

**MERGERS AND MONOPOLIES: AN EXAMINATION OF THE
CYCLICAL EFFECT OF ANTI-COMPETITION AND A LACK OF
RATE REGULATION IN HEALTH CARE**

ABSTRACT

Health care costs continue to rise, forcing consumers to make difficult choices between seeking expensive treatment and risking the consequences without. To combat the inflation of health care costs, the Affordable Care Act implemented a number of policies aimed at improving the quality of care while lowering the cost of that care. In order to accomplish the goals of the Affordable Care Act, health care systems began merging with one another and acquiring smaller groups to incorporate into a vast network of providers. However, many of these mergers offer little value to consumers. Instead, they ultimately drive up the cost of health care services, often with minimal improvements in the quality of care. On the other side of the health care spectrum, medical device manufacturers have managed to control lawmakers through extensive lobbying efforts, eliminating competition from more affordable alternatives and limiting regulations that could be beneficial for consumers. Using a health system and a medical device case study to examine such problems, this article demonstrates how anti-competitive behavior and a lack of rate regulation negatively impact health care costs. It will also propose solutions to resolve these problems so consumers can take back control of their health care.

I. INTRODUCTION

“What we have in the industry, in the provider market, is a hard-wired market strategy to seek and exploit market power,” Barak Richman, Professor of Law at Duke University¹

Competition laws have long been an issue of contention with hospital mergers and acquisitions. More recently with the advancement of treatment options, the medical technology field has also become rife with monopolistic concerns. With the ever-increasing market goal of expansion, profitability, and market-control in health care, antitrust issues are highly relevant today.² Contributing to the care provider side of this, the Affordable Care Act (ACA) encourages hospitals, physician groups, and even insurers to create accountable care organizations (ACOs) or similar coordinated care systems in the hope that they will increase quality and access to health care while reducing costs for all.³ A pattern has emerged within the health care industry that suggests there is a relationship between competition problems and rate regulations. Because of the unique nature of health care, each level of provider contributes to the rising costs of medical care through this relationship.

Health care provider groups often merge with each other to create larger organizations for financial reasons, and most do not present competition concerns for antitrust authorities.⁴ However, mergers that do raise concerns are typically handled federally by the Federal Trade Commission (FTC) or the United States (U.S.) Department of Justice’s (DOJ) Antitrust Division, although state attorneys general are also able to investigate cases.⁵ Often when antitrust issues develop, the solution is a consent agreement between the parties, wherein the competitive concern is eliminated, usually through divestiture of an interest, and the agreement can continue.⁶ Sometimes, the

1. Jay Hancock, *Expert: Hospital’s ‘Humongous Monopoly’ Drives Prices High*, KAISER HEALTH NEWS (Mar. 4, 2013), <http://kaiserhealthnews.org/news/expert-hospitals-humongous-monopoly-drives-prices-high/>.

2. See generally Jenny Gold, *Accountable Care Organizations, Explained*, KAISER HEALTH NEWS (Sept. 14, 2015), <http://kaiserhealthnews.org/news/aco-accountable-care-organization-faq/> (warning that ACO’s “could lead to greater consolidation in the health care industry, which could allow some providers to charge more”); see also Martin Gaynor, Dir., Bureau of Econ., Fed. Trade Comm’n, Letter to the Editor, *Health Law and Antitrust*, N.Y. TIMES, Feb. 17, 2014, at A22, <http://www.nytimes.com/2014/02/18/opinion/health-law-and-antitrust.html>.

3. See generally Gold, *supra* note 2.

4. *Guide to Antitrust Laws: Mergers*, FED. TRADE COMMISSION, www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers (last visited Feb. 16, 2015). Ninety-five percent of mergers raise no competition concerns. *Id.*

5. *Guide to Antitrust Laws: The Enforcers*, FED. TRADE COMMISSION, www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/enforcers (last visited Feb. 16, 2015).

6. See *Guide to Antitrust Laws: Mergers*, *supra* note 4.

FTC or DOJ will bring the matter before a court to prevent the merger from occurring in any form.⁷

Historically, there were periods of time when companies were more successful with freely merging, and others, like now, when the agencies are more successful in controlling the parameters of mergers.⁸ One of the greatest differences between older cases and more recent cases is the effect the ACA has had on the design of care systems. The goal of the ACA is to improve access to affordable, quality health care, but also to encourage providers to be more efficient and better utilize available funds and incentives.⁹ The eventual goal of the ACA is to reduce spending for consumers and the government, in an attempt to substantially, yet gradually, lessen the national expenditures associated with health care services.¹⁰ Health care providers hope to fulfill the ACA's goals by joining together and implementing new policies to improve patient quality and decrease provider spending.¹¹ However, as providers take steps toward achieving the goals of the ACA, the methods used to achieve this success often include reducing vital competition. The reduction of provider competition has helped enable health care costs to soar well beyond that of other developed nations, while offering few quality improvements compared to those nations.¹²

7. *Id.*

8. See Michael R. Bissegger, *The Evanston Initial Decision: Is There a Future for Patient Flow Analysis?*, 39 J. HEALTH L. 143, 154 (2006). Most cases lost by the DOJ and FTC were due to the agencies' inability to demonstrate a relevant geographic market. *Id.* In the late 1980s and 1990s, these agencies began better defining a narrow geographic market area in antitrust disputes and consequently were more successful in their actions against merging care groups. *Id.* This created the rule of thumb for merger analysis as "narrow market, government wins; broad market, government losses." *Id.*

9. See generally Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2012).

10. *Deficit-Reducing Health Care Reform*, THE WHITE HOUSE, www.whitehouse.gov/economy/reform/deficit-reducing-health-care-reform (last visited Jan. 30, 2016).

11. See Press Release, Dep't of Health & Human Servs., New hospitals and Health Care Providers Join Successful, Cutting-edge Federal Initiative That Cuts Costs and Puts Patients at the Center of Their Care (Jan. 11, 2016), www.hhs.gov/about/news/2016/01/11/new-hospitals-and-health-care-providers-join-successful-cutting-edge-federal-initiative.html (announcing 121 new participants in Medicare ACOs).

12. Diane Archer, *No Competition: The Price of a Highly Concentrated Health Care Market*, HEALTH AFF. BLOG (Mar. 6, 2013), <http://healthaffairs.org/blog/2013/03/06/no-competition-the-price-of-a-highly-concentrated-health-care-market/>; *Health Spending: Trends and Impact*, KAISER FAM. FOUND., slide 4 (Apr. 16, 2013), www.slideshare.net/KaiserFamilyFoundation/health-spending-trends-and-impact?redirected_from=save_on_embed; KAREN DAVIS ET AL., COMMONWEALTH FUND, MIRROR, MIRROR ON THE WALL: HOW THE PERFORMANCE OF THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY 26 (2014).

Another factor influencing the exorbitance of health care costs is a lack of substantial rate regulation in the American economy.¹³ This concept of rate regulation refers to the government's ability to monitor and control rates in various industries through the creation of regulations.¹⁴ The regulatory issues in health care are widely attributable to the political atmosphere that has developed national policies over the past several decades.¹⁵ This issue of rate regulation, or lack thereof, is troubling for the American population as health care expenses now make up around seventeen percent of the gross domestic product, for a total expense of 2.9 trillion dollars for American consumers.¹⁶ To understand the issues surrounding rate regulation, it is important to understand the foundation of the health care payment system that has allowed physicians, hospitals, and other health care organizations to transform the health care industry into an extremely profitable field. It is also important to understand the role secondary industry participants, like manufacturers of medical devices, play in this payment scheme and the lack of effective rate regulation. These two relatively different industries create a tale of two cities, with each demonstrating separate paths for the rise and maintenance of market power, yet with interwoven effects that ultimately yield the same result.

To put some of these issues in context, this article will examine the factors that have created the inefficient health care market the U.S. has today. This article will then examine and compare the competitive concerns of two health care industries: the provider industry and the medical device industry. These two industries utilize different approaches to maneuver through applicable laws and regulations, but both have resulted in financial harm to consumers. In performing this analysis, this article will scrutinize a contested settlement in Massachusetts between Partners HealthCare System and the state attorney general. This case analysis will demonstrate the antitrust issues and ultimate costs that eventually fall to consumers when hospitals and other health care organizations merge. This article will also discuss the drawbacks and benefits to merging and consolidating services in relation to patient expenses. Further,

13. Noam Schimmel, Opinion, *Regulating U.S. Health Care*, N.Y. TIMES (Sept. 17, 2012), www.nytimes.com/2012/09/18/opinion/regulating-us-health-care.html.

14. See *State Approval of Health Insurance Rate Increases*, NAT'L CONF. ST. LEGISLATURES, <http://www.ncsl.org/research/health/health-insurance-rate-approval-disapproval.aspx> (last visited Feb. 2, 2016) (providing an example of the government's ability to monitor and control rates in the health insurance industry through regulation of premiums).

15. See generally Timothy S. Jost, *Eight Decades of Discouragement: The History of Health Care Cost Containment in the USA*, 15 FORUM FOR HEALTH ECON. & POL'Y 53 (2012).

16. Micah Hartman et al., *National Health Spending in 2013: Growth Slows, Remains In Step For Overall Economy*, 34 HEALTH AFF. 150, 150 (2015); see also *National Health Expenditures 2014 Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS., www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (last visited Feb. 16, 2015).

it will demonstrate how the rising medical costs come full circle, beginning with the manufacturing of the products all the way to the consumer's pocket. It will also investigate various proposals to reduce costs, though the effectiveness of these proposals may vary. As consumers become more aware of the factors that influence quality and cost of health care, there is hope that combined pressure from a variety of sources will force providers and secondary health care companies to lower prices, or, in the alternative, that this pressure will lead to stricter rate regulations of the provider and medical device industries.

