (4th Cir. 2003) (No. 03-1675) (Aug. 18, 2003)</i></li> </ul>
<p><b>American College of Nurse-Midwives</b></p>	<ul style="list-style-type: none"> <li>• <i>Addendum of Cases and Articles For Statement of Lynne Loeffler for the American College of Nurse-Midwives (July 25, 2003)</i></li> </ul>
<p><b>American Congress on Electroneuromyography</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Health Care and Competition Law and Policy (July 15, 2003)</i></li> </ul>
<p><b>American Health Planning Association (AHPA)</b></p>	<ul style="list-style-type: none"> <li>• <i>AHPA Testimony Support Information (June 10, 2003)</i></li> <li>• <i>Certificate of Need and Related Health Services Regulation, Representative Publications and Reports</i></li> <li>• <i>Health Service Volume and Treatment Outcome, Representative Published Studies</i></li> <li>• <i>Comparative Studies of For-Profit and Not-For-Profit Health Care Services, Representative Publications and Reports</i></li> <li>• <i>Thomas R. Piper, Certificate of Need: Protecting Consumer Interests</i></li> </ul>

<p><b>American Medical Association (AMA)</b></p>	<ul style="list-style-type: none"> <li>• <i>Health Care Competition Law and Policy – Quality and Consumer Information: Market Entry (June 10, 2003)</i></li> <li>• <i>Physician Information Sharing (Sept. 24, 2003)</i></li> <li>• <i>Physician IPAs: Patterns and Benefits of Integration, and Other Issues (Sept. 25, 2003)</i></li> <li>• <i>Physician IPAs: Messenger Model (Sept. 25, 2003) [Oral Statement of J. Edward Hill]</i></li> <li>• <i>Health Care Competition Law and Policy – Quality and Consumer Information: Physicians (May 30, 2003) [Presented by Nancy H. Nielsen]</i></li> <li>• <i>The Impact of Monopsony on the Practice of Medicine: Market Definition, Competitive Effects and Countervailing Power Theory and Practice (Apr.-May 2003) [Presented by Stephen E. Foreman]</i></li> </ul>
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<p><b>American Nurses Association</b></p>	<ul style="list-style-type: none"> <li>• <i>American Nurses Association, Testimony Before the Federal Trade Commission and Department of Justice on Perspectives on Competition Policy and the Health Care Marketplace (Feb. 27, 2003) [Presented by Winifred Carson-Smith]</i></li> <li>• <i>Attachment A - State Legislation Which Affects Nursing Practice (1999 Chart)</i></li> <li>• <i>Attachment B - Linda Pearson, Fifteenth Annual Legislative Update: How Each State Stands on Legislative Issues Affecting Advanced Nursing Practice, 28 THE NURSE PRACTITIONER 26 (2003)</i></li> <li>• <i>Attachment C - References to Advanced Practice Nurses As Primary Care Providers in State Statute (Feb. 2002)</i></li> <li>• <i>Attachment D - States Which Offer Nurse Privileging (2001 Chart)</i></li> <li>• <i>Attachment E - Joint Regulation of Advanced Nursing Practice (1992, revised 1997)</i></li> <li>• <i>Attachment F - Letter from Geri Marullo, Executive Director, American Nurses Association, to Dennis O'Leary, President, Joint Commission on the Accreditation of Healthcare Organizations (Mar. 17, 1995)</i></li> <li>• <i>Attachment G - Letter from Winifred Y. Carson, Nurse Practice Counsel, American Nurses Association, to David J. Rubben, Legal Counsel, Secretary, United Behavioral Health (July 21, 1997)</i></li> </ul>
<p><b>Jonathan Bates</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Health Care Competition Law and Policy (July 21, 2003)</i></li> </ul>
<p><b>Patricia Cameron</b></p>	<ul style="list-style-type: none"> <li>• <i>Personal Views</i></li> </ul>
<p><b>Dan Caldwell</b></p>	<ul style="list-style-type: none"> <li>• <i>Health Care Competition Law and Policy Hearings (Editorial submitted to Modern Healthcare weekly magazine) (June 5, 2003)</i></li> </ul>
<p><b>California Association of Physician Groups (CAPG)</b></p>	<ul style="list-style-type: none"> <li>• <i>Clarifying the Health Care Statements' Policies of Clinical Integration and Ancillarity (Mar. 2004)</i></li> </ul>

