Price Wars and Patent Law: Reducing the Cost of Health Care Through Medical Device Price Transparency

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I. INTRODUCTION AND BACKGROUND

If you think modern day prices are high, imagine living in medieval England or Western Europe when the monarchy awarded monopoly rights as favors.[1] Back then, almost all goods, including the daily necessities of life, were sold at unchecked monopolistic prices.[2] Indeed, we are very fortunate that the English Parliament abolished all monopolies, except for those on new inventions, before the United States inherited patent laws from England.[3] However, despite this blessing, a form of medieval monopoly still exists in some sectors of the U.S. health care industry.

One such sector is the medical device industry, which is an area often overlooked in health care cost-control discussions. This oversight

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1. FRED RHODES, ELEMENTS OF PATENT LAW 1 (1949).
2. *Id.*
3. *Id.* at 2.

allows the medical device industry, which enjoys the protection of patent laws and the unique benefits of an irrational health care market, to charge absurd prices. This Comment contends that, firstly, health insurance subsidies distort market forces in the health care market, making it behave at odds with the rational market theory. This is because health care goods are not purchased directly by consumers (i.e., patients) but rather by uninformed third-party hospital agents. Secondly, as will be discussed later, the medical device industry makes every effort to conceal device prices, keep buyers uninformed, and vigilantly pressure federal agencies to approve devices hastily and without sufficient clinical data. Despite these known flaws, device prices are completely unregulated under patent law, and the industry is often exempt from antitrust laws. Thus, akin to medieval times, the medical device industry enjoys a virtually unchecked monopoly. Because taxpayers finance nearly half of the rising $2.2 trillion annually spent on health care, it is a critical and opportune time to correct market inefficiencies in the device industry.[4] Although multiple solutions are conceivable, this Comment proposes requiring the Food and Drug Administration (FDA) to collect and publicize data on the costs and benefits of each device it approves to correct current market deficiencies.

Part II of this Comment establishes the connection between the rise in health care spending and patent law. Part III offers the reader an overview of patent law, the justifications for giving monopoly protections to inventors, and reasons why the health care market must be treated differently. Part IV offers examples of device industry practices that are detrimental to society's interests and that are designed to maintain anticompetitive pricing strategies. Finally, Part V offers the reader a solution to these ills.

II. THE CONNECTION BETWEEN PATENT LAW AND RISING HEALTH CARE COSTS

The United States is the only industrialized nation that does not offer basic health care coverage to all of its citizens; in fact, 45.7 million Americans lacked health insurance in 2007.[5] Yet in 2007, Americans spent $2.2 trillion dollars on health care costs. To put this figure in perspective, this constitutes a staggering 16.2% of the gross domestic

4. Micah Hartman et al., *National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998*, 28 HEALTH AFFAIRS 246 (2009).

5. *Census: Number of Uninsured Dropped in 2007: Poverty Rate Holds Steady at 12.5 Percent; Household Income Rose Slightly*, MSNBC, Aug. 26, 2008, http://www.msnbc.msn.com/id/26404454/ (last visited Sept. 5, 2009).

product (GDP), or a $7421 price tag per citizen.[6] Despite spending more money on health care than any other industrialized nation,[7] the U.S. health care system ranks 37th out of 191 countries surveyed.[8] The ranking slips to 54th on fairness of health care costs, as reflective of citizens' ability to pay.[9]

Health care spending has been rising far ahead of the GDP every year since 1970,[10] and experts estimate that, if left unchecked, it will account for 49% of the U.S. GDP by 2082.[11] There are many explanations for the relentless rise in health care spending, but the reason most often cited is increased technological innovation.[12] At least 3 studies have examined the aggregate cost of new technology in the health care sector; each attributing between 38% to more than 65% of spending to new innovation.[13] Another study, examining price inflations between 1972 and 1981, found that 68% of the total increase in health care spending is due to inflated prices, rather than an increase in consumption or quality.[14] Arguably, U.S. patent protections allow these inflated prices to thrive.[15]

III. OVERVIEW OF THE LAW GOVERNING THE DEVICE INDUSTRY

Three federal agencies assist device makers in turning ideas into marketable goods. First, an inventor usually obtains a patent from the U.S. Patent and Trademark Office (PTO), then the FDA ensures the device's safety and effectiveness and, often simultaneously, manufacturers petition the Center for Medicare and Medicaid (CMS) to provide payment and coverage for devices once they become available in the

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6. Hartman et al., *supra* note 4.

7. *See* World Health Org., *Selected National Health Accounts Indicators: Measured Levels of Expenditure on Health, 2001-2005*, http://www.who.int/nha/country/nha_ratios_and_percapita_levels_2001-2005.pdf (last visited Sept. 5, 2009) (listing health care expenditure trends around the world).

8. Rosie Mestel, *Despite Big Spending, U.S. Ranks 37th in Study of Global Health Care*, L.A. TIMES, June 21, 2000, at A20, *available at* http://articles.latimes.com/2000/jun/21/news/mn-43335 (measuring, among the 195 countries in the world, the quality of health system morbidity, mortality rates, and access to health care).

9. *Id.*

10. Paul B. Ginsburg, *High and Rising Health Care Costs: Demystifying U.S. Health Care Spending* 3 (The Synthesis Project, Research Synthesis Report No. 16, 2008).