II. BACKGROUND

The history of health care demonstrates that Americans have tried many approaches to create an affordable system with quality care.¹⁷ But why is it that Americans have been forced to do this time and time again? With each new health system approach, prices have risen, but quality of care has not. American consumers are constantly searching for the next best affordable option to health care, yet they continue to pay more for it than any other developed nation.¹⁸ In the U.S., consumers spend almost twenty percent of their gross domestic product on health care, which is double the amount spent in most other developed nations.¹⁹ Many researchers and economists highlight this discrepancy, coupled with the fact that “the results [the American] health care system produces are no better and often worse than the outcomes in those [other developed] countries.”²⁰

As a whole, health care systems in America have become so powerful that they “dominate the nation's economy and put demands on taxpayers to a degree unequalled anywhere else on earth.”²¹ It is because of this that every decade or so a new health care model evolves to curb the ever-growing expenses of health care.²² To demonstrate this, the Kaiser Family Foundation graphed the cost of health care over the past fifty years and drew attention to the rapid increases Americans have paid for their health care.²³ Each decade has seen exponential growth in payments, as expenses double about every ten

17. See generally Michael Millenson, *Analysis: ACOs Could Have The Medicare Muscle To Transform Health System*, KAISER HEALTH NEWS (May 2, 2012), khn.org/news/millenson-acos-muscle-to-transform-system/.

18. KAISER FAM. FOUND., *supra* note 12.

19. Steven Brill, *Bitter Pill: Why Medical Bills are Killing Us*, TIME (2013), <http://www.uta.edu/faculty/story/2311/Misc/2013,2,26,MedicalCostsDemandAndGreed.pdf>.

20. *Id.*

21. *Id.*

22. Millenson, *supra* note 17.

23. KAISER FAM. FOUND., *supra* note 12, at slide 1.

years.²⁴ This trajectory is not sustainable for the American consumers whose income has not inflated as quickly as their medical expenses have.²⁵

A. *Health Care Providers*

Throughout the past few decades, the health care industry has seen many payment system reforms in attempts to control rising costs and improve deficient care. These payment reforms signified the beginning of the managed care era of organizations.²⁶ In the 1980s, Congress passed legislation that dramatically altered hospital payments for Medicare services.²⁷ This renewed plan was a “prospective payment system” in which Medicare paid pre-determined flat rates for services based on a patient’s diagnosis.²⁸ That system eliminated the “cost plus” system previously utilized, wherein hospitals were guaranteed a profit margin.²⁹ While ideally the set-fee payment system saved Medicare from overspending, in reality, it often resulted in reduced care quality for patients.³⁰ For instance, because hospitals no longer received payment for extended patient stays in hospitals or additional tests conducted, patients were released sooner than medically necessary in some cases—a problem which became known as the “quicker and sicker” issue.³¹ Determined to find ways around this flat-payment schedule, hospitals began transferring patients to other managed care settings like outpatient centers, where the prospective payment system did not apply.³²

Following the Medicare overhaul of the 1980s, health maintenance organizations (HMOs) and other private insurers flourished in the 1990s by offering fixed payments for services in an effort to control wasteful spending by health care organizations.³³ This plan was not without its faults though; hospitals went to extremes to cut patient costs in an effort not to lose money themselves.³⁴ Trial and error of payment systems has resulted in some success and some failure, leaving legislators, health care organizations, and insurers confused on how best to manage costs and care.

24. *Id.*

25. *See id.* at slide 15.

26. Jost, *supra* note 15, at 58, 60-70.

27. Millenson, *supra* note 17.

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. Millenson, *supra* note 17.

33. *Id.*

34. *Id.*

A health care organization is at its heart a business; its goal is to maintain profitability while providing health care services,³⁵ an ironic, yet necessary aspect of most any health care business. It is necessary because, without profits, these organizations cannot perform their most basic function: care and treatment. This is true regardless of tax status; organizations with non-profit, tax-exempt status must make money to function, just as for-profit organizations must. In fact, research suggests there may be little difference between the amount of charitable care that results in lost profits provided by non-profit care facilities and the amount provided by for-profit facilities.³⁶ Regardless, to create profitability, health care organizations need to have high patient volume and reimbursements and low debt and spending.³⁷

One recent push from Congress to control health care spending and quality comes from the ACA. Encouraged by the ACA, ACOs have become the latest payment system introduced to curb costs and improve care.³⁸ These ACOs offer benefits to patients and providers alike, which makes them ideal compared to previous models.³⁹ However, initial projections and the latest data reports show some potential concerns in whether they will ultimately garner a great enough market share to create a substantial benefit.⁴⁰

To help increase involvement in ACOs, the Centers for Medicare and Medicaid Services (CMS) has enacted a variety of incentive programs to entice care groups into the ACO structure.⁴¹ These benefits include profit-sharing without risk of loss-sharing when organizations do not exceed designated

35. See David A. Hyman, *Hospital Conversions: Fact, Fantasy, and Regulatory Follies*, 23 J. CORP. L. 741, 742, 744 (1998).

36. See also David Blumenthal & Nigel Edwards, *The Tale of Two Systems: The Changing Academic Health Center*, 19 HEALTH AFF. 86, 86 (2000); Gabriel Picone et al., *Are For-Profit Hospital Conversions Harmful to Patients and to Medicare?*, 33 RAND J. ECON. 507, 507 (2002). See generally Hyman, *supra* note 35; FED. TRADE COMM'N & DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), http://www.justice.gov/atr/public/health_care/204694.pdf.

37. See generally BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 630 (West 7th ed. 2013) (nonprofits chapter).

38. Gold, *supra* note 2.

39. *Accountable Care Organizations (ACO)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/aco> (last visited Feb. 17, 2015).

40. *Fact Sheets: Medicare ACOs continue to succeed in improving care, lowering cost of growth*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 16, 2014), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-09-16.html> (noting that only a small portion of Medicare Shared Savings Program (MSSP) ACOs actually garnered enough savings to share in them and many ACOs have dropped out of the program since inception).

41. See *Accountable Care Organizations (ACO)*, *supra* note 39; see also *News and Updates*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/News.html> (last updated Mar. 6, 2015).

benchmarks for the first three years of inception.⁴² By utilizing a gradual entry into the ACO cost-sharing program, care organizations are given time to acclimate to structural changes required of an ACO so they can become profitable with considerably less risk.⁴³ If organizations are unable to reach enough benchmarks to share in savings, they may drop out of the incentive program altogether, opting for a non-ACO model instead.⁴⁴ As such, there is an incentive for the government to structure the ACO benefits to be more attainable, which is why CMS has solicited suggestions and created a variety of ACO models to make the program more beneficial for all.⁴⁵

The problem ACOs and many other CMS initiatives are designed to fix is the popular fee-for-service model of payments for physician services. The fee-for-service model is one in which a physician receives a payment for each individual service performed, as opposed to a bundled payment model, which would bundle a group of services together for a set fee.⁴⁶ Fee-for-service has been the accepted method of payment in the U.S. for some time now,⁴⁷ but its popularity does not mean it is the best payment system.

Like the prospective payer system and HMOs of the 1980s and 1990s, fee-for-service can incentivize doctors to make medical decisions motivated by profit.⁴⁸ However, unlike the previous models, which undercut quality by potentially reducing services to fit a budget, fee-for-service encourages excessive care from physicians.⁴⁹ By receiving a payment for each service provided, physicians are incentivized to order as many tests as possible to ensure the patient is well cared for, even if his wallet is not.⁵⁰ This system has led to financial waste, as many services provided are not medically necessary.⁵¹ It has also allowed prices for equipment and services to sky-

42. CTRS. FOR MEDICARE & MEDICAID SERVS., *METHODOLOGY FOR DETERMINING SHARED SAVINGS AND LOSSES UNDER THE MEDICARE SHARED SAVINGS PROGRAM* 3, 6 (2014), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf.

43. *Id.* at 2-3.

44. S. Lawrence Kocot et al., *The Medicare Shared Savings Program: CMS Turns To Stakeholders On Incentivizing ACO Risk*, HEALTH AFF. BLOG (Dec. 19, 2014), <http://healthaffairs.org/blog/2014/12/19/the-medicare-shared-savings-program-cms-turns-to-stakeholders-on-incentivizing-aco-risk/>.

45. *Id.*

46. *Bundled Payments for Care Improvements Initiative Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 30, 2014), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-01-30-2.html>.

47. See Julie Barnes, *Moving Away From Fee-for-Service*, ATLANTIC (May 7, 2012), <http://www.theatlantic.com/health/archive/2012/05/moving-away-from-fee-for-service/256755/>.

48. AM. HOSP. ASS'N, *ISSUE BRIEF: MOVING TOWARDS BUNDLED PAYMENT 1* (2013).

49. *Id.*

50. See *id.*

51. See *id.*

rocket, giving all involved in the care of a patient—from device manufacturer to physician—a piece of the profit margin.⁵²

Fee-for-service insurance coverage also exacerbated the problem of moral hazard, which has contributed to the overuse and overcharging of health care services.⁵³ The moral hazard concept points to the overuse of unnecessary medical services because such services are available and covered.⁵⁴ The American approach to health care is that more care equals better health; however, this is not always true.⁵⁵

B. *Medical Device Industry*

Medical devices have been part of the U.S. health care industry since the civil war.⁵⁶ By the mid-1960s, the first regulations were enacted by then President John F. Kennedy in an effort to prosecute companies for product liability.⁵⁷ The Food and Drug Administration (FDA) regulates the medical device industry,⁵⁸ however, the power of the FDA in the 1960s was very limited in regards to medical devices.⁵⁹ Throughout the next few decades, the FDA's ability to monitor and regulate the medical device industry grew.⁶⁰ While the government attempted to impose regulations on the field, the companies producing the medical devices began to develop and grow more

52. *See id.*

53. *See generally* Patrick Bajari et al., *Moral Hazard, Adverse Selection, and Health Expenditures: A Semiparametric Analysis*, 45 RAND J. ECON. 747, 761 (2014).

