

# PHARMACEUTICAL LEMONS: INNOVATION AND REGULATION IN THE DRUG INDUSTRY

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*Before a new drug can be marketed, the Food and Drug Administration must be satisfied that it is safe and effective. According to conventional wisdom, the cost and delay involved in this process diminish the incentives to invest in the development of new drugs. Accordingly, several reforms aimed at restoring such incentives have been implemented or advocated. This Article challenges the central argument that drug regulation and drug innovation are necessarily at odds with one another. Although intuitively appealing, the argument that drug regulation negatively affects the incentives to innovate does not fully capture the role that regulation plays in this industry. This Article shows that the regulatory framework is not solely a burden imposed on the industry; it also provides a valuable service to the industry. Specifically, drug regulation provides certification of drug quality. Such certification, which may not be easily achieved by private market-based mechanisms, prevents the market from becoming a market for “lemons.” Therefore, rather than decreasing the expected returns to innovation, this aspect of regulation contributes to the value of new drugs and may actually encourage innovation. This point has largely been absent from most cost-benefit analyses of drug regulation, yet without it any discussion of the merits of regulation is incomplete.*

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## I. INTRODUCTION

On the evening of November 13, 1891, Mrs. Carlill saw an advertisement in the *Pall Mall Gazette*, promising, on behalf of the Carbolic Smoke Ball Co., a reward of £100 to “anyone who contracted influenza, colds, or any diseases caused by taking cold,” after using the ball three times daily for two weeks and in accord with the printed directions supplied with each ball.<sup>1</sup> Not knowing that her story would be familiar to most lawyers in the common law world more than a century later,<sup>2</sup> Mrs. Carlill purchased a smoke ball from her local pharmacy and, despite assiduously using the ball for two weeks as instructed (and perhaps longer than that), contracted influenza. She did not receive the promised reward and legal action against the manufacturer followed. In a canonical decision the court ruled that the advertisement contained a legally binding and enforceable promise, and that the advertisement was an offer Mrs. Carlill accepted by performing the conditions contained therein.<sup>3</sup> But this

1. A.W.B. Simpson, *Quackery and Contract Law: The Case of the Carbolic Smoke Ball*, 14 J. LEGAL STUD. 345, 257 (1985). All of the recited facts about the *Carlill* case are based on this article.

2. See Simpson, *supra* note 1, at 345.

3. *Carlill v. Carbolic Smoke Ball Co.*, [1892] 1 Q.B. 256 (A.C.).

Article is not about contract law. Rather this Article discusses the mechanisms that have made medicines, such as the Carbolic Smoke Ball, a curiosity for contemporary consumers of medicines.

As was quite evident to Mrs. Carlill in retrospect, and as may be well known today, inhaling carbolic acid fumes cannot prevent the flu. Not only is it ineffective, carbolic acid is a poison that the Privy Council eventually added to the list of scheduled poisons to restrict its availability.<sup>4</sup> But Mrs. Carlill's incident was not singular, nor were Britain's drug markets unique. Late nineteenth century American drug markets greatly resembled those in Britain, where the smoke ball saga had taken place. Most available products were totally ineffective for their stated purpose and often worsened the conditions they purported to cure. If they existed at all, the few manufacturers with medicines that had at least some therapeutic benefit were lost in a sea of potentially harmful nostrums and other quack remedies. Not only were the medicines ineffective, the lists of maladies they purported to cure were as extensive as they were false.<sup>5</sup> Manufacturers adapted curative claims to the perceived needs of the market, rather than advertising the actual properties of the remedy.<sup>6</sup> Outraged by this reality, Dr. Oliver Wendell Holmes wrote that he "firmly believe[d] that if the whole materia medica, *as now used*, could be sunk to the bottom of the sea, it would be all the better for mankind,—and all the worse for the fishes."<sup>7</sup>

By the turn of the century, the industry had so increased in scope as to precipitate a series of articles in *Collier's* magazine, written by "muckraker" journalist Samuel Hopkins Adams. Adams began the series, published in 1905–1906 with these words:

Gullible America will spend this year some seventy-five millions of dollars in the purchase of patent medicines. In consideration of this sum it will swallow huge quantities of alcohol, an appalling amount of opiates and narcotics, a wide assortment of varied drugs ranging from powerful and dangerous heart depressants to insidious liver stimulants; and, far in excess of all other ingredients, undiluted fraud.<sup>8</sup>

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4. Simpson, *supra* note 2, at 367.

5. Losing the case to Mrs. Carlill did not prevent Mr. Roe, the manufacturer of the carbolic smoke ball, from doubling the promised reward and adding eighteen more ailments that the ball would purportedly cure. Simpson, *supra* note 2, at 371.

6. See JAMES HARVEY YOUNG, *THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION* 247–48 (1961). See also Simpson, *supra* note 2, at 352.

