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Assembled Products: The Key to More Effective Competition and Antitrust Oversight in Health Care

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ASSEMBLED PRODUCTS: THE KEY TO MORE EFFECTIVE COMPETITION AND ANTITRUST OVERSIGHT IN HEALTH CARE

William M. Sage†

This Article argues that recent calls for antitrust enforcement to protect health insurers from hospital and physician consolidation are incomplete. The principal obstacle to effective competition in health care is not that one or the other party has too much bargaining power, but that they have been buying and selling the wrong things. Vigorous antitrust enforcement will benefit health care consumers only if it accounts for the competitive distortions caused by the sector's long history of government regulation. Because of regulation, what pass for products in health care are typically small process steps and isolated components that can be assigned a billing code. even if they do little to help patients. Instead of further entrenching weakly competitive parties engaged in artificial commerce, antitrust enforcers and regulators should work together to promote the sale of fully assembled products and services that can be warranted to consumers for performance and safety. As better products emerge through innovation and market entry, competition may finally succeed at lowering medical costs, increasing access to treatment, and improving quality of care.

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INTRODUCTION: THE CHALLENGE OF COMPETITION IN HEALTH CARE

Six years after the passage of the Patient Protection and Affordable Care Act of 2010 (ACA), what has been mainly ideological opposition to "Obamacare" is acquiring a more operational character. Critics are being forced to define more specifically the reasons for their discontent and to formulate modifications short of repeal. Thus far, the health reform debate has focused primarily on coverage mandates and associated subsidies for the poor and uninsurable. As will become apparent, however, the big issue in American health care is not redistribution. The big issue is inefficiency.

As conservatives re-engage the health reform debate, their asserted belief in the power of market forces cannot sidestep a simple question: Why does the ostensibly competitive U.S. health care system cost so much and deliver so little? In other sectors of the economy, the United States celebrates, relies on, and legally protects market competition.³ Health care in this country is similarly dominated by private, revenue-seeking activity.⁴ Yet the outcomes of competition in health care significantly lag performance in other industries.⁵

Is competition anemic in health care because legal oversight is lax? 6 Is not enough attention paid to monopoly and

¹ See David Lawder, Senate Republicans Pass Budget Plan, Eye Obamacare Repeal, Reuters (May 5, 2015), http://www.reuters.com/article/2015/05/06/us-usa-budget-idUSKBNONQ2DD20150506 [http://perma.cc/5U9X=GLTP] (noting that while President Obama will certainly veto any repeal of the ACA, the possibility of negotiating changes thereto remains open); Heidi Przybyla, Senate Budget Allows Republicans to Seek Obamacare Repeal, Bloomberg Bus. (May 5, 2015), http://www.bloomberg.com/news/articles/2015-05-05/senate-adopts-budget-that-lets-republicans-seek-obamacare-repeal [http://perma.cc/M6UU-EUXG] (stating that the chances of outright appeal of the ACA are slim).

² See Gail R. Wilensky, The Shortfalls of "Obamacare," 367 New Eng. J. Medicine 1479, 1479 (2012); Przybyla supra note 1.

³ See, e.g., FED. TRADE COMM'N, CASES AND PROCEEDINGS, https://www.ftc.gov/enforcement/cases-proceedings [https://perma.cc/76L6-GPDM] (detailing various cross-sector enforcement actions brought by the FTC with the goal of protecting market competition).

⁴ See Carl F. Ameringer, The Health Care Revolution: From Medical Monopoly to Market Competition 135–36 (2006) (discussing the FTC's removal of barriers to competition in the health care space and the dominance of the private market).

⁵ See id. (discussing industry-specific struggles that the FTC faced).

⁶ Legal oversight of competition is accomplished primarily through antitrust law. Federal antitrust law consists of a small number of statutes that authorize the U.S. Department of Justice and the FTC, as well as private litigants, to seek sanctions against parties engaging in anticompetitive practices. *See* Sherman Act of 1890, 15 U.S.C. §§ 1–7 (2012); Clayton Antitrust Act of 1914, 15 U.S.C. §§ 12–27, 29 U.S.C. 52–53 (2012); Federal Trade Commission Act of 1914, 15 U.S.C. §§ 41–58 (2012). Antitrust law generally develops from judicial interpreta-

oligopoly? Are cartels less effectively detected and deterred? Do more subtle collusive behaviors among health care providers, insurers, and suppliers harm consumers but not provoke a legal response? Or are there other explanations for the failure of competition in health care to deliver the best possible products at the lowest possible price?

These questions are coming to the fore as implementation of the ACA continues, leading more health care organizations to consolidate and coordinate their activities.⁷ For the first time since the 1990s, policymakers face critical decisions about the focus and intensity of federal antitrust enforcement activities.⁸

This Article proposes a competition policy for American health care that not only is consistent with generally applicable antitrust law but also works together with regulatory reform to improve market outcomes for health care consumers. Such a policy must be more than a political and legal settlement between collectivist and free-market ideologies for control of the U.S. health care system. It must revisit basic questions about who competes in health care, what they compete to provide, and how that competition can be vigorous and successful. The stakes are considerable. The United States devotes nearly one-sixth of its economy to health care, or crowding out other productive activities and denying Americans those benefits as both consumers and citizens.

The Article suggests a new explanation for why the American health care system is only weakly competitive and offers guidance to the federal antitrust agencies, health care regulators, and the courts regarding a more effective competition policy as health reform proceeds. In addition to consolidation, previous analyses have emphasized lack of consumer information, moral hazard from insurance, and the need for treatment

tion of these statutes, the enforcement decisions of the two federal agencies, and guidance documents that the agencies release from time to time. States have similar laws, often enforced by state attorneys general.

 $^{^7~}$ See Erin C. Fuse Brown, Irrational Hospital Pricing, 14 Hous. J. Health L. & Pol'y 11, 28 (2014) (discussing the consolidation of the health care industry as a response to the ACA).

⁸ See, e.g., ROBERT A. BERENSON & RACHEL A. BURTON, HEALTH POLICY BRIEF: NEXT STEPS FOR ACOS 1, 5 (2012) (discussing the controversy regarding modifications to the antitrust enforcement regime for accountable care organizations, or ACOs).

⁹ CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES 2013 HIGHLIGHTS (2013), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf [http://perma.cc/95DF-4SH9].

among those without the ability to pay for it. Some of these factors are cited by supporters of single-payer systems and other forms of national health insurance, while critics of such "socialized medicine" argue that government failure from supplanting the market would be worse than market failure is today.

Instead, this Article posits that prices for health care are too high, quality too unreliable, and innovation too limited in large part because we have been buying and selling the wrong things. In other complex economic sectors, consumers purchase assembled products from which they expect concrete, demonstrable benefits. Producers aggressively manage their supply chains, product performance can be measured, and products can be warranted for safety and effectiveness. In health care, by contrast, most consumers purchase only isolated process steps and components.10 Physicians strive to deliver reimbursable relative value units (RVUs),11 not definitive treatment packages. Hospitals coproduce care in vague collaboration with physicians and often have limited leverage over expensive inputs such as medical devices. 12 This causes the health care we receive to be shoddily put together, overly costly to produce, insufficiently responsive to consumers' needs, and difficult to monitor for quality.

Why did assembled health care products not develop naturally as an outgrowth of competition? Presumably, it is not because consumers of health care prefer confusion, unaccountability, or waste. Rather, it is because government policies, not free enterprise, have made the principal revenue-seeking actors in the U.S. health care system look and act the way they do. 13 Put differently, many health care transactions are socially constructed rather than market-driven, which creates the illusion of competition but not the reality.

The American health care system is rife with laws that shape the competitive terrain, largely dictating how competition occurs, which parties it involves, what dimensions it em-

¹⁰ See Gail R. Wilensky, *Developing a Viable Alternative to Medicare's Physician Payment Strategy*, 33 HEALTH AFF. 153, 154–55 (2014) (discussing the division of health care services into discrete units of service).

 $^{^{11}}$ See id. at 155 (reviewing history of Medicare physician payment based on relative value units).

¹² See Nathan Cortez, Regulating Disruptive Innovation, 29 Berkeley Tech. L.J. 175, 225–26 (2014) (discussing the FDA's gatekeeping power with respect to new medical devices).

¹³ ROBERT I. FIELD, MOTHER OF INVENTION: HOW THE GOVERNMENT CREATED FREE-MARKET HEALTH CARE 24 (2014) (discussing the crucial role of public initiatives in contemporary private health care).

phasizes, and whether it succeeds or fails in generating economic benefits for consumers. Many laws are of such longstanding duration that they have become deeply ingrained in industry culture and practice. The cumulative effects of this regulatory history are to define products based on professional traditions rather than demonstrated utility and to render many prices arbitrary, particularly for hospital services.

Regulation influences not only static characteristics of health care markets but also their dynamic potential—the forms innovation takes and the processes by which it occurs. Nearly all industries take pride in making their products and services less expensive, more convenient, and more reliable. The health care system has downplayed these consensus goals of innovation. It generates new "stuff" in abundance, particularly patentable technologies with specialized uses, regardless of cost, convenience, or certainty of benefit. It devotes far less attention to process reengineering, supply chain management, and other ways to improve productive efficiency and satisfy consumer preferences. For a more optimistic view of the future, see James C. Robinson, *Biomedical Innovation in the Era of Health Care Spending Constraints*, 34 Health Aff. 203, 203 (2015) (arguing that the era of "cost-unconscious" innovation described above is over and health care innovation is now likely to become more efficient while focusing on "design, pricing, and distribution principles").

Although antitrust law polices private conduct that impedes competition, it yields readily to other laws, whether federal or state, intended to regulate economic activity on a less competitive basis. See Matthew McDonald, Antitrust Immunity Up In Smoke: Preemption, State Action, and the Master Settlement Agreement, 113 COLUM. L. REV. 97, 97–98 (2013) (discussing states' regulatory actions that would otherwise result in violations of the federal antitrust laws). However, the regulatory environment is not a defense to private anticompetitive conduct under the antitrust laws unless Congress impliedly repeals those laws or states adopt structured alternatives to competition that qualify for "state action" immunity. The Supreme Court recently issued proenforcement rulings in three cases brought by the FTC that involved regulated entities: the acquisition by a public hospital of its principal competitor, FTC v. Phoebe Putney Health Systems, 133 S. Ct. 1003 (2013) (public authority to acquire hospitals did not create state action immunity), a "reverse payment settlement" in which the plaintiff paid the defendant to resolve an infringement suit involving a generic challenger to a patented drug, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (reverse payment settlements subject to antitrust scrutiny under the rule of reason), and a campaign by a state dental board to threaten nondentist teeth whitening businesses and their landlords with criminal prosecution, North Carolina State Board of Dental Examiners v. FTC, 135 S. Ct. 1101 (2015) (licensing board controlled by members of the regulated profession must be actively supervised by the state itself to claim antitrust immunity).

¹⁶ See Steven Brill, Bitter Pill: How Outrageous Pricing and Egregious Profits Are Destroying Our Healthcare, TIME, Mar. 4, 2013, at 24–26 (criticizing the exorbitant cost of hospital services). Similar forces are at play in countries with socialized health care systems, but constraints on medical spending are stronger, so that the competitive distortions they produce are smaller. See Jonathan Oberlander & Joseph White, Public Attitudes Toward Health Care Spending Aren't the Problem; Prices Are, 28 HEALTH AFF. 1285, 1285 (2015) (discussing the United States' high medical spending compared to nations with greater constraints on spending).

Rather than argue against medical markets, the Article calls on competition policymakers to rethink the product as they carry out their legally mandated functions. No matter how aggressively antitrust law is enforced, it remains a weak tool for improving consumer welfare in health care if many prices, nonprice attributes, and choices relate mainly to faux products. Better outcomes are possible only if the antitrust authorities demand greater competition to deliver fully assembled products that have measurable value to consumers, and if those authorities work closely with legislators and regulators to remake the laws that hinder such products from developing on their own.

Some competition policy is already moving in this direction as the health care industry restructures in response to existing pressures on its financial model and to the likely direction of health care reform. 17 But much is not. In particular, fear of higher provider prices following consolidation has led the federal antitrust enforcement agencies to bring a new series of challenges to hospital mergers and acquisitions. 18 The evaluation under antitrust law of consumer harm from consolidation and restructuring should be a forward-looking inquiry, particularly in health care where prevailing market conditions do not reflect a private competitive equilibrium and where regulatory developments continually change the dimensions and dynamics of competition. Yet much of the agencies' skepticism of consolidation assumes the continuation of regulatory policies that are clearly obsolete.

¹⁷ See Martin Gaynor & Robert Town, Robert Wood Johnson Found., The Impact of Hospital Consolidation—Update 2 (2012) (noting the more aggressive stance of the FTC in recent years as the health care industry restructures).

See id. at 1-2. In 2015, a series of high-profile mergers were announced among health insurers. See Robert Laszewski, Health Insurer Merger Mania-Muscle-Bound Competitors and a New Cold War in Health Care, FORBES (July 27, 2015, 2:55 PM), http://www.forbes.com/sites/robertlaszewski2/2015/07/27/ health-insurer-merger-mania-muscle-bound-competitors-and-a-new-cold-warin-health-care/ [https://perma.cc/7HKZ-ZCQS] (discussing possible motives and effects of insurer consolidation). There are several possible motives for sudden consolidation among insurers, including economies of scale, countervailing bargaining power against large hospital systems, and maintaining dominance in local markets. In addition, consolidated insurers would be "too big to fail," and would be in a position of particular advantage when doing business with the federal government in Medicare managed care (so-called Medicare Advantage plans) and in the ACA's health insurance exchanges. The consolidation of health insurers today therefore is reminiscent of defense contractors following the end of the Cold War. See, e.g., Lawrence J. Korb, Merger Mania: Should the Government Pay for Defense Industry Restructuring?, BROOKINGS INST. (1996), http:// www.brookings.edu/research/articles/1996/06/summer-defenseindustry-korb [http://perma.cc/4Y7J-TUKN].

This does not mean that the current wave of health care provider consolidation is necessarily benign, or that antitrust enforcers should lighten their hand. ¹⁹ It does imply, however, that the antitrust agencies should work closely with federal and state regulators as the ACA is implemented to refine predictive tools, reduce barriers to entry and innovation, and orient both regulatory and enforcement activities explicitly to desired outcomes.

This approach to market oversight would consciously identify and promote specific dimensions and dynamics of competition that have been less than vigorous in the past, such as the characteristics of health care products, rather than assuming that those practices reflect consumer preferences. Instead of refighting the last war over managed care, which emphasized contract negotiations between health insurers and large health care providers, competition policymakers would urge the health care establishment to redefine and improve the products it sells. They would also protect emerging subsectors of the health care system that might generate more meaningful products from appropriation by entrenched provider, insurer, or supplier interests.

Part I of the Article explains why the nature of the product is a critical but previously unrecognized determinant of health care competition, tracing its origins to a legal and regulatory regime that has long distorted and constrained medical markets. Part II describes recent experience with managed care and hospital mergers and demonstrates the perils of making assumptions about health care antitrust enforcement as the regulatory environment changes. Part III identifies aspects of antitrust analysis that bear directly on product improvement, makes enforcement recommendations regarding case selection and evaluation, and proposes a set of priorities that antitrust

¹⁹ See GAYNOR & TOWN, supra note 17, at 6 (summarizing further changes in the structure of the health care market and the policy effect of the FTC's aggressive response to consolidation); WILLIAM B. VOGT & ROBERT TOWN, ROBERT WOOD JOHNSON FOUND., HOW HAS HOSPITAL CONSOLIDATION AFFECTED THE PRICE AND QUALITY OF HOSPITAL CARE? 11-12 (2006) (outlining the changes in hospital structure and quality of care brought about by consolidation and potential policy shifts in reaction thereto); Daniel P. Kessler & Mark B. McClellan, Is Hospital Competition Socially Wasteful?, 115 Q.J. ECON. 577, 577 (2000) (concluding that, in the 1980s, the welfare effects of competition were ambiguous; in the 1990s, however, competition improved social welfare); Daniel P. Kessler & Jeffrey J. Geppert, The Effects of Competition on Variation in the Quality and Cost of Medical Care 3-4 (Nat'l Bureau of Econ. Research, Working Paper No. 11226, 2005) (analyzing the effects of hospital competition on the level of and the variation in quality of care and hospital expenditures for elderly Medicare beneficiaries suffering heart attacks); see also infra text accompanying notes 366-77.

enforcers and health care regulators should pursue jointly to induce commerce in more meaningful products.

I
THE HIDDEN PROBLEM: UNASSEMBLED PRODUCTS

Vigorous demand for health care, meaning both willingness and ability to pay for it in private marketplaces, should create strong incentives for capable supply: high output, competitive prices, quality, choice, and innovation. This has not happened. After decades of rhetoric unsupported by data, the United States has finally begun to acknowledge that its health care system is not superior to other countries'.²⁰ The overall quality of care we provide is average, and it is plagued by shameful amounts of error, inattention, and waste.²¹ Our clinical technologies remain marvels, but we deploy them with appalling mediocrity. In the aggregate, nearly \$1 trillion of the over \$3 trillion invested annually on American health care may be misspent.²²

American health care innovation, itself an important competitive outcome, has neglected improvements in the organization of care delivery and the achievement of verifiable health outcomes at both the individual and population levels.²³ Instead, it has mainly served to proliferate diagnostic and therapeutic technologies that are improperly used in many instances.²⁴ Antitrust enforcers assert a desire to promote innovation through competition, but the most important innovations in health care delivery will focus on better ways to incorporate technology into processes of care, not just technology for its own sake.

A. Unassembled Products and the Hegemony of U.S. Physicians

In his Pulitzer prize-winning 1982 book, sociologist Paul Starr catalogued the 150-year transformation of American medicine into the powerful economic and scientific engine it is

See generally SHERRY GLIED, CHRONIC CONDITION: WHY HEALTH REFORM FAILS 1–2 (1997) (discussing public opinion supporting a need for drastic reform to the U.S. health care system).

 $^{^{21}\,}$ Inst. of Med., Best Care at Lower Cost: The Path to Continuously Learning Health Care in America 101–02 (Mark Smith et al. eds., 2012) (discussing the costs of the U.S. health care system's current inefficiency and the need for a system-wide transformation).

²² Id.

²³ See id.

²⁴ See id.

today.²⁵ At the heart of his analysis was the American medical profession, which he portrayed as the fixed point of control on which "revolutionary" change in health care ultimately turned.²⁶ Although several massive industries have grown alongside the medical profession, competitive models of health care delivery still rely heavily on physician direction, as do proposals for new organizational forms such as the Accountable Care Organization (ACO) and the "patient-centered medical home" (PCMH).²⁷

In keeping with this core assumption, antitrust law has been solicitous of good-faith efforts by physicians to improve care or reduce costs and has been deferential to the methods they choose to accomplish those goals.²⁸ When physicians stray beyond even these generous boundaries, moreover, antitrust enforcers often have been satisfied merely to exact a promise to behave better in the future.²⁹ Contrary to the general preference in antitrust law for structural rather than conduct remedies for proven anticompetitive activities,³⁰ the enforcement agencies and the courts have only rarely attempted to influence how health care organizations that include physicians should be organized, or how unconcentrated markets for physician services should remain.³¹

To a surprising degree, even highly sophisticated medical services are still conceptualized as extensions of an individual doctor's traditional black bag and prescription pad. There was a time, increasingly remote from the present day, when diagnosis, prognosis, and treatment were solo tasks using handheld

²⁵ See Paul Starr, The Social Transformation of American Medicine (1982) (discussing the social history of the medical profession in America).

²⁶ See id. at 17–20.

A patient-centered medical home (PCMH) is a primary care model that offers coordinated, accessible care that is focused on quality and safety. *Patient-Centered Medical Home Recognition*, NCQA, http://www.ncqa.org/Programs/Recognition/Practices/PatientCenteredMedicalHomePCMH.aspx [http://perma.cc/6YUV-RX24].

Antitrust law was rarely engaged with medicine until the 1970s. *See* Carl F. Ameringer, The Health Care Revolution: From Medical Monopoly to Market Competition 136–37 (2008) (discussing key events that led to the United States' market-based health system); *see infra* text accompanying notes 335–40 (discussing clinical integration).

²⁹ Thomas L. Greaney, *The Tangled Web: Integration, Exclusivity and Market Power in Provider Contracting*, 14 HOUS. J. HEALTH L. & POL'Y 59, 88–90 (2014).

³⁰ See Deborah Platt Majoras, Deputy Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, Antitrust Remedies in the United States: Adhering to Sound Principles in a Multi-Faceted Scheme (Oct. 4, 2002), http://www.justice.gov/atr/public/speeches/200354.htm [https://perma.cc/YHL6-6TJ7].

³¹ Greaney, *supra* note 29, at 70 (discussing the failure of enforcement agencies and the courts to influence hospital organizational structure).

equipment. Recommended medication was conveyed directly from physician to patient with instructions for administration. Transfer of care from one physician to another was complete when it occurred, albeit with transfer back to the original physician in most cases involving general practitioners and specialists.

The only aspect of this paradigm that remains similar today is the strength of the therapeutic bond between a patient and the individual that patient perceives as his or her expert caregiver. Chemical complexity of therapeutic agents was largely solved within the conventional framework by having physicians write prescriptions to be filled by pharmacies for substances developed by pharmaceutical manufacturers. But nearly everything else modern medicine offers, beginning with surgical treatment, requires the coordinated participation of many individuals with different skills and training in one or more settings with advanced physical plants, fixed technologies, consumable supplies, and information resources.

What is bought and sold in health care markets has not kept pace with these technical advances. In other industries, complex products are sold as assembled units that consumers understand, that function as advertised, and that can be compared to one another. They are constructed by the manufacturer and typically are offered with some form of warranty for performance as intended. By contrast, health care emphasizes incomplete process steps and isolated components rather than assembled products. Each physician not only performs personal tasks and prescribes medication but also "orders" goods and services from diagnostic tests to hospitalization, all of which are provided by others. The same physician also "refers" patients for consultation by additional physicians and other health professionals. Many of these consultants behave similarly. Coordination among physicians caring for a particular patient tends also to be unstructured, governed more by professional conventions than by industrial principles.

Consequently, although the fees that physicians earn amount only to about 15% of annual health care expenditures in the United States, an additional 50% or so is initiated and channeled by physicians through their ordering and referral behavior.³² Among other things, this telling statistic explains

³² Health policy experts generally put this number at between 2/3 and 3/4 of health care spending. *Cf.* Louis Goodman & Timothy Norbeck, *Who's to Blame for Our Rising Healthcare Costs?*, FORBES (Apr. 3, 2013, 9:31 AM), http://www.forbes.com/sites/realspin/2013/04/03/whos-to-blame-for-our-rising-

the proliferation of fraud and abuse laws. The federal government, which administers Medicare and Medicaid, has enacted sweeping prohibitions on the payment of remuneration to physicians in exchange for orders or referrals, and on "self-referral" to entities in which the physician has a financial interest.³³ These laws envision physicians as expert, unbiased purchasing agents for individual inputs, rather than as key personnel in organized systems of care. Exceptions to fraud laws have been created to accommodate situations in which physician organizations offer integrated products, but these provisions are often unrealistically prescriptive because product assembly remains so atypical.³⁴

Such a fragmented model of health care services bodes poorly for competition: price, quality, choice, and even innovation mean little if the product is incoherent. The absurdity of selling unassembled health care products has been parodied in print and on YouTube.³⁵ Among market participants, recognition of excessive fragmentation has rekindled interest in integrated systems such as Kaiser-Permanente and the Geisinger Health System and has motivated private and public insurers to experiment with payment for "bundled, episodic care" delivered to patients with both acute and chronic illnesses.³⁶ In early 2015, the Secretary of Health and Human Services announced an ambitious goal of tying 90% of Medicare payments to quality or value by 2018, with 50% governed by payment arrangements other than fee-for-service.³⁷ It has also been

healthcare-costs/ [https://perma.cc/5Q9T-E4SK] (citing 80% as a "frequently used number" for the percentage of health care costs that is directed by physicians).

³³ TERRY S. COLEMAN, MEDICARE LAW 294–99 (2d ed. 2006) (discussing the self-referral system in Medicare).

³⁴ See, e.g., Jennifer Staman, Cong. Research Serv., RS22743, Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview, 7–8 (2013) (criticizing in-office exceptions to fraud law); see also James F. Blumstein, The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy, 22 Am. J.L. & Med. 205 (1996) (pointing out that fraud and abuse laws frequently penalize efficiency).

Jonathan Rauch, If Air Travel Worked Like Health Care, NAT'L J. (Sept. 25, 2009) (parodying health care system inefficiency); TheNewAltons, If Air Travel Were Like Health Care, YouTube (Jan. 4, 2010), https://www.youtube.com/watch?v=5J67xJKpB6c [http://perma.cc/B4KC-FKZU].

³⁶ M. Susan Ridgely et al., *Bundled Payment Fails to Gain a Foothold in California: The Experience of the IHA Bundled Payment Demonstration*, 33 HEALTH AFF. 1345, 1352 (2014) (discussing California's bundled care initiative).

³⁷ Press Release, U.S. Dep't of Health & Human Servs., Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value (Jan. 26, 2015), http://www.hhs.gov/news/press/2015pres/01/20150126a.html [https://perma.cc/6B8E-5KYV].

noted by management theorists. In his work on redesigning primary care, for example, Harvard business professor Michael Porter divides patients into subgroups for whom the core product, not just its nominal price or general quality, differs based on its value to that subgroup.³⁸

Lack of product assembly has not, however, been incorporated into health care antitrust analysis or competition policy more generally.³⁹ It is true that professional services are less likely to follow an assembly model, not only because of regulatory protectionism but also because—unlike physicians—professionals such as lawyers and accountants still sell mainly their personal time and effort. Even these professions, however, tend to assemble their expertise, information resources, and professional processes into units, which has opened them up to competition from online, do-it-yourself companies such as LegalZoom and TurboTax.⁴⁰ Medical markets lag rather than lead with respect to such developments,⁴¹ notwithstanding the fact that health care is both more industrialized and more expensive than other professional domains.

B. Regulatory Determinants of Faux Products

Why do medical markets systematically conflate process steps, components, and inputs with products? Health economist Sherry Glied distinguishes between traditional "medicalist" models of health care services and more recent "marketist" models.⁴² Whereas classic economics regards the tradeoffs between cost and quality that individuals make in market transactions as worthy of respect, "medicalists" reject market preferences as a basis for health care decisions.⁴³ Instead,

Michael E. Porter et al., Redesigning Primary Care: A Strategic Vision to Improve Value by Organizing Around Patients' Needs, 32 Health Aff. 516, 525 (2013) (offering a framework to address primary care's lack of infrastructure and inability to attract new physicians); see generally Michael E. Porter & Elizabeth Olmsted Teisberg, Redefining Health Care: Creating Value-Based Competition on Results 97–98, 200–02 (2006) (reframing health care around integrated practice units receiving value-based payment).

³⁹ Various regulatory proposals for bundled payment exist, as well as private bundled payment initiatives. *See infra* text accompanying notes 103–05, 122, 140 (discussing bundled payment initiatives).

When health care is sufficiently basic or standardized so that it does not require assembly before purchase, chances are that it also can be accessed and coordinated directly by the consumer, without reliance on a physician at all.

⁴¹ See infra notes 56–58 and accompanying text.

⁴² SHERRY GLIED, CHRONIC CONDITION: WHY HEALTH REFORM FAILS 18–28 (1997) (discussing different health care service models).