Sandy <b>Duffy</b>	<ul style="list-style-type: none"> <li>• <i>Testimony of Sandy Duffy, Before the Government Reform Committee, Wellness and Human Rights Subcommittee (May 8, 2003)</i></li> </ul>
Einer <b>Elhauge</b>	<ul style="list-style-type: none"> <li>• <i>Antitrust Analysis of GPO Exclusionary Agreements (Sept. 26, [2]003)</i></li> </ul>
Melissa M. <b>English</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Anti-Competition Practices (July 22, 2003)</i></li> </ul>
Michael <b>Greger</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Health Care and Competition Law and Policy: Specifically in Reference to the Practice of Unauthorized Pelvic Exams in Medical Training</i></li> </ul>
<b>Health Industry Group Purchasing Association (HIGPA)</b>	<ul style="list-style-type: none"> <li>• <i>Group Purchasing Organizations (Sept. 26, 2003) [Submitted by Robert Betz]</i></li> </ul>
Joe <b>Holzer</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Healthcare Competition Law &amp; Policy (July 10, 2003)</i></li> </ul>
<b>Independence Blue Cross</b>	<ul style="list-style-type: none"> <li>• <i>FTC/DOJ Hearings on Health Care and Competition Law and Policy (July 23, 2003) [Submitted by John A. Daddis]</i></li> </ul>
<b>Institute on Health Care Costs and Solutions</b>	<ul style="list-style-type: none"> <li>• <i>Transparency and Disclosure: The Route to Accountability, 2 ISSUEBRIEF 1 (Mar./Apr. 2003)</i></li> </ul>
James J. <b>Kane, Jr.</b>	<ul style="list-style-type: none"> <li>• <i>Health Care Competition Law and Policy Hearings (June 4, 2003)</i></li> </ul>
<b>Massachusetts Council of Community Hospitals (MCCH)</b>	<ul style="list-style-type: none"> <li>• <i>Comments (Apr. 3, 2003) [Submitted by Donald J. Thieme]</i></li> <li>• <i>Cape Ann Economics Report for MCCH (June 2001)</i></li> </ul>
Robert M. <b>McNair, Jr.</b>	<ul style="list-style-type: none"> <li>• <i>FTC/DOJ Hearings on Health Care and Competition Law and Policy (July 24, 2003)</i></li> </ul>
Woodrow A. <b>Myers</b>	<ul style="list-style-type: none"> <li>• <i>Quality and Consumer Information (May 29, 2003)</i></li> </ul>
<b>National Association of Clinical Nurse Specialists (NACNS)</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Health Care and Competition Law and Policy (Nov. 24, 2003)</i></li> </ul>

<b>National Board for Certification of Hospice and Palliative Nurses (NBCHPN)</b>	<ul style="list-style-type: none"> <li>• <i>NBCHPN Response to Hearings on Health Care and Competition Law and Policy Regarding Advanced Practice Registered Nurse Task Force of the National Council for State Boards of Nursing, Inc. (Sept. 30, 2003)</i></li> <li>• <i>Attachment A - Backgrounds and Qualifications of the Content Expert Panel for the Advanced Practice Palliative Care Certification Examination</i></li> <li>• <i>Attachment B - Fifth Iteration Draft of the Voluntary Consensus Standards for Quality Palliative Care</i></li> <li>• <i>Attachment C - Selected Provision of the Bylaws of NCSBN</i></li> </ul>
<b>National Council of State Boards of Nursing, Inc. (NCSBN)</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Health Care and Competition Law and Policy (July 31, 2003) [Submitted by Donna M. Dorsey]</i></li> <li>• <i>Comments Re: Letter from the National Board for Certification of Hospice and Palliative Nurses (Jan. 8, 2004) [Submitted by Donna M. Dorsey]</i></li> </ul>
<b>National Surgical Hospitals</b>	<ul style="list-style-type: none"> <li>• <i>Single Specialty Hospitals (Mar. 27, 2003)</i></li> </ul>
<b>National Women's Law Center (NWLC)</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Health Care and Competition Law and Policy (Nov. 25, 2003)</i></li> </ul>
<b>Noreen Farrell Nickolas</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Health Care and Competition Law and Policy (July 17, 2003)</i></li> </ul>
<b>NOVA Biomedical</b>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Health Care and Competition Law and Policy (Nov. 7, 2003) [Submitted by Howard Deahr]</i></li> </ul>
<b>Lynne Odell-Holzer</b>	<ul style="list-style-type: none"> <li>• <i>Comments: FTC/DOJ Hearings Regarding Anti-competitive Practices in Healthcare Industry</i></li> </ul>
<b>PacifiCare of California</b>	<ul style="list-style-type: none"> <li>• <i>Health Insurance Monopoly Issues – Competitive Effects (Apr. 23, 2003) [Statement of Fred Dodson]</i></li> </ul>
<b>Roger G. Pariseau, Jr.</b>	<ul style="list-style-type: none"> <li>• <i>Comments</i></li> </ul>
<b>Partners</b>	<ul style="list-style-type: none"> <li>• <i>Comments (Apr. 11, 2003) [Submitted by Brent L. Henry]</i></li> </ul>