7. OLIVER WENDELL HOLMES, *MEDICAL ESSAYS*, 202–03 (1891) (italics in original).

8. Samuel Hopkins Adams, *The Great American Fraud* 36 *COLLIER'S* 14 (Oct. 7, 1905), available at <http://www.mtn.org/quack/ephemera/oct7-01.htm>.

Adams' series of articles contributed greatly to the mounting pressure, to which the medical and pharmaceutical professions gradually joined to enact a national law regulating the food and drug industries.

Eventually this pressure led to the passage of the Pure Food and Drugs Act of 1906.<sup>9</sup> Congress has revised and reformed the Act several times since its enactment a century ago. The basic structure of current drug regulation was shaped in 1962, with the passage of the Kefauver-Harris Amendments to the Food, Drug, and Cosmetics Act. Since 1962, before a new drug can be marketed in the United States, the Food and Drug Administration (FDA) must approve it as safe and effective.<sup>10</sup> This expansion of the regulatory framework sparked considerable controversy. If eliminating quack medicine from the marketplace were the only effect of such regulation, very few would object. However, some critics have also blamed the new regulatory framework for causing more deaths and morbidity.<sup>11</sup> The requirement to satisfy the FDA that a new drug is safe and effective ordinarily demands a series of costly and lengthy clinical trials. This has increased the costs of developing new drugs and delayed their introduction into the market.<sup>12</sup>

Furthermore, if the new drug is patented, and new drugs often are, the time it takes to get the approval encroaches upon the period of effective patent life (EPL). This happens because patents are granted for twenty years from the time of filing the application,<sup>13</sup> and filing usually happens at a very early stage in the development process of a new drug. On average, after getting a patent it takes an additional eight years before the FDA approves the drug for marketing.<sup>14</sup> As a result, EPL is much shorter than twenty years.<sup>15</sup>

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9. JAMES H. YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 188-93 (1989); see also Marc T. Law, *History of Food and Drug Regulation in the United States*, in EH.NET ENCYCLOPEDIA (Robert Whaples ed., 2004), available at <http://eh.net/encyclopedia/article/Law.Food.and.Drug.Regulation>.

10. Similar regulatory requirements exist in most developed countries and elsewhere.

11. See *infra* Part II.

12. See *infra* Part II.

13. 35 U.S.C. § 154 (2002).

14. F. M. Scherer, *Pricing, Profits, and Technological-Progress in the Pharmaceutical-Industry*, 7 J. ECON. OF PERSP. 97, 99 (Summer 1993).

15. A common misconception is to ascribe the entire shortening of EPL to the regulatory process. Because a drug company would rarely have a ready-to-market product upon being issued a patent, some delay between a patent's issuance and marketing a drug is inevitable and independent of the regulatory process. Marcia Angell notes that the average time of FDA review was sixteen months in 2002, and in some cases even less than this. See MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES 35 (2004). In 2005, the twenty new therapeutics approved by FDA were reviewed in an average of less than fourteen months. See PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, NEW DRUGS APPROVALS IN 2005 1 (2006), available at <http://www.phrma.org/files/NDA%202005.pdf>. See also U.S. GENERAL ACCOUNTING OFFICE, FOOD AND DRUG ADMINISTRATION: EFFECT OF USER FEES

This is an unfortunate reality for drug companies, who would obviously prefer a longer EPL over a shorter one, but our concern is not with the loss of patent-induced monopoly profits as such. As a society, we should be concerned that the loss of such monopoly profits, assumed to encourage innovation, would decrease the amount and speed of new drugs available to consumers.<sup>16</sup> We should be worried that as a result of the cost and delay imposed by the regulatory approval process, thousands of potential new drug beneficiaries would die or unnecessarily suffer.<sup>17</sup>

Several studies of the effects of the 1962 Amendments have corroborated these concerns. They attributed an observed reduction in the number of new drugs to the regulatory change.<sup>18</sup> Consequently, regulation of new drugs has been perceived to negatively affect the incentivizing effect of patents, with negative consequences not only for drug companies, but also to the public at large. To mitigate such concerns, a few reforms have been adopted. Some reforms were aimed at speeding-up the regulatory process by restructuring FDA internal processes. Others sought to provide greater funding for the process.<sup>19</sup> As a result of such reforms, the FDA “has moved from being the slowest

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ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 3 (2002) (noting that:

[f]rom 1993 to 2001, the median approval time for new drug applications for standard drugs dropped from 27 months to 14 months. The median approval time for new drug applications for priority drugs has remained stable at 6 months since 1997. However, the approval time for standard new molecular entities (NME), drugs containing active ingredients that have never been marketed in the United States in any form, has increased since 1998 from about 13 months to 20 months. In contrast, median approval times for new biologic applications have fluctuated since 1993, ranging from a low of 12 months in 1997 to a high of about 32 months in 1995. In 2001, the median approval time for biologic applications was about 22 months.)