11. *Id.* at 5 (assuming that health care spending will concretively grow 1% ahead of GDP, as opposed to the historical 2.5% growth).

12. *Id.* at 10.

13. *Id.* at 11 (attributing the portion of spending that cannot be assigned to any other factor affecting health care spending to technological changes in society).

14. John R. Virts & George W. Wilson, *Inflation and Health Care Prices*, 3 HEALTH AFFAIRS 91 (1984).

15. ABA SECTION OF ANTITRUST LAW, INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK 17 (2007).

market. A brief discussion of the applicable patent law follows immediately, and the rules pertaining to FDA and CMS will be discussed as they become pertinent.

A. Patent Law

Medical devices are governed by general patent law.[16] Article I, Section 8, Clause 8, of the United States Constitution provides that "Congress shall have the power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writing and Discoveries."[17] Congress exercises this power by giving inventors the right to exclude others from making, using, offering, or selling patented inventions for a set period.[18]

Inventors can seek one of three types of patents: utility patents, plant patents, or design patents.[19] Utility patents involve a "new and useful process, machine, composition of matter, or useful improvement thereof,"[20] whereas plant patents are limited to "new varieties of plants that the applicant has discovered and asexually reproduced" and, finally, design patents are obtained for "any new, original, and ornamental design for an article of manufacture."[21] Patents are obtained through a process known as patent prosecution. The American Bar Association explains the process as such:

> If an inventor wishes to seek a patent, the inventor (or, more commonly, the inventor's assignee) files an application with the U.S. Patent and Trademark Office (PTO). The PTO grants a patent when an inventor can show five things: an invention fits one of the general categories of patentable subject matter; it has not been preceded in identical form in the public 'prior art'; it is useful; it represents a nontrivial extension of what was known; and the application discloses and describes the invention in such a way as to enable others to make and use the invention.[22]

A successful patent prosecution gives the inventor 20 years of market monopoly under utility and plant patents, and a 14-year monopoly on design patents.[23]

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16. LAWRENCE SUNG, MEDICAL DEVICE PATENTS 3 (2008).
17. U.S. CONST. art. I, § 8, cl. 8.
18. 35 U.S.C. § 271(a) (2006).
19. ABA SECTION OF ANTITRUST LAW, *supra* note 15, at 19.
20. *Id.*
21. *Id.*
22. *Id.*
23. *Id.*

B. Policy Justifications for the Current Patent System and Society's Interests

There are several accepted justifications for protecting monopolies under patent law. First, the patent system is a way to "encourage innovation by increasing the returns from innovative activity."[24] It is presumed that without patents, free riders will enrich themselves at the expense and labor of inventors.[25] However, all acknowledge that pecuniary incentives are "not *always* necessary nor the sole motivation behind innovation and creation."[26] For instance, "simple personal satisfaction, the quest for respect and esteem, . . . the power of convention[, and] the first-mover advantage[]" are sometimes sufficient to inspire innovations.[27] However, even critics admit that inventions requiring high development costs depend, at least in part, on pecuniary incentives like patents.[28]

Second, patents are a means to disseminate information because "absent patent protection, inventors would be more likely to rely on secrecy to obtain their innovation rewards."[29] Here again, however, some note that modern patent law encourages a "race to be first" as well as "distrust between students and faculty members . . . in a way that threatens the progress of science and the useful arts."[30]

Third, patents are said to "induce development and commercialization of initial inventions that have little or no value in their initial form but need further development to be commercially valuable."[31]

Finally, patents for first inventions are said to inspire follow-up technologies.[32] At any rate, it is a foregone conclusion, and one which this Comment does not dispute, that patents are an essential and necessary part of the economy.

However, whether or not patents are valuable has little relevance if the average American cannot afford the benefits provided by patented

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24. *Id.* at 98.

25. *Id.*

26. Steve P. Calandrillo, *An Economic Analysis of Intellectual Property Rights: Justifications and Problems of Exclusive Rights, Incentives To Generate Information, and the Alternative of Government-Run Reward System*, 9 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 301, 323 (1999).

27. *Id.* at 305-06.

28. *Id.* at 323.

29. ABA SECTION OF ANTITRUST LAW, *supra* note 15, at 98-99.

30. Kristen Nugent, *Patenting Medical Devices: The Economic Implications of Ethically Motivated Reform*, 17 ANNALS HEALTH L. 135, 144 (2008).

31. ABA SECTION OF ANTITRUST LAW, *supra* note 15, at 99.

32. *Id.* at 100.

technologies.[33] In other words, while the patent system is very effective in protecting a patent owner's right to charge premium prices, it has no controls to prevent patent owners from employing abusive pricing tactics at the expense of society's interest.[34]

The patent system relies on external checks to ensure that innovations are priced fairly. Among these checks are antitrust laws and the efficient market theory. Antitrust laws act to protect consumers from detrimental pricing strategies.[35] Prohibited practices include: concerted action (i.e., unreasonable restraints on competition), exclusionary unilateral actions (i.e., excluding or attempting to exclude others from the market on bases other than efficiency), and mergers or merger-like combinations.[36] However, in modern courts, antitrust laws often succumb to a patent holder's right of monopoly.[37] As one court stated, "[i]n the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws."[38] This means patent-heavy industries, like the medical device industry, are often almost entirely exempt from antitrust laws.