54. *Id.* at 753, 761.

55. Eve Kerr & John Ayanian, *How to Stop the Overconsumption of Health Care*, HARV. BUS. REV. (Dec. 11, 2014), <https://hbr.org/2014/12/how-to-stop-the-overconsumption-of-health-care>.

56. Michael MacRae, *The Civil War and the Birth of the U.S. Prosthetics Industry*, AM. SOC'Y MECHANICAL ENGINEERS, www.asme.org/engineering-topics/articles/bioengineering/the-civil-war-and-birth-of-us-prosthetics-industry (last visited Feb. 1, 2016).

57. *Brief History of US Medical Device Regulation*, EMERGO, <http://visual.ly/brief-history-us-medical-device-regulation> (last visited Feb. 24, 2016); *see Significant Dates in U.S. Food and Drug Law History*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm> (last updated Dec. 19, 2014).

58. *What We Do*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last updated Dec. 7, 2015).

59. Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years*, 50 FOOD & DRUG L.J. 163, 164 (1995).

60. *Id.* at 168. *See generally Significant Dates in U.S. Food and Drug Law History*, *supra* note 57.

powerful as the technology advanced.⁶¹ The most growth has occurred over the last few decades, as have the rates charged for the products.⁶²

As far as regulations are concerned, the medical device industry has protected itself from most regulation for years through its successful and extensive lobbying efforts.⁶³ It has managed to garner support from both Republican and Democratic members of Congress, particularly from those members in whose states the manufacturers are found.⁶⁴ These lobbying efforts are exemplified in the recent attempts to repeal the medical device tax that was included in the ACA.⁶⁵

Part of what has enabled the medical device industry to grow so rapidly and have such high profitability is the same moral hazard and American overuse-of-health-care approach described in the health care industry section above. This approach includes the idea that the most expensive option must be the best option, thus encouraging the medical technology industry to continually create new or modified drugs and devices, even when the results are the same as the older, cheaper, less advanced products.⁶⁶ With each new device that boasts some new benefit, a medical device company is potentially able to reduce its competition and increase the price of the product.

III. GOVERNING LAWS AND AGENCIES

There are three federal laws of relevance to the health care antitrust discussion: the Sherman Act,⁶⁷ the Clayton Act,⁶⁸ and the Hart-Scott-Rodino

61. *The Medical Device Industry in the United States*, SELECT USA, <http://selectusa.com/merce.gov/industry-snapshots/medical-device-industry-united-states.html> (last visited Feb. 2, 2016).

62. *Id.*; *Snapshots: How Changes in Medical Technology Affect Health Care Costs*, KAISER FAM. FOUND. (Mar. 2, 2007), <http://kff.org/health-costs/issue-brief/snapshots-how-changes-in-medical-technology-affect/>; INT'L TRADE ADMIN., *MEDICAL DEVICES INDUSTRY ASSESSMENT 3* (2010), <http://ita.doc.gov/td/health/medical%20device%20industry%20assessment%20final%20ii%203-24-10.pdf>.

63. *Medical Supplies: Lobbying, 2014*, CTR. FOR RESPONSIVE POL., www.opensecrets.org/industries/lobbying.php?cycle=2014&ind=H4100 (last visited Apr. 21, 2016) (demonstrating that the total amount in dollars spent on lobbying by the medical device and supplies industry for 2014 was \$33,322,243 on behalf of 108 companies).

64. Gregory W. Daniel, *5 Questions About the Medical Device Tax, and Its Potential for Repeal*, BROOKINGS INST. (Nov. 12, 2014), <http://www.brookings.edu/research/opinions/2014/11/12-medical-device-tax-daniel>.

65. Daniel, *supra* note 64. For a greater discussion of the medical device tax and congressional efforts to repeal it, *see infra* Part V.

66. *See* Merrill Goozner, *High-Tech Medicine Contributes to High-Cost Health Care*, KAISER HEALTH NEWS (Feb. 15, 2010), <http://kaiserhealthnews.org/news/ft-health-care-high-tech-costs/>.

67. Sherman Act, 15 U.S.C. §§ 1-7 (2012).

68. Clayton Act, 15 U.S.C. §§ 12-27 (2012).

Antitrust Improvements Act.⁶⁹ Anti-competition laws have existed since the original Sherman Act of 1890, which first codified a federal prohibition of anti-competitive or monopolistic practices.⁷⁰ After the Sherman Act was written, the Clayton Act further clarified that the government could prevent and eliminate any business activities involving illegal tying contracts or corporate mergers and acquisitions.⁷¹ The Hart-Scott-Rodino Act amended the Clayton Act by mandating certain companies to file premerger notifications with the FTC and the DOJ's Antitrust Division if they planned to integrate.⁷² These premerger notifications give the reviewing agencies time to analyze mergers and determine whether they are fair to consumers.⁷³ In addition to those laws, there are also state laws governing antitrust practices, and the FTC has its own, known as the Federal Trade Commission Act, which grants the agency the power to reject or accept mergers, investigate potential cases, prescribe trade regulation rules, and issue monetary redress against businesses that violate these laws.⁷⁴ Beyond the scope of health care, the FTC and DOJ's Antitrust Division oversee all types of competition issues and utilize a multitude of antitrust laws and regulations that have been created over the years to govern each field.⁷⁵ The state attorneys general play a similar role in monitoring, investigating, and prosecuting companies that exhibit anti-competitive practices to the degree that consumers are harmed.⁷⁶

IV. EFFECTS OF ANTI-COMPETITIVE PRACTICES

A. *Health Care Provider Case Study and Anti-Competitive Effects*

To examine the effects of competition, or lack thereof, on health care service rates, the Partners HealthCare system (Partners) and the recent antitrust lawsuit associated with the system in Massachusetts make an excellent case study.⁷⁷ Partners, a non-profit organization, was originally formed when two

69. Hart-Scott-Rodino Antitrust Improvements Act, 15 U.S.C. §§ 15(c)-15(h), 18(a), 66 (2012).

70. 15 U.S.C. §§ 1-7.

71. 15 U.S.C. §§ 12-27.

72. 15 U.S.C. § 18(a).

73. *Id.*

74. Federal Trade Commission Act, 15 U.S.C. §§ 41-58 (2012).

75. See *Statutes Enforced or Administered by the Commission*, FED. TRADE COMMISSION, <http://www.ftc.gov/enforcement/statutes> (last visited Feb. 17, 2015); *Antitrust Enforcement and the Consumer*, U.S. DEP'T JUST., http://www.justice.gov/atr/public/div_stats/antitrust-enfor-consumer.pdf (last visited Feb. 17, 2015).

76. *About NAAG*, NAT'L ASS'N ATTORNEYS GEN., http://www.naag.org/naag/about_naag.php (last visited Feb. 17, 2015).

77. See Robert Weisman & Scott Allen, *Partners Pays a Price After Bid for South Shore*, BOS. GLOBE (Nov. 9, 2014), <http://www.bostonglobe.com/business/2014/11/08/partners-quest-for>

hospitals, Brigham and Women's Hospital and Massachusetts General Hospital, merged in 1994.⁷⁸ It now boasts an impressive list of "community and specialty hospitals, a managed care organization, a physician network, community health centers, home care[,] and other health-related entities."⁷⁹ In its twenty-one years since inception, Partners has accumulated forty-three "members," affiliated programs and centers, and collaborates with four research and development (R&D) programs.⁸⁰ Clearly evident from the numbers, Partners is a massive health care organization within the state of Massachusetts.⁸¹

In line with the ACA's goals, Partners has rearranged itself as an ACO to improve coordinated care for patients and promote cost savings.⁸² As the largest health care system in the state of Massachusetts,⁸³ Partners also holds the majority market share of health care business in the Boston area.⁸⁴ Recently, in 2012, Partners attempted two new acquisitions of South Shore Hospital and Harbor Medical Associates, as one group, and Hallmark Health System, which would further expand its market power to dominate other provider systems in the northeastern area of Massachusetts.⁸⁵

There are benefits and drawbacks to such a large health care system. The coordinated care aspect across the system and greater access to state-of-the-art

-south-shore-hospital-fueled-backlash-and-debate-over-how-big-too-big/XDPn96u1jqpM8X5GBZ3n8H/story.html.

78. *About Partners HealthCare*, PARTNERS HEALTHCARE, <http://www.partners.org/About/Default.aspx?id=1> (last visited Feb. 17, 2015).

79. *Id.*

80. *Partners HealthCare Members and Affiliations*, PARTNERS HEALTHCARE, <http://www.partners.org/About/Company-Information/Members.aspx> (last visited Feb. 17, 2015).

81. CTR. FOR HEALTH INFO. & ANALYSIS, ANNUAL REPORT ON THE PERFORMANCE OF THE MASSACHUSETTS HEALTH CARE SYSTEM 2 (2014) [hereinafter CHIA REPORT]. According to a report released in September 2014, in 2011, the most recent analysis performed by the Center for Health Information and Analysis (CHIA), Partners HealthCare had accumulated twenty-eight percent of the market share of hospital and physician payments. *Id.* Most notably, this number was three times larger than the next largest provider system. The four largest providers accounted for around fifty percent of the provider market. *Id.*

82. PARTNERS HEALTHCARE, PARTNERS HEALTHCARE 2013 ANNUAL REPORT 1, 3 (2013), <http://partnershealthcare.uberflip.com/i/307830/3>.