It does not mean, however, that the actual delay or cost caused by regulation is only sixteen or fourteen months (on average) since in theory drug companies could be spending a lot of time preparing for the review that they would not have spent otherwise.

16. While the actual relationship between patents and innovation is more complex than this initial assumption of the patent system and may vary across industries, patents are considered to be highly important for innovation in the pharmaceutical industry. *See, e.g.*, Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 818–31 (2002).

17. SAM PELTZMAN, REGULATION AND THE NATURAL PROGRESS OF OPULENCE, 2004 Distinguished Lecture AEI-Brookings Joint Center for Regulatory Studies 15–16 (Sept. 8, 2004) (summarizing the conclusions of his earlier studies).

18. *See infra* Part II.

19. In 1992, the U.S. Congress passed the Prescription Drug User Fee Act, Pub. L. No. 102–571, §§ 101–108, 106 Stat. 4491, which authorized the FDA to collect fees from drug companies seeking to get marketing approval for new drugs. As a result, new—drug review times decreased by as much as fifty percent. *See* Mary K. Olson, *Pharmaceutical Policy Change and the Safety of New Drugs*, 45 J.L. & ECON. 615, 620 (2002).

regulatory drug agency in the developed world to being the fastest.”<sup>20</sup> Other reforms sought to compensate drug companies for the shorter EPL to restore the incentive that the patent system promised, and that regulation, arguably, has not kept.

The proposed compensation can take different forms. The most straightforward form is the extension of patent terms. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)<sup>21</sup> makes it possible for drug patentees to have the term of their patent extended for as much as five years if they meet certain criteria. The House Report of the Act explicitly recognized that the enactment was motivated by drug companies’ complaints that the federal government’s “regulatory review eroded the effective market life” of patented drugs.<sup>22</sup> In Japan, Section 67(2) of the Patent Law provides that “the term of the patent right may be extended . . . by a period not exceeding five years if, because of the necessity of obtaining an approval . . . there was a period in which it was not possible to work the patented invention.”<sup>23</sup> In the European Union, Council Regulation 1768/92 created a new instrument, Supplementary Protection Certificate (SPC), which extends market exclusivity for patented drugs by denying marketing approval to generic competitors for a period of up to five years after the expiry of the patent.<sup>24</sup> While de jure an SPC is not a patent, for practical purposes the instruments are equivalent.<sup>25</sup> The preamble to Regulation 1768/92 provides the following rationale:

Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide sufficient protection to encourage such research;

Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market

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20. ANGELL, *supra* note 15, at 35.

21. 35 U.S.C. § 156 (2007).

22. See H.R. REP. No. 98-857, pt. 2, at 3 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2687.

23. Patent Law, Japan Law No. 121 of 1959, art. 67(2) (amended by Law No. 220 (1999)), *available at* [http://www.wipo.int/clea/docs\\_new/pdf/en/jp/jp036en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/jp/jp036en.pdf).

24. Council Regulation 1768/92, 1992 O.J. (L 182) 1 (EC).

25. See Edward H. Mazer, *Supplementary Protection Certificates in the European Economic Community*, 48 FOOD & DRUG L.J. 571 (1993).

makes the period of effective protection under the patent insufficient to cover the investment put into the research;

Whereas this situation leads to a lack of protection which penalizes pharmaceutical research;<sup>26</sup>

This Article questions this justification for patent term extension, and challenges the argument that drug regulation and drug innovation are at odds. Although intuitively appealing, the argument that new drug regulation negatively affects the incentives for new drug innovation does not fully capture the role that regulation plays in the industry. I will show that the regulatory framework is not solely a burden imposed on the industry, but also a valuable service of drug quality certification. I will suggest that rather than decreasing the expected returns to innovation, this aspect of the regulation, which may not be easily substituted by private market-based mechanisms, contributes to the value of new drugs and therefore may actually encourage innovation. Consequently, the effect of drug regulation may be a complement, rather than antithetical to the patent system.

This Article has a modest purpose. Rather than aiming to defend the current method of drug regulation and every particular aspect of it, or advocate its inherent superiority over other forms of quality assurance, I simply aim to highlight another aspect of drug regulation which so far has been insufficiently studied. This aspect may be nonetheless too important to omit from the cost-benefit analysis of drug regulation or proposals for its reform. As such, this Article's contribution lies mainly in setting an agenda for future research, not in concrete conclusions or suggestions for reform.

## II. THE INTERPLAY BETWEEN DRUG REGULATION AND PATENTS

The standard justification for drug regulation is a perceived market failure. It is assumed that in unregulated markets, supplying firms would perform insufficient pre-market testing to avoid the high costs of testing or to gain advantage in the market as first movers. Some fear such firms would overstate positive features and understate negative ones in promoting and labeling their products.<sup>27</sup> This market failure results from information imperfection: customers' inability to obtain full information

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26. Council Regulation 1768/92, 1992 O.J. (L 182) 1 (EC).