<p><b>Elissa Schoenlank</b></p>	<ul style="list-style-type: none"> <li>• <i>Federal Trade Commission and U.S. Department of Justice Hearings on Health Care and Competition Law and Policy (Feb. 25, 2003)</i></li> <li>• <i>Exhibit A - BlueCross BlueShield of Utica - Watertown Comprehensive Coverage</i></li> <li>• <i>Exhibit B - Letter from Woods McCahill, Medical Director, Health Centers (Apr. 9, 2002)</i></li> <li>• <i>Exhibit C - Letter from Debra Mangino, Memorial Sloan-Kettering Cancer Center</i></li> <li>• <i>Exhibit D - Letter from Kitty Houghtalling, Customer Advocate Associate, BlueCross BlueShield, to Karl F. Glindmyer, Examiner, Consumer Service Bureau, State of New York Insurance Department (Sept. 3, 2002)</i></li> <li>• <i>Exhibit E - List of Account Services</i></li> </ul>
<p><b>Vincent Scicchitano</b></p>	<ul style="list-style-type: none"> <li>• <i>Contracting Practices (Mar. 27, 2003)</i></li> </ul>
<p><b>Service Employees International Union (SEIU)</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Health Care and Competition Law and Policy</i></li> </ul>
<p><b>Spectrum Health</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Health Care Competition Law and Policy (June 26, 2003) [Submitted by Michael Freed]</i></li> <li>• <i>Medicare Study Shows Best Care Isn't Always the Most Expensive, THE WALL STREET JOURNAL (Feb. 18, 2003)</i></li> <li>• <i>Spectrum Health, Defining Health Care Value (Sept. 2002)</i></li> </ul>
<p><b>Christine A. Sullivan</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Health Care Competition Law and Policy (Sept. 19, 2003)</i></li> </ul>
<p><b>Reed V. Tuckson</b></p>	<ul style="list-style-type: none"> <li>• <i>UnitedHealth Group Initiatives to Improve Quality, Safety and Consumer Decision Making (May 30, 2003)</i></li> </ul>
<p><b>Cathryn Wright</b></p>	<ul style="list-style-type: none"> <li>• <i>Comments Regarding Hearings on Health Care Competition Law and Policy (July 22, 2003)</i></li> </ul>

## APPENDIX C: GLOSSARY OF HEALTH CARE TERMS AND ACRONYMS

**Primary Sources:** The National Library of Medicine’s (NLM) controlled vocabulary database, Medical Subject Headings (MeSH), at <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=mesh>, and Peter R. Kongstvedt, *Glossary of Terms and Acronyms*, in *ESSENTIALS OF MANAGED HEALTH CARE* (Peter R. Kongstvedt ed., 4th ed. 2003).

TERM	DEFINITION
Allied Health Professional (AHP)	AHPs are individuals trained to support, complement, or supplement the professional functions of physicians, dentists, and other health professionals in the delivery of health care to patients. They include physician assistants, dental hygienists, medical technicians, nurse midwives, nurse practitioners, physical therapists, psychologists, and nurse anesthetists.
Ambulatory Care	Health care services provided to patients on an ambulatory basis, rather than by admission to a hospital or other health care facility. The services may provided at a hospital or a free-standing facility.
Ambulatory Payment Classification (APC)	This is the method used by CMS to implement prospective payment for ambulatory procedures. APC clusters many different ambulatory procedures into groups for purposes of payment.
Ambulatory Surgery Center (ASC)	Surgery performed on an outpatient basis, either hospital-based or performed in an office or surgicenter.
Any Willing Provider Laws	Any willing provider laws take many different forms, but they typically restrict the ability of managed-care organizations to use a closed panel of physicians, hospitals, or other providers.
Average Wholesale Price (AWP)	Average Wholesale Price of brand-name pharmaceuticals, as stated by the manufacturer, is used as a basis for determining discounts and rebates.
Capitation	Capitation pays the provider a fixed amount for each of the patients for whom he agrees to provide care, regardless of whether those patients seek care or not. Payment is typically based on a set number of dollars “per member-per month.”
Care Management Protocols (CMPs)	Care Management Protocols specify utilization and treatment standards for various diagnoses.
Certificate of Need (CON)	A certificate issued by a governmental body to an individual or organization proposing to construct or modify a health facility, or to offer a new or different service. The process of obtaining the certificate is included in the term.
Certification	Certification is a voluntary system of standards that practitioners can choose to meet to demonstrate accomplishment or ability in their profession. Certification standards are generally set by non-governmental agencies or associations.