83. HEALTH POLICY COMM'N, REVIEW OF PARTNERS HEALTHCARE SYSTEM'S PROPOSED ACQUISITION OF HALLMARK HEALTH CORP. 8 (2014) [hereinafter HPC HALLMARK REPORT]; see also CHIA REPORT, *supra* note 81, at accompanying text.

84. Weisman & Allen, *supra* note 77; HA T. TU ET AL., COMMUNITY REPORT: STATE REFORM DOMINATES BOSTON HEALTH CARE MARKET DYNAMICS 4-5 (2010) (noting that the prestige and brand name of Partners hospitals in the Boston area allow the hospitals to exercise market leverage beyond what the market share suggests).

85. HPC HALLMARK REPORT, *supra* note 83, at 78.

treatment and facilities are certainly beneficial to consumers.⁸⁶ However, with that improved care comes the substantial risk of increased costs to consumers because of the increase in market power, and, thus, the ability to demand higher prices from insurers as well as establish higher fees for services.⁸⁷

Evidence suggests there is a direct relationship between the increase in market power and the decrease in market competition, which results when health organizations merge.⁸⁸ There is significant factual support that greater market power and less competition result in greater costs to consumers.⁸⁹ A 2012 update to a 2006 survey confirmed the findings of two prominent health and antitrust economists who found that hospital mergers do not typically yield significant savings, and those that do generally do so only because they merged operations completely.⁹⁰ These economists also found that while such mergers generally raise prices significantly, they tend to lower the quality of care offered, an alarming trend for consumers.⁹¹ This survey is especially relevant to the Partners discussion described herein because it focused on the effects of a combination of horizontal and vertical acquisitions, both of which occur in the Partners case.⁹²

In Partners' latest acquisition attempt of Hallmark Health System, South Shore Hospital, and Harbor Medical Associates, an investigation was conducted by both the then Attorney General of Massachusetts, Martha

86. David M. Cutler & Fiona Scott Morton, *Hospitals, Market Share, and Consolidation*, 310 [J]AMA 1964, 1967 (2013).

87. *Hearing on Health Care Industry Consolidation Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 112th Cong. 7 (2011) (statement of Martin Gaynor, Professor, H. John Heinz III School of Public Policy and Management, Carnegie) [hereinafter Statement of Gaynor].

88. *Id.* at 6.

89. HPC HALLMARK REPORT, *supra* note 83, at 44; *see also* Statement of Gaynor, *supra* note 87, at accompanying text; Cutler & Morton, *supra* note 86, at accompanying text; CHIA REPORT, *supra* note 81, at 14. In a comparison of the physician groups' total medical expenditures (TME), the four largest all reported expenditures higher than the designated +3.6% benchmark in the major payor networks. *Id.* Partners Community HealthCare, Inc. (PCHI), a member of the Partners HealthCare System, was the only group to report that its expenditures were higher than the network average and TME that had increased across all payors. *Id.*

90. WILLIAM B. VOGT & ROBERT J. TOWN, HOW HAS HOSPITAL CONSOLIDATION AFFECTED THE PRICE AND QUALITY OF HOSPITAL CARE?, RESEARCH SYNTHESIS REPORT NO. 9 10 (2006); Brief for Leemore Dafny et al. as Amici Curiae at 4, Commonwealth of Mass. v. Partners HealthCare Sys., Inc., No. 14-2033-BLS (Mass. Super. Ct. July 21, 2014) [hereinafter Dafny et al.].

91. MARTIN GAYNOR & ROBERT TOWN, SYNTHESIS PROJECT, THE IMPACT OF HOSPITAL CONSOLIDATION-UPDATE 1, 3 (2012).

92. *Id.*

Coakley, and the DOJ.⁹³ After conducting her investigation, the Attorney General came to an unexpected solution. Instead of rejecting the merger as some anticipated, Coakley offered a settlement option to Partners, wherein the merger would be accepted with conditions that extended through the next five to ten years.⁹⁴

This proposed settlement was so unexpected that over 170 organizations submitted a brief to the court in favor of or against it.⁹⁵ As a result, the settlement was amended to include a few more restrictions,⁹⁶ although the judge's approval was still required before the merger could continue. The final proposed settlement would allow Partners to acquire the desired hospitals and systems with the following stipulations: payors could split Partners into separate contracting entities for up to ten years; Partners would be prevented from contracting with affiliate physician groups not already within its own hospitals for ten years; health costs would be capped at the rate of inflation across the entire Partners network through 2020; physicians' growth would be capped for five years; and additional Partners hospital expansion in eastern Massachusetts would be blocked for the next seven years.⁹⁷ Furthermore, a monitor would be appointed by the Attorney General's office and would be paid for by Partners to ensure compliance with these conditions over the next ten years.⁹⁸

The Attorney General believed this settlement would reduce Partners' bargaining power in the market for a substantial number of years, while providing the most benefit to the consumers.⁹⁹ This approach is less commonly utilized,¹⁰⁰ but may become more popular as states and agencies look to promote the goals of the ACA through care and data integration.

As part of her investigation, Coakley enlisted the services of the Massachusetts Health Policy Commission (Commission or HPC) to research the potential effects that would occur from this merger.¹⁰¹ The Commission

93. Plaintiff Commonwealth of Massachusetts Response to Public Comments at 3, *Commonwealth of Mass. v. Partners HealthCare Sys., Inc.*, No. 14-2033-BLS2 (Mass. Super. Ct. Sept. 25, 2014). Note, the DOJ findings have not been released as of January 2016.

94. *See generally* Joint Motion for Entry of Final Judgment by Consent, *Commonwealth of Mass. v. Partners HealthCare Sys., Inc.*, No. 14-2033-BLS2 (Mass. Super. Ct. June 24, 2014) [hereinafter Joint Motion for Consent Judgment].

95. Weisman & Allen, *supra* note 77.

96. *See generally* Joint Motion for Entry of Amended Final Judgment by Consent, *Commonwealth of Mass. v. Partners HealthCare Sys., Inc.*, No. 14-2033-BLS2 (Mass. Super. Ct. Sept. 25, 2014) [hereinafter Joint Motion for Amended Judgment].

97. *Id.*

98. *Id.*; Joint Motion for Consent Judgment, *supra* note 94.

99. Joint Motion for Amended Judgment, *supra* note 96.

100. Brief for the Am. Antitrust Inst. as Amicus Curiae at 2, *Commonwealth of Mass. v. Partners HealthCare Sys., Inc.*, No. 14-2033-BLS (Mass. Super. Ct. Sept. 11, 2014).

101. HPC HALLMARK REPORT, *supra* note 83, at 1.

was established in 2012 to help control rising health care costs for consumers in Massachusetts.¹⁰² For 2014, the Commission established a benchmark of 3.6% for a sustainable rate of growth of health care expenditures, meaning that such expenditures should not exceed that growth rate.¹⁰³ The Commission undertook the task of analyzing whether the proposed merger between Partners, South Shore, and Hallmark would actually benefit consumers or whether it would force costs to exceed the benchmark. It wrote multiple reports analyzing the proposed merger and settlement, all of which found critical information lacking to support the parties' assertions or found that the merger would harm consumers.¹⁰⁴

For this review, the Commission looked at the stated goals of the merger and all information provided by the parties that supported how and when the merger would improve the market.¹⁰⁵ The Commission's Hallmark Final Report noted that Partners and Hallmark had the highest share of inpatient and primary care services and Partners hospitals had higher prices than almost all others in each region in which it operated.¹⁰⁶ Both Hallmark and Partners hospitals generally met or exceeded quality benchmarks, though physician groups for Hallmark met or were below the state average.¹⁰⁷ Most substantial in the report, the Commission found that rather than reduce spending, the proposed settlement would increase spending in northeast Massachusetts by \$15.5 to twenty-three million dollars each year.¹⁰⁸ The Commission determined that this increase would not be offset by savings from reduced utilization of services through population health management.¹⁰⁹ The Commission noted that the merger would likely increase care access and improve quality, but that the health system failed to provide critical information to prove that these assertions would actually come to fruition.¹¹⁰

In the Commission's South Shore and Harbor Medical Final Report, it reported very similar findings. It determined that medical spending would actually increase twenty-three million dollars to twenty-six million dollars each year because of increased physician prices and facility utilization.¹¹¹ Therefore, the system would be able "to leverage higher prices and other favorable

102. *Id.* at Introduction.

103. *Id.*

104. *Id.* at 1-4.

105. *Id.* at Introduction.

106. HPC HALLMARK REPORT, *supra* note 83, at 2.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.* at 4.

111. HEALTH POLICY COMM'N, REVIEW OF PARTNERS HEALTHCARE SYSTEM'S PROPOSED ACQUISITION OF SOUTH SHORE HOSPITAL AND HARBOR MEDICAL ASSOCIATES 2 (2014) [hereinafter HPC SOUTH SHORE REPORT].

contract terms in negotiations with commercial [payors].”¹¹² Moreover, this improved leverage is not included in the increased medical spending estimates stated above.¹¹³ Again, the Commission noted that while there would likely be improvements in care delivery and health outcomes, Partners again did not provide enough evidence to prove that increased costs would affect overall quality performance at the South Shore facilities, where such performance is already strong.¹¹⁴ The Commission determined that these mergers would not be an economically beneficial decision for consumers without additional information explaining why integration is necessary to accomplish Partners’ goals.¹¹⁵

In early 2015, the judge presiding over the case rejected the entire settlement, finding that there was not enough evidence of pro-competitive effects to counter the potential anti-competitive harm.¹¹⁶ After receiving this blow, Partners decided to withdraw its acquisition of South Shore Hospital, although it planned to continue its acquisition of Hallmark Health Corp.¹¹⁷

The Partners merger is a great example of the correlation between anti-competitive provider behavior and rising health care costs. It shows, through all the empirical evidence analyzed and described by the Commission, how a lack of regulation or insufficiently utilized, authoritative power over an industry has the potential to elicit detrimental consequences on consumers.