27. HENRY G. GRABOWSKI & JOHN M. VERNON, *THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS* 7 (1983); see also Patricia M. Danzon, *The Pharmaceutical Industry*, in 3 *ENCYCLOPEDIA OF LAW & ECONOMICS*, 1055, 1058 (Boudewijn Bouckaert & Gerrit De Geest, eds. 2000) available at <http://encyclo.findlaw.com/5880book.pdf>.

about the benefits and risks of new drugs.<sup>28</sup> This in turn leads firms to take advantage of the imperfection, and supply less accurate information about their products, and cause consumers to waste money on drugs that may be harmful or simply unnecessary. While such imperfections characterize many consumer products, the potentially severe and irreversible threats to human health from drug consumption justify extensive government intervention<sup>29</sup> beyond the general domains of tort law or consumer protection law.<sup>30</sup> Seen in this light, drug regulation is essentially paternalistic because it seeks to protect the misinformed consumer from better-informed sellers.

Drug regulation critics would not generally dispute that such market failure may exist, but would point out the unfortunate existence of a concurrent regulatory failure. Such critics argue that the regulatory costs of increased mortality and prolonged morbidity that result from reduced innovation and delay are greater than the social cost of market failure.<sup>31</sup> Following an influential study by Sam Peltzman in 1973, many economists' views on drug regulation, and specifically the 1962 Amendments, have been overwhelmingly negative. Peltzman, who studied the effects of the 1962 Amendments, after observing a sharp post-Amendments decline in the introduction of new drugs (or new chemical entities (NCEs)), attributed this decline to the Amendments' stringent conditions for marketing new drugs.<sup>32</sup> He concluded that the benefit of saving consumers money on ineffective drugs was far outweighed by the various costs created by reduced innovation.<sup>33</sup> In 1974, Peltzman published a larger study, which expanded his analysis to include a measurement of the health-related effects of delays in innovation attributed to the Amendments.<sup>34</sup> He calculated extremely high costs of delay<sup>35</sup> based on measurable effects on productivity as a result of morbidity, mortality, or costs of treatment attributable to the delay.<sup>36</sup>

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28. GRABOWSKI & VERNON, *supra* note 27, at 7.

29. *Id.*

30. Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357, 370 (1984).

31. GRABOWSKI & VERNON, *supra* note 27; Sam Peltzman, *Evaluation of Consumer Protection Legislation—1962 Drug Amendments*, 81 J. POL. ECON. 1049, 1090 (1973).

32. Peltzman, *supra* note 31, at 1073–76.

33. *Id.* at 1089.

34. SAM PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS (1974).

35. *Id.* at 58–69 (estimating the two year cost-of-delay to be \$2 billion for tuberculosis therapy, \$1.4 billion for tranquilizers, and \$150 million for polio vaccinations, and estimating the two year cost-of-delay at several billion dollars and upwards of 100,000 lives for heart disease and cancer treatments).

36. *Id.*



While other economists criticized Peltzman's studies on several grounds,<sup>37</sup> and the decline in new drug introduction has changed its course during the 1980s and the 1990s,<sup>38</sup> the perception that drug regulation, and especially the 1962 Amendments, have negatively affected pharmaceutical innovation has prevailed.<sup>39</sup>

Pursuant to this perception of drug regulation, the respective roles of patent laws and drug regulation laws are seen as an exercise in balancing two opposing interests: those of industry (through patents), and those of consumers (through drug regulation). Patent laws, by providing market exclusivity, generate the financial incentives to innovate. In contrast, drug regulation laws keep unsafe and ineffective drugs off the market to protect consumers, but diminish incentives to innovate.

However, the relationship between patents and drug regulation is more complicated. As Rebecca Eisenberg has already noted, "Although patents often take most of the credit for the profits of drug development, while drug regulation takes much of the blame for its costs, upon closer inspection these two legal regimes operate in tandem to limit competition in lucrative markets for drugs."<sup>40</sup> She argues that by forcing drug

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37. See, e.g., PETER TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* 147 (1980) (maintaining that Peltzman overestimated the effect of the Amendments, and noting that "the amendments took effect gradually over the years and did not cause the drop in new drug introductions in the early 1960s"). But see Steven N. Wiggins, *Product Quality Regulation and New Drug Introductions: Some Evidence from the 1970s*, 63 *REV. ECON. & STAT.* 615 (1981) (concluding that regulation indeed led to a decline in the introduction of new drugs).

38. During the 1980s, the number of approvals per year increased 35% to 18.5. In the 1990s, the approvals grew an additional 48% to 27.4. See Joseph A. Dimasi, *New Drug Innovation and Pharmaceutical Industry Structure: Trends in the Output of Pharmaceutical Firms*, 34 *DRUG INFO. J.* 1169, 1172 (2000). This turnaround has been explained by adaptation of drug companies to the new regulatory regime, as well as new discovery opportunities that resulted from breakthroughs in biochemistry, enzymology, molecular biology, *id.* at 1172, and genetic engineering, Scherer, *supra* note 14, at 100. More recently there has again been a downturn. F. M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 *NEW ENG. J. MED.* 927, 927 (2004).