The patent system most heavily relies on market forces to set sensible prices. The assumption here is that consumers will set prices by the way they spend their dollars. Under this premise, patents are supposed to encourage private research and development leading to innovations that are then sold in an efficient market capable of setting the optimal price or value for each innovation.[39] While this state of equilibrium might exist in some markets, the health care market does not conform to traditional market forces. I discuss below what makes the health care market unique and unsusceptible to market forces.

C. The Unique Characteristics of the Health Care Market

In most markets, sellers set prices as dictated by market forces, and buyers choose whether they want to purchase the goods at the offered

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33. Ginsburg, *supra* note 10, at 7.
34. Nugent, *supra* note 30, at 139.
35. ABA SECTION OF ANTITRUST LAW, *supra* note 15, at 1.
36. *Id.*
37. *Id.* at 86-87.
38. *Id.* at 87 (citing *In re* Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1327 (Fed. Cir. 2000)).
39. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK 216 (2008).

price.[40] At some point, a "transaction," where value is exchanged, occurs between the seller and the buyer. Thus, as one commentator explains:

> Decisions made by purchasers, in terms of which services are chosen and which prices are paid, send important signals to producers as to where to extend capabilities, where to invest, and where to innovate. These signals are most effective when purchasers have good information on the price and performance of particular services, when they are paying for those services directly and without subsidies, and when they possess the capability to compare among alternatives, including services that resemble one another and those that accomplish the same ends through different means.[41]

In the health care industry, health insurance distorts this direct link between buyers and sellers. Health care goods are purchased through a chain of negotiations between health care consumers, their employers, insurance companies, hospitals, third-party purchasing agents, and device manufacturers.[42] More specifically, for medical devices:

> [C]hoice[s] among technologically advanced and evolving products is made by the surgeon, in consultation with the patient, but purchasing is performed by the hospital or ambulatory surgery center. Device costs are then bundled by the facilities into prices charged to insurers, either implicitly in per case or per diem rates or explicitly when carved out and billed on a fee-for-service (invoice or itemized charges) basis.[43]

Furthermore, most medical devices are sold in oligopolistic markets with few powerful manufacturers who are able to greatly influence prices and other market forces.[44] As such, hospitals rarely have the necessary purchasing power essential to maintaining an efficient market.[45]

In addition to distorting the link between health care consumers and sellers, health insurance also disguises the true cost of health care goods from the patients who ultimately receive them. Basically, health care consumers base their purchasing decision on minimal co-pays of about $15 to $20. Consequently, they overlook the full cost of the care they receive. Worse yet, because more expensive devices are often perceived to be of higher quality, manufacturers have an incentive to price new

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40. Kelly A. Hunt & James R. Knickman, *Financing for Healthcare*, *in* HEALTH CARE DELIVERY IN THE UNITED STATES 46, 47 (James R. Jonas & Anthony R. Kovner eds., 8th ed. 2005).

41. James C. Robinson, *Value-Based Purchasing for Medical Devices*, 27 HEALTH AFFAIRS 1523, 1523-24 (2008).

42. *Id.*

43. *Id.* at 1524.

44. Mark V. Pauley & Lawton R. Burns, *Price Transparency for Medical Devices*, 27 HEALTH AFFAIRS 1544 (2008).

45. *Id.*

devices above existing devices. This cycle leads to a concept commonly called a "moral hazard," which is defined "as excessive expenditure due to eligibility for insurance benefits."[46] In effect, the insured is subsidized in his purchases and, as a consequence, continues to spend after marginal benefit falls below marginal cost.[47] Eventually, insurance companies pass on the direct cost of the "moral hazard" to consumers by increasing insurance premiums, resulting in societal deadweight loss associated with insurance subsidies.[48]

The effects of overconsumption are evident in the current status of U.S. health care system. U.S. health insurance premiums are rising 5 times faster than wages,[49] more than 45 million Americans are uninsured,[50] 25 million more are underinsured,[51] and due to rising insurance premiums, an increasing number of small businesses, who employ over 60 million Americans, are eliminating health benefits.[52] Meanwhile, device manufacturers command as much as $1600 for a single screw used in spinal surgery and over $10,000 for artificial knees.[53] Moreover, American device prices substantially vary from those of most other nations. For example, Europeans pay about 25% of what Americans pay for artificial hips, and stents selling for $1500 in Europe cost $2200 in the United States.[54]

It might be tempting to attribute the high cost of health care to a rise in consumer expectations due to modern medical advances. After all, "[i]f spending on [say] computers increased sharply, most would label this a success story, meaning that improvements in the products were so meaningful to consumers that they have decided to sacrifice other goods and services to spend more on computers."[55] So why should we worry when the increased spending is on health care goods? The answer is twofold; first, the health care market, unlike the computer market, is inefficient in controlling prices; and secondly, nearly 50% of the U.S.

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46. John M. Marshall, *Moral Hazard*, 66 AM. ECON. REV. 880 (1976).

47. *Id.*

48. *Id.*

49. Todd Zwillich, *Health Insurance Costs Outpace Wages: Study Shows Premiums Rise Faster than Workers' Incomes*, WEBMD HEALTH NEWS, Oct. 23, 2008, http://www.webmd.com/news/20081023/health-insurance-costs-outpace-wages.