⁴³ See Kenneth J. Arrow, Uncertainty and the Welfare Economics of Medical Care, 53 Am. Econ. Rev. 941, 941–43 (1963).

they assert that medical science determines a unique, correct method of care, albeit one that requires customization based on each patient's specific clinical circumstances and exercise of autonomy in consenting to treatment after being advised of its risks.⁴⁴ If medical need is determined by scientific objectivity, then U.S. physicians—who are selected and trained to epitomize those qualities—can be trusted to apply their own skills and to recruit outside resources in the correct quantities *ad hoc* without prior assembly.

However, an openly market-based model of health care delivery would seem to compare favorably with the randomness that actually exists. Decades of data convincingly refute the medicalist model as an accurate description of prevailing practice. Since the 1970s, John Wennberg and others have documented the inconsistency of health care from place to place across the United States ("small-area variation"), variability that has no discernable relation to either the prevalence or severity of illness or the outcomes of treatment.⁴⁵

Care processes that meet scientific guidelines—so-called evidence-based medicine—continue to be a goal of many health care policy experts. Even if unjustified clinical variation could be eliminated by enforcing guidelines, however, it would still be necessary to produce each scientifically indicated service at acceptable cost, both for paying customers and for those who require public assistance. Competition would seem important to this process, although countries with socialized health care systems tend to rely on second-best strategies such as controls on capital expenditures, global budgets, price-fixing, and rationing. 47

⁴⁴ If medical care is dictated by science but individualized through physician judgment and compassion, the process of care converges conceptually with its outcome. As economist Kenneth Arrow noted half a century ago, medicine can be regarded as an "experience good" not capable of advance evaluation by consumers because "the outcome of medical care cannot be separated from the process of receiving it." *Id.* at 941–47 (analyzing the operation of the health care industry and the efficacy with which it satisfies the needs of society).

The Dartmouth Atlas of Healthcare, *Understanding of the Efficiency and Effectiveness of the Health Care System* (2015), http://www.dartmouthatlas.org [http://perma.cc/6ENP-ZDN6].

⁴⁶ Harvey V. Fineberg, *Foreword to* Mark B. McClellan et al., Inst. of Med., Evidence-Based Medicine and the Changing Nature of Healthcare: 2007 IOM Annual Meeting Summary, at v (2008) (exploring evidence-based medicine as a potential key driver toward greater value and efficiency in medical care).

⁴⁷ See generally The Commonwealth Fund, International Profiles of Health Care Systems, 2013 (Sarah Thomson et al. eds., 2013), http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2013/Nov/1717_Thomson_intl_profiles_hlt_care_sys_2013_v2.pdf [http://perma.cc/Y73H-UJ9S] (comparing countries with socialized health care systems).

1. Physician Services

In the private system that prevails in the United States, the medicalist model has been formalized through laws and norms that institutionalize deference to physician expertise. For over a century, health care in the United States has been under the direction of the American medical profession, which was granted extraordinary privileges to define its exclusive domain and to oversee its own clinical and economic conduct.⁴⁸ At the same time, physicians have been sheltered by law from both private corporate control and explicit public governance.⁴⁹

The unlicensed practice of medicine is prohibited by law in every state, and the scope of practice for other professionals, such as nurses and pharmacists, is strictly circumscribed, often by physician-controlled state licensing boards. Generous subventions for medical education and training, as well as costless access for physicians to technologically advanced hospital resources, have fostered the growth of medical specialists and further increased the economic and political influence of the profession. Very little of the regulation adopted under this "professional paradigm" directly promoted market competition; to the contrary, the activities of physicians only slowly became subject to federal antitrust law as industry revenues rose. 2

Compared to unregulated markets, competition in health care therefore relies more on physician-sellers' fiduciary obligations of loyalty to patients, and less on direct consumer voice and exit (choice). Albert O. Hirschman, Exit, Voice and Loyalty: Responses to Declines in Firms, Organizations, and States 1, 40, 63–65 (1970) (discussing alternative ways of reacting to deterioration in business firms and dissatisfaction with organizations). Accordingly, it is skewed toward nonprice dimensions, while competition on price is often anemic.

⁴⁹ STARR, *supra* note 25, at 13–24.

⁵⁰ See id. at 77–78 (discussing the role that industrialization has played in incentivizing medical professionals to specialize).

James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459, 1506 (1994) (examining the competing visions of medical care represented by the professional paradigm and the market-based economic paradigm); Charles D. Weller, *Free Choice as a Restraint of Trade in American Health Care Delivery and Insurance*, 69 IOWA L. REV. 1351, 1392 (1984) (characterizing the traditionally fragmented health care system as "guild-free choice").

Clark C. Havighurst, *Health Care as a (Big) Business: The Antitrust Response*, 26 J. Health Pol. Pol'y & L. 939, 940–43, 953 (2001) (discussing antitrust law's engagement with health care as a consequence of its rapid growth and commercialization after government became a major purchaser). Over fifty years elapsed between the passage of the Sherman Act and its application to the American Medical Association's overt exclusionary policies. *See, e.g.*, Am. Med. Ass'n v. United States, 317 U.S. 519, 530–36 (1943) (holding that a restraint of trade could be evidenced by the fact that physicians and their medical societies conspired to exclude competing physicians affiliated with nontraditional methods of

The effect of this history has been to equate health care products with professional process steps. As the technical capacity of medicine increased and health insurance grew common, each new process step became associated with a billing code, most notably through the compendium of Current Procedural Terminology (CPT) codes that the American Medical Association maintains (and copyrights).⁵³ Using these codes, health insurance reimburses physicians and other providers for the costs associated with each process step, the term "reimbursement" conveying both the presumed nondiscretionary nature of the steps taken and the primarily nonfinancial motivation ascribed to the health professionals and nonprofit institutions providing that care.⁵⁴ Government payment policies, particularly under Medicare, have perpetuated this approach to health care products.⁵⁵

Refinements in the fee-for-service approach to physician payment have attempted to discern the true value of care by paying fairly for each process step but have seldom questioned the overall coherence of defining medical products in this fashion. The best example is Medicare's shift in the early 1990s from reimbursing "customary, prevailing, and reasonable" physician fees to using a resource-based relative value scale (RBRVS) intended to capture the difficulty and expense of providing individual services. Medicare's Relative Value Scale Update Committee (RUC) even confers authority on the medical profession to advise CMS regarding both what processes of care should be represented in Medicare's CPT-based physician fee schedule and how much money physicians should receive for

financing from local societies and to refrain from referrals and consultations with group practice physicians). And it was not until well after the enactment of Medicare that specific transactions involving health professionals became targets for antitrust enforcement. *See, e.g.*, Arizona v. Maricopa Cty. Med. Soc'y, 457 U.S. 332 (1982) (holding that maximum fee agreements among physicians constituted price fixing and were per se unlawful).

⁵³ AM. MED. ASS'N, *CPT Coding, Medical Billing and Insurance* (2014), http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance.page? [http://perma.cc/K3V5-LQF9].

⁵⁴ See Miriam J. Laugesen, Roy Wada & Eric M. Chen, In Setting Doctors' Medicare Fees, CMS Almost Always Accepts the Relative Value Update Panel's Advice on Work Values, 31 HEALTH AFF. 965, 968–70 (2012).

⁵⁵ See generally Katharina Janus & Lawrence D. Brown, *Medicare as Incubator for Innovation in Payment Policy*, 32 J. Health Pol. Pol'y & L. 293, 294 (2007) (noting the role of Medicare in shaping the U.S. healthcare system).

⁵⁶ AM. MED. ASS'N, *Overview of the RBRVS* (2014), http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/overview-of-rbr vs.page [http://perma.cc/5WJF-EHBP].

engaging in them.⁵⁷ Unsurprisingly, the RUC has proved a formidable obstacle to reducing fees or requiring covered services to be of demonstrable value to patients.⁵⁸

2. Hospital-Based Services

The longstanding fragmentation of health care delivery among both health professionals and health care facilities and the lack of connection between those two critical sectors are also largely the result of government regulation and payment policies. Even the inpatient services that continue to comprise the largest portion (roughly 30%) of national health expenditures are requisitioned by physicians but organized and delivered independently of them.⁵⁹ Improved efficiency therefore will require both new forms of payment and substantial changes to hospital structures, including physician affiliation and employment practices.

A major defect in medical product design is that inpatient units of service are bifurcated into "professional" and "facility" components, even though hospitalized patients generally require close coordination between professional skills and institutional resources. For example, a patient undergoing surgery will be charged by the hospital for everything except physician services, while the surgeons, anesthesiologist, and surgical pathologist will each generate a separate invoice. Both private and public insurers typically process claims on this basis. As a result, physicians and hospitals become nonexclusive coproducers of care within hospital walls. Their services are "complementary" but poorly integrated: the physician's contribution to patient care is not an input for the hospital's output, nor is the hospital's contribution an input for the physician's output.

The RUC is composed of 31 physician members approved by the AMA, with 21 nominated by major national medical specialty societies. AM. MED. ASS'N, *The RVS Update Committee* (2014), http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/the-rvs-update-committee.page [http://perma.cc/FN3D-LAUC] (overview of RUC composition).

⁵⁸ See Miriam J. Laugesen et al., In Setting Doctors' Medicare Fees, CMS Almost Always Accepts the Relative Value Update Panel's Advice on Work Values, 31 HEALTH AFF. 965, 968–70 (2012).

⁵⁹ See CTRS. FOR DISEASE CONTROL & PREVENTION, Health Expenditures (2014), http://www.cdc.gov/nchs/fastats/health-expenditures.htm [http://perma.cc/PE8C-37L5].

⁶⁰ See EINER ELHAUGE, Why We Should Care About Health Care Fragmentation and How to Fix It, in The Fragmentation of U.S. Health Care: Causes and Solutions 1, 5 (Einer Elhauge ed., 2010).

⁶¹ Id. at 9.

Absent regulation, physicians and hospitals would have a very different economic relationship. Most American hospitals—and nearly all of the most prominent institutions—are chartered as nonprofit corporations under state law and are exempt from federal and state taxation.⁶² Nonprofit hospitals may seem like competitive businesses delivering patient care, but their roots are as community resources and physicians' workshops.⁶³

Legal constraints on the profit-seeking behavior of nonprofit hospitals have been a mixed blessing for U.S. health policy. Because charitable corporations reinvest revenues in operations rather than paying them as profits to owners, nonprofit hospitals have helped maintain access to unprofitable services. At the same time, however, they have catered excessively to the preferences of physicians on whom they depend for admissions. Nonprofit hospitals have contributed substantial amounts of uncompensated care, but they have failed to avert far more massive inefficiencies in the production of hospital services, the assurance of clinical quality and

AM. HOSP. ASS'N, AHA HOSPITAL STATISTICS: 2012 EDITION, at 12 (2012) (showing that 2904 hospitals are nonprofit out of 4985 total in the United States). Nonprofit hospitals must be organized and operated exclusively for charitable purposes, may not distribute earnings to private parties, and must provide community benefit through activities such as serving the poor, maintaining an emergency department, and allowing community physicians to join their medical staffs. I.R.C. § 501(c)(3) (2010). Even so, many nonprofit hospitals are multibillion dollar enterprises that wield significant economic and political influence. In recent years, community benefits and other indicia of nonprofit performance have been made more tangible through detailed reporting requirements and, in a few states, specified minimum dollar contributions. Section 9007 of the ACA requires tax-exempt hospitals to (i) conduct a community health needs assessment at least once every three years; (ii) make financial assistance policies widely available; (iii) comply with new billing and coding restrictions; and (iv) limit charges for emergency or other medically necessary care. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 9007, 124 Stat. 855 (2010); see also James R. Hines, Jr. et al., The Attack on Nonprofit Status: A Charitable Assessment, 108 MICH. L. REV. 1179, 1184-85 (2010) (describing the federal and state legal and tax requirements for nonprofit tax privileges).

The prohibition on private shareholding also implies that nonprofit hospitals need only support current operations and repay long-term bondholders from revenues in order to survive, and need not meet short-term earnings targets or impress the public equity markets with rapid growth, as would be true of for-profit hospitals. This was intended to reinforce their charitable purposes, but it also tends to make them complacent. Rosemary Stevens, In Sickness and in Wealth: American Hospitals in the Twentieth Century 40–46, 351–52 (1999) (voluntary not-for-profit hospitals have been profit-maximizing enterprises, despite viewing themselves as charities serving the community).

⁶⁴ David W. Johnson & Nancy M. Kane, *The U.S. Health Care System: A Product of American History and Values*, in The Fragmentation of US Health Care: Causes and Solutions 323, 339 (Einer Elhauge ed., 2010).

⁶⁵ *Id.* at 338–40.

safety, and the coordination of care with other providers and settings.⁶⁶ Nonprofit hospitals have normalized the invention and dissemination of expensive medical technologies, but they have never taken money out of the health care system that could be used more productively elsewhere, in either the public or the private economy.⁶⁷

U.S. hospitals typically have an open, self-governing medical staff through which physicians voluntarily affiliate themselves with the facility, earning "privileges" to admit and care for patients through screening and ongoing evaluation by other physicians performing peer review.⁶⁸ The potential for established competitors to disadvantage new entrants using peerreview processes has long been recognized.⁶⁹ More generally, open medical staffs have enabled many physicians, particularly specialists who cannot function without hospital resources, to remain organizationally separated from, and subject to different incentives than, the hospitals in which they work and even from their physician colleagues within those hospitals.⁷⁰

⁶⁶ Id. at 341.

⁶⁷ Id. at 340.

Open medical staffs have been encouraged by state law, and for many years helped nonprofit hospitals receive favorable federal tax treatment by serving as evidence of charitable purpose. Internal Revenue Service, Health Care Provider Reference Guide (2004), http://www.irs.gov/pub/irs-tege/eotopicc04.pdf [http://perma.cc/2Z48-Y74W] (federal tax guidance for health providers); see also Jill R. Horwitz, Why We Need the Independent Sector: The Behavior, Law, and Ethics of Not-for-Profit Hospitals, 50 UCLA L. Rev. 1345, 1384 (2003) (discussing IRS guidelines encouraging open medical staff organization and governance); John P. Marren, G. Landon Feazell & Michael W. Paddock, The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions, 12 Annals Health L. 179, 226-28 (2003) (discussing the current structure of U.S. hospital governance and hospital administrators/board members' inability to overrule medical staff). Medical staff selfgovernance is also ingrained in the accreditation standards of the Joint Commission, compliance with which qualifies hospitals to participate in Medicare and Medicaid. See The Joint Commission, Medical Staff (CAMH/Hospitals) (Mar. 10, 2011), http://www.jointcommission.org/mobile/standards_information/jcfaqde tails.aspx?StandardsFAQId=435&StandardsFAQChapterId=74 [http://perma.cc /9DAB-LFZQ]; Benefits of Joint Commission Accreditation, JOINT COMMISSION (Aug. 28, 2015), http://www.jointcommission.org/benefits_of_joint_commission_ac creditation/[https://perma.cc/X3WR-ASA8].

⁶⁹ See Philip C. Kissam et al., Antitrust and Hospital Privileges: Testing the Conventional Wisdom, 70 Calif. L. Rev. 595, 636–37 (1982) (analyzing potential antitrust problems with medical staff self-governance leading to privilege denials of other practitioners); see also Patrick v. Burget, 486 U.S. 94, 105 (1988) (holding the state-action doctrine did not protect Oregon physicians from federal antitrust liability for their activities on hospital peer-review committees).

⁷⁰ Kissam et al., *supra* note 69, at 612–13.

This loose form of physician-hospital collaboration is common only in the United States and Canada. In most other developed countries, primary care physicians work exclusively in their private offices or small clinics, and specialist physicians are hospital employees.⁷¹ In the last few years, employment of physicians by hospitals has grown rapidly in states that permit it.⁷² Because of decades of customary practice, however, merely employing physicians has rarely induced hospitals to create true "integrated practice units."⁷³ In several states (including Texas and California), moreover, legal prohibitions on the corporate practice of medicine continue to restrict the direct employment of physicians by other entities, making it even more difficult to coordinate the services of health professionals and health care facilities.⁷⁴

The cumulative effect of the regulatory environment has been to disaggregate hospital care into the smallest possible units of service, promote rapid adoption of new technologies while freezing their prices at high initial levels, encourage hospitals to incur reportable and therefore reimbursable costs, and create an equally stylized set of "charges" of uncertain relationship to reported costs.⁷⁵ As a result, U.S. hospital prices are shockingly high, variable, and arbitrary, recently reaching a degree of irrationality and unfairness that has attracted criticism not only from journalists but also from schol-

⁷¹ THE COMMONWEALTH FUND, supra note 47, at 13–14.

⁷² See generally Am. HOSP. ASS'N, supra note 62.

 $^{^{73}}$ See Michael E. Porter & Thomas H. Lee, *The Strategy That Will Fix Health Care*, 91 HARV. BUS. Rev. 50 (2013) (listing integrated practice units as a core component of value).

See, e.g., Cal. Bus. & Prof. Code §§ 2400, 2052 (West 2012) (regulations providing that corporations cannot have professional licenses and requiring physicians to have a license in order to practice medicine); TEX. OCC. CODE. ANN. §§ 155.001, 155.003, 157.001, 164.052, 165.156 (West 2012) (regulations on physicians licensing and corporation's ability to hire physicians); People v. Cole, 135 P.3d 669, 672 (Cal. 2006) (describing California law that bans corporate practice of medicine); Flynn Bros., Inc. v. First Med. Assocs., 715 S.W.2d 782, 785 (Tex. App. 1986) (holding that a corporation of lay people is unlawfully practicing medicine when it hires physicians to treat patients). Other states have limited exceptions for licensed hospitals. N.Y. EDUC. LAW § 6522 (McKinney 2006) (statute requiring physicians to have a license); People v. John H. Woodbury Dermatological Inst., 85 N.E. 697, 698 (N.Y. 1908) (holding that specially licensed hospitals were the only corporations with the authority to practice medicine). In 1997, the Illinois Supreme Court clarified that licensed hospitals (but not other corporations) could legally employ physicians. Berlin v. Sarah Bush Lincoln Health Ctr., 688 N.E.2d 106, 114 (Ill. 1997).

 $^{^{75}}$ See Steven Brill, Bitter Pill: Why Medical Bills Are Killing Us, Time (Mar. 4, 2013).

ars and regulators.⁷⁶ This fact alone has serious adverse consequences for market efficiency, which depends on honest prices to convey granular information to both producers and consumers about production options and their associated costs.⁷⁷ Moreover, hospitals have had little incentive to measure, much less attempt to reduce, the aggregate resource costs of treating a patient for a particular condition, in large part because hospital services are sold as physician-ordered care components, not assembled services.⁷⁸

Per-service hospital prices are poor predictors of overall hospital spending because the volume of service—both the decision to hospitalize and the intensity of treatment once hospitalized—typically remains under the discretionary authority of physicians who are subject to a different set of financial and nonfinancial incentives. For example, control over per-service prices without control over the volume of services delivered was a recognized problem with Medicare's RBRVS program from the outset, justifying the inclusion of a Volume Performance Standard (VPS) or "behavioral offset" that automatically reduced fees in response to unjustified increases in volume.⁷⁹

Care is also poorly coordinated between different facilities and with community-based sources of treatment. "Post-acute" services such as rehabilitation, for example, are currently a major source of cost variability for the Medicare program. 80 More broadly, efficient care delivery—and ultimately improved health—requires most services to be accessible outside of the

⁷⁶ See id.; see also Fuse Brown, supra note 7, at 39–41 (criticizing hospital health care service prices); MASS. ATTY GEN.'S OFFICE, Examination of Health Care Cost Trends and Cost Drivers, pursuant to G.L. c. 6D, § 8 1, 6–8 (2013) (analyzing recent market developments and Massachusetts's efforts to promote efficient and effective delivery of health care).

⁷⁷ See Friedrich A. Hayek, The Use of Knowledge in Society 12–13 (1945) (arguing that a centrally planned economy could never match the efficiency of an open economy because of the dispersed nature of information spread throughout society).

⁷⁸ See Fuse Brown, supra note 7, at 23.

⁷⁹ See John M. Eisenberg, Rethinking the Role of Health Care Providers: The Physician's Perspective, in IMPROVING ACCESS TO AFFORDABLE HEALTH CARE: THE PROVIDER PERSPECTIVE 22, 37 (1991).

David C. Grabowski et al., *Medicare Postacute Care Payment Reforms Have Potential to Improve Efficiency of Care, But May Need Changes to Cut Costs,* 31 HEALTH AFF. 1941, 1947 (2012) (discussing the ACA's potential to compromise the delivery of patient-appropriate post-acute services). A major goal of Medicare's new bundled payment program for joint replacement is to normalize postacute spending. *See* Steven A. Farmer et al., *Breaking Down Medicare's Bold New Proposal to Transform Hip and Knee Replacements,* BROOKINGS (Aug. 11, 2015, 1:12 PM), http://www.brookings.edu/blogs/health360/posts/2015/08/joint-replacement-model-care [http://perma.cc/YZM5-SMA7].

hospital setting, both at reconfigured ambulatory care sites and in more innovative locations such as retail stores, schools, and workplaces.⁸¹

3. Insurance Assemblages

Over the last half century, the percentage of health care costs paid directly by patients has diminished substantially, while the amount paid through health insurance has increased. For private health insurance markets, this growth reflects the fact that serious illness can be an unpredictable and expensive event, augmented by the scale economies and tax subsidies associated with insurance coverage being offered as a fringe benefit of employment. For public insurance programs such as Medicare and Medicaid, growth represents a combination of social solidarity for the elderly regardless of income and redistributive commitments to groups of lower-income individuals deemed deserving of assistance. 83

Critics of health insurance often attribute overuse of services and general price insensitivity within the health care system to the moral hazard inherent in third-party payment.⁸⁴ However, health insurance also perpetuates false products by aggregating professional process steps and other traditional care components and inputs into assemblages that appear coherent but remain disconnected from the efficient solution of complex medical problems.⁸⁵

⁸¹ See Cynthia Napier Rosenberg et al., Results from a Patient-Centered Medical Home Pilot at UPMC Health Plan Hold Lessons for Broader Adoption of the Model, 31 HEALTH AFF. 2423, 2423–24 (2012) (describing the innovative delivery of health care through patient-centered medical homes); William M. Sage, Out of the Box: The Future of Retail Medical Clinics, 3 HARV. L. & POLY REV. ONLINE 1, 4–6 (2009) (discussing the potential efficiencies of retail medical clinics).

⁸² CTRS. FOR MEDICARE & MEDICAID SERVS., National Health Expenditures 2013 Highlights (2013), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/high lights.pdf [http://perma.cc/KJC2-NLBQ] (reporting national health care costs for 2013).

⁸³ See Theodore R. Marmor, American Health Care Policy and Politics: Is Fragmentation a Helpful Category for Understanding Health Reform Experience and Prospects?, in The Fragmentation of U.S. Health Care: Causes and Solutions 343, 356 (Einer Elhauge ed., 2010); David M. Cutler & Jonathan Gruber, The Effect of Medicaid Expansions on Public Insurance, Private Insurance, and Redistribution, 86 Health Econ. 378, 379 (1996).

⁸⁴ D. Andrew Austin & Thomas L. Hungerford, Cong. Research Serv., R40834, The Market Structure of the Health Insurance Industry 18–19 (2010); Liran Einav et al., Selection on Moral Hazard in Health Insurance, 103 Am. Econ. Rev. 178, 217 (2013) (discussing health insurance moral hazards and causes).

⁸⁵ See, e.g., Julie Creswell & Reed Abelson, Medicare Bills Rise for Stents Put into Limbs, N.Y. TIMES, Jan. 30, 2015, at A1 (questioning Medicare payment to cardiologists for peripheral arterial stents).

Modern health insurance in the United States began with Blue Cross, which was a collective endeavor by hospitals to assure themselves of payment during the Great Depression by offering their communities a way to prepay for services if needed.86 Physicians came up with a related strategy, Blue Shield, setting the tone for partitioning institutional and professional services within insurance coverage.87 When Medicare was enacted in 1965, it replicated this structure by creating a compulsory social insurance system to cover hospitals and other facilities (Part A) and a separate, voluntary but subsidized premium system to cover care by physicians and other health professionals (Part B).88 Separating hospital from physician coverage in Medicare using constructs familiar from private indemnity insurance both blunted organized medicine's opposition to "socialized medicine" and allayed its fear of corporate control.89

Supported by state and federal law, most private and public health insurance policies still employ this piecemeal approach to benefit design, typically adding more categories of covered services that are merely care components or inputs, such as diagnostic testing, prescription drugs, and durable medical equipment. Within each category, coverage may still be denied if a service is not "medically necessary," but determinations of medical necessity are linked to claims, and claims are almost always for unassembled products. 92

Taking a longer view of health care markets, moreover, commercial insurers act as purchasing intermediaries, not actual consumers of health care. At best, they are weak agents for buyers; at worst, they are self-interested middlemen. They

Alex Blumberg & Adam Davidson, *Accidents of History Created U.S. Health System*, NPR (2009), http://www.npr.org/templates/story/story.php?storyId=11 4045132 [https://perma.cc/P635-VERJ] (detailing creation of Blue Cross health insurance as a consequence of historical events).

Marc Lichtenstein, Health Insurance from Invention to Innovation: A History of the Blue Cross and Blue Shield Companies, Blue Cross Blue Shield Blog (2015), http://www.bcbs.com/blog/health-insurance.html#.VfYwHdNViko [http://perma.cc/6FTB-89GL].

⁸⁸ CTRS. FOR MEDICARE & MEDICAID SERVS., *History* (2014), http://www.cms.gov/About-CMS/Agency-Information/History/index.html?redirect=/history/[http://perma.cc/7HX9-K8EE].

⁸⁹ Shawn Martin, *Medicare and Medicaid: 'Doing the Right Thing for Those in Need*,' AAFP: In the Trenches (June 23, 2015), http://blogs.aafp.org/cfr/inthe trenches/entry/medicare_and_medicaid_doing_the [http://perma.cc/ZM2Y-LPXNI.

⁹⁰ Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1647 n.31 (1992).

⁹¹ *Id.*

⁹² See id. at 1666-68.

turn a respectable profit and have every reason to maintain their existing market role and business practices. Many are for-profit organizations facing limited competitive pressure. 93 Whether to comply with regulation, reduce potential legal liability, or simply avoid controversy, insurers tend to refrain from directly influencing clinical care and focus their attention on negotiating fees for conventional services. 94

Inertia and such perverse incentives make it unlikely that private insurers will convert their covered benefits from assemblages of process steps into assembled products anytime soon. Much of their business is not even true insurance with risk of loss, in that many insurers administer coverage for self-insured employers or base their premiums on highly predictable annual group experience.⁹⁵ Most health insurers earn revenue primarily by processing claims involving large networks of participating providers that also contract with rival companies or by doing similar tasks as subcontractors for Medicare. 96 Consequently, they have little cause to decrease the volume of claims by moving from reimbursable process steps to assembled products, a transition that would also force them to revisit the basic structure of their benefits. To the contrary, offering seemingly comprehensive coverage of faux products through inclusive networks of hospitals and physicians discourages competition from other insurers, while (falsely) reassuring regulators that policyholders are not receiving less than they contracted to receive.