39. One study considered five hypotheses that were advanced for explaining the decline in NCEs in the post-Amendment period: (1) tighter regulation of the industry by the FDA following the Amendments, as suggested by Peltzman; (2) that the decline is in fact illusory; that the number of "important" new drugs introduced annually (as opposed to total number) has not declined; (3) that the decline was a natural consequence of the rapid rate of new drug development in the 1950s, which led to "depletion of research opportunities" in subsequent years; (4) that the tragic thalidomide episode in the early 1960s increased drug firms' and physicians' caution in their decisions concerning the marketing and prescribing of new drugs; and (5) that the costs of developing new drugs increased as a result of advances in pharmacological science. See Henry G. Grabowski et al., *Estimating Effects of Regulation on Innovation—International Comparative Analysis of Pharmaceutical Industry*, 21 *J.L. & ECON.* 133 (1978). They concluded that that the first cause, the enactment of the 1962 Amendments, was the primary (although not exclusive) reason for the decline in NCEs. *Id.* at 159.

40. Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 20 *HEALTH AFF.* 119, 132 (2001).

companies to conduct clinical trials and submit their results to independent expert scrutiny, “the FDA plays an important structural role in promoting a valuable form of biomedical R&D that private firms are undermotivated to perform on their own.”<sup>41</sup> Moreover, she shows how drug regulation laws often support the profitability of new drugs. In some cases, drug laws provide market exclusivity directly, irrespective of patent protection. For example, the Orphan Drug Act of 1983 directs the FDA to provide seven years of market exclusivity for new drugs developed for treating rare diseases and conditions that affect fewer than 200,000 patients in the US.<sup>42</sup> Developers of pioneering NCEs not previously approved may get five years of exclusivity, and the introduction of changes in approved products may qualify for three years of exclusivity.<sup>43</sup> Drug regulation also benefits incumbent drug companies by creating indirect barriers for the entry of competitors. Post patent expiry, and despite lower regulatory burdens, regulatory requirements create a significant entry barrier for generic drugs,<sup>44</sup> and may effectively prevent parallel imports or re-imports of approved drugs even if patent law failed to do the same.<sup>45</sup> But even Eisenberg, in her more nuanced account of how patent laws and drug laws intertwine, sees the mere requirement to prove safety and efficacy as a regulatory burden: one that justifies compensating measures in the form of market exclusivity beyond that granted by patent law.<sup>46</sup>

Yet, the intuitively appealing argument that regulatory approval reduces the expected returns from drug innovation, and therefore justifies the extension of patent terms, is potentially flawed. The question is not whether or not regulation eats into effective patent life because undoubtedly it does this. The question is whether regulatory review of new drugs erodes drug companies’ profits and thereby reduces the incentive to invest in innovative drugs. This is a question about cause and effect and the opportunity cost of regulation. To assess regulatory review’s effect on drug companies, one should ask, with any given patent term, under which conditions drug companies will do better: with or without regulatory review. Only if the combination of regulatory review and patents reduces drug companies’ expected profits compared to patents without such review will regulation correctly be seen as a burden. If the combination of patent and regulation yields greater profits, then regulation,

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41. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 370 (2007).

42. Eisenberg, *supra* note 40, at 123; Eisenberg, *supra* note 41, at 359.

43. Eisenberg, *supra* note 40, at 123; Eisenberg, *supra* note 41, at 359–60.

44. Eisenberg, *supra* note 40, at 121; Eisenberg, *supra* note 41, at 356–57.

45. Eisenberg, *supra* note 40, at 131.

46. *Id.* at 123.

although coupled with reduced EPL, benefits drug companies, and by implication, benefits innovation.<sup>47</sup> To illustrate, higher education undoubtedly reduces one's effective "job-market life." Yet this tells us nothing about the expected income one earns after graduation. If higher education improves one's skills, the delay in entry into the job market increases one's expected income. Moreover, even if higher education does not improve one's productivity but merely serves as a screening device, allowing employers to distinguish between potential employees of differing abilities, pursuing higher education may be worthwhile for such individuals who thereby signal their quality.<sup>48</sup> Similarly, if regulatory review of new drugs increases their value and marketability, a certain amount of regulation increases the expected profits from patented drugs and the incentive to innovate.