50. Hartman et al., *supra* note 4.

51. Parija B. Kavilanz, *Underinsured Americans: Cost to You*, CNNMONEY, Mar. 5, 2009, http://money.cnn.com/2009/03/05/news/economy/healthcare_underinsured/index.htm.

52. NAT'L COAL. ON HEALTH CARE, THE IMPACT OF RISING HEALTH CARE COSTS ON THE ECONOMY (Nov. 5, 2008), http://www.nchc.org/documents/Costs-Small%20Businesses-2009.pdf.

53. MAGGIE MAHAR, MONEY DRIVEN MEDICINE: THE REAL REASON HEALTH CARE COSTS SO MUCH 286 (2006).

54. *Id.*

55. Ginsburg, *supra* note 10, at 6.

health care spending is financed by taxpayers.[56] Worse yet, public financing is outgrowing the private sector, growing at an average rate of 7.2%, compared to 5.9% growth in the private sector.[57] As a result, more than half of the $2.2 trillion spent on health care will soon come from taxpayer pockets. Thus, inefficiencies in the health care market directly affect society's welfare. Unfortunately, an in-depth analysis of the inadequacies of our health care system is beyond the scope of this Comment. This Comment only attempts to provide root-cause analysis and solutions for the rapidly increasing prices of medical devices.

IV. THE DEVICE INDUSTRY: ABUSE AND EXCESSIVE PRICES

It is often said that on the frontier of innovation are small companies that depend on patent protections for research and development (R&D) investment fundraising.[58] However, the medical device industry, which is projected to generate over $336 billion in 2009, is hardly dependent on small companies.[59] For instance, of the approximately 20,000 medical device companies in the world, the largest 25 generate over 60% of the industry's sales.[60] Likewise, of the 6000 device companies in the United States, the largest 2% generate over 50% of U.S. sales.[61] Furthermore, the industry's revenues grow at a staggering 23%, and their profit margins are higher than most other industries' (18% in 2002).[62]

As to be expected, the most profitable device companies also hold the most patents. For example, the top 2007 performer, Johnson & Johnson (bringing in over $21 billion),[63] received the highest number of patents in the "biotech and pharma" industry (530 patents in 2007 alone).[64] In all, the majority of the patents awarded in 2007 were given to

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56. Hartman et al., *supra* note 4, at 254.

57. *Id.* at 249.

58. *See, e.g.*, D. Clay Ackerly et al., *Fueling Innovation in Medical Devices (And Beyond): Venture Capital in Health Care*, 28 HEALTH AFFAIRS W68 (Dec. 2, 2008), http://healthaff.highwire.org/cgi/reprint/hlthaff.28.1.w68v1.pdf.

59. Michael Rosen, Global Medical Device Market Outperforms Drug Market Growth (June 2, 2008), http://wistechnology.com/articles/4790/.

60. *Id.*

61. CTR. FOR MEDICARE & MEDICAID SERVS., HEALTH CARE INDUSTRY MARKET UPDATE: MEDICAL DEVICES AND SUPPLIES 10 (Dec. 5, 2003), http://www.cms.hhs.gov/CapMarketupdates/Downloads/hcimu120503.pdf.

62. *Id.*

63. *See* Rosen, *supra* note 59.

64. Posting of Donald Zuhn to Patent Docs: Biotech & Pharma Patent Law & News Blog, http://patentdocs.typepad.com/patent_docs/2008/05/ipo-releases-li.html (May 22, 2008, 23:42).

the 47 largest biotechnology, pharmaceutical, and device companies (a staggering total of 6999 patents).[65]

Moreover, although industry giants claim they charge high prices to recoup high R&D costs, in reality, only about 6% of industry earnings are reinvested in R&D.[66] This means that device makers charge a premium "not because they *must* (to recoup the enormous investment that they're making in scientific research), but simply 'because they *can*.'"[67] The industry employs its size and power to influence regulators, alienate hospitals from useful information, and preserve the right to charge exorbitant prices. I discuss here three common industry practices designed to safeguard high device prices.

A. Influencing Regulatory Agencies

After a patent is granted, the FDA and CMS are the main federal agencies overseeing the device industry. The FDA is often caught in a war between industry lobbyists, who complain that the agency takes too long to approve devices, and consumer protection advocates, who argue that FDA approvals are lax and influenced by industry lobbyists.[68]

Interestingly, Congress might have created the platform for an FDA conflict of interest with the passage of the Prescription Drug User Fee Act of 1992[69] and, later, with the Medical Device User Fee and Modernization Act of 2002.[70] Both regulations allow the FDA to collect user fees from drug and device companies to fund and accelerate the approval process for drugs and devices. These laws changed the dynamics of the FDA's budget and, arguably, placed the agency at the mercy of the industry it regulates. For example, in 2006, 42.5% of the agency's human drug program budget[71] and more than 12.2% of the total device review budget came from user fees.[72] Data suggests that FDA

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65. *Id.* (adding up the total patents granted to each company listed).

66. MAHAR, *supra* note 53, at 271.

67. *Id.* at 289.

68. Richard A. Deyo, *Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice*, 17 J. AM. BOARD FAM. PRAC. 142, 146 (2004), *available at* http://www.jabfm.org/cgi/reprint/17/2/142.pdf.