In addition to separating physician from hospital coverage, Medicare as enacted in 1965 included several features intended to gain critical support from organized medicine. These compromises further subsidized trade in unassembled products: a pledge of noninterference with existing medical practice, repayment of hospitals' reported costs plus a reasonable profit margin and capital cost allowance, payment of physicians' "customary and prevailing" fees, and claims

⁹³ Fuse Brown, *supra* note 7, at 54–55.

See Elhauge, supra note 60, at 9; Clark C. Havighurst, Professional Restraints on Innovation in Health Care Financing, 1978 Duke L.J. 303, 338 (1978).
 See Cong. Research Serv., supra note 34, at 23–25.

⁹⁶ U.S. GEN. ACCOUNTING OFFICE, GAO/OSI-99-7, IMPROPRIETIES BY CONTRACTORS COMPRISED MEDICARE PROGRAM INTEGRITY (1999) (analyzing whether Medicare contractors participated in any improper or questionable practices that contributed to fraud, waste, or abuse in the Medicare federal health insurance program). Serving government programs more profitably seems to be a motivator of recent health insurance merger activity. See Pear, infra note 131.

⁹⁷ See Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965).

administration by familiar private organizations (mainly Blue Cross and Blue Shield plans)⁹⁸ rather than a government agency.⁹⁹ Although most of these characteristics have been modified, they set a tone for public coverage in the United States that was deferential to private practice and welcoming of entrepreneurial investment but undemanding with respect to competitive outcomes.

Public funding generally comes with strings attached, and Medicare and Medicaid are replete with conditions of participation, payment specifications, and associated procedures and prohibitions. Beginning as early as 1972, for example, Congress set in motion a series of increasingly strict penalties for "fraud and abuse." 100 Unfortunately, the broad restrictions on financial transactions imposed by these laws have served as much to deter potentially efficient contractual affiliations between physicians and hospitals as to reduce unnecessary care. 101 Because hospitals design their clinical and financial workflow primarily to comply with the rules and respond to the incentives established by Medicare and Medicaid, and private payers routinely adopt standards and practices based on government benchmarks, this additional disincentive to product assembly spilled over to the private insurance marketplace as well.

C. Advantages of Assembled Products

In the vast majority of commercial markets, competition reduces price, increases timeliness of access or use, and improves performance. Although those goals are mainstays of industrial engineering, health care markets have typically regarded such pedestrian objectives with disdain or embarrassment. 102 Competition policy needs to overcome this resistance

⁹⁸ See Rick Mayes, The Origins, Development, and Passage of Medicare's Revolutionary Prospective Payment System, 62 J. HIST. MED. & ALLIED Sci. 21, 23–24 (2007).

^{99 79} Stat. at 291, 309–11, 322–23.

¹⁰⁰ 42 U.S.C. § 1320a-7c (2012); *see also* Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (2012) (prohibiting the exchange, or offer of exchange, of any remuneration to reward, or induce, referrals of business for federal health care programs, including Medicare and Medicaid).

James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 224 (1996) (discussing inconsistencies between fraud law and market need).

¹⁰² See, e.g., Susan Dentzer, It's Past Time to Get Serious About Transforming Care, 32 HEALTH AFF. 6, 6 (2013) ("One eternal mystery of US health care is why patients and payers have been loath to demand attributes they take for granted in other sectors of the economy, such as convenience, price transparency, and reasonable costs.").

and restore normalcy to the first-pass criteria for what makes a health care product "better." From this perspective, selling more health care products on a fully assembled basis has substantial advantages.

A range of assembled products can be designed to meet clinical need and consumer demand, but they are not explicitly distinguished in the health policy literature from their less cohesive counterparts based on the effectiveness of the competition that they are capable of generating. Assembled products offering definitive care for an acute problem (e.g., joint replacement, coronary artery bypass grafting) might include all professional services, facility use, and medical supplies, plus standard rehabilitative care, and might come with a warranty to cover treatment failure or complications. Patients with chronic disease might purchase a year of maintenance therapy and secondary prevention. Assembled diagnostic services might range from an examination with explanation and reassurance, to a single scan for follow-up of a known condition, to a full work-up for grave or unusual symptoms.

Several assembled products exist today, such as simple diagnostics and definitive treatments for minor illnesses and injuries. 104 Others are being developed, such as all-inclusive treatment for cardiac conditions, orthopedic problems, or cancers, and packaged maintenance therapy for chronic diseases. 105 Medical tourism often involves assembled products. 106 Even end-of-life care can be thought of in terms of assembled products, as the hospice industry demonstrates. 107

Price and Convenience.

Prices should be known to individual buyers in advance, should be transparent to buyers as a group, and should tend to

¹⁰³ See, e.g., Porter et al., supra note 38, at 521–22 (suggesting that bundled payments may result in better value for patients).

 $^{^{104}~}$ See William M. Sage & Kelley McIlhattan, Upstream Health Law, 42 J.L. Med. & Ethics 535, 540–41 (2014).

¹⁰⁵ See Terry Shih et al., Will Bundled Payments Change Health Care?: Examining the Evidence Thus Far in Cardiovascular Care, 131 CIRCULATION 2151, 2152, 2154 (2015); Cheryl Clark, CMS Announces Bundled Care Payments for Oncology, HEALTHLEADERS MEDIA (Feb. 16, 2015), http://healthleadersmedia.com/content/QUA-313227/CMS-Announces-Bundled-Care-Payments-for-Oncology [http://perma.cc/RBV7-8F2C].

¹⁰⁶ See Devon M. Herrick, Nat'l Ctr. for Policy Analysis, Medical Tourism: Global Competition in Health Care 4 (2007).

¹⁰⁷ MEDICARE LEARNING NETWORK, DEP'T OF HEALTH & HUMAN SERVS., HOSPICE PAYMENT SYSTEM: PAYMENT SYSTEM FACT SHEET SERIES 4 (2013).

the uniform (i.e., not be highly variable or discriminatory). ¹⁰⁸ If sellers cannot compete on price, it is a clue that the product is wrong. In the health care system, accurate prices are often unavailable because assembly is done piecemeal as charges accrue.

When health care products are unassembled and disorganized, moreover, it is difficult to determine and reduce the cost of producing them. For example, a large amount of waste occurs within hospitals in connection with the treatment of serious illness, in part because facilities that are paid for disaggregated units of service tend to be much better attuned to their revenue streams than to their cost structures. Production models for facility-based care also typically place physicians in independent, loosely supervisory roles rather than as part of integrated and experienced teams.

Health care is seldom convenient even when it is affordable. The inconvenience of accessing care in most instances, despite the enormous private and social resources devoted to it, is another indication that it is being delivered in arbitrary increments rather than being packaged into service units that correspond to patient benefit. Convenience is also a proxy for innovation given the many barriers to entry by new competitors that result from strong traditions of physician control and associated professional regulation.¹¹¹

Consider products that might improve underlying health. Americans are far less healthy than our wealth suggests we should be. ¹¹² Empowering markets to redesign health care as they do other consumer goods would distribute both basic medical care and health-protective services widely across com-

¹⁰⁸ Since the 1990s, policymakers and researchers have worked energetically toward measurable, transparent quality of care. *See, e.g., About Us, NAT'L QUALITY F. (2015), http://www.qualityforum.org/story/About_Us.aspx [http://perma.cc/Z94Z-5M4P].* These efforts, while laudatory, largely presuppose a tradeoff between price and quality that has seldom characterized the health care system in operation. Quality metrics help improve health outcomes, but by taking the longer view it is hard to escape the conclusion that competition over quality cannot occur unless price competition is also vigorous.

¹⁰⁹ See Blumstein, supra note 34, at 206.

¹¹⁰ See, e.g., TEX. OCC. CODE. ANN. § 157.054 (West 2012).

¹¹¹ See Blumstein, supra note 51, at 1465-66.

¹¹² See Org. for Econ. Cooperation & Dev., OECD Health Statistics 2014: How Does the United States Compare? (2014), http://www.oecd.org/united-states/Briefing-Note-UNITED-STATES-2014.pdf [http://perma.cc/C757-CDZ5] (data comparing the health of U.S. citizens to other countries); see also Barbara Starfield, Commentary, Is US Health Really the Best in the World?, 284 J. Am. MED. ASS'N 483, 483 (2000) (discussing information concerning the deficiencies of U.S. medical care).

munities and embed them in the daily, routine activities of people who need not be labeled as "patients" in order to be served. Competition for these services would promote personal engagement with health on the part of the consumerpatient (e.g., through smartphones) and less expensive, more accessible one-on-one care relationships. Whereas assembled products delivering acute or complex care would likely remain covered by health insurance, consumer choice regarding basic care and health promotion could be more flexible, with a larger range of professional and nonprofessional skills and service settings, and with less insurance involved.

2. Performance and Safety

Assembled products usually work. By contrast, many health care services provided in this country do not meet patients' needs. The Institute of Medicine's estimated \$750 billion in annual waste included \$210 billion for unnecessary services and \$130 billion for inefficiently delivered, sometimes harmful, services. A priority for health care competition is to generate products and services that do people clear good and are priced accordingly.

If each product is delivered assembled, it is easier to warrant against additional cost if there are safety lapses or if results stray from the expected. Warranties have been underused in health care, in large part because lack of product assembly vested physicians with legal liability for failings attributable to their own negligence but denied any single party financial or operational control over quality. In recent years, a few integrated health care organizations have begun to offer

¹¹³ See Sage & McIlhattan, supra note 104, at 535 (defining the "upstream" as where the label of "patient" has not yet attached).

¹¹⁴ INST. OF MED., *supra* note 21, at 102.

¹¹⁵ For example, many providers of in vitro fertilization offer substantial refunds if a live birth does not occur. *See* Jim Hawkins, *Financing Fertility*, 47 HARV. J. ON LEGIS. 115, 115 (2010) (noting that the way in which fertility treatments are financed is virtually unparalleled in other areas of medicine). As this example suggests, quality warranties for products covered by health insurance and for self-paid products are likely to differ.

¹¹⁶ In the 1990s, expectations that fully integrated HMOs would control both cost and quality produced recommendations for both warranties and "enterprise liability" for medical malpractice. William M. Sage, Enterprise Liability and the Emerging Managed Health Care System, 60 L. & CONTEMP. PROBS. 159, 166–67 (1997) (recommending enterprise liability); see William S. Brewbaker III, Medical Malpractice and Managed Care Organizations: The Implied Warranty of Quality, 60 L. & CONTEMP. PROBS. 117, 118 (1997) (recommending warranties). In operation, however, managed care seldom possessed attributes compatible with those approaches. See infra text accompanying notes 142–68.

packaged treatment for a preset price that includes additional care when necessary. This trend should continue as Medicare shifts more covered services to bundled payment.

In addition to enabling outcomes of care to become more reliable, competition in assembled products can make patients safer while they receive care. Uncertainty is part of medicine, but many processes of care are controllable. System failure rather than individual malfeasance is the root cause of most medical errors, 118 and a standardized practice environment with efficient coordination and teamwork is likely to be safer as well as cheaper. 119 The process of keeping patients safe is considerably simpler when the extent of care is determined in advance and sold as a package. 120 Offering a coherent package of services also makes the task of communicating residual risks of treatment failure or physical harm more straightforward (e.g., in the course of obtaining informed consent). 121

Finally, it is important to explain what a move to assembled products is *not*. First, it is not a request for a new government-sponsored compendium of service units that replaces old compendia such as relative value units, CPT codes, or Diagnosis Related Groups (DRGs).¹²² A central thesis of this Article is that markets will supply such products if the regulatory barriers to doing so are removed and if antitrust enforcers are alert to private anticompetitive activity that preserves the status quo. Second, support for assembled products is not an endorsement of "cookbook medicine." ¹²³ Many medical problems

 $^{^{117}\,}$ Geisinger Health Plan is one example, though a less dramatic one than has been suggested. See supra note 36 and infra note 405 and accompanying text.

¹¹⁸ INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 65 (Linda T. et al. eds., 2000) [hereinafter "TO ERR IS HUMAN"].

 $^{^{119}~}$ See Inst. of Med., Crossing the Quality Chasm: A New Health System for the 21st Century 83 (2001) (arguing for increased cooperation between clinicians); To Err is Human, supra note 118, at 37 (suggesting that emergency departments can decrease adverse events by increasing teamwork and standardizing procedures).

¹²⁰ *Cf.* To Err is Human, *supra* note 118, at 36–37 (noting poor systems cause more errors).

 $^{^{121}}$ See generally Jessica W. Berg et al., Informed Consent: Legal Theory and Clinical Practice 212–17 (2d ed. 2001) (summarizing contemporary informed consent).

Medicare's new joint replacement bundles, for example, serve as complex retrospective adjustments to existing payment formulas rather than straightforward invitations to provide integrated care for a flat fee. See Robert E. Mechanic, Mandatory Medicare Bundled Payment—Is It Ready for Prime Time?, 373 NEW ENG. J. MED. 1291 (2015) (explaining the details of the Medicare proposal).

Marshall B. Kapp, Commentary, 'Cookbook Medicine': A Legal Perspective, 150 JAMA Archives Internal Med. 496, 499 (1990) (noting a move toward the use of formalized clinical practice guidelines).

require expert judgment and discretion. That products be offered in assembled form is entirely compatible with customization; assembly merely implies that significantly different clinical needs be properly categorized in advance of sale. Third, assembled products do not represent a frontal assault on professional ethics. Competition policymakers should be skeptical about infusing economic relationships with too much moral content; naïve subsidies for medical professionalism have contributed significantly to the flaws in existing health care products. Well-trained, compassionate people delivering assembled health care products will continue to view the relief of human suffering as their primary duty. But they will pursue this mission with more effective teamwork, clearer accountability, and less waste.

II THE ANTITRUST LEGACY OF FAUX PRODUCTS

To understand competition policy today, it is necessary to go back one generation of health care reform. Health care providers appear to be experiencing a wave of consolidation last seen in the early 1990s. 124 After taking office in January 1993, President Clinton conducted an intensive exercise in policy development within the executive branch, leading to the introduction in Congress later that year of a bill expanding health insurance coverage. 125 The Clinton Administration's health reform bill shared with President Nixon's earlier proposal a mandate on private employers to offer health coverage and a preference for "managed competition" among private health maintenance organizations over a single-payer approach. 126

As the economy revived and health security became a less pressing concern for working Americans, however, public opinion turned against the bill, which came to be viewed as threatening jobs, compromising individual choice, and interposing

¹²⁴ See Fed. Trade Comm'n & U.S. Dep't of Justice, Improving Health Care: A Dose of Competition, ch. 3, at 11 (2004), http://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf [http://perma.cc/9MPE-KHFD].

Health Security Act, H.R. 3600, 103rd Cong. (1994); see generally Wendy K. Mariner, Patients' Rights to Care under Clinton's Health Security Act: The Structure of Reform, 84 Am. J. Pub. Health 1330, 1330–31 (1994) (discussing the history of the Health Security Act).

¹²⁶ Mariner, *supra* note 125, at 1331; *see infra* notes 207–09 (explaining managed competition).

bureaucratic obstacles to care.¹²⁷ The bill's defeat, and the related shift of Congress to Republican control in 1994, ceded the field to private employers and health plan administrators to control costs themselves.¹²⁸ This led to a rapid, nationwide transition to a managed care model that actively involved health insurers in delivering medical care, typically based on contracts with physicians, hospitals, and other health care providers.¹²⁹

Antitrust law played an important role in how health care markets developed following the Clinton reform proposal, and it is likely to do the same today under the ACA. Both efforts promised sweeping legislation that would induce major changes to the health care industry. 130 Then as now, many market participants worried that the restructuring necessary to succeed in a reformed system might subject them to antitrust liability, and they asked the enforcement agencies for clarification and hopefully reassurance. 131 Others circled the wagons intending to insulate their organizations from change, which sometimes forced the agencies to investigate and respond. 132 Both the Clinton proposal and the ACA also provoked a popular backlash, which was sufficiently strong in the former case to prevent the bill's passage. 133 The result in the 1990s was market restructuring undisciplined by a consistent or comprehensive regulatory framework. 134 Whether today's opposition to "Obamacare" leads to a similar situation remains to be seen.

Although a wide range of potentially anticompetitive practices are subject to the antitrust laws, corporate mergers and acquisitions that reduce the number of independent competi-

¹²⁷ See Elizabeth McCaughey, No Exit, New Republic (Feb. 7, 1994), http://www.newrepublic.com/article/health-care/no-exit [http://perma.cc/DHY3-M9Y2] (criticizing the Health Security Act and suggesting "alternatives [could] provide urgently needed reform of the health insurance industry, outlawing its worst abuses, without taking important decisions away from patients and their doctors and without depriving Americans of effective, high-tech medical care when they are seriously ill").

¹²⁸ See William M. Sage, Regulating Through Information: Disclosure Laws and American Health Care, 99 COLUM. L. REV. 1701, 1703–04 (1999).

¹²⁹ See id.

¹³⁰ See Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 1311, 124 Stat. 173 (2010); Health Security Act, H.R. 3600, 103rd Cong. (1994).

¹³¹ See Thomas Greaney, Thirty Years of Solicitude: Antitrust Law and Physician Cartels, 7 Hous. J. Health L. & Poly 189, 205–06 (2007); Robert Pear, As Health Law Spurs Mergers, Risks Are Seen, N.Y. Times, Nov. 21, 2010, at A1, A23.

¹³² See Greaney, supra note 131, at 217; Pear, supra note 131.

¹³³ See William M. Sage, Commentary, Putting Insurance Reform in the ACA's Rear-View Mirror, 51 Hous. L. Rev. 1081, 1104–05 (2014).

¹³⁴ See Sage, supra note 128.

tors tend to be the most visible and controversial transactions. ¹³⁵ Scrutiny of proposed mergers and acquisitions is an important aspect of antitrust enforcement because U.S. law is limited in its capacity to correct problems once market power exists. ¹³⁶ At the same time, merger cases illustrate the path dependence of today's insured health care markets, highlight the constitutive role of government, and demonstrate the hazards of basing competition policy on historical rather than forward-looking assumptions about health care products. ¹³⁷

Integration, bundled and episodic payment, and accountability for outcomes through both financial incentives and better information are now widely discussed and expected among policymakers and the educated public. 138 Yet antitrust enforcement continues to analyze many interactions involving commercial health insurers and hospitals as simple negotiations between buyers and sellers to purchase medical services at agreed upon, "discounted" fees for unassembled products. 139 That model narrowly reflects the contracting practices of the late 1990s and 2000s, a period devoid of major regulatory innovation, and disregards the direction being set for both public and private health insurance under the ACA. 140 Taking a longer view, continually rising health care expenditures and persistent shortcomings in quality and safety suggest that many health insurers and providers have been engaged in Kabuki theatre involving faux products that simulates hardnosed bargaining but fails to demand or deliver value for money, and that not infrequently erects barriers to competitive entry and innovation.

¹³⁵ See 15 U.S.C. § 18a (2012) (detailing the Hart-Scott-Rodino Antitrust Improvement Act's premerger notification requirements).

¹³⁶ Patient Protection and Affordable Care Act, Consolidation, and the Consequent Impact on Competition in Health Care: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law, 113th Cong. 93–96 (2013) (statement of Thomas L. Greaney, Chester A. Myers Professor of Law, St. Louis University School of Law).

¹³⁷ See infra subpart II.B.

¹³⁸ See infra text accompanying notes 338–65.

¹³⁹ See infra subpart II.C.

¹⁴⁰ See infra notes 186–87 and accompanying text; see also Bruce Jaspen, Though Obamacare Pays Less, Providers Flock to 'Bundled' Medicare Payments, FORBES (Feb. 1, 2013, 8:15 AM), http://www.forbes.com/sites/brucejapsen/2013/02/01/though-obamacare-pays-less-medical-providers-flock-to-bundled-medicare-payments/ [http://perma.cc/S36E-GUSE] (explaining how under the ACA many hospitals are moving away from the traditional fee-for-service model towards "bundled" payments).

A. Managed Care and Insurer-Provider Contracting

The political failure of the Clinton administration's Health Security Act in 1994 led government to abandon its leadership position on health care reform and opened an opportunity for private managed care organizations to fill the vacuum. This "managed care revolution" claimed authority to address serious problems with the cost-effectiveness and quality of health care that researchers and policy experts had by then identified. 141 Operating primarily through selective contracting to create tightly controlled networks of providers, managed care organizations instituted aggressive cost containment strategies such as preauthorization requirements for hospital admission and surgical procedures, concurrent review of the necessity of continued hospitalization, mandatory referrals from primary care physician "gatekeepers" to access specialty care, and alternatives to fee-for-service payment (e.g., capitation, withholds) to induce physicians to reduce utilization of services. 142

Prepaid health plans had a long history in the U.S. health care system by the 1990s, but their role was often a marginal one because of organized opposition from American physicians. Had Beginning with the Nixon administration, however, HMOs such as Kaiser-Permanente (from President Nixon's home state of California) became models for national health reform. Had Many of these organizations also had visionary physician leadership capable of both articulating and operationalizing more cost-effective approaches to care emphasizing disease prevention. Indeed, Kaiser-like HMOs sell an assembled, comprehensive insurance product to consumers on a fully budgeted basis. They manage their costs holistically Had

See FIELD, supra note 13, at 38-44.

¹⁴² Capitation is a contracted rate paid in advance to the physician per assigned patient, regardless of the number or nature of health care services provided. See Patrick C. Alguire, *Understanding Capitation*, AM. COLL. PHYSICIANS (2014), http://www.acponline.org/residents_fellows/career_counseling/under standcapit.htm [http://perma.cc/T9JM-YACR].

¹⁴³ See Starr, supra note 25, at 301–06. The first criminal prosecution of health care providers under the Sherman Act involved a physician boycott of a prepaid health plan in Washington, D.C. See AMA v. United States, 317 U.S. 519 (1943).

¹⁴⁴ See generally David Blumenthal & James A. Morone, The Heart of Power: Health and Politics in the Oval Office 227 (2009) (reviewing health policy and the presidency). To both moderate Republicans and the centrist Democrats who succeeded them, "managed competition" among private health plans of the Kaiser variety seemed a promising free-enterprise alternative to European-style single-payer systems.

See Paul J. Feldstein, Health Care Economics 191–96 (7th ed. 2012).

¹⁴⁶ See id.

and may not even track the "reimbursable claims" so beloved by non-HMO commercial insurers and health care providers. On the other hand, HMOs of this type are difficult to launch where they do not already exist, and a geographic market that consists only of such large organizations will almost certainly be concentrated in antitrust terms.

From the perspective of acute care hospitals, managed care in the 1990s was an additional source of financial pressure that prompted the deployment of various business strategies, including the affiliation of previously independent hospitals into larger systems that could share management, reduce the number of governing boards, market themselves more effectively, pursue economies of scale, and engage in group purchasing of supplies. 147 Undoubtedly, many transactions were intended to improve hospitals' economic clout, but most of them, given the mood of the time, were undertaken as adaptive strategies rather than exploitative ones. 148 For the first time since the 1960s, for-profit hospitals were again major market participants, putting the larger, more established community hospitals on the defensive. 149 Several nonprofit Blue Cross plans and a few prominent nonprofit hospitals converted to for-profit status also, and a variety of entrepreneurial intermediaries entered the fray, sensing the upside potential from showing rapid revenue growth during a stock market boom. 150 Even Columbia-HCA and the other for-profit hospital mega-chains were motivated by things besides market power, primarily capturing investors and increasing share value through rapid growth. 151

¹⁴⁷ See AMERINGER, supra note 28, at 156-57.

¹⁴⁸ See id.

¹⁴⁹ See id.

¹⁵⁰ See id. at 156-59.

¹⁵¹ Columbia-HCA, which became the largest hospital company in the United States, started its rapid expansion by acquiring panicked facilities in over-bedded markets, but it eventually turned to fraudulent billing and accounting practices and shady arrangements with referring physicians. See Jeff Goldsmith, Columbia/HCA: A Failure of Leadership, 17 HEALTH AFF. 27–29 (1998). One can tell a similar story about physician services during this period, emphasizing physician-hospital organizations that were launched to contract jointly with insurers, defensive efforts by hospitals to acquire primary care practices and assure patient referrals, and for-profit physician practice management companies seeking to impress Wall Street. See David Hemenway et al., Physicians' Responses to Financial Incentives: Evidence from a For-Profit Ambulatory Care Center, 322 NEW ENG. J. MEDICINE 1059, 1059–63 (1990) (analyzing Health Stop, a for-profit ambulatory management company, which utilized financial incentives for physicians to increase revenues); Robert Kocher & Nikhil R. Sahni, Hospitals' Race to Employ Physicians—The Logic behind a Money-Losing Proposition, NEW ENG. J. MEDICINE

Managed care, however, found it harder than expected to alter clinical behavior in a system so committed to unassembled products, so thoroughly rooted in physician control, and so devoid of objective accountability. Most managed care organizations did not attempt to reconfigure health care directly but instead tried to reset the health care system's financial incentives by shifting the financial risk of overutilizing services from insurers to providers. 152 The centerpiece of this effort, physician capitation, proved particularly difficult to implement. 153 In a health care system accustomed to piecemeal payment for unassembled products, physicians who had learned to keep their appointment books full and to churn patients through RVUs were challenged to distinguish essential from nonessential care. 154 Even physicians who could manage their own care processes effectively were neither organizationally nor financially prepared to assume responsibility for all the inputs that they had previously "ordered" on someone else's account. 155

A regulatory backlash further discouraged managed care from radically remaking American medicine. The general public had no interest in allowing "evil HMOs" to tell their doctors what to do (and, more importantly, what not to do) should they become seriously ill, while a general economic recovery took some of the pressure off cost containment as a consumer concern. Congress and state legislatures responded to popular fears through regressive legislation that restricted the tools of managed care. Denominated "patient protection acts," these laws mainly sheltered physicians and hospitals from competitive pressure. Several states even adopted "any willing provider" or "freedom of choice" laws, which limited the ability of managed care organizations to develop and manage narrow provider networks.

^{1790, 1790–91 (2011) (}explaining that hospitals in the 1990s acquired primary care practices to assure patient referrals to their respective hospitals).

See Feldstein, supra note 145, at 192–93; Samuel H. Zuvekas & Joel W. Cohen, Paying Physicians by Capitation: Is the Past Now Prologue?, 29 Health Aff. 1661, 1661 (2010).

¹⁵³ See Zuvekas & Cohen, supra note 152, at 1666 (describing the history of physician capitation in the 1980s and 1990s and its failure).

¹154 See generally FELDSTEIN, supra note 145, at 194–96 (explaining the benefits and drawbacks of physician capitation payments).

¹⁵⁵ See id

¹⁵⁶ AMERINGER, supra note 28, at 177-84.

¹⁵⁷ See id. at 180-81.

¹⁵⁸ See id. at 173-74.