But why would regulation increase the expected profit from patented drugs? New drugs are "credence goods" because consumers are never sure about their quality or whether they actually need them.<sup>49</sup> Severe asymmetry of information exists between drug companies and consumers regarding drugs' safety and efficacy ("quality").<sup>50</sup> Consequently, in the absence of mechanisms to signal and commit to the quality of drugs, the market for drugs may become a "market for lemons": a smaller market in which only low quality drugs are sold, by non-trustworthy sellers; a market in which Carboloc Smoke Balls and other snake oils are the common cures for diseases. With a few recent exceptions,<sup>51</sup> most scholarship has overlooked this aspect of drug regulation.<sup>52</sup>

If the assumption that without regulation or other forms of quality assurance the market will become a market for lemons is true, then rather than a burden, regulatory review of new drugs may actually be an effective mechanism for assuring the quality of drugs, one that drug

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47. The debate assumes that shorter EPL and the costs of compliance with regulation reduce drug companies' profits, and thus reduce the expected return on innovation. It should be noted though that expected profits are just one of the factors that influence innovation.

48. Kenneth J. Arrow, *Higher Education as a Filter*, 2 J. PUB. ECON. 193, 194 (1973). See generally Michael Spence, *Job Market Signaling*, 87 Q.J. ECON. 355 (1973).

49. As will be explained below, not only patients are uncertain about the quality of drugs but also physicians who decide which drugs to prescribe.

50. The choice of one term such as "quality" to describe both safety and efficacy is more than mere convenience, as the two are interdependent. Anita Bernstein and Joseph Bernstein explain that because all drugs are poisons and can do harm, the term "safe" should be understood in the context of a drug's potential benefits. Consumers may be interested, and regulators may "tolerate grim side effects in a lifesaving drug that would be fatal to the approval of a drug with superficial and cosmetic effects, or for yet another beta blocker." See Anita Bernstein & Joseph Bernstein, *An Information Prescription for Drug Regulation*, 54 BUFF. L. REV. 569, 573 (2006).

51. See Daniel Carpenter, *A Proposal for Financing Postmarketing Drug Safety Studies by Augmenting FDA User Fees*, 24 HEALTH AFF. W5-469 (2005); Law, *supra* note 9.

52. See *id.*

companies would have had to establish themselves in order to avoid the “lemons” problem (e.g. by establishing their own certifying body).<sup>53</sup> Furthermore, as will be explained in more detail below, it is possible that the government is even more suitable to perform this function because it is a disinterested third party. Government can effectively enforce compliance with the approval process and impose sanctions for attempts and perceived attempts to cheat the process. Rather than a drag on innovation, regulatory approval of new drugs may actually perform a valuable service that increases the expected returns from innovation. Drug regulation provides the quality assurance necessary to persuade consumers to purchase drugs, and patents provide the mechanism for recouping the investment necessary for developing both the drugs and information regarding their quality.<sup>54</sup>

Moreover, even if drug regulation increases the cost of innovation, it increases the cost of all new drugs so it “simultaneously discourages creative destruction through between-patent competition . . . [thus providing] an improved patent by keeping out low-quality innovators that could have competed with high-quality innovators.”<sup>55</sup> However, the cost of regulation is not equal for all drugs. Testing and approving a new drug whose safety and efficacy are apparent will be less costly than testing and approving a new drug that is less effective and causes more side effects and complications. Therefore, drug regulation’s discouraging effect affects low quality drugs more than it affects high quality drugs, which then face less intense competition in the market place.

### III. THE ECONOMICS OF INFORMATION ASYMMETRY IN PHARMACEUTICALS

#### A. *Information Asymmetry and Market Failures*

Economic theory distinguishes between three types of goods, according to the nature and timing of information that consumers can

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53. Bernstein & Bernstein, *supra* note 50, at 572 (highlighting a distinction between drug regulation in which the industry pursues the same thing that the regulator demands, as both the regulators and the regulated seek safe and effective drugs, and other instances of regulation (such as pollution prevention, securities regulation or workplace safety) where regulation “points at the dark underbelly of a business”).

54. Eisenberg, *supra* note 41, at 370. Eisenberg argues that the weaker regulation of vitamins and dietary supplements makes sense because in the absence of patents on such products, manufacturers will not be able to capture the value of clinical trials. Therefore, the likely result of applying the same regulatory standard to pharmaceuticals will not be improved quality but disappearance of these products from the market. *Id.* at 379–80.

55. Frank R. Lichtenberg & Tomas J. Philipson, *The Dual Effects of Intellectual Property Regulations: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry*, 45 J.L. & ECON. 643, 651 (2002).

obtain about their quality. The quality of “search goods” can be ascertained before purchase, whereas for “experience goods,” quality can only be learned through use.<sup>56</sup> The quality of the third category, “credence goods,” cannot be evaluated through normal means. Assessing credence goods’ value requires additional costly information. Repair of durable machines or human beings are the classic examples because most consumers are highly unfamiliar with their intricacies and peculiarities.<sup>57</sup>

The line between experience goods and credence goods may not always be sharp, especially if quality will eventually be discerned through use after the lapse of considerable time.<sup>58</sup> Furthermore, most goods possess many attributes: some are learned before purchase, some after purchase, and some are never learned.<sup>59</sup> For example, a potential buyer of canned tuna can know before purchase that she buys a canned product, and can know after purchase that the content of the can indeed looks and tastes like tuna. However, she may find it more costly to verify that it is indeed tuna (and not some imitation). She will find it prohibitively costly to verify whether eating this particular tuna is safe (e.g., not contaminated), or verify other attributes that some consumers may deem important such as whether the product contains genetically modified organisms, whether it was derived from organic farming, the age and working conditions of the labor force, the environmental impact of the production process, compliance with animal welfare standards, nutritional properties, or the geographical origin of the product.<sup>60</sup> Nevertheless, despite its limitations, the classifications of search, experience, and credence are useful for our analysis.