69. Pub. L. No. 102-571 (1992).

70. Pub. L. No. 107-250 (2002).

71. SCH. OF PUB. HEALTH & HEALTH SERVS., THE GEORGE WASHINGTON UNIV. MED. CTR., REAUTHORIZING THE PRESCRIPTION DRUG USER FEE ACT: HOW ARE PDUFA, THE FDA BUDGET, AND DRUG SAFETY RELATED? 2 (Apr. 2007), http://www.gwumc.edu/sphhs/about/rapidresponse/download/RapidResponse_PDUFA.pdf.

72. ERIN D. WILLIAMS, CONG. RESEARCH SERV., MEDICAL DEVICE USER FEE AND MODERNIZATION ACT (MDUFMA) REAUTHORIZATION (2007), *available at* https://www.policyarchive.org/handle/10207/3235.

approvals have in fact substantially accelerated since passage. However, some argue this acceleration is at the expense of FDA integrity and neutrality.[73] The FDA's own "report in 2002 indicated that a third of FDA employees felt uncomfortable expressing 'contrary scientific opinions' to the conclusions reached in drug trials" as they feared upsetting their corporate sponsors who may complain and cause Congress to alter user fees.[74]

Device makers are especially aggressive in their efforts to influence FDA decisions because doing so could determine whether they get a premarket approval (PMA) or 510(k) approval process. Just briefly, devices that are unlike any existing device undergo an expensive PMA process, which includes clinical trials to demonstrate reasonable safety and effectiveness.[75] Alternatively, if a device maker can convince FDA scientists that the new device is substantially similar to an existing FDA-approved device, FDA approval proceeds under a much faster and cheaper process known by its old statutory number, 510(k).[76] Under a 510(k) process, the FDA forgoes clinical trials and implies safety and effectiveness from the existing device.[77] The benchmark in a 510(k) review is whether the new device is substantially equivalent to a device marketed before 1976, and the final determination of this element depends on the subjective views of FDA scientists.[78] Thus the more aggressive a device company is, the better its chance is of getting its devices approved through 510(k) process. So just how influential is the device industry? So much so that nearly 98% of the dangerous Class II and Class III devices enter the market through a 510(k) review.[79]

A recent story in the *Wall Street Journal* demonstrates how far device companies go to get a 510(k) classification. ReGen Biologics Inc. (ReGen) is in the process of introducing a new device that targets

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73. One source stated: "Median review time for standard new drugs was 27 months in 1993, 14 months in 2001 and 10.5 months in 2004. Similarly, the median review time for priority drugs—those for serious and life-threatening diseases that lack satisfactory treatments—was 21 months in 1993 and six months in 2004." SCH. OF PUB. HEALTH & HEALTH SERVS., *supra* note 71, at 1.

74. Deyo, *supra* note 68.

75. Stanley S. Wang & John J. Smith, *Potential Legal Barriers To Increasing CMS/FDA Collaboration: The Law of Trade Secrets and Related Considerations*, 58 FOOD & DRUG L.J. 613, 614-15 (2003).

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.* The 1976 Medical Device Amendments categorize medical devices in to three different levels of regulation, I, II, and III—Class I posing the least risk of physical harm and Class III posing the highest. In 1990 Congress passed amendments that allowed FDA greater flexibility over whether to impose special safety controls. *See* Deyo, *supra* note 68, at 145.

common knee injuries, which was recently approved through the 510(k) process.[80] Intriguingly, however, there has never been an FDA-approved device like ReGen's, and FDA scientists have repeatedly denied 510(k) classification because the device was very different than any on the market. Additionally, ReGen executives chaired the only clinical trial that was ever conducted.[81] ReGen overcame FDA resistance by having four Congressmen contact FDA executives, which led to the assembly of a special review panel.[82] ReGen was then allowed to choose the members in their special review panel, which, at the request of ReGen, excluded any FDA staffers and scientists who previously opposed the product. Amazingly, ReGen was also allowed to exclude any "knee-replacement surgeons" from the panel "because they might stand to lose money if a new device made knee replacements less common."[83]

Hasty 510(k) approvals may be profitable for drug and device companies, even if they lead to later recalls. For example, one study found that between 1993 and 2000, the FDA recalled seven drugs which were hastily approved.[84] Combined, they contributed to some 1002 deaths and probably increased overall health care costs.[85] Their inventors, on the other hand, made over $5 billion in sales before the drugs were recalled.[86]

Like the FDA, CMS also plays a significant role in facilitating a new device's successful market entry. CMS administers Medicare's $431.2 billion health insurance budget, which benefits older and disabled Americans.[87] CMS's role is to decide whether Medicare will cover the new device, and if so, how much it will pay for it. Most coverage determinations are made by local contractors, and in order "to allow for regional differences in medical practice, Medicare provides contractors some flexibility in making coverage decisions."[88] As a general practice, Medicare allows coverage for all FDA-approved devices automatically; special review is triggered only when CMS fears the device will result in

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80. Alicia Mundy, *Political Lobbying Drove FDA Process*, WALL ST. J., Mar. 6, 2009, at A1.
81. *Id.*
82. *Id.*
83. *Id.*
84. Deyo, *supra* note 68, at 146.
85. *Id.*
86. *Id.*
87. CTR. FOR MEDICARE & MEDICAID SERVS., *supra* note 61, at 10.
88. *Id.*

an unusually high volume of costly claims.[89] In the latter case, CMS evaluates the device on merits. If CMS excludes FDA-approved devices from coverage, the industry is quick to accuse CMS of arbitrary decision making and of impeding medical innovations. For example, one article denounced CMS for apparently bankrupting small companies because CMS asked for further medical research before paying $500 for a wheelchair cushion or $26,100 for an iBot stair-climbing wheelchair.[90]