 $^{^{159}}$ See, e.g., VA. CODE ANN. § 38.2-3407 (West 2008) ("No hospital, physician or type of provider . . . willing to meet the terms and conditions offered to it or him shall be excluded."); ALA. CODE § 27-45-3 (1988) ("No health insurance policy or

Once managed care was hamstrung, insurers retreated to business strategies that aroused less public controversy than a frontal assault on wasteful treatment. Rather than be seen as limiting choice and rationing care, for example, health insurers began signing contracts with all the hospitals (and nearly all the physicians) in each community and negotiated "discounted" rates for their services. 160 Blue Cross plans—the Oldsmobiles of health insurance—were suddenly back "in"; highly selective HMOs were "out." 161 Large hospitals, many of which had been considered moribund or at least fungible in a managed care world focused on prevention and ambulatory care, found themselves again in control, outpacing both insurers and physicians in both organizational strength and financial wherewithal. 162 Private employers who sponsored health coverage were appeased by shifting more costs to beneficiaries, which proved easier (and less visible) than actually managing care. 163

What remained after the political dust settled was a faux-competitive market in which each private insurer negotiated fees with every hospital and nearly every physician in their geographic regions but did little else to reduce cost or improve quality. Correspondingly, the main goal of providers became to hold their own in these negotiations. Criticizing this minimally managed style of managed care, one physician-health policy expert quoted ironically from a letter he had recently received from a California health insurer, welcoming him to its "carefully selected panel of more than 300 hospitals and 21,000 physicians." These broad, overlapping networks of providers agreed to accept specified prices for unassembled services, or to make percentage concessions from reportedly standard charges that nobody actually paid. A hospital admission

employee benefit plan . . . shall . . . [p]revent any person who is a party to or beneficiary of any such health insurance policy or employee benefit plan from selecting the pharmacy or pharmacist of his choice"). For a discussion of the evolution of "any willing provider" and "freedom of choice" laws, see Fred J. Hellinger, *Any-Willing-Provider and Freedom-of-Choice Laws: An Economic Assessment*, 14 HEALTH AFF. 297 (1995).

¹⁶⁰ See discussion infra subsection III.B.1(d).

See Feldstein, supra note 145, at 207–08.

¹⁶² See id. at 301-02.

¹⁶³ See id. at 190-91.

Robert A. Berenson, *Beyond Competition*, 16 HEALTH AFF. 171, 176 (1997) ("The alignment between health plans and providers envisioned in managed competition is virtually impossible.").

Lisa Kinney Helvin, Note, *Caring for the Uninsured: Are Not-for-Profit Hospitals Doing Their Share?*, 8 YALE J. HEALTH POLY L. & ETHICS 423–24 (2008) (noting that hospitals often charge the poorest patients the highest rates for services).

remained a "blank check" experience, with insurers paying heavily discounted rates for a seemingly endless list of arbitrarily priced items appearing on the final bill and patients bearing significant residual costs. 166

By the turn of the millennium, contractual bargaining over discounted fees was the principal accomplishment that the managed care industry could trumpet to a still skeptical public. Contracts for disaggregated hospital services give insurers somewhat greater predictability regarding cost than would indemnity reimbursement, but they do little to promote efficiency in care delivery. Although proponents of managed care continued to tout its potential benefits, the poster children for its success were HMOs such as Kaiser with shared values, stable patient populations, and solid capital assets—attributes not easily exported or grown to scale elsewhere. 167 All in all, this was a disappointing end to a decade that had begun with high hopes of expanded access, reduced cost growth, and better overall quality of care. One commentator neatly summed up the competitive payoff to managed care by asking: "Is that all there is?"168

B. Managed Care and Hospital Mergers

Former Supreme Court Justice Potter Stewart once quipped that the sole consistency he could detect in litigation under section 7 of the Clayton Act was that the government always won. ¹⁶⁹ From the late 1980s through the early 2000s,

¹⁶⁶ See Fuse Brown, supra note 7, at 15–20, 40–41.

¹⁶⁷ See generally George C. Halvorson & George J. Isham, Epidemic of Care: A Call for Safer, Better, and More Accountable Health Care (2003) (calling for more integrated care through HMOs).

Robert A. Berenson, *Market Competition—Is That All There Is?*, 22 Health Aff. 274 (2003) (reviewing Halvorson & Isham, *supra* note 167). When the economic boom of the 1990s and early 2000s eventually slowed and reversed, broadnetwork HMO products with minimal cost-sharing—which were common in the late 1990s—became unaffordable and, in most markets, unavailable. Only sharp increases in deductibles and copayments prevented PPO-based insurance products from suffering a similar fate. More recently, narrow-network HMOs in which care is more tightly managed seem to be making a comeback, a trend that reduces the bargaining power of hospitals except in true monopoly markets. This newer generation of managed care plans also includes intermediate forms, such as tiered networks with differential cost sharing. David H. Howard, *Adverse Effects of Prohibiting Narrow Provider Networks*, 371 New Eng. J. Medicine 591 (2014) (discussing new network structures).

¹⁶⁹ United States v. Von's Grocery Co., 384 U.S. 270, 301 (1966) (Stewart, J., dissenting) (action by United States to enjoin acquisition by one grocery company of its direct competitor, even though neither has a large market share).

the DOJ and FTC unexpectedly lost seven consecutive challenges to hospital mergers. 170

The government brought cases that fit its horizontal merger guidelines neatly, and anticompetitive effects seemed readily provable using established metrics.¹⁷¹ Because hospitals are large, complex institutions, proposed mergers in many communities tended to be associated with both high premerger HHIs and large potential HHI increases if four hospitals became three or three became two. 172 There are often no substitutes for hospitalization, and patients can travel only so far when seriously ill. Hospitals are hard to build or move, creating barriers to entry by new competitors. 173 Finally, the arguments that community hospitals made in defense of consolidation, such as their service to the poor and their desire to avoid duplicating expensive services (often called a "medical arms race"), fell outside the economic frame that is supposed to govern merger analysis and therefore seemed not to be cognizable in court.174

Why, then, did the government lose so consistently? Although the hospital mergers challenged by the government

See Tenet Healthcare Corp. v. FTC., 186 F.3d 1045 (8th Cir. 1999) (Poplar Bluff, MO) (FTC and state of Missouri unsuccessfully sought to enjoin merger of two hospitals); California v. Sutter Health Sys., 84 F. Supp. 2d 1057 (N.D. Cal. 2000), affd, 217 F.3d 846 (9th Cir. 2000) (Oakland, CA) (state of California unsuccessfully brought suit against two hospitals, claiming that proposed merger would have anticompetitive effect); United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121 (E.D.N.Y. 1997) (Nassau County, NY) (government unsuccessfully sought to enjoin merger of two not-for-profit "anchor hospitals"); FTC. v. Butterworth Health Corp., 946 F. Supp. 1285 (W.D. Mich. 1996) (Grand Rapids, MI) (FTC unsuccessfully sought preliminary injunction to prevent merger of two hospitals); United States v. Mercy Health Servs., 902 F. Supp. 968 (N.D. Iowa 1995), vacated as moot, 107 F.3D 632 (8th Cir. 1997) (Dubuque, IA) (government unsuccessfully brought antitrust action against two hospitals to enjoin proposed merger); FTC. v. Freeman Hosp., 911 F. Supp. 1213 (W.D. Mo. 1995), aff d, 69 F.3d 260 (8th Cir. 1995) (Joplin, MO) (FTC unsuccessfully filed motion for preliminary injunction seeking to prohibit consolidation of hospitals pending resolution of administrative proceedings as to legality of consolidation); FTC v. Hosp. Bd. of Dirs. of Lee County, No. 94-137-CIV-FTM-25D, 1994 U.S. Dist. LEXIS 19770 (M.D. Fla. May 16, 1994), aff d, 38 F.3d 1184 (11th Cir. 1994) (Lee County, FL) (FTC unsuccessfully filed complaint to prevent county hospital board's proposed purchase of private hospital in county, alleging that purchase would be anticompetitive in violation of Clayton Act).

¹⁷¹ U.S. DEP'T OF JUSTICE, 1984 MERGER GUIDELINES § 3 (1984), http://www.justice.gov/atr/hmerger/11249.htm [http://perma.cc/QQ3S-YH5K?type=source] (horizontal merger guidelines in 1984).

 $^{^{172}}$ Id. $\S 3.1$ Concentration and Market Shares (discussing the Herfindahl-Hirschman Index).

¹⁷³ Id. § 4.131 Market Concentration (discussing barriers to entry).

 $^{^{174}}$ $\,$ Id. § 2.12 Relevant Evidence (discussing types of evidence used in merger analysis).

conveyed a clear picture of illegality when seen from the economics-driven middle ground of conventional merger analysis, the image evaporated both higher up and lower down. From the high ground, the cases seemed backwards. In the prevailing narrative of the time, nonprofit hospitals were good guys even if they happened to be sellers, managed care organizations were bad guys even if they happened to be buyers, and the government should not help the latter exploit the former. 175 Down in the weeds, within "markets" that were really communities, the merging hospitals enjoyed a high degree of trust, including from prominent businesspeople who sat on their governing boards and who were also buyers of hospital services for their workers. 176 In one case, the proposed merger was undertaken partially in response to the recommendations from a formal community-based needs assessment, an overhang of 1970s-style health planning that did not confer formal immunity under antitrust law but that nevertheless evidenced the good citizenship of the hospitals.177

Moreover, in the much less sophisticated market that existed then for economic expertise in antitrust litigation, defendants were able to create enough noise in the data to disrupt the evidentiary base needed to find anticompetitive effect. ¹⁷⁸ In particular, geographic markets turned out to be surprisingly malleable, ¹⁷⁹ especially when judges and juries were sympa-

¹⁷⁵ See, e.g., Butterworth Health Corp., 946 F. Supp. at 1302 ("In the real world, hospitals are in the business of saving lives, and managed care organizations are in the business of saving dollars.").

¹⁷⁶ See, e.g., id. at 1296 (detailing defendant hospitals' argument that "non-profit hospitals do not operate in the same manner as profit maximizing businesses," as nonprofit hospital boards "are comprised of community business leaders who have a direct stake in maintaining high quality, low cost hospital services"); FTC. v. Freeman Hosp., 911 F. Supp. 1213, 1222–23 (W.D. Mo. 1995), aff'd, 69 F.3d 260 (8th Cir. 1995) (explaining that because the combined Board is composed primarily of persons who "indirectly represent the interests of hospital consumers... it would not be in these individual Board member's best economic interest to permit prices to be raised beyond a normal competitive level"). Even large insurers could be complacent, allowing courts to infer that competitive harm was unlikely. United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121, 132 (E.D.N.Y. 1997) (quoting the CEO of a major New York insurer as admitting that the merging hospitals were "doing exactly what they should do . . . [to] enable them to deliver a better health care product . . . [and] a much more cost effective system." (alteration in original) (internal quotation marks omitted)) .

Butterworth Health Corp., 946 F. Supp. at 1289.

 $^{^{178}}$ See id. at 1302-03 ("The Court, . . . having duly considered the voluminous exhibits introduced by the parties, . . . concludes that defendants have persuasively rebutted not only the FTC's prima facie case but also the FTC's additional evidence of anticompetitive effect.").

¹⁷⁹ Tenet Health Care Corp. v. FTC, 186 F.3d 1045, 1051–54 (8th Cir. 1999); Long Island Jewish Med. Ctr., 983 F. Supp. at 140–43.

thetic toward the merging parties, and even substantial increases in concentration were interpreted as harmless to consumers using the analytic methods then in vogue. 180

The prosecutorial failures of the 1990s did not sit well with the FTC and DOJ. During the 2000s, while the government's litigators were licking their wounds and very little of interest was happening in the delivery of health care, agency economists and academic researchers studied both the markets involved in these cases and the more general relationship between provider consolidation and price/quality characteristics. This research was collected and analyzed by a Robert Wood Johnson Foundation initiative called the Synthesis Project, which published a report in 2006 and an update in 2012.¹⁸¹ The Synthesis Project concluded that less competitive hospital markets have higher prices and may have lower quality. 182 Moreover, there was no relationship between the fee-forservice prices charged by hospitals and their status as charitable or proprietary entities. 183 In fact nonprofit hospitals as well as for-profit hospitals acquired and exercised market power to the detriment of consumers. 184

The narrative of good and evil changed as well, reinforcing the agencies' commitment to hospital merger enforcement. Managed care had been defanged, and it was no longer considered a public menace. With health care costs continuing to rise and large hospitals seemingly contemptuous of real-world eco-

¹⁸⁰ See Kenneth G. Elzinga & Anthony W. Swishier, Limits of the Elzinga-Hogarty Test in Hospital Mergers: The Evanston Case, 18 Int'l J. Econ. Bus. 133, 142–43 (2011); Cory S. Capps et al., The Silent Majority Fallacy of the Elzinga-Hogarty Criteria: A Critique and New Approach to Analyzing Hospital Mergers 27–29 (Nat'l Bureau of Econ. Research, Working Paper No. 8216, 2001) (predicting the increase in price that various mergers would generate and concluding some hospital mergers could lead to significant price increases); see also Butterworth Health Corp., 946 F. Supp. at 1295 (describing studies conducted by the defendant's economic expert, Dr. William J. Lynk, which found that higher hospital concentration benefits consumers by decreasing nonprofit hospital prices).

 $^{^{181}}$ $\,$ See Gaynor & Town, supra note 17 (studying why the rapid consolidation of hospitals occurred and what impact it had on the price and quality for patients, and the cost of care for hospitals); Vogt & Town, supra note 19.

¹⁸² GAYNOR & TOWN, supra note 19, at 1.

¹⁸³ David Dranove & Richard Ludwick, *Competition and Pricing by Nonprofit Hospitals: A Reassessment of Lynk's Analysis*, 18 J. HEALTH ECON. 87, 97 (1999) (concluding that prices charged by nonprofit and for-profit hospitals post-merger are similar).

¹⁸⁴ Emmett B. Keeler et. al, *The Changing Effects of Competition on Non-profit and For-Profit Hospital Pricing Behavior*, 18 J. Health Econ. 69, 69, 83 (1999) (study showing "the association of hospital prices with measures of market concentration changed steadily [from 1986–94], with prices [at the end of the study] higher in less competitive areas, even for non-profit hospitals").

nomic constraints, providers that were the apparent victims twenty years ago saw their reputations tarnished and their business deals scrutinized once again. A series of reports by the Attorney General's Office in Massachusetts, for example, blamed hospitals—including several world-famous institutions—for charging arbitrary and exorbitant prices. An outgrowth of Massachusetts' enactment in 2006 of state-based universal coverage, these documents presaged the current debate over provider consolidation as the ACA is implemented nationwide.

At the same time, the FTC and DOJ began reinvestigating past transactions and reinvigorating enforcement procedures. The legal payoff from renewed enforcement has been substantial, with the agencies successfully halting or unwinding several recent hospital mergers. ¹⁸⁶ Following its re-analysis of the Evanston, Illinois, market, for example, FTC staff filed an administrative action to challenge a transaction there five years after it had been consummated. ¹⁸⁷ In 2005, an administrative law judge concluded that the merger should be unwound. ¹⁸⁸ More recently, the FTC succeeded in obtaining both a preliminary injunction in federal district court and an ALJ determination of anticompetitive effect in connection with a hospital merger in Toledo, Ohio, and a preliminary injunction against a proposed merger in Rockford, Illinois. ¹⁸⁹

C. Preparing to Fight the Last War: Merger Policy and the ACA

The tide may have turned once again in favor of close scrutiny of hospital consolidation, but recent merger enforcement continues to view hospital markets largely through a late 1990s

¹⁸⁵ Mass. Att'y Gen.'s Office, supra note 76, at 1, 19.

 $^{^{186}}$ $\,$ In re Evanston Northwestern Healthcare Corp. & ENH Med. Group, Inc., No. 9315, 144 F.T.C. 1, 521–23 (Aug. 2, 2007) (Evanston, IL); FTC v. OSF Healthcare Sys., 852 F. Supp. 2d 1069, 1095 (N.D. Ill. 2012) (Rockford, IL); FTC v. ProMedica Health Sys., No. 3:11 CV 47, 2011 U.S. Dist. LEXIS 33434, at *50 (N.D. Ohio Mar. 29, 2011) (Toledo, OH).

 $^{^{187}}$ Complaint at 1, In re Evanston Northwestern Healthcare Corp., (No. 9315), 2005 WL 2845790 (F.T.C.) (Feb. 10, 2004).

 $^{^{188}}$ *In re* Evanston Northwestern Healthcare Corp., 2005 WL 2845790, at *177–78 (F.T.C.) (Oct. 20, 2005). On review, the full Commission agreed the merger was anticompetitive but declined to order divestiture. *In re* Evanston Northwestern Healthcare Corp., 2007 WL 2286195, at *78–79 (F.T.C.) (Aug. 6, 2007).

 $^{^{189}\,\,}$ FTC v. OSF Healthcare Sys., 852 F. Supp. 2d 1069, 1095 (N.D. Ill. 2012); FTC v. ProMedica Health Sys., No 3:11–CV–47, 2011 WL 1219281, at *50 (N.D. Ohio Mar. 29, 2011); In re ProMedica Health System Inc., F.T.C. No. 9346 (Dec. 12, 2011).

lens. To the enforcement agencies, intervention in hospital mergers is still justified primarily by the belief that the merged hospitals will increase their negotiating clout vis-à-vis insurers, not by concern over output restriction and deadweight loss, or even managerial slack, that traditionally comprise the chief harms from market power.¹⁹⁰

Current agency guidance bases enforcement decisions on a model of "two-stage competition" in hospital markets. First, hospitals bargain over the terms of inclusion in insurers' networks; second, insured patients choose among contract facilities for specific services.¹⁹¹ The two-stage construct, however, is a compromise that emerged from the regulatory backlash against managed care in the late 1990s, which discouraged selective contracting and tightly managed care, and normalized broad networks that promise enrollees negotiated prices for covered but unmanaged services.¹⁹² Perpetuating such a stylized, effete form of managed care is hardly a compelling rationale for hostility to provider consolidation among antitrust enforcers.

The Synthesis Project, for example, was a product of its time, and speaks mainly to the effects of health care consolidation between the Clinton administration's health care reform effort in 1993–94 and the passage of the ACA in 2010.¹⁹³ Few of the studies it collected demonstrated specific benefits from lack of hospital consolidation beyond the routine ascription of increased consumer welfare to reduced prices for disaggregated services.¹⁹⁴ As the Institute of Medicine and others have explained, American health care is so routinely wasteful that it is difficult to regard small pricing changes alone as evidence of substantial improvement.¹⁹⁵

¹⁹⁰ In its successful enforcement action in Rockford, Illinois, for example, the FTC argued that "the merger would still harm competition . . . as health plans would have greater leverage playing three hospital systems off one another rather than merely two." Plaintiff's Supplemental Post-Hearing Memorandum in Support of Preliminary Injunction at 8, F.T.C. v. OSF Healthcare Sys., 852 F. Supp. 2d 1069 (N.D. Ill. 2012) (No. 11 C 50344).

 $^{^{191}\,}$ Gregory Vistnes, Hospitals, Mergers, and Two-Stage Competition, 67 Antitrust L.J. 671, 673–74 (2000).

¹⁹² See Paul B. Ginsburg, Competition in Health Care: Its Evolution Over the Past Decade, 24 HEALTH AFF. 1512, 1516–17 (2005).

¹⁹³ See GAYNOR & TOWN, supra note 17; VOGT & TOWN, supra note 19.

 $^{^{194}}$ See Gaynor & Town, supra note 17, at 6; Vogt & Town, supra note 19, at 8-9.

 $^{^{195}}$ INST. OF MED., supra note 21, at 99–105 (estimating annual healthcare waste to be at \$750 billion). For a skeptical view about understanding competition based on merger retrospective studies, see Gregory J. Werden, Inconvenient Truths on Merger Retrospective Studies 19 (Jan. 5, 2015) (unpublished working

Moreover, the enforcement agencies may be inventing problems in markets that happen to be easy to evaluate instead of evaluating markets that have the biggest problems. 196 Price discounting became ubiquitous among hospitals because so many had been built in response to decades of government subsidies and cost-unconscious insurance payment practices. 197 In particular, hospital beds proliferated in small and medium-sized geographic markets, which is where the enforcement agencies tend to concentrate their merger prevention ef-Without Hill-Burton funds, tax-exempt bond forts. 198 financing, Medicare cost-plus and capital cost reimbursement, and other nonmarket supports, these communities would have built fewer and smaller hospitals to begin with. 199 Even after hospital consolidation, there is no evidence that these communities are a major source of waste and inefficiency in health care or that hospitals in larger cities systematically outperform them.

An additional challenge is that the analytic methods currently in vogue depend almost entirely on historical patterns to predict the competitive outcomes of hospital mergers.²⁰⁰ This may be appropriate in times of relative stability, but it is hazardous when the regulatory determinants of health care markets are undergoing rapid change. In the *Marshfield Clinic* case, then Chief Judge Posner justified the defendant's size and scope on the grounds that smaller providers would be

paper), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2545343 [http://perma.cc/6297-5LTV].

¹⁹⁶ It will usually be possible to show high market shares and large changes in concentration whenever one in three or one in four hospitals ceases to operate as an independent business. Under the Merger Guidelines, virtually any merger involving competitors in a market with four hospitals or less would be "presumptively unlawful." *See* U.S. DEP'T OF JUSTICE, *supra* note 171, §§ 4–5.

¹⁹⁷ See Comment, The Hill-Burton Act, 1946–1980: Asynchrony in the Delivery of Health Care to the Poor, 39 MD. L. REV. 316, 324 (1979) [hereinafter "The Hill-Burton Act"].

¹⁹⁸ See Peter J. Hammer & William M. Sage, Critical Issues in Hospital Antitrust Law, 22 Health Aff. 88, 89 (2003). The federal enforcement agencies refrain from challenging the great majority of merger and acquisition transactions that occur each year. In 2013, the Agencies were notified of 1326 total mergers or acquisitions across all industries (the FTC challenged 23 and DOJ challenged 15). Of 59 transactions involving health care services of which they were notified, the government challenged three. Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report: Fiscal Year 2013 (2014), http://www.ftc.gov/system/files/documents/reports/36th-report-fy2013/140521hsrreport.pdf [http://perma.cc/M9F5-K68X].

¹⁹⁹ See The Hill-Burton Act, supra note 197, at 324.

See generally U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (2010), http://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf [http://perma.cc/32RW-D2ED].

"competing to provide horse-and-buggy medicine."²⁰¹ Similarly, a standalone hospital today that is unable to combine its services with those of physicians or adopt new organizational structures and information systems would be competing to provide overly expensive, insufficiently effective "twentieth century medicine," not the high-quality, cost-effective health care needed in the twenty-first century.

Basing enforcement priorities on predictive models that rely so heavily on past conditions is likely to be misleading at best, and at worst to cause substantial harm by chilling productive innovation. The United States is now experiencing another discontinuity in regulation and payment, with profound implications for health care markets.²⁰² Much as government has heavily influenced market structure, conduct, and performance in the past, changes in regulation will influence future competitive outcomes as the ACA is implemented.²⁰³

From one perspective, the ACA was narrowly partisan legislation. From another perspective, the ACA was an extraordinary achievement—the successful culmination of a 100-year effort to universalize health coverage in the United States. ²⁰⁴ Its passage after decades of political and policy failure completed the New Deal pledge of solidarity in the face of adversity and finally brought the United States into the company of the world's other developed nations, all of which make health insurance universally available to their citizens.

 $^{^{201}\,\,}$ Blue Cross & Blue Shield United v. Marshfield Clinic, 65 F.3d 1406, 1412 (7th Cir. 1995).

See Frederick M. Rowe, The Decline of Antitrust and the Delusions of Models: The Faustian Pact of Law and Economics, 72 GEO. L.J. 1511, 1540-41 (1984). The FTC has cautioned in its public statements not to "ignore the lessons of the last quarter century" regarding market power and health care costs. Antitrust Enforcement in the Health Care Industry: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary, 111th Cong. 11 (2010) (statement of Richard A. Feinstein, Dir. of the Bureau of Competition, Fed. Trade Comm'n) [hereinafter "Antitrust Enforcement in the Health Care Industry"]. The first attempt to bring the U.S. health policy more in line with the progressive social democracies of Western Europe was Theodore Roosevelt's 1912 campaign as the presidential nominee of the "Bull Moose" party. Brian Palmer, Obama Says Theodore Roosevelt Lobbied for Health Care Reform, SLATE (Mar. 9, 2010, 4:46 PM), http://www.slate.com/articles/news_and_politics/explainer/ 2010/03/obama_says_theodore_roosevelt_lobbied_for_health_care_reform_.html [http://perma.cc/PP9Q-DG22]. These efforts were renewed by every subsequent Democratic administration and some Republican ones, culminating in the landmark 1965 enactment of Medicare and Medicaid as a medical safety net for the elderly and indigent. See Blumenthal & Morone, supra note 144 (exploring how modern presidents approached the politics of health care and health care reform).

Although its insurance reforms remain controversial in to-day's political environment, the ACA solves on paper the two problems that most had limited Americans' health coverage: uninsurability based on health status and inability to afford insurance.²⁰⁵ But that is not all. The ACA's true breakthrough is its ambition also to address the inefficiency of health care delivery and the nation's poor underlying health.²⁰⁶ The ACA adheres closely to the established path for U.S. health reform, "managed competition," to accomplish these goals, implying that competition must do better in the future than in the past.²⁰⁷ A principal objective of managed competition, strongly evident in the ACA, is to channel insurers into competing on the care they deliver rather than the actuarial risk they bear.²⁰⁸

Managed competition is not synonymous with managed care, but proposals to universalize private health insurance

The ACA addresses the former problem by simultaneously prohibiting insurance companies from rejecting or surcharging applicants because of their health and penalizing individuals who still fail to become insured. The ACA addresses the latter problem by providing tax subsidies to working-class Americans and by giving states generous financial assistance to make Medicaid available to all citizens with income near or below the federal poverty line. Sage, *supra* note 133, at 1082–83.

²⁰⁶ *Id.* at 1082–85. The Institute for Healthcare Improvement, a pioneer in medical quality and safety, has challenged the health care system to pursue a "Triple Aim" of improving the patients' experience of care, improving the health of populations, and reducing per capita cost. INST. FOR HEALTHCARE IMPROVEMENT, IHI TRIPLE AIM INITIATIVE (2015), http://www.ihi.org/Engage/Initiatives/TripleAim/pages/default.aspx [http://perma.cc/3XX3-EE5V].

Thomas L. Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo?*, 89 OR. L. REV. 811, 816–17, 826 (2011). "[M]anaged competition" is most closely associated with the Clinton administration's failed Health Security Act. Sage, *supra* note 133, at 1088. In "single-payer" systems, government acts as sole insurer and pays health care providers directly for covered services, usually at administratively determined rather than competitive rates. Under "managed competition," by contrast, government structures and monitors competition among private health insurers to deliver covered services at market prices. *Id.* at 1089; *see* Alain Enthoven & Richard Kronick, *A Consumer-Choice Health Plan for the 1990s: Universal Health Insurance in a System Designed to Promote Quality and Economy (First of Two Parts), 320 New Eng. J. Med. 29, 34–35 (1989); Alain Enthoven & Richard Kronick, <i>A Consumer-Choice Health Plan for the 1990s: Universal Health Insurance in a System Designed to Promote Quality and Economy (Second of Two Parts), 320 New Eng. J. Med. 99–100 (1989).*

Sage, *supra* note 133, at 1090. The ACA mandates the establishment of public health insurance exchanges across the country to broker coverage for individuals and small employers. Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 1311, 124 Stat. 173 (2010). Insurers participating in these exchanges operate under very different rules from traditional health plans, including offering standardized benefits and complying with a blanket prohibition on medical underwriting. *Id.* § 1302 (outlining essential health benefits); *id.* § 1201 (prohibiting underwriting based on preexisting conditions). The ACA also creates significant incentives to create or expand "private exchanges" not limited to a single employer, which are subject to slightly different rules. *Id.* § 1311–12.

have generally contemplated a leading role for "good" managed care organizations that improve the cost-effectiveness of health care delivery.²⁰⁹ The ACA takes a similar approach, looking to organized systems of care that are publicly accountable for quality as well as cost.²¹⁰ Some of these are likely to be true HMOs such as Kaiser, while others will be conventional health insurers responding to the ACA's changed incentives, and still others will be experimental forms of health care delivery such as ACOs and PCMHs.²¹¹

The ACA also offers a framework for a new vision of competition based on clinical outcomes and value-for-money, employing a variety of tools to change how physicians, hospitals, and insurers do business.²¹² For hospital care, these include strong inducements, both financial and organizational, to avoid expensive inpatient care and, if it becomes necessary, to provide it as safely and cost-effectively as possible.²¹³ For example, in combination with the Medicare program's related commitment to ACOs and medical homes, the ACA shifts payment models away from professional piecework, and toward bundled or global payment for measurable improvements in health outcomes.²¹⁴ CMS directives also call for greater coordination among hospitals, physicians and ancillary care provid-

²⁰⁹ Sage, supra note 133, at 1091.