Most drugs can be easily characterized as credence goods, particularly with regard to their most important attributes: efficacy and safety. For some common symptoms a consumer may easily assess how effective a drug is, especially with frequent use. Thus, setting aside placebo effects, most consumers who suffer from headaches could immediately assess the efficacy of a pain killer. Similarly, most men suffering from erectile dysfunction could easily determine the effectiveness of a drug like Viagra. However, for many drugs whose expected effect is not immediate or immediately observable, or which must be combined with other drugs

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56. Phillip Nelson, *Information and Consumer Behavior*, 78 J. POL. ECON. 311, 311–12 (1970) (suggesting the style of a dress as an example for a search good and the taste of a particular brand of canned tuna as an example of an experience good).

57. Michael R. Darby & Edi Karni, *Free Competition and the Optimal Amount of Fraud*, 16 J.L. & ECON. 67, 69 (1973).

58. *Id.* at 69 n.5.

59. JEAN TIROLE, *THE THEORY OF INDUSTRIAL ORGANIZATION* 106 (1988).

60. Giovanni Anania & Rosanna Nistico, *Public Regulation as a Substitute for Trust in Quality Food Markets: What if the Trust Substitute Cannot Be Fully Trusted?*, 160 J. INSTITUTIONAL & THEORETICAL ECON. 681, 682 (2004).

or treatments, assessing how effective a drug is can be extremely difficult. First, as Peter Temin points out, the concept of effectiveness is itself vague, as it relates not only to the drug's ability to correct some undesirable condition but it can relate to other characteristics such as the method of administration (oral, injectible, or topical) and the dosage required.<sup>61</sup> Even more difficult for most consumers is knowing and evaluating the expected long-term effects of the drug, the possible complications, or the reactions with other substances.<sup>62</sup> Moreover, even if they were affluent enough to do so, because combining different drugs may be ineffective, or even lethal, consumers cannot simply try every drug and every cure until they find the one that works. They need to know before they commit to a specific drug that it is likely to work.

Second, and perhaps more importantly, however dramatic the effect of a drug on one person may be, since the effect of drugs may vary from person to person, meaningful information on drugs' quality can be obtained only by looking at large samples and carefully applying statistical methods.<sup>63</sup> Not only is this type of epidemiological research beyond the reach of consumers, it is also beyond the reach of most practicing physicians.<sup>64</sup>

Therefore, if sellers (drug companies) have better information about the efficacy and safety of their products, severe asymmetry of information about the quality of drugs (their efficacy and safety) may occur.<sup>65</sup> And when the information held by sellers and buyers is asymmetric the market may fail, as George Akerlof showed in his famous "lemons market" paper.<sup>66</sup>

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61. TEMIN, *supra* note 37, at 9.

62. *Id.* at 9–10.

63. *Id.* at 10; *see also* Bernstein & Bernstein, *supra* note 50, at 578–81.

64. TEMIN, *supra* note 37, at 10. *See also* JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 275 (2004).

65. The fact that statistically significant information about the quality of drugs can be obtained only by looking at large numbers may suggest that, at least in the case of new drugs, there is no information asymmetry but rather symmetry of misinformation. However, assuming that drug companies will always conduct some pre-marketing testing, the assumption of information asymmetry seems correct. At any point in time, the drug company will have better information than that available to the individual consumer.

66. George A. Akerlof, *The Market for "Lemons"—Quality Uncertainty and Market Mechanism*, 84 Q.J. ECON. 488 (1970). Note that uncertainty about the quality of a good is distinguished from information asymmetry. If both sellers and buyers face the same uncertainty about the value of the good, there is no asymmetry. In Akerlof's example of cars, there is no asymmetry of information about whether a specific new car is good or is a lemon. In the case of used cars, however, asymmetry of information develops because the owner of a specific car has used it for a while and formed a good idea about its quality. While it could be argued that producers of new drugs that have not been subjected to extensive testing lack information as to their quality, just as consumers do, this argument would be false. Even in the extreme case in which the producer had not performed any testing of the drug, the very fact