B. Price Variation Between Hospitals

Another destructive practice among device companies is charging scaled prices based on each hospital's purchasing power. In fact, a recent study revealed "'an unsustainable dispersion of pricing . . . that is . . . not related to case volume'" discounts in the device industry.[91] For example, hip implant prices can vary from $2300 to $7300, depending on who is purchasing the device.[92]

Traditionally, hospitals rarely concerned themselves with device prices. Nowadays, however, rising health care costs are forcing hospitals to embrace value-based purchasing.[93] Device makers see this as a threat and have begun enforcing common confidentiality clauses prohibiting hospitals from sharing their purchase price with any "third parties," including patients, physicians, and consultants.[94] So far, two cases emerged from this controversy. First, in 2004, Guidant Sales Corporation (Guidant) sued Aspen Healthcare Metrics (Aspen) for tortious interference with a contract.[95] The complaint alleged that Guidant entered into a purchase contract with a certain hospital and that a few months after the sale, the hospital breached their contract in favor of a better deal with Aspen.[96] Guidant accused Aspen of inducing the hospital to reveal Guidant's sale price in violation of the hospital's confidentiality

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89. John B. Reiss, *Commentary on Payment and Reimbursement Issues Affecting the Marketing of Drugs, Medical Devices, and Biologics, with Emphasis on the Anti-Kickback Statute and Stark II*, 52 FOOD & DRUG L.J. 99, 100 (1997).

90. medGadget, Medicare Spending Decreasing for Medical Devices (June 5, 2006), http://www.medgadget.com/archives/2006/06/medicare_spendi.html.

91. Jeffery C. Lerner et al., *The Consequence of Secret Prices: The Politics of Physician Preference Items*, 27 HEALTH AFFAIRS 1562 (2008).

92. *Id.*

93. *See generally* Robinson, supra note 41, at 1523 (explaining that device buyers must become informed purchasers).

94. *See* Arlen Specter Speaks on the Senate Floor Regarding the Transparency in Medical Devices Act (Oct. 23, 2007), http://specter.senate.gov/public/index.cfm?FuseAction=NewsRoom.ArlenSpecterSpeaks&ContentRecord_id=cf655dfb-1321-0e36-bab2-05c5b6002908.

95. Guidant Sales Corp. v. Aspen Health Care Metrics, No. 04CV0408, 2004 WL 4909865 (D. Minn. Sept. 8, 2004) (case settled out of court and not reported).

96. *Id.*

agreement.[97] The court agreed with Guidant and upheld the confidentiality clause, forcing Aspen to settle the case for an undisclosed amount.[98]

After concluding that case, Guidant pursued heavyweight violators such as Emergency Care Research Institute (ECRI), a not-for-profit research center that provides information to more than 5000 hospitals.[99] Guidant sent a cease and desist letter to ECRI that prohibited any disclosure of device prices in ECRI's PriceGuide reports.[100] ECRI sought a declaratory judgment in response to the letter. According to the complaint, ECRI's PriceGuide reports have been around since 1996 without violating confidentiality clauses.[101] Guidant settled the case out of court before a judgment was issued, apparently allowing ECRI to continue publishing its reports as long as the "information [did] not violate confidentiality agreements."[102] This probably means that ECRI must remove device specific data from its reports, which, presumably, makes the reports less useful to hospitals.

Price secrecy is so stringent that, in 2007, Senator Charles Grassley (R-IA) and Senator Arlen Specter (R-PA) introduced a bill requiring device makers to report prices to CMS, so it can make the data available to the public.[103] In his congressional testimony, Senator Specter testified that many hospitals had written to him "about the secrecy that the medical device industry is trying to impose around pricing," whereby "[h]ospitals are being told they can't share pricing information with any 'third parties.'"[104] One hospital wrote that it spends $300 million annually, and although devices such as pacemakers and orthopedic implants represent only 3% of the total items it purchases, these devices consume 40% of its total spending.[105]

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97. *Id.* para. 35.

98. Guidant Sales Corp. v. Aspen Health Care Metrics, No. 04-CV-4048, 2006 WL 2330617 (D. Minn. May 26, 2006) (dismissal order).

99. Emergency Care Research Inst. v. Guidant Corp., No. 06-CV-1898, 2006 WL 1344306 (E.D. Pa. May 3, 2006) (case settled out of court and not reported).

100. *Id.*

101. *Id.* para. 14.

102. Bus. Strategy for Med. Tech. Executives, ECRI-Boston Scientific Settlement Raises Transparency Issues, http://devicelink.com/mx/issuesupdate/07/12/ECRI.html (last visited Sept. 22, 2009).

103. Transparency in Medical Device Pricing Act of 2007, S. 2221, 110th Cong. (2007), *available at* https://www.ecri.org/Documents/Transparency_in_Medical_Device_Pricing_Act_of_2007.pdf.