Chronic Illness	Diseases which have one or more of the following characteristics: they are permanent, leave residual disability, are caused by nonreversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation, or care.
CMS	Centers for Medicare and Medicaid Services.
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1986.
Collective Bargaining	Collective bargaining refers to bargaining by union members, which is authorized by the NLRA, or non-unionized physicians' attempts to obtain the right to bargain collectively.
Computerized Physician Order Entry (CPOE)	Computer physician order entry (CPOE) is an electronic prescribing system. With CPOE, physicians enter orders into a computer rather than on paper. Orders are integrated with patient information, including laboratory and prescription data. The order is then automatically checked for potential errors or problems.
Coronary Artery Bypass Graft (CABG)	Surgical therapy of ischemic coronary artery disease, achieved by grafting a section of saphenous vein, internal mammary artery, or other substitute between the aorta and the obstructed coronary artery distal to the obstructive lesion.
Critical Loss Analysis	A two step analysis is used to perform a critical loss analysis. The first step identifies, for any given price increase, the amount of sales that can be lost before the price increase becomes unprofitable. The second step considers whether or not the actual level of sales lost due to the price increase will exceed this amount.
Diagnosis Related Group (DRG)	DRGs form the cornerstone of the prospective payment system. A DRG is a cluster of diagnoses that are expected to require comparable hospital resources and lengths of stay.
Durable Medical Equipment (DME)	Devices which are very resistant to wear and may be used over a long period of time. DME includes items such as wheelchairs, hospital beds, artificial limbs, etc.
EMTALA	Emergency Medical Treatment and Active Labor Act of 1986.
End-Stage Renal Disease (ESRD)	An irreversible and usually progressive reduction in renal function in which both kidneys have been damaged by a variety of diseases to the extent that they are unable to adequately remove the metabolic products from the blood and regulate the body's electrolyte composition and acid-base balance. Chronic kidney failure requires hemodialysis or kidney transplantation.
ERISA	Employee Retirement Income Security Act.
Fee-for-Service (FFS)	In FFS, a provider is paid based on the number and type of services that are performed.

Formulary	A list of approved drugs for treating various diseases and conditions.
Group Purchasing Organization (GPO)	A shared service which combines the purchasing power of individual organizations or facilities in order to obtain lower prices for equipment and supplies.
HIPAA	Health Insurance Portability and Accountability Act of 1996 .
Health Plan Employer Data and Information Set (HEDIS)	A set of standardized performance measures designed to ensure that purchasers and consumers have reliable information with which to compare the performance of MCOs.
Herfindahl-Hirschman Index (HHI)	The Herfindahl-Hirschman Index is a commonly accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. The HHI takes into account the relative size and distribution of the firms in a market. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases.
Independent Practice Association (IPA)	IPAs are networks of independent physicians that contract with MCOs and employers. IPAs may be organized as sole proprietorships, partnerships, or professional corporations.
Inpatient Prospective Payment System (IPPS)	Medicare’s payment system for inpatient hospitals and facilities. The specific amount that is paid is based on the DRG for the hospital admission.
Licensure	A mandatory system of state-imposed standards that practitioners must meet to practice a given profession.
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
Managed Care Organization (MCO)	MCOs integrate, to varying degrees, the financing and delivery of health care services.
Maximum Allowable Cost (MAC)	Maximum Allowable Cost, or Charge. The maximum that a vendor may charge for something. This term is often used in pharmaceutical contracting.
Medicare + Choice (M+C)	Also known as Medicare Part C. The Balanced Budget Act of 1997 (BBA) established the Medicare+Choice program. Under this program, an eligible individual may elect to receive Medicare benefits through enrollment in a Medicare+Choice plan, which generally takes the form of a MCO.
Medicare Advantage (MA)	As of 2003, the new name for Medicare+Choice (M+C).