²¹⁰ See Terry L. Corbett, Healthcare Corporate Structure and the ACA: A Need for Mission Primacy Through a New Organizational Paradigm?, 12 IND. HEALTH L. REV. 103, 165–66 (2015).

For a comparison of various types of organized systems of care see AM. HOSP. ASS'N, ACCOUNTABLE CARE ORG.: AHA RESEARCH SYNTHESIS REPORT 4-5 (2010). Among those changes are the following: (i) Essential Health Benefits, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1302, 124 Stat. 119 (2010); (ii) zero cost sharing for US Preventive Services Task Force A- or Brated services, id. § 4003; (iii) the Patient-Centered Outcomes Research Institute (PCORI) (comparative effectiveness research), id. § 6301; (iv) the Independent Medicare Advisory Board, id. §§ 3403, 10320; (v) Accountable Care Organizations (Medicare Shared Savings Program), id. § 3022, (vi) Patient-Centered Health Homes (Medicaid), id. § 2703; (vii) bundled (episodic) payment pilot program for acute and post-acute care, id. § 3023; (viii) the Center for Medicare and Medicaid Innovation (CMI) to test new, budget-neutral models for care delivery and provider payment, id. § 3141, (ix) the hospital value-based purchasing program (Medicare pay-for-performance), id. § 10326, (x) an expanded Medicare hospital quality reporting system, id. § 3001; (xi) an expanded Medicare physician quality reporting system, id. § 3002; and (xii) the Independence at Home Demonstration Program to avoid hospitalization (Medicare), id. § 3024.

 $^{^{214}}$ On January 26, 2015, the Secretary of the Department of Health and Human Services announced that Medicare would pursue an aggressive transition from fee-for-service to other forms of provider payment. See U.S. Dep't of Health & Human Servs., supra note 37.

ers to meet demand for health promotion, disease prevention, chronic care management, and successful treatment of illness.²¹⁵ Hospitals will only be able to deliver and receive compensation for these more coherent products if they can measure and report both their own performance and the performance of their partners and affiliates, including physicians and other health professionals.²¹⁶

Provider consolidation today therefore represents a renewed search for efficient scope and scale not seen since the early 1980s, when the introduction of Medicare DRGs shocked hospitals into rethinking their business models.²¹⁷ Even taking the efficiency claims of merging parties with a large grain of salt, restructuring may enable hospitals to more accurately assess their costs and outcomes, offer services jointly with physicians and other providers, and accept new forms of payment that reward productive efficiency instead of billable volume. Advances consequent to restructuring might even include improvements in safety and quality that ultimately reduce the need for additional medical services. Given these pressures and expectations, forcing provider markets to remain artifi-

²¹⁵ See, e.g., Patient Protection and Affordable Care Act § 3022 (establishing the Medicare Shared Savings Program for Accountable Care Organizations). Drawing from the "Triple Aim," the three overarching goals of the Centers for Medicare and Medicaid Services (CMS) for Accountable Care Organizations are to enable (i) better care for individuals, (ii) better health for populations, and (iii) lower growth in Medicare Parts A and B expenditures. See Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,803 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425). CMS has also established the Center for Medicare & Medicaid Innovation, which will test innovative payment and delivery models in order to lower costs and enhance quality of care. Stuart Guterman et al., Innovation in Medicare and Medicaid Will Be Central to Health Reform's Success, 29 HEALTH AFF. 1188, 1188–89 (2010).

 $^{^{216}\,}$ For example, section 3025 of the ACA implements the Hospital Readmissions Reduction Program, which decreases Medicare DRG payments for certain hospitals with high readmissions rates. Patient Protection and Affordable Care Act \S 3025. The Affordable Care Act also expands the use of pay-for-performance initiatives in Medicare. *Id.* \S 10326.

²¹⁷ See David Dranove, Viewing Health Care Consolidation Through the Lens of the Economics of Strategy, in Robert Wood Johnson Foundation Changes in Healthcare Financing and Organization Report 2–3 (2010), https://www.academyhealth.org/files/publications/HCFOReportMarch2010.pdf [http://perma.cc/73HY-JY8Z] (noting that hospitals claim mergers bring much-needed efficiencies and prevent cost-increasing medical arms' races). However, hospital consolidation since the 1990s has almost always been limited to the corporate shell. Very few facilities actually have been closed or downsized, which also suggests that consolidated hospitals seldom reduce output as would a classic monopolist. See Kathryn Saenz Duke, Hospitals in a Changing Health Care System, 15 Health Aff. 49, 54 (1996). This departure from the conventional economics of market power provides additional support for the idea that health care products are unlike products elsewhere in the economy.

cially fragmented may actually reduce competing providers' incentives and ability to improve their products. For example, providers in more concentrated markets may be better able to invest in community health and disease prevention, which are essential to long-term cost control.

The tension between old-market and new-market perspectives is evident in a recent judicial decision involving a hospital merger or acquisition, *FTC v. St. Luke's Health System, Ltd.*²¹⁸ In *St. Luke's*, the federal government and the state of Idaho sued a Boise hospital system that had acquired a physician group practice in the adjoining community of Nampa, where the hospital already had an inpatient facility.²¹⁹ After a hearing, a federal judge ordered the hospital to divest itself of the acquired physicians, finding that the transaction had increased the hospital's bargaining leverage with health insurers in the market for "primary care physician" services.²²⁰ The judge also concluded that the acquisition would increase prices for certain diagnostic services ordered by the newly affiliated physicians because the hospital would be able to apply more lucrative billing codes associated with hospital-based care.²²¹

At the same time, however, the judge praised the hospital for preparing to compete in a post-ACA environment in which payment will be based on patient outcomes rather than the volume of services. 222 "In a world that was not governed by the Clayton Act," he wrote, "the best result might be to approve the Acquisition and . . . see if the predicted price increases actually occurred. . . . But the Clayton Act . . . does not give the Court discretion to . . . conduct a health care experiment." 223

Indeed, keeping physicians economically independent of hospitals is not a desirable policy over the long term. Similarly, a market for primary care physician services should lose its coherence as other professionals and other modalities become available to provide basic medical care.²²⁴ At the same time, Medicare should, and undoubtedly will, change its rules re-

²¹⁸ Findings of Fact & Conclusions of Law, FTC v. St. Luke's Health System, Ltd., 2014 WL 407446 (D. Idaho Jan. 24, 2014) (No. 1:13–CV–00116–BLW), aff d sub nom. Saint Alphonsus Med. Ctr.-Nampa, Inc. v. St. Luke's Health Sys., Ltd., 778 F.3d 775 (9th Cir. 2015).

²¹⁹ See Saint Alphonsus, 778 F.3d at 781-82.

See Memorandum Decision & Order at 3–4, FTC v. St. Luke's Health System, Ltd., No. 1:13–CV–00116–BLW (D. Idaho Jan. 24, 2014).

²²¹ See Findings of Fact & Conclusions of Law, supra note 218, ¶¶ 124–25.

²²² See id. ¶ 149.

²²³ Id. ¶¶ 76-77.

 $^{^{224}}$ See, e.g., Daniel McCarthy, Note, The Virtual Economy: Telemedicine and the Supply of Primary Care Physicians in Rural America, 21 Am. J.L. & MED. 111,

garding relative payment for hospital-based and nonhospital outpatient services as the competitive landscape evolves.²²⁵

Admittedly, enthusiasm for productive change may fade if politics intervenes, fatigue sets in, another economic bubble begins, or interest in continued reform is eclipsed by other, more pressing national concerns. But it would be a serious mistake for overzealous antitrust enforcement to turn the demise of delivery system reform into a self-fulfilling prophecy by deterring private innovation or persuading regulators that nothing else needs to be done. The last section of this Article proposes a different approach, in which both antitrust enforcers and regulators work in concert to reorient the health care system toward assembled products and the superior competitive outcomes that those products can offer.

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TOWARD BETTER PRODUCTS: ALIGNING ANTITRUST WITH REGULATORY CHANGE

The persistence of unassembled products in health care poses a challenge for antitrust analysis because the economic underpinnings of modern antitrust law—like many welfarist calculations—tend to regard buyers' preferences as exogenously determined and therefore incontestable. In an influential 1978 book, Robert Bork argued that the activist antitrust law of the time paradoxically made markets less rather than more efficient. The "Chicago School" of antitrust analysis that arose in response was based on a reductionist notion, in which enforcement is used sparingly and legal institutions rec-

^{112–13 (1995) (}examining "telemedicine" as a method of providing basic medical care to rural communities).

²²⁵ In fact, payment policy was altered after this Article was written. *See* Medicare Program: Hospital Outpatient Prospective Payment and Quality Reporting Programs, 80 Fed. Reg. 39,200 (July 8, 2015) (to be codified at 42 C.F.R. pt. 410) (discussing a change to Medicare payment for nonhospital outpatient services).

²²⁶ Compare Matthew D. Adler & Eric A. Posner, Rethinking Cost-Benefit Analysis, 109 Yale L.J. 165, 168 (1999) (analyzing cost-benefit analysis from legal, economic, and philosophical perspectives), with Richard H. Thaler & Cass R. Sunstein, Nudge: Improving Decisions About Health, Wealth, and Happiness 4 (2009) (developing a theory of "libertarian paternalism" to overcome cognitive biases).

²²⁷ ROBERT BORK, THE ANTITRUST PARADOX 71 (1978) (arguing the original intent of antitrust laws as well as economic efficiency make consumer welfare and the protection of competition, rather than competitors, the only goals of antitrust law).

ognize their own limitations. 228 It postulates that markets generate their own priorities, and that competition will occur along the dimensions that consumers prefer. 229 It also posits that innovation and new entry will eventually overcome most monopolies. 230

Chicago School antitrust analysis therefore regards with considerable skepticism the argument that the services that consumers appear to want are not in fact the services that health care providers should compete to deliver.²³¹ The classic judicial statement of this perspective, from the Supreme Court's ruling in *Indiana Federation of Dentists v. FTC*, is that a group of professionals may not preempt "the working of the market by deciding for itself that customers do not need that which they demand," which constitutes "nothing less than a frontal assault on the basic policy of the Sherman Act."²³²

A weakness of the Chicago School approach is its relative incompatibility with highly regulated industries, in which neither baseline conditions nor trajectories of change necessarily follow market models. Public regulation coexists with competition in many industrial sectors, ²³³ yet the interaction between the two governance regimes has seldom been a focus of competition policy. The most straightforward accommodations antitrust analysis makes to regulation—state action and implied federal repeal—are not often available to guide enforcement. ²³⁴ States seldom clearly articulate and actively supervise regulatory regimes that supplant competitive processes (all-payer rate setting and certificate of need laws being vestig-

²²⁸ See Richard A. Posner, *The Chicago School of Antitrust Analysis*, 127 U. PA. L. Rev. 925, 928 (1979) (criticizing government intervention in the economy).

²²⁹ See id. at 926.

²³⁰ See id. at 932-33.

 $^{^{231}\,}$ See Thomas L. Greaney, Chicago's Procrustean Bed: Applying Antitrust Law in Health Care, 71 antitrust L.J. 857, 861 (2004) (noting that the Chicago School is resistant to insights from other disciplines that call into question the core assumption of neoclassical economics).

²³² FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 457, 462 (1986) (quoting Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978)) (holding horizontal policy agreement among dental association members to withhold information requested by insurers to violate the Sherman Act).

See, e.g., Harvey L. Reiter, Competition Between Public and Private Distributors in a Restructured Power Industry, 19 ENERGY L.J. 333, 333–34 (1998) (discussing the impact of regulations on private sector energy distributors).

²³⁴ See Bobak Razavi, Harmonizing Antitrust Exemption Law: A Hybrid Approach to State Action and Implied Repeal, 9 J. Bus. & Sec. L. 1, 6–7 (2009) (discussing the implied repeal and state action accommodations to antitrust regulation).

ial counterexamples). 235 Nor does Congress often deliberately substitute federal regulation for marketplace competition (exclusivity rights for biomedical innovation being a persistent counterexample). 236

The neutrality that antitrust law scrupulously displays toward the objectives of competition in less regulated industries is in significant tension with the wasteful production and allocation habits of the ostensibly competitive but underperforming U.S. health care system.²³⁷ Notably, if health care products systematically lack market justification, antitrust enforcement based on Chicago School principles will be at best a weak force serving the public interest. Whether prices for unassembled products are too high or quality too low in a particular case will have less impact on overall consumer welfare than enabling better products to emerge.²³⁸

This suggests that antitrust law should play a more directive role in health care, breaking down regulatory and habitual barriers to market entry by new competitors offering better value for money, and placing a thumb on the scale in dealing with current competitors in favor of assembling today's faux products into more meaningful ones. The former strategy is entirely compatible with prevailing thinking among antitrust economists, although it takes a long-term view of broadening competition through innovation. The latter strategy is more controversial, but it seems a necessary supplement to antitrust enforcement decisions in existing markets. To accomplish it, antitrust law must develop analytics that anticipate future competitive priorities in health care, integrating both market and regulatory governance.

²³⁵ See Erin C. Fuse Brown, Resurrecting Health Care Rate Regulation, 67 HASTINGS L.J. 85, 96, 129 (2015) (noting that two-thirds of all states have certificate of need laws while only one state (Maryland) uses an all-payer rate setting system).

 $^{^{236}}$ See Henry G. Grabowski et al., The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation, 34 HEALTH AFF. 302 (2015) (arguing that patent protection helps encourage innovation in the market for biomedicine).

²³⁷ See Tanya G.K. Bentley et al., Waste in the U.S. Health Care System: A Conceptual Framework, 86 MILBANK Q. 629, 630 (2008) (contending that waste arises in the U.S. health care system because system participants lack incentives to economize).

²³⁸ The statement in *Indiana Federation of Dentists* was also less sweeping than it might seem. At the time of the decision, antitrust enforcers had only just begun to engage the professions. While the enforcers no longer turned a blind eye to blatantly anticompetitive conduct such as price fixing, they remained deferential to the professional judgments and traditions that are constitutive of the health care industry. *See supra* text accompanying note 217.

How can antitrust law induce product improvement? This section of the Article identifies priority areas for antitrust enforcement, such as deterring exclusionary conduct, discusses the relationship between antitrust enforcers and regulators, and proposes ways in which both groups of competition policymakers can collaborate in pursuit of better health care products.

The ACA creates openings for antitrust enforcers and regulators to work in tandem to improve the outcomes of competition in health care, and the federal antitrust agencies are already cooperating in this effort. The FTC delivered a prepared statement in December 2010 to the Judiciary Committee of the U.S. House of Representatives describing its intention to use antitrust enforcement to drive health care reform by lowering prices and fostering innovation through competition.²³⁹ Subsequently, both antitrust enforcement agencies collaborated with Medicare on rules for the Shared Savings (ACO) Program that attempt to harmonize competition analysis with evolving federal regulation.²⁴⁰

A. Product-Enhancing Antitrust Analysis

If close scrutiny of merger transactions in medium-sized communities is not likely to result in sustained public benefit because it perpetuates an artificial bargaining process between providers and insurers, what enforcement agenda might better serve the goal of product improvement articulated by previous sections of this Article? As a threshold matter, it is important to consider the vocabulary and methods associated with antitrust analysis that bear on the question of using competition policy to help move medical markets toward assembled products.

1. Product Market Definition

Antitrust analysis typically defines a "product market" to analyze the competitive effects of a proposed merger or other challenged conduct.²⁴¹ The product market includes the item being sold and its plausible economic substitutes and excludes

²³⁹ Antitrust Enforcement in the Health Care Industry, supra note 203, at 2.

²⁴⁰ FTC and Dep't of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026–32 (Oct. 28, 2011).

²⁴¹ There is an ongoing debate over the importance of product market definition in merger analysis. *See infra* text accompanying notes 276–78.

other things.²⁴² One clue that disaggregated health care services may not be products in the usual economic sense is that providers with apparent market power may charge higher prices for each service but do not seem to restrict the volume of services as would a classic monopolist or cartel facing a standard demand curve. Instead, health economists use terms like "supplier-induced demand"²⁴³ and the "target-income hypothesis"²⁴⁴ to describe the ability of physicians, in almost any market configuration, to deliver as many services as they choose.²⁴⁵

In delimiting these markets, health care antitrust litigation often finesses the question of how the skills of the providers engaged in the transaction map onto the medical needs of patients—which is another indication that what we have labeled products in health care are not products in the usual sense. When two electronics manufacturers propose to merge, antitrust enforcers define a market for televisions, music players, or computers—not for making blueprints, maintaining "clean rooms," or encasing electronic components in metal frames. However, it is the unusual antitrust case that defines a market for "hip surgery" or "cancer treatment." ²⁴⁷

Admittedly, it would be impractical to measure a merger's effect on competition for each of thousands of billable processes and inputs, or for each of hundreds of medical problems. Enforcement agencies and courts therefore use umbrella terms such as "physician services," "inpatient hospital services," "outpatient services," "acute care services" and the like. In recent litigation, for example, the FTC separated

²⁴² See Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962).

 $^{^{243}}$ Supplier-induced demand occurs when an asymmetry of information exists between supplier and consumer. Feldstein, supra note 145, at 268–69.

²⁴⁴ The target income hypothesis suggests that a physician is motivated to maintain a certain level of desired income and if their actual income falls below this level, a physician will modify his behavior to restore income to the targeted level. *Id.* at 269.

 $^{^{245}}$ This short-term change in output is different from the longer-term changes that occur when newly created diagnoses or therapies turn nonmedical problems into medical ones or alter the risk-benefit calculus of seeking treatment rather than remaining untreated, especially when health insurance moderates the financial consequences.

²⁴⁶ See, e.g., A.I. Root Co. v. Comput./Dynamics, Inc., 806 F.2d 673, 675 (6th Cir. 1986) (defining a "small computer market" in an antitrust case involving electronics manufacturers).

²⁴⁷ See, e.g., Gordon v. Lewistown Hosp., 423 F.3d 184, 212 (3d Cir. 2005) (defining product markets for "general outpatient cataract surgery," "general inpatient cataract surgery," and "general emergency eye surgery").

²⁴⁸ See Findings of Fact & Conclusions of Law, supra note 218, ¶ 49 (identifying the relevant product market as the market for "physician services").

markets for inpatient hospital services from markets for primary care physician services in alleging the likelihood of harm to consumers from the merger of two hospitals with employed physicians.²⁴⁹ This product definition has a superficial appeal because of historical practices generating separate bills for professional and facility fees in both outpatient and inpatient settings. But it fails to capture the intent of Medicare's new care and payment models, which place a heavy emphasis on community-based prevention and management of chronic disease—the dominant source of medical need in the United States today—to reduce the frequency of inpatient acute care.²⁵⁰

In the short term, enforcers and courts are unlikely to shift their approach to product markets in health care from one based on producers or inputs to one based on assembled outputs. Over the longer term, however, they should be open to doing so. As noted above, for example, the market for "primary care physician" services defined in the *St. Luke*'s case may become incoherent when consumers access basic medical care from a variety of sources, ranging from nurse practitioners to mobile medical apps.²⁵¹

There is also a deeper issue. With respect to physicians, we know that most physicians are willing to care for patients with more than a single type of problem, but we also know that very few physicians are willing to care for patients with every type of problem. With respect to hospitals, we know that they do far more than provide a place for patients to sleep, but we are less confident about whether the successful treatment of a particular problem depends primarily on characteristics of the hospital or of the physicians who happen to be present there. If a physician lacks a key credential, or a hospital lacks a critical technology, it may *disqualify* that provider from certain ser-

²⁴⁹ See Complaint for Temporary Restraining Order & Preliminary Injunction, FTC v. OSF Healthcare Sys., 2011 WL 6917813 (N.D. Ill. Nov. 18, 2011) (No. 11–CV–50344); see also Saint Alphonsus Med. Ctr.-Nampa, Inc. v. St. Luke's Health Sys., Ltd., 778 F.3d 775 (9th Cir. 2015).

²⁵⁰ For example, through its authority granted under section 3021 of the Affordable Care Act, the CMS Center for Medicare & Medicaid Innovation created the Comprehensive Primary Care Initiative, which is designed, in part, to encourage primary care in an effort to reduce preventable hospitalizations. See Melinda Abrams et al., The Commonwealth Fund, Realizing Health Reform's Potential: How the Affordable Care Act Will Strengthen Primary Care and Benefit Patients, Providers, and Payers 10 (2011).

²⁵¹ See Miranda Laurant et al., Substitution of Doctors by Nurses in Primary Care (Review), Cochrane Libra, 2005, at 1, 2 (finding that properly trained nurses can produce as high quality care as primary care physicians).

vices—hence notions of "primary," "secondary," and "tertiary" care.²⁵² But what *qualifies* that provider to do a particular task, and what makes that provider truly good at it, are harder concepts to nail down.

2. Payer Submarkets

It is important to include all health care payers in most competitive analyses. Plaintiffs in antitrust cases attempt to draw markets as narrowly as possible, so that market concentration appears higher and the risk of anticompetitive effect greater.²⁵³ One strategy, embraced by both the enforcement agencies and private plaintiffs, has been to limit the alleged product market to health care services purchased by private payers, meaning commercial insurance companies and self-insured employers rather than government health insurance programs such as Medicare and Medicaid.²⁵⁴ The logic behind this position is that government programs pay administered prices, not market prices, and therefore would not be harmed economically by a merger.

However, the scale of government investment in health care renders any analysis of competitive outcomes that focuses only on private market transactions misleading.²⁵⁵ Public payers often set the tone for private payers, and competitive outcomes flow from the interaction between them. Medicare is an essential funder of nearly all hospitals in the United States, and its practices serve as a benchmark for both the amount paid by private insurers and the payment methodology they employ.²⁵⁶ Sometimes this occurs because government takes

 $^{^{252}\,}$ See FTC v. Butterworth Health Corp., 946 F. Supp. 1285, 1288 n.2 (W.D. Mich. 1996) (defining these levels of care).

²⁵³ See Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 469 n.15 (1991) ("Because market power is often inferred from market share, market definition generally determines the result of the case."); JetAway Aviation, LLC v. Bd. of Cty. Comm'rs, 754 F.3d 824, 850 (10th Cir. 2014) (noting that the plaintiff bears the burden of defining the relevant market in antitrust cases).

²⁵⁴ See, e.g., Sidibe v. Sutter Health, 4 F. Supp. 3d 1160, 1165–66 (N.D. Cal. 2013); First Amended Complaint at 16, Sidibe v. Sutter Health, 4 F. Supp. 3d 1160 (N.D. Cal. 2013) (No. 3:12–cv–4854–LB) (noting that plaintiffs argue that the relevant product market consisted of inpatient services not paid for by Medicare, Medicaid, or government payers).

²⁵⁵ Moreover, excluding public payers has the unfortunate consequence of making managed care contracting over faux products even more central to the competitive analysis than if public payers were included. *See supra* text accompanying notes 198–203.

In addition to negotiating discounts based on "charges," private insurers often employ payment approaches based on government programs, such as explicit percentages of Medicare DRG payments, or per diem rates similar to those used by Medicaid. For this reason, it is virtually certain that as Medicare changes

the lead, as in the Medicare PPS (DRG) system, which was tested at the state level and then adopted federally. 257 At other times, it occurs because government, for both political and pragmatic reasons, models its policies on those already in place in the private sector, as with the adoption of Medicare in $^{1965.258}$ Because the ACA relies heavily on both Medicare and Medicaid, public payers will continue to be major drivers of market performance. 259

Although some courts have accepted a payer-specific product market definition, ²⁶⁰ others have not. In *Little Rock Cardiology Clinic v. Baptist Health*, ²⁶¹ the plaintiff alleged a product market limited to only those patients covered by private health insurance. Finding this definition "legally flawed," the district court granted the defendant's motion to dismiss. ²⁶² The Eighth Circuit affirmed, holding that, "as a matter of law, in an antitrust claim brought by a seller, a product market cannot be limited to a single method of payment when there are other methods of payment that are acceptable to the seller." ²⁶³

3. Characterizing the Parties

Properly characterizing the parties in transactions that might move the health care system from unassembled to assembled products is challenging. Antitrust enforcers are accustomed to using labels with clear economic meanings, such as buyer, seller, vertical agreement, horizontal agreement, sub-

its payment methods, collaborative structures (e.g., ACOs, medical homes), and quality benchmarking practices, private insurers will pursue similar purchasing strategies. *See, e.g.*, BERENSON & BURTON, *supra* note 8 (noting that, while ACOs are typically viewed as primarily a Medicare program, Medicare's approach is already affecting the way in which private health plans pay providers, with nearly 100 medical groups on track to become ACOs).

 257 Janus & Brown, *supra* note 55, at 298 (discussing the adoption by the federal government in 1983 of Diagnosis Related Groups (DRGs), which were modeled off a successful program administered by the New Jersey Department of Health in the late 1970s).

William M. Sage, Competition Policy and the Future of Health Care Markets 25 (Sept. 15, 2013) (unpublished manuscript) (on file with the author).

259 See supra text accompanying note 198.

 260 See, e.g., FTC v. OSF Healthcare Sys., 852 F. Supp. 2d 1069, 1080 (N.D. Ill. 2012) (noting that the FTC established a prima facie case that merger of two not-for-profit health care systems would be anticompetitive).

 261 591 F.3d 591, 596–98 (8th Cir. 2009) (holding relevant product market could not be limited to patients using private insurance and relevant geographic market could not be limited to single city).

²⁶² Id. at 595.

263 Id. at 598-99.

stitute, or complement.²⁶⁴ Because of the complicated agency relationships involved, and the consensus need for significant industry restructuring to improve efficiency, these labels are often ambiguous in health care.²⁶⁵ If hospitals and their affiliated physicians join forces to finance and direct comprehensive care, for example, today's providers may be tomorrow's payers. If care continues to move from dedicated facilities to community and home settings, today's hospitals may be tomorrow's physicians. From the perspective of desired innovation, all intermediaries between a patient and the treatment he or she receives are contestable.

The correct status of health insurers in the analysis of competition is particularly difficult to ascertain. Antitrust laws were enacted to protect consumers, and seller conduct in markets has usually been more closely scrutinized than buyer conduct.²⁶⁶ As a result, courts seldom inquire into the priorities and practices of health plans when evaluating hospital mergers.²⁶⁷ However, health insurers can reasonably be regarded not only as buyers from hospital systems but also as potentially competing with those systems to provide coordinated services (i.e., assembled products) for a bundled or global payment. Arranging for comprehensive health care at affordable prices was the expected role for HMOs from the 1970s into the 1990s and is a desired outcome of the current move toward ACOs.²⁶⁸

²⁶⁴ See Thomas G. Krattenmaker et al., Monopoly Power and Market Power in Antritrust Law, 76 Geo. L.J. 241 (1987).