104. Arlen Specter Speaks on the Senate Floor Regarding the Transparency in Medical Devices Act, *supra* note 94.

105. *Id.*

In another testimony, Senator Grassley added that "[w]ithout any available information on fair prices for medical devices, hospitals are involved in one-sided negotiations with device manufacturers."[106] "As a result," he said, "hospitals are at the mercy of medical device makers who have the upper hand. Some hospitals are now paying a lot more than others for the same medical device," which "means health care dollars aren't being spent wisely."[107]

V. RECOMMENDED SOLUTION

Surprisingly, no federal agency—not the PTO, the FDA, nor CMS—appraises the societal costs of new drugs and devices. Device makers have also managed to stifle private efforts to collect data on device prices. Thus far, CMS is the only federal agency attempting to include cost analysis in its coverage decisions. CMS's governing statute prohibits it from paying "any expenses incurred for items or services [that] are not reasonable and necessary for the diagnosis or treatment of illness."[108] So, in an effort to define "reasonable and necessary," CMS proposed a regulation in May of 2000 that included cost-benefit analysis in its coverage decisions.[109] However, the announcement led to an uproar in the drug and device industry and never came to pass.[110]

Despite CMS's foresight, it is probably not the best agency to introduce cost measures into the health care system. First, CMS does not make coverage decisions on a product-by-product basis, but rather, they do so on categories of technology.[111] That being so, the agency typically interacts with multiple manufacturers on any given coverage decision and may not be equipped to evaluate the cost of individual devices.[112] Even if CMS was able to overcome this debility, proper valuation of device prices will require clinical information much like that already collected by the FDA during its approval process. CMS can obtain this information either from device manufacturers or through CMS/FDA information sharing and collaboration. However, because CMS coverage decisions affect multiple manufacturers, "[i]t is unclear that any given

106. Press Release, Office of Sen. Chuck Grassley, Grassley, Specter Introduce Transparency in Medical Device Pricing Act (Oct. 23, 2007), http://finance.senate.gov/press/Gpress/2007/prg102307d.pdf.

107. *Id.*

108. 42 U.S.C. § 1395y(a)(1)(A) (2006).

109. Wang & Smith, *supra* note 75, at 616.

110. *Id.*

111. *Id.*

112. *Id.* at 627.

manufacturer would be willing to provide resources to expedite a decision that would potentially benefit its competition."[113]

Second, CMS/FDA collaboration poses legal problems ranging from trade secret violations to privacy issues.[114] Worse yet, CMS's Medicare is one of hundreds of insurance plans paying for drugs and devices, each with "different rules covering whether and how it will include new drugs, medical devices, or biologics in its program, and each [with] different payment requirements and standards."[115] Any CMS cost-control policy will target Medicare coverage decisions in hopes of having a system-wide effect. This author believes cost/benefit analysis must be injected directly into the entire system. After all, private insurers have a significant impact. As CMS itself notes, "private payers are a more important component in [the] price equation because reimbursement rates are significantly higher through private payers."[116]

The PTO is another agency that some say should address the device industry's pricing abuses. For example, a recent student publication proposed creating special patent rules for medical devices.[117] The author argued that "the medical sector has unique characteristics that make it particularly amenable to special treatment."[118] For example, the justifications behind the current patent system are minute when applied to the medical device industry.[119] The author further noted that the biggest and most active device companies are publicly held, and that their "stocks are subject to wild, short-term swings regardless of their patent position,"[120] thus weakening the "incentive to invest" patent justification being that funding depends on such fragile public offerings. Moreover, device makers have an incentive to disclose only what is absolutely necessary in their patent applications to avoid peer review and criticism that can lead to possible FDA hassles, thus weakening the incentive to disclose justification behind the current patent policy.[121]

The problems with changing the patent system are time and cost, two commodities the health care market lacks. The proposed alternatives to the current patent system also pose significant problems of their own.

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113. *Id.* at 626.

114. *See generally id.* (discussing potential legal barriers to FDA/CMS information collaboration).

115. Reiss, *supra* note 89, at 99.

116. Ctr. for Medicare & Medicaid Servs., *supra* note 61, at 5.

117. Nugent, *supra* note 30, at 150.

118. *Id.*

119. *Id.* at 154-60.

120. *Id.* at 155.

121. *Id.* at 156.

The author proposed alternatives such as reliance on trade secrets alone, shortening the patent term, compulsory licensing, a government reward system, price controls, or combining these various alternatives.[122] While excellent in theory, restructuring the entire patent system for the tiny medical device industry is probably unrealistic and poses significant implementation problems. For example, under each alternative, there is a risk of failure and a need for substantial investments of time and government resources. Therefore, this Comment suggests that it is better to address this issue through another agency, the FDA.

Currently, the FDA does not consider cost in its approval deliberations. In fact, it is said that if a device company sought approval for a $1 million "gold-plated billiard stent" that functions as it should, the FDA must approve it even if a $127 version of the same stent is already available in the market.[123] When approving devices, the FDA only looks at whether there is "valid scientific evidence . . . (i) which is sufficient to determine the effectiveness of a device, and (ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have."[124]

Admittedly, the FDA approval process is already costly and adding another hurdle might add further delays. However, not collecting cost/benefit information might be far more severe in the long run. Currently, newer and more expensive devices replace older devices, even when the new device is inferior.[125] For example, a recent clinical trial indicated that diuretic therapy drugs were found to be more effective at preventing cardiovascular complication of hypertension than calcium channel blockers.[126] Despite this fact, the more expensive, yet inferior, calcium-channeled drugs forced the diuretic drugs off the market.[127] Because cost/benefit data was never collected, hospitals could not compare the alternative treatments, and society suffered as a result.