Medicare Payment Advisory Commission (MedPAC)	The Commission was created by the BBA through a merger of the Prospective Payment Assessment Commission and the Physician Payment Review Commission. MedPAC reviews payment policies under Medicare Parts A and B and the effects of Medicare Part C. MedPAC also evaluates the effect of prospective payment policies and their impact on health care delivery in the US.
Medigap	A supplemental health insurance policy sold by private insurance companies that is designed to pay for health care costs and services that are not paid for by Medicare and any private health insurance benefits.
Metropolitan Statistical Areas (MSA)	Standard metropolitan statistical areas are defined by the U.S. Census so that institutions and individuals gathering statistics on urban areas can use a common definition.
Most Favored Nation (MFN)	A “Most Favored Nation” (MFN) clause is a contractual agreement between a supplier and a customer that requires the supplier to sell to the customer on pricing terms at least as favorable as the pricing terms on which that supplier sells to other customers. These clauses are sometimes found in the contracts health insurers enter into with providers.
Outpatient Prospective Payment System (OPPS)	Medicare’s system for payment to outpatient departments of hospitals and other outpatient facilities. The specific amount that is paid is determined by the relevant APC.
Patient Flow Data	Patient flow data identifies the zip code of each patient discharged from a hospital.
Payment for Performance (P4P)	Payment for Performance pays providers based on their success in meeting specific performance measures.
Pharmacy Benefit Manager (PBM)	A company under contract with managed care organizations, self-insured companies, and government programs to manage pharmacy network management, drug utilization review, outcomes management, and disease management.
Physician-Hospital Organization (PHO)	A PHO is a joint venture between a hospital and some or all of the physicians who have admitting privileges at the hospital.
Point of Service (POS)	A health insurance plan in which members do not have to choose how to receive services until they need them. The most common use of the term applies to a plan that enrolls each member in both an HMO (or HMO-like) system and an indemnity plan. These plans provide different benefits, depending on whether the member chooses to use plan providers or go outside the plan for services.
Preferred Provider Organization (PPO)	A health insurance plan with an established provider network (“preferred providers) that provides maximum benefits when members use a preferred provider.

Quality Improvement Organization (QIO)	Organizations that contract with CMS to review care provided to Medicare beneficiaries.
Resource-Based Relative Value Scale (RBRVS)	The RBRVS determines the rate at which Medicare reimburses physicians on an FFS basis. The RBRVS is calculated based on the cost of physician labor, practice overheads, materials, and liability insurance. The resulting figures are adjusted for geographical differences and are updated annually.
Single Specialty Hospital (SSH)	Specialized hospitals that provide treatment relating to a single specialty (e.g., cardiac or orthopedic services). Many of the physicians who refer patients to an SSH have an ownership interest in the facility.
State Action Doctrine	First articulated in <i>Parker v. Brown</i> , the state action doctrine shields certain anticompetitive conduct from federal antitrust scrutiny.
State Board of Medical Examiners	State Boards of Medical Examiners are typically responsible for licensure and promulgate regulations governing physicians and AHPs.
State Children’s Health Insurance Program (SCHIP)	Also referred to as Children’s Health Insurance Program (CHIP). A program created by the federal government to encourage states to provide insurance coverage for children. SCHIP is funded through a combination of federal and state funds, and administered by the states in conformity with federal requirements.
Telemedicine	Telemedicine involves the use of electronic communication and information technologies to provide or support clinical care at a distance.
Third-Party Administrator (TPA)	A firm that performs administrative functions (e.g., claims processing, membership) for a self-funded plan or a start-up MCO.
Utilization Review	An organized procedure carried out through committees to review admissions, duration of stay, professional services furnished, and to evaluate the medical necessity of those services and promote their most efficient use.

**APPENDIX D:  
SELECTED FEDERAL STATUTES**

**Federal Trade Commission Act**

15 U.S.C. § 45(a)  
15 U.S.C. § 46(f)

**Sherman Act**

15 U.S.C. § 1  
15 U.S.C. § 2  
15 U.S.C. § 3

**Clayton Act**

15 U.S.C. § 18

## **Federal Trade Commission Act**

### **15 U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission**

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade.