Part of what makes the proposed Partners settlement offer so unique is its attempt to regulate the system by applying conditions to be met, known as conduct remedies,¹¹⁸ instead of rejecting the merger or requiring some structural change. There are two types of remedies commonly employed to regulate the massive health care industry—structural remedies, which include divestiture of assets, and conduct remedies, which include obligations or changing conduct.¹¹⁹ However, neither remedy has been able to adequately control the overall cost escalation in the industry.

Structural remedies are often preferred over conduct remedies because they are more effective at eliminating the anti-competitive concern in most mergers,

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.* at 2-3.

116. Priyanka McCluskey & Robert Weisman, *Partners’ Deal to Acquire Three Hospitals Rejected*, BOS. GLOBE (Jan. 29, 2015), <http://www.bostonglobe.com/business/2015/01/29/partners/s9TxpYCBakjPN6pDbBFHGL/story.html>.

117. Press Release, Mass. Attorney Gen. Maura Healey, AG Healey Statement on Partners Decision to Withdraw Intent to Acquire South Shore Hospital (Feb. 17, 2015), <http://www.mass.gov/ago/news-and-updates/press-releases/2015/2015-02-17-ag-stmt-partners-withdraw.html>.

118. Dafny et al., *supra* note 90, at 4-7.

119. *Id.* at 4; DEP’T OF JUSTICE, CHAPTER 9: REMEDIES 149 (2008), www.justice.gov/sites/default/files/atr/legacy/2008/09/12/236681_chapter9.pdf.

but the health care industry has so many additional forces influencing it that these remedies have limited effect.¹²⁰ In other industries, such remedies may be more effective, but the nature of health care is one of continual need. People will never stop needing the services offered, so the providers have an innate power that allots them great control. This power gives them the ability to determine base prices, negotiate with private and public payors, and increase costs virtually whenever they choose. Because of this paradox, rate regulations may be more influential than structural or conduct remedies as the ACA takes effect.

One of the most important effects anti-competitive mergers have on consumers is the rise in health care costs. To understand the way these mergers affect consumer costs, it is crucial to understand how health care organizations charge patients. Most notably, hospitals use a system known as the chargemaster, which allows them to negotiate compensation with payors.¹²¹ A chargemaster is essentially a master list of hospital services, items, and procedures and their associated fees.¹²²

When hospitals first started using chargemasters in the 1930s, all consumers were charged the same rate, which was originally calculated at the cost of providing the service plus ten percent, regardless of insurance.¹²³ However, when Medicare was created, it required a differentiation between actual cost and charges, wherein Medicare paid only the cost, while all other consumers paid charges (service cost plus hospital charges).¹²⁴ Then when managed care took over the market, insurers negotiated reduced rates for their beneficiaries.¹²⁵ These changes eventually led to the chargemaster system in place today, which has little to no relation to the actual costs of items and procedures incurred by the hospitals.¹²⁶

Medicare continues to pay hospitals a flat rate, which it determines based on an evaluation of a multitude of diagnostic-related groups (DRGs) for each hospital.¹²⁷ However, many hospitals say the Medicare rates do not cover the full expenses undertaken by a hospital, and, thus, force the hospital to operate at a loss for those patients.¹²⁸

In markets where a health care system controls a majority of hospitals and physician groups, there are generally higher prices for services and products

120. *Id.*; Dafny et al., *supra* note 90, at 4.

121. Erin C. Fuse Brown, *Irrational Hospital Pricing*, 14 HOUS. J. HEALTH L. & POL'Y 11, 16-24 (2014).

122. *Id.* at 16.

123. *Id.* at 17.

124. *Id.*

125. *Id.*

126. Brown, *supra* note 121, at 17.

127. *Id.* at 19.

128. *Id.* at 24.

offered at those facilities.¹²⁹ Having the majority of market power, or even a large part of it, enables hospitals to set prices for their chagemaster at higher rates because there is less competition.¹³⁰ This has become more evident in some areas, like Boston, where one or two hospital chains dominate a majority of the market and have commanded higher prices from insurers and employers, with little to prevent them from continuing in this pattern.¹³¹ The great variance in pricing is evidence that the health care system needs additional regulation for consideration of anti-competitive behaviors.

Adding to the problem, each insurance company negotiates different rates with each hospital it contracts with as a provider,¹³² so consumers may not always expect to receive the same rate for the same service at any of the in-network facilities. Consumers with insurance coverage pay only a small percentage of the actual chagemaster list price.¹³³ However, for those consumers without insurance or for those who use an out-of-network provider, with whom their insurance company has no contract, the consumer may be forced to pay the full list price,¹³⁴ a daunting prospect to anyone. Even more concerning, the arranged prices between insurers and hospitals are considered confidential,¹³⁵ so price competition is difficult to implement.

This very issue was brought to public light in 1996 when Partners and BlueCross BlueShield of Massachusetts allegedly came to an arrangement regarding price setting for physician services at a significantly higher rate than before.¹³⁶ This agreement allegedly promised that BlueCross BlueShield would give Partners' physicians the biggest insurance payment in exchange for Partners' requiring all other insurers to offer equal or higher payments, thus making BlueCross the most competitive offer though significantly more expensive than before.¹³⁷ Though neither party will admit to this exact deal, the sudden rate increase that occurred shortly after suggests evidence of its truth.¹³⁸ While the public will likely never know officially, a less dramatic version of this is far too common. Insurers negotiate rates with hospitals all the

129. Elisabeth Rosenthal, *As Hospital Prices Soar, a Stitch Tops \$500*, N.Y. TIMES (Dec. 2, 2013), www.nytimes.com/2013/12/03/health/as-hospital-costs-soar-single-stitch-tops-500.html?r=0.

130. *See id.*

131. *Id.*; *see* Weisman & Allen, *supra* note 77.

132. Brown, *supra* note 121, at 21-22.

133. *Id.* at 22.

134. *Id.*; *see also* Rosenthal, *supra* note 129; Brill, *supra* note 19.

135. Brown, *supra* note 121, at 22.

136. Scott Allen & Marcella Bombardieri, *A Handshake That Made Healthcare History*, BOS. GLOBE (Dec. 28, 2008), <http://www.bostonglobe.com/specials/2008/12/28/handshake-that-made-healthcare-history/QiWbywqb8olJsA3IZ1I01H/story.html>.

137. *Id.*

138. *Id.*

time, but consumers are not privy to those conversations or the terms to which they are agreed,¹³⁹ and are thus unable to control their own costs.

Moreover, this system punishes those with the least bargaining power—those who are also the least likely to be able to afford the extraordinary charges.¹⁴⁰ Patients who seek hospital services and are not covered by a government-sponsored program or insurance may expect to pay a markup of 1,400% or more for a simple test.¹⁴¹ This concept of variable rates for different payors is known as price discrimination, and it is completely legal.¹⁴² Hospitals justify this price disparity by explaining that the lost profits from Medicare, Medicaid, or unpaid debts of self-payors require them to make up the difference by charging more to others—a cost-sharing rationale similar to that used by insurance companies—called the cost-shifting theory.¹⁴³

Health economists seem to view this cost-shifting theory promoted by hospitals to rationalize price discrimination with skepticism.¹⁴⁴ In their own studies, some economists found that the reason for higher costs was more likely due to a hospital's market power, not its need to make up for government-payor shortfalls.¹⁴⁵ They also noted that when paid by Medicare, hospitals often cut their own costs or output, thus eliminating the need to offset expenses to other consumers.¹⁴⁶ The fact that these negotiations continue to exist between hospitals and insurers demonstrates the lack of rate regulations that govern these relationships in regards to appropriate payments. Each hospital offers different prices based on whatever factors they believe are

139. Brown, *supra* note 121, at 22.

140. *Id.*

141. *See generally id.*; Brill, *supra* note 19. Patient was charged \$199.50 for Troponin test when Medicare would have paid the hospital \$13.94 for that test. *Id.* This exemplifies the cost valuation that Medicare has deemed appropriate for that service for the hospital including overhead costs, regional differences, and other factors. *Id.*

142. Brown, *supra* note 121, at 24.

143. Uwe Reinhardt, *The Many Different Prices Paid to Providers and the Flawed Theory of Cost Shifting: Is It Time for A More Rational All-Payer System?*, 30 HEALTH AFF. 2125, 2125-26 (2011).

144. *See* Austin B. Frakt, *How Much Do Hospitals Cost Shift? A Review of the Evidence*, 89 MILBANK Q. 90, 90-91 (2011); Chapin White, *Contrary to Cost-Shift Theory, Lower Medicare Hospital Rates for Inpatient Care Lead to Lower Private Payment Rates*, 32 HEALTH AFF. 935, 941-42 (2013).

145. *See* Frakt, *supra* note 144; *see* ROBERT MURRAY & SUZANNE F. DELBANCO, PROVIDER MARKET POWER IN THE U.S. HEALTH CARE INDUSTRY: ASSESSING ITS IMPACT AND LOOKING AHEAD 15-16 (2012).