There are many reasons why the FDA is in a strong position to collect cost comparison data during its review process. First, the FDA already evaluates cost-effectiveness claims that are made in promotional

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122. *Id.* at 161.

123. Deyo, *supra* note 68, at 142.

124. 21 U.S.C. § 360c(a)(3)(B) (2006); *see also id.* § 360c(a)-(e) (stating the entire classification and approval process of new devices).

125. Deyo, *supra* note 68, at 143.

126. *Id.*

127. *Id.* at 144.

materials[128] and so, presumably, is familiar with evaluating cost/benefit data. The FDA is also the only federal agency that evaluates proposed new devices on a case-by-case basis. Again, the cost-comparison requirement can just be an additional item on the list of data the agency already collects. Moreover, the FDA already employs a substantial number of scientists to evaluate safety and effectiveness data, so it should not be extraordinarily difficult to add economists to the list.

A potentially controversial issue is what the FDA should do with the data it collects. One plausible course of action is to mimic other countries and give the FDA the power to regulate device manufacturers by either "setting reimbursement rates . . . based on how [new devices] compare with existing products (Japan), capping profits (Britain), putting a ceiling on total spending (France), or insisting that once a product is on the market, prices cannot increase faster than the general inflation rate (Canada)."[129] As appealing as this role may be, using cost data as a barrier to approval or as a means to cap prices will most likely stifle innovations and run contrary to U.S. patent policy. A recent study even indicates that direct regulation of pharmaceutical prices improves the welfare of the current generation at the expense of future generations.[130] Presumably, the same is true for the medical device industry. To avoid stifling innovative ideas, (1) the FDA should act only as a data collector, (2) cost/benefit findings should not bear on FDA approval decisions, and (3) the FDA should refrain from setting prices.

So what should the FDA do with the data? The collected data should be released to the public either via a Web site or along with device permits. The data referred to here should include a proposed price estimate of the new device, a list of existing devices currently used in similar treatments, and how the new device compares in quality and effectiveness to these devices. The most common objections to FDA cost-benefit analysis are that (1) the FDA lacks the expertise to evaluate economic factors, and (2) even if the FDA acquired such expertise, it is difficult to determine the real price of a device or a drug during FDA approval.[131] Both objections are somewhat dubious considering that even if the FDA does not presently possess the necessary expertise, it could

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128. John E. Calfee & Mark Hayman, *Should the FDA Consider Cost-Effectiveness When Approving New Drug Applications?*, OB/GYN NEWS, Sept. 15, 2004, http://findarticles.com/p/articles/mi_m0CYD/is_18_39/ai_n6225826.

129. MAHAR, *supra* note 53, at 289.

130. Neeraj Sood et al., *The Effect of Regulations on Pharmaceutical Revenues: Experience in Nineteen Countries*, 28 HEALTH AFFAIRS, w125, w126 (Dec. 16, 2008), *available at* http://www.rand.org/pubs/reprints/2009/RAND_RP1381.pdf.

131. Calfee & Hayman, *supra* note 128.

employ economists to evaluate economic factors. Additionally, companies can submit estimates instead of exact prices, which should function as a benchmark in the marketplace.

Injecting cost/benefit information into the health care market should lead to several benefits. Providing this information will likely help hospitals and insurance companies make informed decisions when purchasing or paying for devices.[132] Moreover, a unified approach is needed to address what currently is a fragmented policy. For example, if the FDA assumed this position, it would put an end to the pending Transparency in Medical Device Pricing Act, save CMS from expending resources to lobby for Medicare alone, and forestall litigation over price disclosures. Also, making cost-comparison data available early in the process can speed up the approval and insurance coverage process for affordable and effective devices. Thus, presumably, an incidental benefit will be an increase in cost-reducing innovation that could reverse the current trend of rising health care costs. Indeed, as one writer notes, what the health care market needs is not another expensive device or drug to treat what is already being treated effectively, but rather the development of "innovations that use less costly personnel, materials, and facilities; that do not impose the highest level of performance for patients whose conditions are well treated with less; and that permit and encourage patients to do for themselves some of what has been done to them."[133]

VI. CONCLUSION

There is a common saying in American slang: "If it ain't broke don't fix it!" Well, the U.S. health care market is far beyond broken and needs fixing. Unfortunately, the magnitude of the problem has allowed the abusive practices of small players, like the medical device industry, to go completely unchecked. The device industry makes every effort to maintain a stringent price secrecy code, wards off all attempts to collect data on device prices, and uses its might to pressure federal agencies. Finally, because patent laws protect the industry from competition it enjoys operating in oligopolistic markets, where it can greatly influence prices. This lack of price transparency can be repaired by requiring device makers to submit cost/benefit data during FDA approvals. Arguably, such data will allow hospitals to price-shop openly and

132. *See* Robinson, *supra* note 41, at 1526-28.

133. James C. Robinson & Mark D. Smith, *Perspective: Cost Reducing Innovations in Health Care*, 27 HEALTH AFFAIRS 1353, 1353 (2008).

become generally more informed buyers—an ability that hospitals completely lack at the present time.