²⁶⁵ Peter J. Hammer & William M. Sage, *Monopsony as an Agency and Regulatory Problem in Health Care*, 71 Antitrust L.J. 949, 950 (2004) (suggesting antitrust courts should pay closer attention to agency issues when evaluating the conduct of the buyer in health care).

See El Aguila Food Prods., Inc. v. Gruma Corp., 301 F. Supp. 2d 612, 627 (S.D. Tex. 2003); Robert H. Lande, Wealth Transfers as the Original and Primary Concern of Antitrust: The Efficiency Interpretation Challenged, 34 HASTINGS L.J. 65, 122–29 (1982) (arguing that congressional debates over the Sherman Act condemned trusts and monopolies because they had enough power to unfairly extract wealth from consumers); Robert H. Lande, Proving the Obvious: The Antitrust Laws Were Passed to Protect Consumers (Not Just Increase Efficiency), 50 HASTINGS L.J. 959, 961–62 (1999).

²⁶⁷ Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 COLUM. L. REV. 545, 615 (2002).

Before managed care devolved into insurer-provider bargaining toward the end of the 1990s, hospital companies such as Humana developed or acquired insurance businesses, which they operated alongside their provider businesses as a vertical integration strategy. See David G. Knott, Vertical Integration: 80's Fad or Health Care's Future?, in Strategy & Business (1997), (noting that health care companies, including Humana, attempted to vertically integrate by acquiring hospitals); Hammer & Sage, supra note 267, at 567. After the public backlash against that generation of managed care, integration receded as a corporate goal

Similarly, the distinction between vertical and horizontal agreements under established antitrust law needs to be refined if it is to be correctly applied in health care. The FTC has claimed that ACO-based systems such as Medicare's Pioneer and Shared Savings Programs envision mainly "vertical" integration between hospitals and physicians, not "horizontal" consolidation of hospitals.²⁶⁹ However, this mischaracterizes the physician-hospital relationship and shortchanges the potential efficiency gains from new financing and delivery models. Hospitals are not suppliers to physicians, nor are physicians sales agents for hospitals—both typical vertical relationships. Rather, physicians and hospitals are coproducers of acute and complex medical care. Although collaboration between them could be beneficial, they could as easily compete with each other to deliver that care as medical organizations and products change.

4. Unilateral Effects and Status Quo Bias

Unlike earlier versions, the enforcement agencies' 2010 Horizontal Merger Guidelines emphasize the "unilateral effects" of mergers more than their "coordinated effects."²⁷⁰ Collusion is easier among fewer competitors (oligopoly), as is so-called conscious parallelism, which is why concentrated industries tend to be less competitive.²⁷¹ A merger's "coordinated effects" are a measure of how much more likely it is that the remaining competitors will act as a cartel.²⁷² By contrast, a merger's "unilateral effects" are a measure of whether consumers are likely to be disadvantaged by the elimination of competition between the merging parties, regardless of other market participants.²⁷³ Since the 1990s, antitrust economists have developed increasingly sophisticated (and expensive) modeling tools

and the insurer and hospital businesses were separated again, for fear that unaffiliated hospitals (who had gained influence) would refuse to do business with an insurer connected to a rival hospital system.

²⁶⁹ See Complaint for Temporary Restraining Order and Preliminary Injunction at 15–22, F.T.C. v. OSF Healthcare Sys., 2012 WL 1144620 (N.D. Ill. Apr. 5, 2012) (No. 11–cv–50344), 2011 WL 6917813; see also U.S. Dep't of Justice & Federal Trade Commission, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011).

U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, supra note 200, at 20.

There are many duopolies that are fiercely competitive, sometimes because the rivalry between the two companies has acquired a personal dimension. See id.; Erwin A. Blackstone et al., The Case of Duopoly: Industry Structure is Not a Sufficient Basis for Imposing Regulation, 34 REG. 12, 17 (2012).

U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, supra note 200, at 2.

²⁷³ Id. at 20.

to demonstrate potential harm from consolidation, including by estimating unilateral effects.²⁷⁴

One problem with unilateral effects analysis is that it biases the evidence toward past events even if the market environment is changing rapidly, as is the case today in the health care system. Whether a market will be more collusive in the future requires assessing the commercial conditions that are likely to prevail in the future, as well as incorporating any evidence that exists of past collusion. However, only historical data on competition between the merging parties is sufficiently comprehensive to feed the econometric models that estimate unilateral effects. For example, these models use such data to estimate the amount of business that each hospital would lose to the other should it raise prices as an indicator of whether a merger between them would eliminate an important source of market discipline.²⁷⁵

The other problem with unilateral effects analysis is that it often substitutes for defining markets with precision when evaluating a merger of two large competitors. In fact, the 2010 Horizontal Merger Guidelines de-emphasized product market definition because unilateral effects tests seem to *directly* measure diminished competition following a merger.²⁷⁶ To the extent that agencies and courts are persuaded by critical loss analysis and similar econometric models, they may no longer require exact definitions of either product or geographic mar-

²⁷⁴ Examples include willingness to pay (WTP) and diversion analysis, which are simulation-based methods that model patient flows and fee negotiations between health plans and the merging institutions. WTP is the maximum amount an individual is willing to pay for services considering the other available hospitals. Amiram Gafni, Willingness to Pay: What's in a Name?, 14 PHARMACOECONOMICS 465, 470 (1998). Diversion analysis evaluates the degree to which the merging facilities are each other's closest competitors. Subramaniam Ramanarayanan, Diversion Analysis as Applied to Hospital Mergers: A Primer, NERA June 24, 2014 (http://www.nera.com/content/dam/nera/publications/archive2/PUB_Diversion_Analysis_Hospital_Mergers_0614.pdf). Another method, critical loss analysis, which identifies for a given price increase the amount of sales that can be lost before the price increase becomes unprofitable, has been criticized. Daniel P. O'Brien & Abraham L. Wickelgren, A Critical Analysis of Critical Loss Analysis, 71 Antitriust L.J. 161, 161 (2003).

²⁷⁵ O'Brien & Wickelgren, supra note 274, at 163–164.

²⁷⁶ U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 200, at 21 ("Where sufficient data are available, the Agencies may construct economic models designed to quantify the unilateral price effects resulting from the merger... These merger simulation methods need not rely on market definition."). Thus far, courts appear skeptical. *See*, *e.g.*, Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc., No. C-09-3854 MMC, 2010 WL 1541257 (N.D. Cal. Apr. 16, 2010), *aff'd*, 433 F. App'x 598 (9th Cir. 2011) (dismissing a complaint for a wide and unspecific product market definition).

kets. 277 This may not be problematic in many industries, but in health care it allows both enforcers and decision makers to ignore the artificiality of what pass for products today as well as what might be different in the future. 278

Current investigative practices by the enforcement agencies similarly bias enforcement toward the status quo. There is often a long preinvestigation phase, during which agencies contact both the merging parties and others in the community, aggressively elicit detailed testimony from current market participants, and gather large volumes of competitively sensitive historical data for their econometric models.²⁷⁹ Among other things, this approach may induce those interviewed to present a more fixed view of the market than circumstances actually warrant, and it may undervalue entry and innovation.

B. Antitrust Enforcement Actions and Product Improvement

What forms of anticompetitive conduct most hinder product improvement in health care? There are two major categories of disputes in which antitrust enforcement is likely to have beneficial effects. First are cases involving private exclusionary conduct.²⁸⁰ The activity challenged in these cases has one objective: maintaining the status quo.²⁸¹ If health care providers lack a habit of selling assembled products, maybe new competitors—or at least the threat of new competitors—might instill it. Antitrust enforcement can help ensure that these competitors have a fair chance, both to compete as a general matter and to serve particular customers and communities.

Second are situations involving the aggregation of providers or services into groups, the stated purpose of which is to improve quality or efficiency. As Adam Smith recognized centuries ago, gatherings of competitors constitute an invitation to

²⁷⁷ J. Douglas Richards, *Is Market Definition Necessary in Sherman Act Cases When Anticompetitive Effects Can Be Shown with Direct Evidence?*, **26** ANTITRUST 53, 54–55 (2012).

²⁷⁸ See supra text accompanying notes 154–56.

²⁷⁹ See, e.g., U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS 4 (2000) (noting procedures for initial examinations of mergers and subsequent investigations) [hereinafter "ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS"].

 $^{^{280}\,}$ Jonathan B. Baker, Exclusion as a Core Competition Concern, 78 ANTITRUST L.J. 527, 532 (2013) (recognizing exclusion as a core concern of competition policy).

See Hammer & Sage, supra note 267 at, 630 (noting that strict limitation of standing to traditional customers and competitors in an industry will favor the status quo).

behave anticompetitively.²⁸² In health care, however, physicians have been so atomized for so long—and so separated from hospitals—that they need time and space to learn to work together. In these situations, therefore, antitrust enforcers need to be sensitive to context in order to judge whether a particular aggregation is likely to succeed in bringing providers together to construct assembled products, or whether it is more likely to turn collusive or exclusionary.

1. Exclusionary Conduct Cases

Antitrust enforcement to prevent the exclusion of sellers from markets is an important part of promoting product improvement. Although antitrust laws protect competition as a whole, not individual competitors, it will be hard to move toward assembled health care products if potentially "disruptive" innovators find themselves excluded from the boat for rocking it. This is not to say that any party should have open access to contracting partners or that established resources constitute "essential facilities." To the contrary, producing an assembled product may well require greater rather than less exclusivity. However, given the historically constrained patterns of buying and selling health care products that currently prevail, making sure that new competitors can get a foot in the door is important.

a. Professional Boards and Purported State Action

Obstacles to product improvement in health care may be exacerbated by the intransigence of professional licensing bodies, which are authorized by state law but function as industry self-regulators.²⁸⁵ Assembled health care products require standardized production, organization and teamwork, warran-

 $^{^{282}\,}$ Adam Smith, The Wealth of Nations 117 (Alfred A. Knopf ed., 1910) ("People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices.").

²⁸³ Clayton M. Christensen, *Disruptive Innovation* (2015), http://www.clayton christensen.com/key-concepts/ [http://perma.cc/68NG-BV3V] (describing a process by which a product or service takes root initially in simple applications at the bottom of a market and then relentlessly moves up market, eventually displacing established competitors).

Robert Pitofsky et al., *The Essential Facilities Doctrine Under U.S. Antitrust Law*, 70 Antitrust L.J. 443, 462 (2002) (noting that essential facilities doctrine is applied cautiously in lower courts pursuant to limiting principles).

²⁸⁵ See Aaron Edlin & Rebecca Haw, Cartels by Another Name: Should Licensed Occupations Face Antitrust Scrutiny?, 162 U. PA. L. REV. 1093, 1096–97 (2014) (noting that licensing agencies often insulate incumbents from competition).

ties for poor quality, and continuous innovation in response to consumer preferences. Health professional licensing bodies, especially state boards of medicine, represent the opposite values: professional discretion, generous payment, individual physician control, accountability only for egregious harm, and practice set by habit and tradition under the guise of ethics.

Scholarly criticism of occupational licensing, previously associated mainly with libertarian thought, is becoming significantly broader. Because most members of licensing bodies are selected from the profession they oversee, they tend to guard their professional turf and view most issues through the lens of their own training and practice. They understand their job as protecting the public, but they seldom offer the public a strong or direct voice. As a result, it is the rare professional board that acts contrary to the economic interests of its licensees. Nor do they tend to work cooperatively with licensing boards for other professions, even those that are engaged in service to the same clientele.

A recent upturn in federal antitrust challenges to anticompetitive conduct by professional licensing boards is a positive sign for product enhancement in health care. A watershed case is *North Carolina Board of Dental Examiners v. FTC*,²⁸⁷ which was decided by the United States Supreme Court in early 2015. *North Carolina Board* involved cease-and-desist letters sent by a state dental board to nondentist sellers of teeth whitening services, as well as to owners of the shopping malls where many such businesses are located.²⁸⁸ The letters advised them, without any formal legal determination under the Board's statutory authority, that their activities constituted the unlicensed practice of dentistry and could be prosecuted as

Professional licensing boards, especially the powerful medical boards controlled by physicians, have attracted criticism from conservative economists for decades. Milton Friedman wrote in 1962, "I am . . . persuaded that [restrictive] licensure has reduced both the quantity and quality of medical practice; . . . that it has forced the public to pay more for less satisfactory medical service, and that it has retarded technological development both in medicine itself and in the organization of medical practice." MILTON FRIEDMAN, CAPITALISM AND FREEDOM 149–59 (1962). See also Edlin & Haw, supra note 285, at 1094 (contending that the state action doctrine should not prevent antitrust suits against state licensing boards that are comprised of private competitors); Alexander Volokh, The New Private-Regulation Skepticism: Due Process, Non-Delegation, and Antitrust Challenges, 37 HARV. J.L. & PUB. POL'Y 931, 933 (2014) (suggesting useful tools to challenge self-interested private regulation).

 $^{^{287}}$ $\,$ 135 S. Ct. 1101, 1101 (2015), $\it aff g$ N.C. State Bd. of Dental Exam'rs v. FTC, 717 F.3d 359 (4th Cir. 2013).

²⁸⁸ See id. at 1109.

a crime.²⁸⁹ FTC's Bureau of Competition challenged this collective conduct as an unfair trade practice by representatives of the private dental profession, and its internal adjudicatory ruling was upheld on appeal by the Fourth Circuit.²⁹⁰ Affirming that decision, the Supreme Court held categorically that professional boards and other state agencies controlled by current market participants could not claim state action immunity unless their conduct is actively supervised by the state itself.²⁹¹ This holding may have lasting benefits for competitive entry in professional services, much of which should involve assembled products that appeal to consumers.

b. Excluding Rival Professions

If health care products are to improve, it is important that professionals with diverse training, skills, priorities, and ways of doing things be allowed access to health care markets. However, physicians often have discouraged both competition and innovation by excluding other classes of health professionals or nonprofessional actors from providing health care services. Often this is done through state legislation or the actions of licensing boards described above. But it can also be attempted in private, particularly in connection with limiting the classes of provider who receive hospital privileges or are permitted to join managed care networks. In the latter case, insurers may be complicit in imposing restrictions because admitting new types of professionals would likely expand the number and variety of disaggregated process steps that they are obligated to cover and finance.

Most litigated cases have been brought by private parties and have involved longstanding professional rivalries, such as between orthopedic physicians and chiropractors, or between physician ophthalmologists and optometrists. In *American Chiropractic Association v. Trigon Healthcare Inc.*, a chiropractic group sued Virginia's largest health insurance company, claim-

²⁸⁹ Id

²⁹⁰ See N.C. State Bd. of Dental Exam'rs, 717 F.3d at 375.

 $^{^{291}\,}$ The Supreme Court had previously addressed the state action doctrine in 2013, holding unanimously that a Georgia public hospital's acquisition of its principal rival was not authorized by state law in a manner that shielded it from antitrust scrutiny. See FTC v. Phoebe Putney Health Sys., Inc., 133 S. Ct. 1003, 1007 (2013).

 $^{^{292}}$ See Philip C. Kissam, Government Policy Toward Medical Accreditation and Certification: The Antitrust Laws and Other Procompetitive Strategies, 1983 Wis. L. Rev. 1, 7–12 (1983).

 $^{^{293}}$ $\,$ See Little Rock Cardiology Clinic PA v. Baptist Health, 591 F.3d 591, 594 (8th Cir. 2009).

ing it conspired with its advisory committee of physicians and "created false referral guidelines meant to limit the usage of chiropractors for the treatment of lower back pain."²⁹⁴ In *Abraham v. Intermountain Health Care, Inc.*, a group of optometrists sued an integrated delivery system that includes both hospitals and managed care plans, alleging that it conspired with ophthalmologists "to exclude optometrists as a class" from providing nonsurgical eye care services to enrollees.²⁹⁵ These private complaints have seldom succeeded in court,²⁹⁶ but the antitrust agencies should be alert to situations involving dominant insurers and large groups of favored practitioners.

c. Excluding Specialty Hospitals and Their Physician-Owners

"Specialty hospitals" have been plaintiffs in several recent antitrust disputes.²⁹⁷ These cases typically involve allegations that traditional hospitals conspired together and with health insurers to keep a physician-owned hospital out of the market.²⁹⁸ As one court noted, these cases

ultimately involve[] the proper place of physician-owned healthcare ventures in the broad landscape of United States healthcare. Both sides insist they solely possess the moral high ground . . . [but n]either side can make a colorable argument that the parties' profits is not a central factor in their dispute. 299

 $^{^{294}}$ 367 F.3d 212, 221 (4th Cir. 2004) (rejecting the claim on the ground that a corporation cannot conspire with itself, and deeming the committee its corporate agent).

 $^{^{295}}$ 461 F.3d 1249, 1256 (10th Cir. 2006) (dismissing the claims for lack of standing or antitrust injury).

²⁹⁶ See id. at 1266.

See, e.g., Med. Ctr. at Elizabeth Place, LLC v. Premier Health Partners, 294 F.R.D. 87, 87-88 (S.D. Ohio 2013) ("[P]hysician-owned hospital...alleg[ed] that defendants coerced commercial health insurers to refuse plaintiff full access to their networks and that defendants coerced insurers to provide reimbursement rates below market and below the rates defendants demanded for the same services."); Rome Ambulatory Surgical Ctr., LLC v. Rome Mem'l Hosp., Inc., 349 F. Supp. 2d 389, 389 (N.D.N.Y. 2004) ("[A]mbulatory surgical facility that went out of business sued non-profit community hospital, alleging antitrust violations under Sherman Act.").

²⁹⁸ *See supra* note 294–95.

Heartland Surgical Specialty Hosp., LLC v. Midwest Div., Inc., 527 F. Supp. 2d 1257, 1264 (D. Kan. 2007) (denying summary judgment in a suit by a physician-owned hospital offering orthopedic, neurological, plastic, and general surgery, as well as pain management, against two managed care organizations and four hospitals). But see Little Rock Cardiology Clinic PA v. Baptist Health, 591 F.3d 591, 594 (8th Cir. 2009) (dismissing claims that the largest hospital company and the largest insurer in Arkansas conspired "to restrain trade in, and monopolize the market for, cardiology services for privately insured patients" by

While the majority of these cases are brought privately, and none have been initiated by the DOJ or FTC, at least one case involved public enforcement. In Texas v. Memorial Hermann Healthcare System, the state attorney general filed suit against a major hospital system, alleging it discouraged health insurers from doing business with Houston Town and Country Hospital by threatening to terminate contracts with, or impose substantial rate increases on, health plans that contracted with the physician-owned facility. 301

Specialty hospitals represent a mixed blessing for improving the products sold in health care markets. On one hand, evidence exists that these physician-owned businesses may cherry-pick lucrative procedures on well-insured patients, leaving community hospitals fewer resources with which to finance comprehensive services and care for the uninsured. For these reasons, the federal government placed a three-year moratorium on specialty hospitals in the early 2000s, which was essentially made permanent by changes to federal fraud and abuse law in the ACA.

On the other hand, provider organizations with strong physician leadership and a commitment to excellence in a limited number of services are more likely to offer them on an assembled basis for a competitive price. It is therefore likely that federal law will change again in the future to allow physician-owned specialty hospitals, ambulatory surgery centers, and other integrated clinical organizations receiving bundled payments to compete against traditional community hospitals.

revoking a cardiology group's admitting privileges and in-network contract after it launched a new heart hospital).

 $^{^{300}}$ See Plaintiff's Original Petition, Texas v. Mem'l Hermann Healthcare Sys., (No. 2009–04609) (2009).

³⁰¹ Id

³⁰² See Lawrence P. Casalino et al., Focused Factories? Physician-Owned Specialty Facilities, 22 Health Aff. 56, 67 (2003) (describing the recent increase in physician-owned specialty hospitals, reasons for this increase, possible impacts, and potential policy options).

 $^{^{303}}$ Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108–173, \S 117, 117 Stat. 2066 (2003).

³⁰⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6001, 124 Stat. 119 (2010).

³⁰⁵ See Surgery Ctr. of Okla., Surgery Pricing (2015), http://www.surgery centerok.com/pricing/ [http://perma.cc/A45F-8SX7]; see generally Regina E. Herzlinger, Market-Driven Health Care: Who Wins, Who Loses in the Transformation of America's Largest Service Industry 157–99 (1997) (hypothesizing that integrated delivery systems will give way to "focused factories" that offer all the care needed to treat a particular disease).

d. Contractual Entrenchment

Close scrutiny of provider-insurer arrangements that deter competitive entry on one or both sides of the payment relationship is an important part of competition policy. Health care products cannot be efficiently assembled and sold without contractual flexibility. On Longstanding control by the medical profession, which traditionally assumed privileges and obligations based on status, led the health care system to underuse contracts for most of its history.

However, contracts involving dominant players in current health care markets can deter entry by new competitors and consequent innovation by making the business opportunities they cover less contestable. Economist Fiona Scott Morton describes these as "contracts that reference rivals." Antitrust enforcers should scrutinize these contracts for unreasonable restraints of trade that exclude potential competitors on either side of the transaction.

It is tempting to think of a health insurer as a motivated purchaser of medical care, but insurers are imperfect agents for policyholders and for the private employers who sponsor most health coverage.³⁰⁹ Unlike physicians, who tend to work through licensing boards or professional groups to exclude unwelcome competitors, health insurers and hospitals are corporate organizations that more often erect barriers to competition as part of their private business agreements.³¹⁰

In some cases, an insurer or provider alleges that another provider and insurer have entered into an agreement that excludes it but sues only its direct competitor. The counterparty to the agreement is seen as grudgingly participating to ensure that it is not harmed. In other cases, insurers and providers seem to be willfully working together for their mutual benefit,

³⁰⁶ See Dranove & Ludwick supra note 183.

³⁰⁷ Compare Clark C. Havighurst, Health Care Choices: Private Contracts as Instruments of Health Reform 250 (1995) (outlining how innovative health care contracts can be structured to provide varied levels of coverage and pricing in order to allow real choice in benefits and costs, rather than letting the federal government dictate the degree of insurance one must purchase), with Henry Maine, Ancient Law (1861) (positing a general transition of legal obligations from status in ancient societies to contract in modern ones).

 $^{^{308}}$ Fiona M. Scott Morton, Contracts that Reference Rivals, 27 Antitrust 72, 72 (2013) (defining such contracts as "a contract between a buyer and a seller that refers to, and whose terms may depend on, information $\it outside$ this 'standard' buyer-seller contractual relationship . . . [based on] information . . . from other transactions to which those same firms are . . . party." (emphasis added)).

³⁰⁹ See Hammer & Sage, supra note 267.

³¹⁰ See supra notes 297–99.

and both parties are sued by the excluded rival. 311 Most antitrust cases that arise from these situations are brought by private plaintiffs, but public enforcement also plays an important role. 312

DOMINANT INSURERS AND MFNs. Large incumbent firms can use "most-favored-customer" clauses (also called "most-favored-nation" clauses or MFNs) to discourage vendors from price discounting to smaller competitors or potential entrants, which may also deter quality-based competition and product innovation. This is a common tactic among large medical and dental insurers in their provider agreements with hospitals and health professionals.313 Traditionally, courts regarded MFNs as "standard devices by which buyers try to bargain for low prices" and therefore procompetitive. 314 However, some courts have recognized the potential for MFNs to facilitate cartelization among sellers and increase prices, or-with the most direct consequences for innovation—to raise costs for potential market entrants.315 The weight of recent opinion is critical of MFNs, which is good news for competition policymakers attempting to dislodge entrenched parties and encourage new competitors who are more likely to offer better products.

Three lawsuits have been brought against Blue Cross Blue Shield of Michigan for its use of MFN clauses in contracts with hospitals, with the first filed by the DOJ in 2010.³¹⁶ At the time, the defendant's health plans covered 60% of Michigan's

 $^{^{311}}$ See, e.g., West Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 100 (3d Cir. 2010).

As a matter of agency jurisdiction, these cases are typically brought by the DOJ, not the FTC. *See, e.g.*, United States v. Blue Cross Blue Shield, 809 F. Supp. 2d 665 (E.D. Mich. 2011) (denying motion to dismiss Sherman Act case against dominant health insurer for including "most-favored-customer" clauses in contracts with hospitals); Press Release, U.S. Dep't of Justice, Justice Department Reaches Settlement with Texas Hospital Prohibiting Anticompetitive Contracts with Health Insurers (Feb. 25, 2011), http://www.justice.gov/atr/public/press_releases/2011/267648.htm [https://perma.cc/78S7-LCC5] (litigation against dominant hospital for entering into contracts with health insurer that prohibit dealing with other hospitals).

³¹³ See, e.g., Blue Cross Blue Shield, 809 F. Supp. 2d at 669.

³¹⁴ Blue Cross Blue Shield United v. Marshfield Clinic, 65 F.3d 1406, 1415 (7th Cir. 1995) (stating that MFN clauses do not, as a matter of law, violate the Sherman Act).

³¹⁵ See United States v. Delta Dental of Rhode Island, 943 F. Supp. 172, 192 (D.R.I. 1996) ("The net effect is an alleged detrimental impact on the dental market without any *discernible* competitive benefits.").

³¹⁶ See Blue Cross Blue Shield, 809 F. Supp. 2d. Additional suits based on the same facts were filed by a competing insurer, Aetna Inc. v. Blue Cross Blue Shield, No. 11–CV–15346, 2013 WL 1831320 (E.D. Mich. June 14, 2012), and by a class of individuals and business that purchased health insurance, Shane Grp., Inc. v. Blue Cross Blue Shield, No. 10-14360, 2012 WL 5990219 (E.D. Mich. Nov. 30,

commercially insured population, and it had agreements containing MFNs with over 40% of Michigan's general acute care hospitals.³¹⁷ The hospitals were seen as having little choice and were not sued; the court's opinions suggest that a hospital that declined to sign would have been paid up to 16% less by Blue Cross.³¹⁸ The State of Michigan subsequently enacted laws banning the use of MFNs by the health insurance industry.³¹⁹

DOMINANT HOSPITALS. Large hospitals may also disadvantage potential rivals by contract. In Palmyra Park Hospital, Inc. v. Phoebe Putney Memorial Hospital, a smaller for-profit hospital alleged that a nonprofit facility forced health insurers to deal with it only.320 Palmyra claimed that "Phoebe Putney leverage[s] its monopoly power over the medical services requiring [certificates of need] to force Blue Cross (and other insurers) to exclude Palmyra from their provider networks" for all services, in violation of the Clayton Act's prohibition on tying arrangements.³²¹ Reversing the lower court, the Eleventh Circuit held Palmyra had antitrust standing to sue. 322 In United States v. United Regional Health Care System of Wichita Falls, Texas, 323 the DOJ and the Texas attorney general brought suit to enjoin United Regional from inserting terms into contracts with insurers that prevented those insurers from contracting with its competitors.³²⁴ United Regional had a market share of approximately 90% for inpatient hospital services and 65% for outpatient hospital services, and insurers unwilling to contract exclusively with it paid substantially more for services.³²⁵

MUTUAL ADVANTAGE. Breaking up cozy relationships that keep out other competitors is a valuable aspect of antitrust enforcement. Large providers and large insurers have a mutual interest in maintaining the status quo. In particular, the notion of "must-have" hospitals in insurance networks has invited dealmaking that is almost certainly adverse to consumers. The infamous "handshake in the snow," for example, resolved a standoff between Partners HealthCare in Boston and

^{2012).} In each case the District Court denied Blue Cross's motion to dismiss, finding that the plaintiffs met the requirements for antitrust standing.