146. *See* David Dranove et al., *How Do Hospitals Respond to Negative Financial Shocks? The Impact of the 2008 Stock Market Crash 5* (Nat'l Bureau of Econ. Research, Working Paper No. 18853, 2013). *But see* James Robinson, *Hospitals Respond To Medicare Payment Shortfalls By Both Shifting Costs And Cutting Them, Based On Market Concentration*, 30 HEALTH AFF. 1265, 1269-70 (2011) (concluding that hospitals may cut costs, although some may shift costs, depending on location or market).

important and there is no national or state standard that hospitals must follow to determine these prices.¹⁴⁷

B. Medical Device Industry Case Study and Anti-Competitive Effects

There are other factors that play into the rates set by hospitals, primarily the increasing cost of medical devices, drugs, and equipment, which themselves are controlled by the same market power concept of hospitals and health care groups. For instance, one of the most common surgical procedures in America today is joint replacement.¹⁴⁸ The price for these procedures varies from hospital to hospital, as the chargemaster prices are determined on an individual hospital basis.¹⁴⁹

As an example, for one man, a hip replacement in the U.S. was estimated to cost \$78,000 plus other fees, with \$13,000 of that being the actual device.¹⁵⁰ That steep price for a replacement joint was the “list price” with no markup, essentially the price the hospital paid for the device.¹⁵¹ Due to the high cost of the repair in the U.S., the man opted to get the joint replaced in Belgium, where he paid \$13,660 including surgery, device, therapy, and airfare.¹⁵² This anecdote shows not only the great discrepancy in health care treatment costs, but also the discrepancy of the medical equipment costs between the U.S. and other developed nations.¹⁵³

Even though there are thousands of medical device companies worldwide, many of the markets are controlled by a select few. For instance, despite there being about 6,500 medical device companies in the U.S., ninety-one percent of the joint replacement market is controlled by six companies in the U.S.¹⁵⁴ The global medical device industry is also dominated by U.S. companies, which

147. Brill, *supra* note 19. There is “no process, no rationale, behind the core document that is the basis for hundreds of billions of dollars in health care bills.” *Id.*

148. Elisabeth Rosenthal, *In Need of a New Hip, but Priced out of the US*, N.Y. TIMES (Aug. 3, 2013), http://www.nytimes.com/2013/08/04/health/for-medical-tourists-simple-math.html?_r=0 [hereinafter *Hip*]; see also Brown, *supra* note 121, at 12.

149. *Hip*, *supra* note 148.

150. *Id.* One estimate found that a manufacturer spends about \$350 to make a single hip joint, but price markups lead to these devices being sold for thousands of dollars. *Id.* (estimating the price for actual manufacturing cost, not including other factors like R&D); see also Asha S. Geire, Comment, *Price Wars and Patent Law: Reducing the Cost of Health Care Through Medical Device Price Transparency*, 12 TUL. J. TECH. & INTELL. PROP. 239, 246 (2009) (noting artificial knees can cost over \$10,000 and a single spinal screw can cost \$1,600 in the U.S.).

151. *Hip*, *supra* note 148.

152. *Id.*

153. Geire, *supra* note 150 (“[f]or example, Europeans pay about 25% of what Americans pay for artificial hips”).

154. ORTHOWORLD, STRATEGIC INSIGHTS INTO THE ORTHOPEDIC INDUSTRY 1-2 (2012), <https://www.orthoworld.com/index.php/fileproc/index/knowentADJADJorthoknowADJADJ2012ADJADJorthoknow1206LXLXLXpdf>.

hold thirty-eight percent of the entire industry market as of 2012.¹⁵⁵ These companies have managed to limit or avoid many regulations through their extensive lobbying of Congress,¹⁵⁶ though they have experienced some pushback from the DOJ relating to kickback schemes.¹⁵⁷

The medical device companies often manage to undercut the industry and prevent generics and foreign-made products from entering the market largely through trade policy, patents, and an expensive FDA process that discourages potential start-ups.¹⁵⁸ While trying to prevent foreign countries from exporting devices to the U.S., these companies expect the U.S. government to negotiate with other countries to reduce barriers for U.S. products.¹⁵⁹

Additionally, health care organizations that buy the products have surprisingly little bargaining power, much like the uninsured do against hospitals, because there are so few options and products are not bought in bulk.¹⁶⁰ The parallel between hospitals and the medical device manufacturing industry versus consumers and hospitals is ironically clear. Both of these relationships exemplify the effects of strong market power, lack of competition, and lack of rate regulation. Unfortunately, the ultimate loser of both battles is the consumer, who will likely bear the large brunt of the costs that pass on to them.

V. ADDITIONAL ANTITRUST CONSEQUENCES AND CONCERNS

Despite the general antitrust laws that help monitor and prohibit anti-competitive business practices before they happen, there is also a huge problem of what happens to consumers after mergers are allowed. Specifically, once hospitals merge and create massive health systems, do those governing agencies actually protect consumers from price-gouging? Once hospitals have taken over a large part of the market, there is little that can be done to reduce costs to consumers.¹⁶¹ Even if the hospital systems have “passed the tests” of

155. SELECT USA, *supra* note 61.

156. See CTR. FOR RESPONSIVE POL., *supra* note 63.

157. Press Release, U.S. Dep’t of Justice, Office of Pub. Affairs, Medical Device Company Smith & Nephew Resolves Foreign Corrupt Practices Act Investigation (Feb. 6, 2012), <http://www.fbi.gov/washingtondc/press-releases/2012/medical-device-company-smith-nephew-resolves-foreign-corrupt-practices-act-investigation>; Press Release, U.S. Attorney Dist. of N.J., Wright Medical Technology, Inc. Agrees to Corporate Compliance Reforms and Monitor Oversight to Address Alleged Violations of Federal Anti-Kickback Statute (Sept. 30, 2010), <http://www.justice.gov/usao/nj/Press/files/pdf/2010/Wright%20Medical%20Complaint,%20DPA%20PR.pdf>.

158. See INT’L TRADE ADMIN., *supra* note 62, at 13.

159. *Id.*

160. See Rosenthal, *supra* note 129.

161. To demonstrate this problem, the amicus brief filed in the Partners case noted a prominent FTC case from 2000. See Dafny et al., *supra* note 90, at 5. There, Evanston

competitive effect, they may still conduct unfair consumer practices in the way they charge for services, treatments, and general care.¹⁶² This is one of the biggest reasons health care today is so expensive in the U.S.¹⁶³

A. *Partners' Settlement Concerns*

The scenario described above is also a potential reason the Attorney General in Massachusetts may have proposed a settlement with Partners—as an effort to control rate-hikes for the following five to ten years. However, the biggest complaint by opposition against this settlement was the concern for what happens when this time constraint runs out. The settlement offered no permanent solutions that would effectuate long-term change for the health care system. While potentially beneficial for the next five to ten years, after that deadline, Partners would be free to increase rates to whatever it chooses, though it would likely remain within the allotted benchmark for medical expenditures. This means that Partners' hospitals could and would likely increase the chargemaster prices that are determined for services and equipment offered by the hospital. Furthermore, Partners would be very capable of demanding higher insurance payments for physicians within its system because it would have such a dominant market share within the area.¹⁶⁴

Without the merger, Partners had a twenty-eight percent share of the entire Massachusetts market, but with the merger, this number would certainly increase.¹⁶⁵ In fact, using data from the Center for Health Information and Analysis (CHIA) and the HPC, the merger would give Partners roughly a fifty percent market share within metro Boston, a fifty percent share within South Shore, and a forty-seven percent and thirty-five percent share in North Boston and West Boston, respectively.¹⁶⁶ Even with the restrictions the settlement would place on Partners limiting further expansion for the next five to ten

Northwestern Healthcare was able to acquire Highland Park hospital with no structural or conduct remedies. *Id.* Shortly after, inpatient prices increased by fifty percent to payors, significantly greater than others in the area. *Id.* There were no noticeable quality improvements either. *Id.* The merger was found anti-competitive in 2005 and affirmed by the FTC in 2007, but at that point, too much integration had occurred, and it was impossible to force divestiture of the hospital. *Id.* The FTC issued an independent contract negotiating team for the Highland hospital but this team was never utilized because its usefulness would be minimal. *See* Dafny et al., *supra* note 90, at 5.

162. *Id.*

163. Brill, *supra* note 19.

164. *See* Dafny et al., *supra* note 90, at 6-7. When a similar conduct remedy was offered to a merging health care system in Grand Rapids, Michigan in 1996, the prices increased twelve percent when the remedy terms expired in 2004. *Id.* These rates continued to exceed the consumer price index for years following the terms' expiration. *Id.*

165. *See* CHIA REPORT, *supra* note 81, at 6.

166. *See* Weisman & Allen, *supra* note 77 (these figures were determined by adding the market share controlled by Partners to the market share of South Shore and Hallmark, as the graph indicates on the article).

years, it is virtually impossible that any other health care system in the area would have a comparable market share in that time. Every other health care system in the area would have to merge into one system to match that kind of market share. This type of merger almost certainly would be rejected by the attorney general, the FTC, or the DOJ because of the clear anti-competitive effect it would have in creating a two-player market where a multi-player market previously existed.