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 18(f)(3) [15 USCS § 57a(f)(3)], Federal credit unions described in section 18(f)(4) [15 USCS § 57a(f)(4)], common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to the Federal Aviation Act of 1958 [49 USCS §§ 40101 et seq.], and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 USCS §§ 181 et seq.], except as provided in section 406(b) of said Act [7 USCS § 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless--

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect--

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States . . . .

### **15 U.S.C. § 46(f). Publication of information; reports.**

To make public from time to time such portions of the information obtained by it hereunder as are in the public interest; and to make annual and special reports to the Congress and to submit therewith recommendations for additional legislation; and to provide for the publication of its reports and decisions in such form and manner as may be best adapted for public information and use: Provided, That the Commission shall not have any authority to make public any trade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential, except that the Commission may disclose such information to officers and employees of appropriate Federal law enforcement agencies or to any officer or employee of any State law enforcement agency upon the prior certification of an officer of any such Federal or State law enforcement agency that such information will be maintained in confidence and will be used only for official law enforcement purposes.

## **Sherman Act**

### **15 U.S.C. § 1. Trusts, etc., in restraint of trade illegal; penalty**

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$10,000,000 if a corporation, or, if any other person, \$350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

### **15 U.S.C. § 2. Monopolization; penalty**

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$10,000,000 if a corporation, or, if any other person, \$350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

### **15 U.S.C. § 3. Trusts in Territories or District of Columbia illegal; combination a felony**

(a) Every contract, combination in form of trust or otherwise, or conspiracy, in restraint of trade or commerce in any Territory of the United States or of the District of Columbia, or in restraint of trade or commerce between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia and any State or States or foreign nations, is declared illegal. Every person who shall make any such contract or engage in any such combination or conspiracy, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$10,000,000 if a corporation, or, if any other person, \$350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

(b) Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce in any Territory of the United States or of the District of Columbia, or between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia, and any State or States or foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$10,000,000 if a corporation, or, if any other person, \$ 350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

## Clayton Act

### **15 U.S.C. § 18. Acquisition by one corporation of stock of another**

No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

No person shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of one or more persons engaged in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition, of such stocks or assets, or of the use of such stock by the voting or granting of proxies or otherwise, may be substantially to lessen competition, or to tend to create a monopoly.

This section shall not apply to persons purchasing such stock solely for investment and not using the same by voting or otherwise to bring about, or in attempting to bring about, the substantial lessening of competition. Nor shall anything contained in this section prevent a corporation engaged in commerce or in any activity affecting commerce from causing the formation of subsidiary corporations for the actual carrying on of their immediate lawful business, or the natural and legitimate branches or extensions thereof, or from owning and holding all or a part of the stock of such subsidiary corporations, when the effect of such formation is not to substantially lessen competition.

Nor shall anything herein contained be construed to prohibit any common carrier subject to the laws to regulate commerce from aiding in the construction of branches or short lines so located as to become feeders to the main line of the company so aiding in such construction or from acquiring or owning all or any part of the stock of such branch lines, nor to prevent any such common carrier from acquiring and owning all or any part of the stock of a branch or short line constructed by an independent company where there is no substantial competition between the company owning the branch line so constructed and the company owning the main line acquiring the property or an interest therein, nor to prevent such common carrier from extending any of its lines through the medium of the acquisition of stock or otherwise of any other common carrier where there is no substantial competition between the company extending its lines and the company whose stock, property, or an interest therein is so acquired.

Nothing contained in this section shall be held to affect or impair any right heretofore legally acquired: Provided, That nothing in this section shall be held or construed to authorize or make lawful anything heretofore prohibited or made illegal by the antitrust laws, nor to exempt any person from the penal provisions thereof or the civil remedies therein provided.

Nothing contained in this section shall apply to transactions duly consummated pursuant to authority given by the Secretary of Transportation, Federal Power Commission, Surface Transportation Board, the Securities and Exchange Commission in the exercise of its jurisdiction under section 10 of the Public Utility Holding Company Act of 1935 [15 USCS § 79j], the United States Maritime Commission, or the Secretary of Agriculture under any statutory provision vesting such power in such Commission, Board, or Secretary.





**Department of Justice  
Antitrust Division  
202-307-0001  
[www.usdoj.gov/atr](http://www.usdoj.gov/atr)**



**Federal Trade Commission  
For the Consumer  
1-877-FTC-HELP  
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