³¹⁷ Blue Cross Blue Shield, 809 F. Supp. 2d at 668–69.

³¹⁸ Id. at 669.

^{319 2013} Mich. Pub. Acts 4, 5.

^{320 604} F.3d 1291, 1303 (11th Cir. 2010).

³²¹ Id. at 1296.

³²² *Id.* at 1303.

³²³ No. 7:11CV00030, 2011 WL 846762 (N.D. Tex. Feb. 25, 2011).

³²⁴ *Id.* at *17.

³²⁵ Id. at *12-14.

Blue Cross Blue Shield of Massachusetts but did not secure any competitive gains for the market.³²⁶

Another example is Western Pennsylvania, which has experienced over a decade of contractual maneuvering intended to keep new competitors out of the market. Private health care in Pittsburgh and environs has long been dominated by the University of Pittsburgh Medical Center (UPMC), which owns a majority of the hospital beds and employs a very large number of physicians, and by Highmark, a nonprofit health insurer that combines the former Blue Cross and Blue Shield plans of western Pennsylvania.327 The second-largest hospital organization in the area is West Penn Allegheny Health System (WAHS), a combination of several smaller hospitals.³²⁸ In the early 2000s, Highmark attempted to undermine UPMC's dominant position by providing a large loan to WAHS and setting up a low-cost insurance option that paid hospitals less than UPMC, but not WAHS, was willing to accept.329 UPMC responded by creating its own health plan to compete against Highmark.330

In 2005, however, Highmark and UPMC began to act more like allies. UPMC refused to discount fees for hospital services to other health plans that were considering entering the Pennsylvania market, and Highmark increased its reimbursement rates to UPMC.³³¹ UPMC scaled back its own health plan, and Highmark shut down its low-cost insurance option that had not included UPMC.³³² Highmark declined to refinance its loan to WAHS, and UPMC began a systematic effort to hire away several of WAHS's best physicians.³³³ WAHS eventually filed an antitrust suit against UPMC and Highmark that paints a clear picture of Highmark and UPMC "[conspiring] to protect one another from competition."³³⁴ Subsequent market developments have been ratified by state regulators but have not increased competition.³³⁵

³²⁶ Scott Allen & Marcella Bombardieri, *A Handshake that Made Healthcare History*, Boston Sunday Globe, Dec. 28, 2008, at A1, A14.

³²⁷ West Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 91–92 (3d Cir. 2010).

³²⁸ *Id.* at 92.

³²⁹ Id.

³³⁰ Id.

³³¹ Id. at 93.

³³² Id.

³³³ Id. at 94.

³³⁴ *Id.* at 91 (denying motion to dismiss).

³³⁵ In 2011, while still in litigation, Highmark changed its strategy and partners yet again, and it offered to become affiliated with WAHS. WAHS accepted the

2. Joint Production or Pricing Cases

The second major category of antitrust cases important to inducing the development of assembled products involves the process of production and associated pricing. Full corporatization of health care delivery with employed, salaried physicians may be years away, if it comes at all. For the foreseeable future, then, there cannot be a sizable complement of assembled products unless independent economic actors come together to produce them and to negotiate their sale.

Not surprisingly, collective activity of this sort may raise concerns regarding its anticompetitive potential. The FTC website provides a list of all the agency's health care antitrust actions since 1996.³³⁶ Of 190 cases the agency initiated, 33 (17%) were collective bargaining or horizontal price-fixing cases filed in 2000 or later, typically involving joint pricing by physicians of their own services.³³⁷ Unlike exclusion cases, however, which typically require more aggressive enforcement, joint production or joint pricing cases may require *less* aggressive, or at least more selective, enforcement if assembled products are to develop.

a. "Clinical Integration" and New Products

In the early years of managed care, it often proved difficult to persuade physicians in private practice to bear financial risk when joining a new contracting intermediary such as an independent practice association.³³⁸ Because joint price negotiation by physicians who did not share substantial financial risk

offer. Press Release—Highmark, West Penn Allegheny Health System (WPAHS) and WPAHS Bondholder Representatives Reach an Agreement that Positions the Health System for Financial Stability, HIGHMARK (Jan. 16, 2013), https://www.highmark.com/hmk2/newsroom/2013/pr011613.shtml [http://perma.cc/CCU2-BAMJ]. After undergoing regulatory review, the transaction received approval from the Pennsylvania Department of Insurance, subject to certain conditions. Pennsylvania Insurance Dep't, Opinion Letter on West Penn Allegheny Health System entering into a \$700,000,000 term loan and the guaranty by Highmark Inc. of that term loan (May 20, 2014).

³³⁶ See Cases Tagged with Health Care, FED. TRADE COMM'N, https://www.ftc.gov/enforcement/cases-proceedings/terms/282 [http://perma.cc/9UVF-GYHQ].

³³⁷ Id.

³³⁸ See Jonathan P. Weiner & Gregory de Lissovoy, Razing a Tower of Babel: A Taxonomy for Managed Care and Health Insurance Plans, 18 J. HEALTH POL., POLY & L. 75, 83 (1993) (offering a taxonomy of managed care organizations).

was considered a per se violation of the Sherman Act,³³⁹ physician networks faced a significant barrier to formation.

Since the mid-1990s, the antitrust agencies have permitted independent physicians who participate in provider networks and are "clinically integrated" to jointly negotiate fees with insurers without it automatically constituting unlawful price fixing. Clinical integration was rationalized by the enforcement agencies as akin to offering a new product, which might justify joint pricing even without shared financial risk. However, nothing approximating the delivery of assembled products—which would be indisputably "new"—has been demanded of physicians. Instead, the agencies have accepted a variety of joint investments in quality or efficiency of care as clinical integration, such as shared health information systems, common treatment protocols, and uniform processes for reviewing the quality and cost-effectiveness of care.

Going forward, the enforcement agencies should narrow the clinical integration exception, obligating providers who are not sharing financial risk to demonstrate that they have reengineered care to create assembled products and have measured outcomes associated with those products. Much as prices should relate to complete services, not isolated inputs, quality benchmarks should represent actual utility, not technical details that at best represent minor contributors to the ultimate success of care.³⁴⁴

 $^{^{339}}$ See Arizona v. Maricopa Cty. Med. Soc'y, 457 U.S. 332, 348 (1982) (holding maximum–fee agreements for physician services to be per se unlawful under the Sherman Act).

³⁴⁰ See U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care 90–91 (1996), http://www.justice.gov/atr/public/guidelines/0000.htm [http://perma.cc/DA4Z-H6NX]; Letter from Fed. Trade Comm'n to John J. Miles, Esquire, Counsel for MedSouth Inc. 1–2 (Jun. 18, 2007), http://www.ftc.gov/sites/default/files/documents/advisory-opinions/medsouth-inc./070618medsouth.pdf [http://perma.cc/LE4Q-AZX5] [hereinafter "Statements of Antitrust Enforcement Policy 1996"].

 $^{^{341}}$ See Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 23 (1979) (holding the issuance of blanket licenses does not constitute price fixing per se unlawful under the antitrust laws because, in part, blanket licenses are a new product).

 $^{^{342}~}$ $\it See$ Fed. Trade Comm'n & U.S. Dep't of Justice, $\it supra$ note 124, at 39 n.275.

 $^{^{343}}$ See Statements of Antitrust Enforcement Policy 1996, supra note 340, at 111.

³⁴⁴ See generally William M. Sage et al., Why Competition Law Matters to Health Care Quality, 22 HEALTH AFF. 31, 34–36 (2003) (surveying the ways competition law and policy have affected quality-based competition in health care).

b. Product Bundling

Because large providers and large insurers have a mutual interest in maintaining the status quo, the challenge for competition policymakers is to distinguish insurer-provider transactions that make products more useful for patients from transactions that shelter existing businesses from competitive threats. For example, insurers often require hospitals with which they contract to negotiate fees for all of their services simultaneously, instead of as single services or in discrete groups.³⁴⁵ One interpretation of this practice is that insurers are assembling products to be sold to policyholders, and that less than comprehensive services and associated coverage would have lower value for consumers.

The problem is that a large hospital able to do business on these terms becomes a "must-have" for health insurance networks, conferring economic benefits on large hospitals that are not available to smaller hospitals. And insurers that prove their ability to negotiate comprehensively over fees acquire similarly special cachet with their employer clients. This can happen notwithstanding the fact that unassembled services are still unassembled services, even if they all appear on a single list of negotiated prices. Although packaged treatments for episodes of care will usually improve competition, "bundles" of per-service fees not tied to the treatment of any particular illness may render markets less contestable by preventing competitors from offering more limited, but lower-priced or higher-quality alternatives. 347

c. ACOs and Provider Bottlenecks

As with bundling of covered services into all-or-nothing aggregates, having physicians contract exclusively with a single managed care network or other integrated organization may either improve the products offered to consumers or erect a barrier to competition. The DOJ and FTC favor nonexclusive contracts, particularly for medical specialists, under which physicians who agree to provide services to one insurer or in-

³⁴⁵ See Clark C. Havighurst & Barak D. Richman, *The Provider Monopoly Problem in Health Care*, 89 Or. L. Rev. 847, 876 (2011) (noting "hospitals' practice of negotiating a comprehensive pricing formula for large bundles of their services" with purchasers like insurance companies).

 $^{^{346}}$ See id. at 853 (suggesting that large hospitals with greater market power enjoy a competitive advantage).

 $^{^{347}}$ See id. at 876 (suggesting that antitrust enforcers should require hospitals to unbundle services to allow purchasers to negotiate lower fees).

termediary organization still may serve other insurers or organizations as well. 348

The theory behind physician nonexclusivity is that exclusive contracting deters entry by new insurers hoping to form their own networks because existing providers have been "locked up."³⁴⁹ Exclusivity also aggregates physicians into groups that might themselves gain market power over consumers. The perspective of assembled products, however, context matters. If physicians are simply fungible inputs to insurance networks, nonexclusivity may be preferable in order to prevent bottlenecks in supply from forming. If physician commitment drives performance, however, exclusive relationships may be more conducive to meeting industrial standards for quality and reliability, and therefore may enable provider organizations to develop assembled products that are more rather than less competitive.

This question has been important to the antitrust guidance the DOJ and FTC offer to Accountable Care Organizations (ACOs). Medicare's "shared-savings" ACO model rewards physician-hospital partnerships that meet quality benchmarks at lower cost than traditional, fee-for-service Medicare. ACOs enable physicians and hospitals to work together more efficiently because of greater transparency, stronger accountability metrics, and better-designed incentives. Accordingly, ACO theorists endorse competition among ACOs in communities that can support more than one ACO, but do not assume that each existing hospital in a community will draw primary care physicians into orbit around it and survive only on the specialized business they refer.

³⁴⁸ See Greaney, supra note 29, at 71.

³⁴⁹ See id. at 74.

³⁵⁰ Even physicians who have the right to contract with several organizations may not do so, particularly if they are earning high fees because of the market power inherent in their existing organization. *See id.* at 77–78 (discussing the failure of enforcement agencies and the courts to influence hospital organizational structure).

³⁵¹ See Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026, 67,026 (Oct. 28, 2011).

³⁵² See id. at 67,8104, 67,810, 67,804.

That model had failed in the early 1990s. Managed care organizations had instituted crude "gatekeeping" requirements to reduce direct access to physician specialists. Hospitals responded by building satellite clinics and acquiring primary care practices to keep the patients coming anyway. *See* George B. Moseley, III, Managed Care Strategies: A Physician Practice Desk Reference 130 (1st ed. 1999) (recommending the use of primary care physicians as "gatekeepers" to specialist referrals and opening satellite clinics in response to the demands of managed care organizations).

The enforcement agencies initially proposed requiring Medicare ACOs exceeding certain physician participation thresholds to obtain antitrust preclearance but retreated from that position in the final rule.³⁵⁴ Still, ACOs need to be more than "good guys" bearing insurance risk, like the stillborn "provider-sponsored organizations" that politicians supported as physician-led alternatives to commercial HMOs in the 1990s.³⁵⁵ Antitrust enforcers evaluating ACOs therefore should urge them to design and deliver assembled products, and should work with regulators to institute systems of payment based on the value to patients of the specific products ACOs offer as well as on the aggregate savings they generate for Medicare.

d. Price Information

Because assembled products will not be developed unless patients demand them, better consumer information is essential if they are to become marketable. When private sellers share information about pricing in real time, however, antitrust enforcers worry that it will facilitate price fixing. The agencies' 1996 joint Policy Statement on Antitrust Enforcement in the Healthcare Industry both acknowledges the competitive benefits of information and attaches conditions to private sharing. Although the DOJ has issued favorable business review letters to payers sharing hospital costs among themselves and with providers, the agencies also have signaled their concern

 $^{^{354}}$ See Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. at 67,026-32.

³⁵⁵ See Edward Hirshfeld, Assuring the Solvency of Provider-Sponsored Organizations, Health Aff., 1996, at 28, 29–30 (discussing solvency risks).

³⁵⁶ See Fed. Trade Comm'n & U.S. Dep't of Justice, supra note 124, at 41.

³⁵⁷ See Statements of Antitrust Enforcement Policy 1996, supra note 340, at 55–57. The agencies agreed not to take action if the information was (1) managed by a third party, (2) based on data more than three months old, (3) aggregated from at least five providers, (4) not including more than 25% of any single provider's business, and (5) not identifiable to any individual provider.

³⁵⁸ See Letter from Christine A. Varney, Assistant Att'y Gen., U.S. Dep't of Justice, to Mit Spears, Esquire, Counsel for Ropes & Gray LLP (Apr. 26, 2010), http://www.justice.gov/atr/public/busreview/258013.htm [http://perma.cc/V9XJ-7TCV] (Department of Justice Business Review Letter on "value indices"); see also Letter from William J. Baer, Assistant Att'y Gen., U.S. Dep't of Justice, to Colin R. Kass, Esquire, Counsel for Proskauer Rose LLP (Jan. 16, 2013), http://www.justice.gov/atr/public/busreview/291451.htm [http://perma.cc/RM9W-DDZ4] (Department of Justice Business Review Letter on gainsharing).

about potential collusion arising from information sharing in other industries. 359

Economic theory holds that a market with very similar pricing across competitors can be collusive, but it can also be perfectly competitive. Health care remains inefficient in part because prices paid in past transactions are often kept secret. On balance, it seems likely that opaque or incoherent pricing has caused more harm to competition in health care than could plausibly result from greater transparency. Absent unusual circumstances, therefore, antitrust enforcers should be open to information sharing and should encourage prices for comparable, useful products and services to become as readily available to consumers in health care as in other industries.

Reduced price discrimination is another potential benefit of price transparency, especially for assembled products. Legal prohibitions on price discrimination under the Robinson-Patman Act do not apply to service markets,³⁶¹ and antitrust law has generally favored unconstrained bargaining between buyers and sellers.³⁶² In health care, however, the relationship between prices and underlying costs has been obscured by third-party payment, fragmented care delivery, and traditions of shifting expense from price-sensitive to price-insensitive buyers.³⁶³ Each health care provider charges a range of prices to different customers, typically offering substantial discounts to health insurers and charging self-pay patients full freight.³⁶⁴ For disaggregated products, this variation not only reflects each provider's uneven bargaining power vis-à-vis particular payers but also suggests that many providers have a less-than-

³⁵⁹ See In re Sigma Corp., FTC File No. 101 0080 (2012), http://www.ftc.gov/os/caselist/1010080/index.shtm [http://perma.cc/5ZZC-BNQN] (consent decree involving the three major U.S. suppliers of ductile iron fittings).

³⁶⁰ See Alan M. Garber & Jonathan Skinner, *Is American Health Care Uniquely Inefficient?*, 22 J. Econ. Persp. 27, 28 (2008) ("The fundamental cause is a combination of high prices for inputs, poorly restrained incentives for overutilization, and a tendency to adopt expensive medical innovations rapidly, even when evidence of effectiveness is weak or absent."); Morgan A. Muir et al., *Clarifying Costs: Can Increased Price Transparency Reduce Health Care Spending?*, 4 WM. & MARY POL'Y REV. 319, 323 (2013) (noting that a lack of transparency regarding health care may contribute to higher prices).

³⁶¹ Robinson-Patman Act, 15 U.S.C. § 13 (1936).

³⁶² See supra notes 266-67.

³⁶³ See FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, supra note 124, at 19, 35; Antitrust Enforcement in the Health Care Industry, supra note 203, at 9.

 $^{^{364}}$ Under the ACA, federally tax-exempt hospitals may not collect amounts from uninsured individuals exceeding what the hospitals would have collected from a typical private insurer.

firm grasp of the cost of producing their services.³⁶⁵ Nondiscriminatory pricing for basic medical services therefore may have competitive benefits, encouraging providers to investigate and optimize their cost structures, allowing consumers to comparison shop, and blunting the bargaining advantages currently enjoyed by large, but often unimaginative and self-interested payers.

C. Coordinated Strategies for Improving Health Care Products

Developing a "new normal" of improved competition to deliver assembled products will require deliberate alignment between antitrust enforcement and the regulatory environment as health reform proceeds. Federal antitrust enforcement is often a prosecutorial enterprise, but both agencies engage in other activities as well. From to time, for example, the DOJ and FTC have jointly issued industry-specific policy statements regarding their enforcement practices and priorities in health care.³⁶⁶ The impetus for the initial set of policy statements, released in 1993, was stakeholder uncertainty regarding the lawfulness of new business configurations and collaborations that might help the industry adapt to the Clinton administration's health reform proposal.³⁶⁷ A similar need motivated the guidance issued with respect to ACOs after the ACA was enacted, although nothing as comprehensive as the policy statements of the 1990s has yet been released.

The 1993 policy statements were expanded and clarified in 1994 and 1996, painting a reasonably complete picture of how the agencies perceived collective activity in connection with the managed care practices of that era.³⁶⁸ Although the "safety zones" identified in the 1996 statements were still relatively narrow, they were based on greater experience with health care and therefore did significantly more work than the 1993 statements, which essentially restated then-current law in simple

³⁶⁵ See Robert S. Kaplan et al., Using Time-Driven Activity-Based Costing to Identify Value-Improvement Opportunities in Healthcare, 59 J. Healthcare Mgmt. 399 (2014) (proposing methods for accurate cost measurement).

³⁶⁶ See, e.g., Antitrust Guidelines for Collaborations Among Competitors, supra note 279; Statements of Antitrust Enforcement Policy 1996, supra note 340.

³⁶⁷ See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT POLICY STATEMENTS IN THE HEALTH CARE AREA 1–2 (1993).

³⁶⁸ See Statements of Antitrust Enforcement Policy 1996, supra note 340; U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust (1994).

language.³⁶⁹ Around the same time, the FTC began issuing advisory opinions on proposed transactions in response to inquiries from private parties, and the DOJ continued its similar practice of issuing business review letters.³⁷⁰

In the years between the Clinton proposal and the ACA, the agencies remained active in policy formation, generally aligning their pronouncements with regulatory developments. Led by the FTC, both agencies even systematically surveyed the competitive landscape of health care in the early 2000s, holding months of hearings and publishing a book-length report.³⁷¹

On the other hand, the economics-driven documents that the agencies use to communicate some of their most important enforcement policies are not industry specific, and they seldom take account of the regulatory environment. The joint venture guidelines released in 2000, for example, clearly present the prevailing framework for legal analysis but mention neither direct government regulation nor professional self-regula-Similarly, the 2010 FTC/DOJ Horizontal Merger Guidelines instruct antitrust oversight agencies to scrutinize the realities of competition in actual markets,³⁷³ but they use far less regulated industries than health care to illustrate their analytic points.³⁷⁴ The agencies' caution in this regard is understandable because guidelines that set special rules for some industries might send inaccurate messages to others. But the result is to deny industry participants detailed guidance about how the agencies interpret the competitive landscape in health care given its regulatory peculiarities.

The FTC engages the regulatory environment most directly through its "competition advocacy" agenda. Using hearings, reports, and cautionary communications to state governments and public agencies, the FTC has identified and attempted to reduce several regulatory obstacles to health care competition.³⁷⁵ The successful legal challenge to the North Carolina

³⁶⁹ STATEMENTS OF ANTITRUST ENFORCEMENT POLICY 1996, supra note 340, at 2.

³⁷⁰ See Fed. Trade Comm'n, Advisory Opinions (1993–2015), https://www.ftc.gov/policy/advisory-opinions [https://perma.cc/8HC6-VU9A]; U.S. Dep't of Justice, Business Review Letters and Reguest Letters (1992–2015), http://www.justice.gov/atr/business-review-letters-and-request-letters [http://perma.cc/6PAH-4TV7].

FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, supra note 124.

³⁷² See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, supra note 279, § 3.1.

³⁷³ See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, supra note 200, §§ 1-2.

³⁷⁴ See, e.g., id. § 4 (providing examples relating to, among other markets, motorcycles and glass containers).

³⁷⁵ See, e.g., FED. TRADE COMM'N, Health Care Competition, https://www.ftc.gov/news-events/media-resources/mergers-competition/health-care-

Board of Dental Examiners discussed above, for example, followed a sustained effort to convey to state governments the FTC's concern about the misuse of state action immunity.³⁷⁶

Explicit collaboration between antitrust enforcers and regulators to improve health care products would be a welcomed development in U.S. health and competition policy as the ACA is implemented. The coordinated statements issued in 2011 by the antitrust agencies, fraud regulators, and the Internal Revenue Service set a useful precedent for policy collaboration but lacked a clear vision of what competition involving ACOs might achieve.³⁷⁷

In designing and executing a collaborative agenda, competition policymakers should urge regulators to reimagine health care as a dynamic terrain of contestable markets open to new skills, organizations, and technologies, rather than regarding it as a mature economic sector limited to an established set of professional and institutional actors. Among other things, policymakers should work to dispel myths about price-quality tradeoffs in health care that have long boosted physicians' incomes and limited consumer choice. Rather than allowing entrenched interests to assert without evidence the necessity of allowing individual physicians broad discretion over the deployment of complex and costly resources, policymakers should assess the competitive consequences of relying to a greater extent on industrial production models with standardization, quality control, and supply chain management.

Both antitrust enforcers and relevant regulators also should explicitly connect the strategies they pursue to product improvement. Most important are bundled forms of provider payment that neither reimburse disaggregated services nor simply shift insurance risk from one level of organization to another. Other desirable approaches include transparency regulation that enables consumers to more easily compare price and quality; liberalized professional licensing laws that increase access to affordable basic care; standards for inter-

competition [http://perma.cc/3V2E-4BX2]. The FTC has also hosted public events on a range of new developments in the health care industry under both its competition and its consumer protection authorities.

 $^{^{376}~}$ See N.C. State Bd. of Dental Exam'rs v. FTC, 717 F.3d 359 (4th Cir. 2013), $af\!f d$, 135 S. Ct. 1101 (2015) (state board engaged in anticompetitive conduct by sending cease-and-desist letters to nondentists engaged in tooth whitening).

³⁷⁷ See Antitrust Enforcement in the Health Care Industry, supra note 203; Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026–32 (Oct. 28, 2011).

operability among health information systems and digital medical devices; and modifications to government oversight that increase the diversity of cost-effective diagnostic and therapeutic aids, such as mobile health technologies for remote care and self-management.

1. Stop Paying for Random Inputs

Payment reform is both the most promising and the most often attempted strategy to improve health care products. Although the health care system has experimented for decades with different approaches to provider payment, until recently little attention had been paid to delivering useful increments of care at the lowest possible cost of production. In addition to the systematic efforts currently being tested, a few innovative health care providers have voluntarily adopted assembled, "all-inclusive" prices for some surgical procedures and selected other services.³⁷⁸

Some private insurers employ a technique called "value-based insurance design" (V-BID), which offers more generous coverage of services that are known to be effective. The BID is often applied to preventive screening based on the predictive value of particular tests in a given subpopulation, but coverage can also be modified to induce beneficiaries to receive care that meets clinical guidelines, or to seek services from providers of demonstrably higher quality or greater cost-effectiveness. V-BID represents an indirect strategy to improve the assembly of individual treatments into effective packages through informed, incentivized consumer choice; it does not explicitly require providers to alter their production functions.

"Bundled payment" programs come much closer to paying for products rather than process steps or isolated inputs and do so more directly.³⁸² "Bundled" usually refers to a single payment that encompasses both the professional (physician)

Michael E. Chernew et al., *Value-Based Insurance Design*, 26 HEALTH AFF. 195, 196 (2007); Tina Rosenberg, *Revealing a Health Care Secret: The Price*, N.Y. TIMES, July 31, 2013 (describing the Surgery Center of Oklahoma, an ambulatory surgery center owned by a group of conservative physicians).

³⁷⁹ See Chernew et al., supra note 378, at 203 (asserting value-based insurance Design (VBID) explicitly acknowledges and responds to patient heterogeneity).

³⁸⁰ *Id.* at 195–96.

³⁸¹ Id.

³⁸² Jaspen, *supra* note 140 (explaining how bundled payment systems function); Jordan Rau, *Hospitals Face Pressure From Medicare to Avert Readmissions*, N.Y. TIMES, Nov. 27, 2012, at D1 (explaining how, under the traditional payment model, hospitals were not concerned with readmissions).

and facility (hospital) components of conventional reimbursement systems, thereby rewarding care in which individuals with complementary skills work together in technologically advanced practice settings.³⁸³ Such payments are also usually "episodic," meaning that they encompass a sustained period of time, such as a full course of illness or the duration of a definitive (and typically effective) modality of treatment. The PROMETHEUS project, for example, was an early bundled payment initiative in which private insurers attempted to reward the coordinated delivery of care that met clinical practice guidelines for quality.³⁸⁴

An important bundled payment experiment was a pilot program sponsored by the Integrated Healthcare Association and the federal Agency for Healthcare Research and Quality. It aspired to negotiate twenty contracts between California insurers and providers for bundled payment, and to test not less than 500 paid bundles for cost and quality.³⁸⁵

The pilot concluded in early 2014 and was judged a failure by its evaluators, largely because it did not achieve the desired scale. However, other experts drew constructive if nuanced lessons from the experience that will be important in any larger move toward assembled products that distinguishes bundled payment from the wholesale transfer of insurance risk to providers. These lessons include paying retrospectively for the care bundles actually delivered rather than projecting utilization in advance, incorporating care redesign when creating payment bundles, targeting markets that currently pay providers using fee-for-service rather than capitation, and allowing Medicare to lead the effort because of its size and measurement capacity. 387

Despite these results, Medicare doubled down on bundled payment in 2015. CMS expanded its optional Bundled Payment for Care Improvement (BPCI) program and declared that

³⁸³ Holly Korda & Gloria N. Eldridge, *Payment Incentives and Integrated Care Delivery: Levers for Health System Reform and Cost Containment*, 48 INQUIRY 277, 280–82 (2011).

 $^{^{384}\,\,}$ Peter S. Hussey et al., The PROMETHEUS Bundled Payment Experiment, 30 Health Aff. 2116 (2011) (explaining that the name Prometheus was chosen in the hopes that health care would be forever changed).

Tom Williams & Jill Yegian, Bundled Payment: Learning Payment from our Failures, Health Aff. Blog (Aug. 5, 2014), http://healthaffairs.org/blog/2014/08/05/bundled-payment-learning-from-our-failures/ [http://perma.cc/7BZA-GZZ4].