B. Medical Device Competition Concerns

For medical devices, the competition issues for consumers are somewhat different. Unlike hospitals and physician groups, which seem always to be on the search for their next merger, the big medical device companies are not necessarily interested in merging with one another to take over a specific region. Some smaller device companies merge with similar-sized and larger companies, and some companies seek mergers abroad.¹⁶⁷ However, these companies are more concerned with excluding their overseas competition from U.S. sales than they are concerned about competition within them.¹⁶⁸ In an article published in April 2014, two attorneys discuss this problem in terms of antitrust concerns and intellectual property laws.¹⁶⁹ The attorneys determined that the medical device companies are not acting anti-competitively because there is no real evidence that they are colluding with each other to raise prices.¹⁷⁰ However, this view overlooks another aspect of antitrust that is very relevant to the antitrust discussion. While hospitals are trying to create super systems to gain market share, these large technology companies are trying to keep smaller and foreign competition, which may offer devices at a significantly lower price, out of the market.¹⁷¹ The device companies likely would prefer to have a larger share of their respective market, but are equally interested in making sure foreign companies do not get a share. Further motivating the domestic device companies to control the market, development of non-U.S. medical device manufacturing has begun to cut into the profitability and global market power of the U.S. companies.¹⁷²

The way in which medical device companies control the market is by spending millions of dollars lobbying in Washington D.C. to control

167. See INT'L TRADE ADMIN., *supra* note 62, at 8-9.

168. *Id.* at 13.

169. Roger D. Blair et al., *Patents, Monopoly Pricing, and Antitrust in Health Care Markets*, ANTITRUST SOURCE, Apr. 2014, at 1, 2.

170. *Id.* at 5.

171. See generally INT'L TRADE ADMIN., *supra* note 62.

172. Compare SELECT USA, *supra* note 61, with INT'L TRADE ADMIN., *supra* note 62, at 4.

regulations that apply to them and their would-be competitors.¹⁷³ Most recently, the medical device industry lobbied hard against a condition written into the ACA that requires a 2.3% tax on the sale of their products.¹⁷⁴ These lobbying efforts seem to have paid off, at least for the next two years.¹⁷⁵ The legislative fight began in the form of a House bill to repeal the tax, a bill that was supported by both republican and democratic members from the states in which the medical device companies are located.¹⁷⁶ In December 2015, both the House and Senate approved a suspension of the tax for two years as part of the congressional spending bill.¹⁷⁷

The medical device companies argued that such a tax would be detrimental to their R&D programs and hinder job growth, and alleged that the tax would ultimately fall on the consumer to pay.¹⁷⁸ However, this argument fails to recognize that only about six percent of the industry's earnings are actually reinvested into R&D for their products.¹⁷⁹ In fact, the Congressional Research Service released its findings on the tax effects in November 2014 and noted that the tax will not likely harm the device companies' profits, and "estimate[d] that it will reduce industry output and employment by no more than .2 percent."¹⁸⁰ Whether or not the tax would actually harm these companies is debatable and only determinable with time, but the consumers would almost certainly draw the short end of the stick, as so often occurs in health care.

Furthermore, the risk of repeal has significantly greater repercussions; if other industries that are disgruntled with ACA monetary provisions see the medical device tax successfully repealed, they too may try to repeal applicable provisions, putting up to \$370 billion at risk.¹⁸¹ The medical device tax alone was expected to garner thirty billion dollars over the next ten years, money that was already earmarked for funding other projects.¹⁸² The statistics and facts seem to indicate that if these companies charge more, it is not because they

173. See CTR. FOR RESPONSIVE POL., *supra* note 63. Over thirty-two million dollars were spent on lobbying by the industry. *Id.*

174. *Id.* (note in charts, the dollars lobbied in 2012-2014 and the states that received the most lobbying support—same as the states with large medical device manufacturing industries); see also 26 U.S.C. § 4191(a) (2012).

175. Kristina Peterson, *Congress Passes \$1.15 Trillion Spending Bill*, WALL ST. J. (Dec. 18, 2015), <http://www.wsj.com/articles/house-passes-1-15-trillion-spending-bill-1450450381>.

176. Daniel, *supra* note 64.

177. *Id.*; Peterson, *supra* note 175.

178. Daniel, *supra* note 64.

179. Geire, *supra* note 150, at 248.

180. Daniel, *supra* note 64 (finding the "domestic revenues for medical technology firms grew 4 percent to \$336 billion in 2013, the first year the tax went into effect – about the same rate from 2012, indicating that the industry seems financially stable for now" with the tax in effect).

181. *Id.*

182. *Id.*

must do so in order to recover losses from manufacturing and development, but perhaps simply because there is no regulation to prevent them from doing so.

VI. RATE REGULATION AND COMPETITION GOING FORWARD

A. *Health Care Industry*

When looking to potential solutions, it is important to remember that there are many hurdles to overcome before most changes can be implemented. Likewise, it often takes a significant amount of time before any changes have a noticeable effect. For instance, realistically, Medicare takes months and sometimes years to change because the process of proposing, commenting on, and finalizing rules requires extensive time. So even if changes are made to the current regulations or laws, like the passage of the Medicare Access and CHIP Reauthorization Act (MACRA) in April 2015,¹⁸³ the effects will take time to develop. Despite this delay, as the ACA begins to have a stronger effect on the overall health care market, solutions are needed to enable its goals and protect consumers. There are, as previously mentioned, options for agencies and attorneys general to use structural and conduct remedies to monitor care mergers.

For the Partners case study described in detail in Part IV.A, the HPC suggested that the Attorney General and the court make the proposed settlement conditions permanent instead of temporary.¹⁸⁴ This way, the extremely powerful Partners system would have been unable to further expand its market control or price out the rest of its competitors permanently. Had the settlement been approved, the DOJ and FTC could have assessed how Partners and its remaining competitors handled the limitations for the next five to ten years. The agencies could have used those results as an opportunity to see whether conduct or structural remedies are truly more effective in the long run. Because the settlement was thrown out, it is difficult to speculate on the potential outcome of the deal. But, similar settlement offers may develop in the future and provide agencies with an opportunity to assess such outcomes.

When the ACA was passed, it included a transparency rule that required all hospitals to make their chargemaster lists publicly available or to publicly disclose how to obtain the information on the lists.¹⁸⁵ However, it has been a struggle to get participation by hospitals. To further enforce this mandate, CMS posted a reminder to hospitals to comply with this condition in its

183. See generally Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015).

184. See HPC HALLMARK REPORT, *supra* note 83.

185. 42 U.S.C. § 300gg-18(e) (2012); *Medicare Provider Utilization and Payment Data*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 30, 2015), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicare-provider-charge-data/>.

proposed rules from May 2014 and reiterated this point in its final rule as well.¹⁸⁶ CMS believes that this pricing transparency will enable patients to be better informed and make smarter financial decisions with health care, while making hospitals more accountable for their prices.¹⁸⁷

To better encourage hospitals to comply with this requirement, CMS could implement a penalty system for noncompliant hospitals in the form of Medicare reimbursement restrictions or monetary penalties imposed on the hospital itself. Some states have also taken a role in this initiative and have passed their own legislation that requires hospitals to post their prices for services.¹⁸⁸ The posting of chargemasters is a step in the right direction for price transparency, but it is limited in effect. Posting chargemaster lists will not guarantee consumers a designated price because each doctor uses different tools, products, and methods to administer a service to patients. Doctors are loyal to different medical device manufacturing companies, which all charge different rates for their products.¹⁸⁹ What consumers need most is a publicly available set price for a service, one that would be the same across the board for all patients.¹⁹⁰ Excluding the public availability of information, this is roughly how insurance plans, Medicare, and Medicaid function, and it has been fairly successful for them.

Additionally, insurers are in the unique position to determine exactly which facilities and doctors they will cover and where geographically they will offer coverage. Because of this, insurers could take advantage of medical care options abroad by extending coverage to certain facilities and doctors that are certified by an organization for offering approved quality care.¹⁹¹ One of the biggest hurdles that these insurers would face is beneficiary concern over foreign standards of care. When this approach was attempted in 2006 in North Carolina and West Virginia, it was rejected because people were hesitant about outsourcing medical care.¹⁹² More education on the available resources abroad may help ease this concern as might the ever-rising medical costs in the U.S.

186. Section M Requirement for Transparency of Hospital Charges Under the ACA, 79 Fed. Reg. 27,978, 28,169 (proposed May 15, 2014) (to be codified at 45 C.F.R. pt. 405, 412, 413, 415, 422, 424, 485, and 488).

187. *Id.*

188. *Transparency and Disclosure of Health Costs and Provider Payments: State Actions*, NAT'L CONF. ST. LEGISLATURES (Aug. 2015), <http://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx>; Christopher Weaver, *Want To Know What A Hospital Charges? Good Luck*, KAISER HEALTH NEWS (June 29, 2010), <http://kaiserhealthnews.org/news/hospital-prices/>.

189. *See Hip*, *supra* note 148.

190. *See Weaver*, *supra* note 188.

191. Rebecca Bennie, *Medical Tourism: A Look at How Medical Outsourcing Can Reshape Health Care*, 49 TEX. INT'L. L.J. 583, 585-86 (2014).

192. *Id.* at 586.

As prices rise, people may be more willing to consider foreign options if they are certified by an organization and covered by their insurance. As the high prices of American health care continue to climb and influence people's medical decisions, more insurers may begin to consider this option. This concept of "medical tourism" offers many positive benefits but is not without its problems. In order for this type of program to be safe and effective, beneficiaries will likely need assurance that their health information is kept private, in other words, that the Health Information Portability and Accountability Act (HIPAA) extends to foreign providers.¹⁹³

There also needs to be a malpractice agreement that gives some power to the beneficiary through a court or arbitration proceeding in case of negligence.¹⁹⁴ These are just a sample of the concerns regarding medical tourism, but, if resolved, Americans and their insurers are likely to experience savings of forty to ninety percent compared to what they would pay for domestic care.¹⁹⁵

An alternative, more favorable solution has been the recent trend of employers and insurers to offer domestic medical tourism to beneficiaries willing to travel to another state for care.¹⁹⁶ The benefit to domestic medical tourism is the guarantee of quality, privacy, and legal rights, in addition to saving money.¹⁹⁷ This trend has seen great success by the companies that have implemented it in their insurance policies.¹⁹⁸ Patients and insurers will not see as great of savings with this option compared to foreign medical tourism, but the greater assurance of quality care may make this option more viable. This domestic tourism could cause medical service prices to increase in the more competitively priced markets being used, but it could also influence other markets to lower their prices to match those prices offered elsewhere. As the domestic medical tourism movement strengthens, it could inadvertently create self-regulation within the health care industry.