 $^{^{386}}$ Ridgely et al., supra note 36 (discussing California's bundled care initiative).

³⁸⁷ Williams & Yegian, *supra* note 385 (suggesting payers, providers, and policy makers should continue to pursue bundled payment initiatives).

its Comprehensive Care for Joint Replacement program would apply bundled payment on a mandatory basis in seventy-five markets.³⁸⁸ After decades of political posturing, Congress also repealed its longstanding but never enforced Sustainable Growth Rate (SGR) limitation on physician fees under Medicare, conditioned on the implementation of value-based payment systems such as bundling.³⁸⁹

Publish Prices and Results

Transparency rivals payment reform as the most popular form of market-oriented health care regulation. Although mandatory disclosure of information about health care delivery can have various objectives—including loyalty to patients, internal process improvement, and stewardship of public resources—most disclosure initiatives over the last twenty years have sought primarily to improve competition by better informing buyers about health plans or health care providers.³⁹⁰

Standardized information is seen as a remedy for unjustified variation in both quality and price. Early transparency programs attempted mainly to measure and compare quality of care. For hospitals and surgeons, they were often a response to research showing wide variation in care processes and results.³⁹¹ For health plans, they were instituted primarily to address public concerns that managed care would shortchange quality in order to reduce cost.³⁹² When aggressive care man-

³⁸⁸ See Robert E. Mechanic, Mandatory Medicare Bundled Payment—Is it Ready for Prime Time?, 373 New Eng. J. Med. 1291, 1291 (2015); Suzanne Delbanco, The Payment Reform Landscape: Bundled Payment, Health Aff. Blog (July 2, 2014), http://healthaffairs.org/blog/2014/07/02/the-payment-reform-landscape-bundled-payment [http://perma.cc/55YV-3YXY]; Steven A. Farmer et al., Breaking Down Medicare's Bold New Proposal to Transform Hip and Knee Replacements, Brookings (Aug. 11, 2015, 1:12 PM), http://www.brookings.edu/blogs/health360/posts/2015/08/joint-replacement-model-care [http://perma.cc/YZM5-SMA7].

³⁸⁹ See Billy Wynne, May the Era of Medicare's Doc Fix (1997–2015) Rest In Peace. Now What?, HEALTH AFF. BLOG (Apr. 14, 2015, 10:09 PM), http://healthaf fairs.org/blog/2015/04/14/may-the-era-of-medicares-doc-fix-1997-2015-rest-in-peace-now-what [http://perma.cc/7SGE-FUNT].

³⁹⁰ Sage, *supra* note 128, at 1713–15 (assessing the justifications for requiring insurance organizations and health care providers to disclose information to the public).

Mark R. Chassin, *Achieving and Sustaining Improved Quality: Lessons from New York State and Cardiac Surgery*, 21 HEALTH AFF. 40, 51 (2002) (explaining that since 1989 the New York State Department of Health has published annual data on risk-adjusted mortality following coronary artery bypass graft surgery by hospital and surgeon).

Anna D. Sinaiko & Meredith B. Rosenthal, *Increased Price Transparency in Health Care—Challenges and Potential Effects*, 364 New Eng. J. Med. 891, 891–92 (2011).

agement receded as a threat to quality but spending continued to rise, price transparency designed to aid comparison shopping became an equally important focus of disclosure initiatives.³⁹³

With respect to quality, process-based measures have long been regarded as inferior to verifiable outcomes such as avoidance of complications, relief of symptoms, or survival.³⁹⁴ But it has been difficult to attribute outcomes to particular providers when a mix of health care professionals and health facilities supply and control care inputs for a given patient, or to meaningfully aggregate results under the umbrella of a health plan when one beneficiary's experience of care is so different from another's.

With respect to prices, publicizing fees for conventional disaggregated services has had a similarly limited impact. For many medical problems, it is often impossible to get a reliable price quote in advance because nobody knows how many billable process steps will be taken or inputs used before diagnosis or treatment is declared complete. Instead, current initiatives to contain cost through price transparency often encourage patients under active treatment to be prudent purchasers of expensive diagnostic services, such as CT or MRI scans, that can be multiply sourced. However, few patients have sufficient expertise to make decisions about marginal inputs to complex care, especially when ill and under time pressure. By contrast, published prices and quality metrics are much more meaningful for assembled products such as full surgical treatment packages. Well-designed programs for

³⁹³ Medicare.gov, *How to Compare Medigap Policies* (2014), http://www.medicare.gov/supplement-other-insurance/compare-medigap/compare-medigap.html [http://perma.cc/QBB3-CAG2]; Sinaiko & Rosenthal, *supra* note 392, at 894 (suggesting one tactic for reducing spending is to increase price transparency in health care).

³⁹⁴ Jonathan Mant, *Process Versus Outcome Indicators in the Assessment of Quality of Health Care*, 13 INT'L J. FOR QUALITY HEALTH CARE 475, 475–80 (2001) (reviewing the relative strengths and weaknesses of outcome and process measures as performance indicators in health care).

³⁹⁵ See Barbara Starfield et al., Ambulatory Care Groups: A Categorization of Diagnoses for Research and Management, 26 HEALTH SERVS. RES. 53, 54 (1991) (explaining that in ambulatory care, for example, doctors make many diagnoses and generate bills at different sites).

 $^{^{396}}$ See Kristin Madison & Peter D. Jacobson, Debate: Consumer-Directed Health Care, 156 U. Pa. L. Rev. 107, 116–17 (2007) (arguing that a transparency-driven system will incentivize underinvestment in preventive measures).

³⁹⁷ At the Surgery Center of Oklahoma, for example, assembled prices available on the website include the facility fee, the surgeon's fee, the anesthesiologist's fee, the initial consultation, and uncomplicated follow-up care. Implants and similar devices are billed at cost without markup. SURGERY CTR. OF OKLA., Surgery

both quality and price transparency therefore can help move health care markets toward assembled products because assembled products are better suited for comparison shopping.

3. Distinguish Warranty Risk from Insurance Risk

Efforts to reduce fragmentation in health care delivery without explicitly redefining the product tend to elide the distinction between "warranty risk" (the risk that a health care service will not work as intended, also called "performance risk") and "insurance risk" (the risk that an individual will have a covered medical need). For example, a commentary on the failure of the IHA bundled payment pilot in California noted: "Prospective bundled payment raised . . . concerns for . . . regulators . . . , including whether providers were assuming insurance risk." Similarly, hospitals and physicians participating in the Medicare shared-savings (ACO) program have discovered that providing disassembled services for less than Medicare expects to spend each year on a given beneficiary requires essentially the same actuarial capacity as becoming a full-fledged Medicare HMO.

That capitation is the opposite of fee-for-service payment has become a common misconception in health policy. The false dichotomy likely arises from the bidirectional heritage of health insurance as it has developed in the United States. On one end of the spectrum, commercial insurers traditionally indemnified policyholders for the cost of process steps and components delivered or ordered by physicians. On the other end of the spectrum, early HMOs such as Kaiser provided comprehensive care directly in exchange for an annual premium. Because neither sufficient capital nor compatible culture existed to replicate Kaiser-like HMOs on a national scale as managed care expended in the 1990s, many provider contracts attempted to make physicians in private practice behave simi-

Pricing (2015), http://www.surgerycenterok.com/pricing/ [http://perma.cc/A45F-8SX7].

³⁹⁸ But cf. Tom Baker, Insuring Liability Risks, 29 GENEVA PAPERS ON RISK & INS. 128, 129 (2004) (offering a taxonomy of liability risk that includes warranty risk). 399 Williams & Yegian, supra note 385 (suggesting payers, providers, and policy makers should continue to pursue bundled payment initiatives despite previous failure in California).

⁴⁰⁰ See, e.g., Susan DeVore & R. Wesley Champion, *Driving Population Health Through Accountable Care Organizations*, 30 Health Aff. 41, 41–49 (2011) (outlining the criteria health systems must meet to participate in the ACO model).

⁴⁰¹ RICKEY HENDRICKS, A MODEL FOR NATIONAL HEALTH CARE: THE HISTORY OF KAISER PERMANENTE (HEALTH AND MEDICINE IN AMERICAN SOCIETY) 1–10 (1993) (presenting a history of Kaiser-Permanente).

larly by paying them a fixed monthly amount for each patient assigned to them (i.e., capitation) regardless of how much care they actually deliver, in essence making them partial insurers of their patients' health. 402

If products are sold assembled, warranty risk has less overlap with insurance risk and can be separately managed. If a course of treatment fails to have the desired effect, a second course of treatment can be delivered without charge. If an unwanted side effect develops, steps to mitigate the effect can be offered, again without charge. If these costs turn out to be excessive for the seller, it is a signal that either the product should be reengineered or the price charged for it should be adjusted. In either event, however, the cost of the warranty remains under the control of the seller and is based on the product's average anticipated user and use. As with many consumer products, more comprehensive warranties might be offered for higher prices, and health care providers (rather than patients) are free to purchase stop-loss insurance against the risk of unexpectedly high warranty costs.⁴⁰³

A few ongoing Medicare and private patient safety initiatives contemplate warranties, including nonpayment policies for hospital readmissions that occur shortly after discharge, or for "never events" such as wrong-site surgery or infections acquired in the hospital that are deemed preventable. ⁴⁰⁴ But government payers and state regulators can encourage warranties to be offered for a broader array of assembled products. Geisinger Health System, for example, has experimented with a

List of SREs (2015), http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx [https://perma.cc/2LZU-EU6X].

⁴⁰² See supra text accompanying note 192.

An interesting question, beyond the scope of this Article, is the potential relationship between warranties for assembled health care products and medical malpractice liability. For example, should a patient's failure to cooperate in treatment constitute product misuse that voids the warranty, akin to contributory negligence in tort? Little has been written about the use of warranties in medical care. See William S. Brewbaker III, supra note 116, at 118–21 (arguing that courts should impose a tort-based implied warranty of quality on managed care organizations, under which they would be liable for selling physician services that are negligently rendered).

Peter J. Pronovost et al., Preventing Bloodstream Infections: A Measurable National Success Story in Quality Improvement, 30 Health Aff. 628, 628–34 (2011) (discussing the success in combating central line-associated bloodstream infections); AGENCY FOR HEALTHCARE RES. & QUALITY, Patient Safety Primers: Never Events, http://psnet.ahrq.gov/primer.aspx?primerID=3 [http://perma.cc/K6PG-BJKM] (defining "never events"); CTRS. FOR MEDICARE & MEDICAID SERVS, Readmissions Reduction Program (2015), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html [https://perma.cc/9ZKK-4Q76]; NAT'L QUALITY FORUM,

flat fee including a 90-day warranty for certain cardiovascular and orthopedic procedures.⁴⁰⁵

4. Try New Products and Producers

Assembled products offering quicker, cheaper, more reliable health care will only develop if competitors with fresh ideas continually enter the market. New competitors are more likely to create products with intuitive appeal and measurable benefits. Generating new health care products and services therefore should be a priority for regulators working in tandem with competition authorities. Unlike many clinical innovations today, notably medical devices and imaging technologies, future entrants should do more than fit their products into the existing schema of "fee-for-input" payment. Over time, this process could induce a virtuous circle that continues to redefine health care products and invites even greater diversity in sources of supply and methods of production.

To encourage competition from unaccustomed sources, policymakers should dismantle regulatory barriers that discourage market entry by new types of health facilities, such as burdensome permitting and certification requirements, 407 and by health care professionals, such as restrictive professional licensing laws. 408 Reducing barriers to entry is also important from the perspective of antitrust enforcement. If entry is easy,

⁴⁰⁵ See Reed Abelson, In Bid for Better Hospital Care, Heart Surgery with a Warranty, N.Y. Times, May 17, 2007, at A1. Not discussed in the article is the fact that Geisinger apparently offers its "Proven Care" guarantee only to patients enrolled in its own health plan and not to those covered by other commercial insurance. This significantly reduces the financial risk of poor performance and allows Geisinger to continue to be paid by others for treating complications.

⁴⁰⁶ Katherine Hobson, *Cost of Medicine: Are High Tech Medical Devices and Treatments Always Worth It?*, U.S. News & World Rep. (July 10, 2009), http://health.usnews.com/health-news/best-hospitals/articles/2009/07/10/cost-of-medicine-are-high-tech-medical-devices-and-treatments-always-worth-it [http://perma.cc/76ZZ-QE6D] (questioning whether expensive medical tools are overused).

⁴⁰⁷ See Nancy Pfotenhauer & Nathan Nascimento, States Strike a Blow for Freedom in the ObamaCare Age, WALL St. J. (Feb. 20, 2015), http://www.wsj.com/articles/nancy-pfotenhauer-and-nathan-nascimento-states-strike-a-blow-for-freedom-in-the-obamacare-age-1424482226 [https://perma.cc/857P-4CM5].

408 See, e.g., N.C. Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101, 1107-17 (2015); see also Teladoc, Inc. v. Texas Medical Board, No. 1:15-cv-00343-RP (W.D. Tex. 2015) (antitrust suit by a telehealth company against a state medical board for prohibiting the writing of a prescription without a face-to-face visit); William M. Sage, Competitive Harm from State Licensing Boards: First North Carolina Dentists, Now Texas Physicians?, HEALTH AFF. BLOG (May 2015), http://healthaffairs.org/blog/2015/05/27/competitive-harm-from-state-licensing-boards-first-north-carolina-dentists-now-texas-physicians/ [http://perma.cc/93ZA-VLTC] (describing and assessing the Teladoc litigation).

market power cannot be exercised even in concentrated markets without attracting alternative sources of supply that would return prices to competitive levels. 409 Moreover, ease of market entry should intensify overall innovation, further reducing the risk of consumer harm from concentration.

5. Empower True Consumers

That patients need to be partners in their own care is a possible objection to assembled products. It is true that patients can either enhance or undercut the effectiveness of treatment and therefore the apparent rewards from offering a superior product. As in other commercial sectors, however, consumers become motivated when they understand what they are buying and can compare their options. People seeking medical care may be vulnerable and in need of compassionate, expert assistance, but being limited to disaggregated, unwarranted services exploits that vulnerability to a greater degree than if products came assembled with warranties.

To date, personal responsibility has mainly been incorporated into health insurance design, not utilization of care. Because of the perverse incentives associated with spending other people's money ("moral hazard"), health savings accounts, high-deductible health plans, and similar forms of "consumer-directed care" have become increasingly popular with more conservative constituencies. However, even prudent people can quickly incur thousands of dollars in health expense for disaggregated services. A move to assembled products would make it easier for such individuals to comparison shop based on price without shortchanging or otherwise misinterpreting their medical needs. Over time, assembled products could bridge the gap between consumer-directed care models and the "comprehensive coverage" mindset of the ACA because direct

 $^{^{409}\,\,}$ U.S. Dep't of Justice & Fed. Trade Comm'n, supra note 200, § 4.2 (discussing barriers to entry).

⁴¹⁰ See Joanna Kaufman, Patients as Partners, 39 Nursing Mgmt. 45, 48 (2008) (discussing the history of the "patients as partners" concept).

Using the more paternalistic terminology of conventional medical professionalism, the same idea is sometimes called "patient compliance," meaning acquiescence in the plan of treatment selected by the physician. See TO ERR IS HUMAN, supra note 118, at 34-35 (pointing out patient noncompliance as an important quality issue in health care).

⁴¹² See John C. Goodman, Priceless: Curing the Healthcare Crisis 143–57 (2012) (asserting the United States needs real health care change, starting with health savings accounts). But see Tom Baker, On the Genealogy of Moral Hazard, 75 Tex. L. Rev. 237, 243 (1996) (exploring the shortcomings of moral hazard as a neutral, technical basis for reforming tort law, workers' compensation, health insurance, and social welfare programs).

sellers of services would have less ability to take advantage of buyers. 413

Regulators therefore might apply a lighter hand to direct-to-consumer sales for assembled than for unassembled health care products, 414 using a consumer protection model to promote both customization of assembled products by sellers and correct use of those products by consumers. Admittedly, it is difficult to draw a line between lack of user friendliness, which producers should have strong incentives to improve, and misuse, which should obligate the consumer to purchase another or a different product. However, complex medical products should not require self-assembly by patients any more than they should require ad hoc assembly by physicians, as they do at present.

6. Assure Interoperability

Many health care services require expert coordination, much as one flies on a reputable commercial airline rather than separately hiring a plane, pilot, and maintenance crew. Because so few health care products are sold assembled, assembly is considerably harder than it should be. Beyond the purely mechanical realm of items such as IV tubing and surgical supplies, surprisingly few components of complex health care fit together.

The development and adoption of industrial standards that enable interoperable technology is a precondition to the efficient production of assembled products in many care settings. Digital devices such as electrocardiogram machines, radiographic scanners, and chemical assayers seldom talk with one another or with the often idiosyncratic electronic health record systems that hospitals and physicians have installed.⁴¹⁵

⁴¹³ For example, the federal government recently prohibited supplemental fees for biopsies performed during screening colonoscopies, which are covered without cost-sharing under the ACA. See Kaiser Family Found., Coverage of Colonoscopies Under the Affordable Care Act's Prevention Benefit 11 (2012), http://kaiserfamilyfoundation.files.wordpress.com/2012/08/8351-coverage-of-colonoscopies-under-the-affordable-care-act.pdf [http://perma.cc/P3P7-QEKL]. In essence, this converted screening colonoscopy into an assembled product for the diagnosis of large bowel disease.

⁴¹⁴ Cf. Matthew F. Hollon, Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand, 281 JAMA 382, 384 (1999) (discussing the pharmaceutical industry's rapid increase in marketing prescription drugs directly to patients and the FDA's relaxed regulation of this practice).

⁴¹⁵ See Inst. of Med., Health IT and Patient Safety: Building Safer Systems for Better Care 19 (2012) (concluding "the current culture of care delivery is often not ready for widespread safer and more effective use of health IT").

Lack of interoperability also extends to communication and teamwork among skilled personnel. Health care teams seldom function as smoothly as teams in true "high-reliability" industries. ⁴¹⁶ Industrial engineering that takes account of human factors in designing standardized work environments and training personnel therefore is critical for preventing medical errors and promoting successful outcomes. ⁴¹⁷

More generally, standards for interoperability tend to improve innovation and induce the entry of additional competitors by reducing the cost of contracting between new and existing market participants. Because of this, dominant health care providers may resist or attempt to undermine standards for interoperability, requiring vigilance by the antitrust enforcement agencies. 19

For simpler health care, standards for interoperability should help individuals assemble their own packages of services. Airlines thrive, but there are few remaining travel agents because most travelers can construct their own itineraries using standardized electronic tools. Similarly, "coordination of care" was traditionally the professional obligation of one's general practice physician, and its loss is often lamented as a casualty of specialization. However, low-risk patients may not need close or comprehensive attention, especially if it adds another layer of intermediation to a system that is already unresponsive to consumer preferences. Instead, regulators should promote "plug and play" capability, including for the exchange of health information, enabling consumers to manage their own care from diverse sources in real time.

7. Clarify the Role of Health Insurers

The unequal distribution of illness, its unpredictable timing, and the high cost of care make insurance an inevitable aspect of a functioning health care system. Still, although

⁴¹⁶ See M. Leonard, S. Graham & D. Bonacum, *The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care*, 13 QUALITY SAFE HEALTH CARE 85, 90 (2004) (noting effective communication and teamwork are essential for the delivery of high quality, safe patient care).

⁴¹⁷ See Lucian L. Leape, Error in Medicine, 272 JAMA 1851, 1851 (1994) (indicating that "a substantial number of patients suffer treatment-caused injuries while in the hospital"); INST. OF MED., supra note 119, at 26 (estimating that as many as 98,000 people die in any given year from medical errors that occur in hospitals).

⁴¹⁸ See Baker, supra note 280, at 560–62 (noting that "antitrust enforcement against exclusionary conduct is important because it fosters economic growth and prosperity, not just because it addresses harms to price competition").

⁴¹⁹ See id. at 561.

commercial health insurers remain ubiquitous, the value they add is increasingly in doubt. As discussed above, underwriting risk has diminished for the majority of health insurers, either because that function can be performed at lower cost by large, self-insured employers and government (Medicare and Medicaid) or because laws such as the ACA limit insurers' actuarial role and cushion the financial uncertainty associated with it.⁴²⁰ Thus, much of what is called health insurance is primarily the provision of administrative services: managing enrollment, verifying eligibility, contracting with health care providers, and processing claims.⁴²¹

Because the future of health insurance beyond administration is uncertain, health insurers are likely to diversify their operations to include other functions, such as care coordination, price brokering, health information stewardship, and health promotion. Whether the ACA will induce more insurers to be actual care managers offering assembled products remains to be seen. Insurers' current dependence on claims processing to earn revenue may exert drag on any shift to assembled products because consolidating services into larger packages would tend to reduce the overall volume of claims. Regulators should be alert to such dampened incentives for change and to status quo bias associated with current patterns of managed care contracting.

If conventional health insurance recedes in importance, regulators will need to anticipate and address other ways in which the unequal distribution of illness may complicate competition over assembled products. Examples include preventing profiteering in connection with urgent care or life-threatening illness, overseeing companies selling warranty insurance to health care providers, and using public funds to support reserve capacity (e.g., emergency care for epidemics or disasters) so that day-to-day production decisions can be made with lean inventory and flexible staffing.

⁴²⁰ See Sage, supra note 133, at 1090.

⁴²¹ See supra text accompanying notes 53–55.

⁴²² One consideration is that the ACA "risk-adjusts" premiums received by health plans to reduce cherry-picking of healthy enrollees, provide assurances of profitability, and maintain overall budget neutrality. *See* Sage, *supra* note 133, at 1090. These risk-reduction devices may promote overall insurance market stability, but they also may tend to diminish competition between carriers.

⁴²³ See supra text accompanying notes 94–100.

8. Promote "Upstream" Health Care

An affordable health care system depends on good underlying health as well as cost-effective treatment.⁴²⁴ It will take innovation for the United States to reduce preventable mortality and morbidity to the levels found in many other developed countries.⁴²⁵ Although population health is often considered a government function administered by state and local health departments, networked technologies create enormous opportunities for private entrepreneurship.⁴²⁶

Imagine people navigating a river, with their health worsening as the journey progresses. As people get farther from home, assistance becomes available, but it is abundant only when travelers are in distant lands and in great peril, with rescue costly and uncertain. This downstream realm represents the vast majority of U.S. health care as currently configured. Upstream, the current is slower, the shore is nearer, and people are closer to home. There are no "patients" removed from their daily lives; there are only people living those lives. Upstream competition policy should foster the development of diverse sources of care widely distributed throughout communities, facilitate public access to these services, and encourage self-management of health and illness. Services that can accomplish these goals may be less complex than those associated with acute or severe illness, but they will still need to be assembled for direct consumer use.

It is therefore important that regulators not allow existing health insurers, health care providers, or pharmaceutical companies to foreclose competition by extending their existing regulatory advantages upstream. Potentially problematic conduct might include influencing professional licensing and discipline, leveraging facility licensing or certificates of need, manipulating accreditation standards, or otherwise taking unfair advantage of incumbents' familiarity with complex regulatory systems. For example, mobile medical applications (mHealth) constitute a rapidly growing commercial sector that

⁴²⁴ See Sage, supra note 133, at 1085.

⁴²⁵ See Steven H. Woolf & Laudan Y. Aron, The US Health Disadvantage Relative to Other High–Income Countries, 309 JAMA 771, 772 (2013) (comparing Americans' health to that of other countries of similar economic status).

⁴²⁶ See, e.g., William H. Frist, Connected Health and the Rise of the Patient-Consumer, 33 HEALTH AFF. 191, 192 (2014) (discussing consumer products to improve health behaviors).

 $^{^{427}}$ Governance of upstream health care will differ in many ways from governance of downstream health care. See Sage & McIlhattan, supra note 104, at 537-38.

the FDA has wisely refrained from regulating unless there is a clear risk to health or safety.⁴²⁸

CONCLUSION

Improved competition, greater productive efficiency, and enhanced consumer value are no longer optional in American health care. Experts agree that the high health care spending that prevails in the United States is not merely the price of scientific progress or the consumption preferences of a prosperous and powerful nation, as it appeared in prior decades. It has become a hard constraint on public money available for other critical needs, such as education and infrastructure, a drain on employment compensation that crowds out cash wages, and a long-term threat to the fiscal stability of the United States. 429

This Article urges antitrust enforcers and regulators to rethink the products that the health care system buys and sells. Because market competition usually determines its own goals, a directive approach to competition policy may seem counterintuitive. Health care products, however, are heavily influenced by decades of accreted laws and professional norms that enable both the medical profession and the insurance industry to cast long shadows over the health care economy. Users of health care are seldom choosers of health care, and even less often bear the costs. As a result, some parts of health care are astonishingly innovative (e.g., how to keep preterm babies alive) while others are surprisingly not (e.g., how to deal with a sprained ankle on a Sunday).

Although the Affordable Care Act articulates a "triple aim" for health care reform, including improvements in individual

⁴²⁸ See FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 8 (2015), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf [http://perma.cc/V38U-XU83]. But see Nathan Cortez, Regulating Disruptive Innovation, 29 BERKELEY TECH. L.J. 175, 227 (2014) (arguing that regulators need not be tentative about regulating mobile health technologies).

⁴²⁹ Political opponents may deride the Obama administration's claim to pursue deficit reduction through health reform, but health care remains the only sector in which achievable efficiencies yield savings exceeding full percentage points of GDP. See Peter R. Orszag, Will Burwell Corral Health-Care Costs?, BLOOMBERGVIEW (Apr. 14, 2014, 11:53 AM), http://www.bloombergview.com/articles/2014-04-14/will-burwell-corral-health-care-costs [http://perma.cc/C38E-9 FSA] (describing potential for health care reform to substantially reduce federal debt).

⁴³⁰ See supra notes 410-12 and accompanying text.

health, population health, and economic efficiency,⁴³¹ antitrust authorities have yet fully to internalize its priorities into their enforcement strategies. Instead, a considerable amount of antitrust enforcement remains mired in market models that emerged during the political backlash against managed care in the late 1990s and that have not produced significant benefits for consumers.⁴³² Antitrust enforcers should recognize the artificiality of what currently passes for competition in health care and should work collaboratively with regulators to move health care markets beyond trade in disaggregated process steps and inputs to the sale of fully assembled products with warranties.

The ACA, which has very likely achieved political permanence, relies primarily on market forces to boost performance in the health care system.⁴³³ Unfortunately, efforts to improve the cost-effectiveness of health care have a discouraging history, with few accomplishments outside the traditional HMO model.⁴³⁴ Reversing the scarcity of assembled products may begin to secure for health care the efficiency gains that free enterprise has brought to almost every other economic sector.

Experienced clinicians are seldom fooled by miracle cures. Serious illnesses that are slow to develop are typically slow to reverse, wisdom that applies also to the severe and complex pathology of the American health care system. Redirecting antitrust enforcement and associated regulation to favor assembled, warrantable products is not a panacea for market failure in health care. It is, however, a critical supplement to the analytics currently being employed by competition policymakers in pursuit of their goals.

See Inst. for Healthcare Improvement, supra note 206.

⁴³² See Berenson & Burton, supra note 8 and accompanying text.

⁴³³ See supra text accompanying notes 1, 7.

⁴³⁴ See supra text accompanying notes 152–55.