193. *Id.* at 598.

194. *Id.*

195. Lee Ann Eissler & John Casken, *Seeking Health Care Through International Medical Tourism*, 45 J. NURSING SCHOLARSHIP, 177, 177 (2013); see M.Z. BOOKMAN & K.R. BOOKMAN, *MEDICAL TOURISM IN DEVELOPING COUNTRIES* 50 (2007).

196. John Graham, *How Domestic Medical Tourism Could Save Us All Money*, WASH. POST (Feb. 6, 2015), https://www.washingtonpost.com/opinions/how-medical-tourism-could-save-us-all-money/2015/02/06/e8e2be28-ad55-11e4-abe8-e1ef60ca26de_story.html; Samuel S. Choy & Stacey L. Stewart, *Domestic Medical Tourism Gaining Traction*, ABA HEALTH ESOURCE (July 2011), https://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1107_choy.html.

197. Graham, *supra* note 196; Choy & Stewart, *supra* note 196.

198. See Choy & Stewart, *supra* note 196.

B. Medical Device Industry

It would be unfair to say that agencies have done nothing to control medical technology companies' antitrust behavior. As mentioned previously, the DOJ investigates these companies often under the False Claims Act and sometimes finds sufficient evidence of illegal kickbacks to physicians by companies encouraging physician use of their products.¹⁹⁹ However, the parties often settle before a final judgment can be made, so the companies are typically only punished monetarily.²⁰⁰ Furthermore, when the DOJ settles with these companies, they are not forced to admit any wrongdoing, thus the companies avoid harsher penalties that may have more influential effects.²⁰¹ As such, financial disincentives from the government do not seem to be effective enough to change the way these companies conduct business. This is evident by the recovery of \$14.2 billion—more than half the total recovery from all False Claims Act cases since 2009—by the DOJ from fraud cases involving federal health care programs.²⁰² In addition to regulatory difficulties, the lobbying stronghold of the medical device industry also poses a great challenge to overcome when seeking governmental action.

Given these challenges, the best method of controlling the rising prices may be in the hands of the parties with whom the companies contract. For instance, CMS contracts with these medical device companies to provide payment for the products used by government-sponsored beneficiaries.²⁰³ Because CMS sets a low threshold for payment, the government could use this threshold as a baseline benchmark and restrict pricing above a certain percentage of that for all negotiating parties, including private and self-payors. This would likely be a fair representation of value since CMS uses a variety of data to determine the actual cost of the products.²⁰⁴ This government-induced

199. Press Release, Dep't of Justice, Minnesota-Based St. Jude Medical Pays U.S. \$16 Million to Settle Claims that Company Paid Kickbacks to Physicians (Jan. 20, 2011), <http://www.justice.gov/opa/pr/minnesota-based-st-jude-medical-pays-us-16-million-settle-claims-company-paid-kickbacks> [hereinafter Minnesota St. Jude Press Release]; Press Release, Dep't of Justice, Manufacturer of Spinal Devices and Surgeon to Pay United States \$2.6 Million to Settle Alleged Kickback Scheme (Aug. 29, 2014), <http://www.justice.gov/opa/pr/manufacturer-spinal-devices-and-surgeon-pay-united-states-26-million-settle-alleged-kickback> [hereinafter Medical Devices Press Release].

200. Minnesota St. Jude Press Release, *supra* note 199; Medical Devices Press Release, *supra* note 199.

201. See Minnesota St. Jude Press Release, *supra* note 199; See Medical Devices Press Release, *supra* note 199.

202. See Medical Devices Press Release, *supra* note 199.

203. *Fact Sheets: CMS Proposed Changes Regarding Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for CY 2015*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 2, 2014), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-07-02.html>.

204. Brown, *supra* note 121, at 19-20.

rate regulation on medical device makers has the potential to be the most effective means of controlling the market prices of the products because the government has the capability to create the regulation and monitor its effectiveness. However, such a government regulation may be unlikely to succeed, especially with the powerful lobbying group the industry has cultivated.

A more likely alternative could be to encourage the insurers and physicians with whom these companies contract to implement a more limited bidding process. For example, a doctor who tried this approach managed to successfully reduce his cost for a product by thirty percent by using a blind bidding process directly with the manufacturers and choosing only to use one of two types of implants.²⁰⁵ Taken on a larger scale, this type of blind bidding process with limited options could be effective in driving down these costs for insurers. The insurance companies are required to cover certain treatment options according to the ACA and their contracts with beneficiaries,²⁰⁶ but they could use a stricter form of blind bidding with limited options to discourage the medical device companies from maximizing rates.

For medical device competition control, there could also be amendments to current intellectual property laws, specifically patent protections. However, patent law is beyond the scope of this article, and, as such, will not be discussed in detail. Such changes would likely be the responsibility of the Patent and Trademark Office (PTO) through stricter regulation management.

The FDA also plays a role in the management of antitrust problems in this industry as well as the management of unnecessary medical expenses. The FDA is the agency that governs medical equipment companies' devices and the marketability of the devices.²⁰⁷ An interesting aspect of the FDA is that it does not consider price when approving a new device for the market.²⁰⁸ Its only requirement for permissibility is that the device is effective in the ways in which it claims to be, and such effectiveness is sufficiently supported through scientific evidence.²⁰⁹ Because of this, one way to control the prices of medical devices is for the FDA to implement a cost analysis in its approval process of new devices. This way, the market would not be inundated with variations of one product, all with new legal protections and high prices attached. The FDA could take many different steps to control these device companies through

205. *Hip*, *supra* note 148.

206. *See, e.g.*, Patient Protection and Affordable Care Act, §§1301-1302, 42 U.S.C. § 18001 (2012); *see also* *What Marketplace Health Insurance Plans Cover*, HEALTHCARE.GOV, <https://www.healthcare.gov/coverage/what-marketplace-plans-cover/> (last visited May 5, 2016).

207. *Overview of Device Regulation*, FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/> (last updated Aug. 14, 2015).

208. Geire, *supra* note 150, at 255.

209. *Id.* (citing 21 U.S.C. §§ 360(a)(3)(B), 360(a)-(e) (2012)).

patent monitoring in conjunction with the PTO. However, as previously noted, patent law is not within the scope of this article.

The federal government or a state government could try an approach similar to that of Belgium's national health care system. In the case study of the man with the joint replacement, he was able to have such affordable treatment because Belgium has a required insurance policy for all citizens and has enacted regulations on hospitals and physicians regarding how much they can be reimbursed for services.²¹⁰ This policy extends to the medical device market as well.²¹¹ Patients can expect a set fee for a service that is negotiated with the government on an annual basis.²¹² Physicians are dis-incentivized from charging more than the government negotiated price because patients know they can seek treatment from a more affordable source.²¹³ Such an approach is very unlikely given the political state of the U.S., but it could make a great example for states to use as a guide or suggestion when considering how best to control health care costs within their own borders.

VII. CONCLUSION

The health care industry in the U.S. is wrought with obstacles for consumers to overcome. Access to quality care is important for all, but it often comes at a high price, especially in markets with less provider competition. In these markets, understanding the economic principles that led to monopolistic health care can help people find solutions to make care more affordable. The lack of regulations governing health care rates and the difficulty in enforcing existing regulations has put this country's consumers at a disadvantage. From the medical device companies that have taken over the market in the past few years to the hospitals that use the products and assign pricing, the consequence of ineffective regulation and reduced competition is apparent in the health care expense statistics.

The overall health care industry's cost to consumers is rising at an unsustainable rate. People simply cannot afford to allocate half of their income towards health care in the future, a very real possibility if significant changes do not occur.²¹⁴ Consumers need regulations from government agencies to help control the rising costs of medical services. They also need better access to

210. *Hip*, *supra* note 148.

211. *Id.*

212. *Id.*

213. *Id.*

214. Geire, *supra* note 150, at 241 (citing PAUL B. GINSBURG, HIGH AND RISING HEALTH CARE COSTS: DEMYSTIFYING U.S. HEALTH CARE SPENDING, RESEARCH SYNTHESIS REPORT NO. 16 1, 5 (2008)) (suggesting that forty-nine percent of U.S. gross domestic product could be spent on health care by 2082).

information so they can be well-informed consumers and make medical decisions that are financially smart.

In order to empower people to take control of their health care, providers within the industry need incentives—positive or negative. In the medical device industry, a stronger concerted effort may be needed from federal and state governments, physicians, hospitals, and private insurers to force lower prices. Similarly, it may take a stronger pushback from public consumers, private insurers, and government to force health care providers with large market power to lower prices, have transparency in costs, and establish set prices for services.

Security in health is one of most important needs of the well-known Maslow's hierarchy of needs, second only to food and shelter.²¹⁵ Americans need to feel secure in their ability to access and afford quality health care. Therefore, it is imperative for the industry to change to meet the needs of the consumers, on whom the industry is dependent in order to be successful. Instead of looking at health care as consumer reliance on the industry for a service, providers must realize that pricing out the consumers will ultimately cycle back to hurt the providers' businesses. Change is necessary to have a sustainable health care future for this country.

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215. Abraham Maslow, *A Theory of Human Motivation*, 50 PSYCHOL. REV. 370, 376 (1943). According to Maslow's theory, "health" falls under the category of "Safety Needs," which is second only to "Physiological Needs," which includes food and shelter. *Id.*

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