Akerlof describes how the interaction between quality heterogeneity and asymmetrical information about the quality of products may lead to the disappearance of a market, despite the fact that sellers of high-quality products are willing to sell at prices below which buyers are willing to buy.<sup>67</sup> In Akerlof's model, the buyer's inability to ascertain the quality of a good creates asymmetry of information, which creates an incentive for low-quality sellers to pass off their goods as higher-quality.<sup>68</sup> The buyer, however, takes this incentive into consideration, and discounts all sellers' quality claims, so that for any given price only the average quality will be considered.<sup>69</sup> As a result, sellers who offer higher-than-average quality will be driven out of the market.<sup>70</sup> Unless credible guarantees of the quality of the good exist, this mechanism, in which the low-quality products drive out the high-quality, repeats itself until a no-trade equilibrium is reached.<sup>71</sup>

Akerlof presented his model using the market for used cars and mentioned a few other examples, such as the unavailability of privately supplied health insurance for the elderly,<sup>72</sup> employers' reluctance to hire members of minority groups,<sup>73</sup> or the dearth of formal credit markets in underdeveloped countries.<sup>74</sup> Nineteenth century drug markets, and perhaps contemporary dietary supplement markets, could easily supplement this list. In Akerlof's stylized model the market disappears, yet in real life markets rarely disappear altogether. They may only shrink as the frequency of transactions decrease in comparison to what would occur if the available information were perfect, or if "anti-lemon devices," mechanisms to credibly assure the quality of products, were available.<sup>75</sup> Akerlof's theory and its prediction that the market disappears is not inconsistent with the fact that a seemingly lively market for quack medicines existed in the nineteenth century. If the costs of producing and selling quack medicines are sufficiently low, and given that such medicines do not require heavy investment in research and development this seems like a fair assumption, even modest sales at low prices would make such a market sustainable. This can happen as long as there are enough consumers who, either out of mere ignorance or rational ignorance, are

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that the drug had not been tested is a very valuable piece of information that the producer would possess and the consumer would not.

67. *Id.* at 490–91.

68. *Id.*

69. *Id.*

70. *Id.* at 490.

71. *Id.* at 490–91.

72. Akerlof, *supra* note 66, at 492–94.

73. *Id.* at 494–95.

74. *Id.* at 497–99.

75. TIROLE, *supra* note 59, at 109.

willing to purchase such medicines.<sup>76</sup> Therefore, it is not the market for quack medicines that disappears under Akerlof's theory, but rather the market for quality medicines which disappears, or more precisely, fails to emerge. Therefore, while a small subset of consumers may deserve paternalistic regulation to protect them from their own ignorance, the more important effect of such regulation is actually on those consumers and sellers who would not otherwise be in the market.<sup>77</sup>

The Akerlovian failure which I present here differs markedly from the informational failure commonly perceived as the basis for drug regulation.<sup>78</sup> While both failures result from information imperfections in the marketplace, in the "traditional" failure, self-interested sellers refrain from acquiring and providing information to consumers, knowing that market imperfections would allow them to profit from such tactics without immediately losing patronage to competitors. This results in "wasted expenditures on ineffective drugs,"<sup>79</sup> and possibly in strategic use of meaningless product innovation or differentiation as an obstacle to price competition.<sup>80</sup> Government intervention that is designed to increase the information available to consumers operates *against* sellers' self interest. As much as consumers would cherish it, producers would loath it. In contrast, in the Akerlovian scenario, honest sellers of high quality credence goods are interested in providing enough accurate information to consumers, yet they cannot credibly do so. Given consumers' inability to distinguish between honest sellers and dishonest ones, sellers face the problem of persuading consumers that the information provided by them is indeed sufficient and accurate. Rather than causing consumers to wastefully expend money on ineffective drugs, this failure to signal quality results in under-expenditure on drugs, which in turn, may lead to under-investment. In the Akerlovian scenario, honest sellers and consumers alike would welcome measures that would allow them to credibly signal their quality. Such measures may include regulatory ones.

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76. Merely ignorant consumers would purchase such drugs believing they would work. Rationally ignorant consumers may suspect that such drugs would not work, but might be willing to take a chance if the price were sufficiently low.

77. Note that under perfectly Akerlovian conditions, *see* Akerlof, *supra* note 66, a paternalistic regulation is not required, because no consumer suffers harm by buying quack medicine. Consumers either fail to buy or buy a lemon at a discounted price which reflects the probability of low quality. As noted, though, in real life some consumers may nevertheless be harmed.

78. *See* GRABOWSKI & VERNON, *supra* note 27; Danzon, *supra* note 27.

79. Danzon, *supra* note 27, at 1058.

80. *Id.* at 1069.



### B. *The Implications for Pharmaceuticals*

The implications for pharmaceuticals are clear. Without mechanisms capable of credibly assuring the quality of drugs, drug markets would perform sub-optimally. They may turn into lemons markets. Anti-lemon devices thus enable both drug consumers and drug producers to increase the available gains from trade. Consumers' trust in the safety and efficacy of drugs means more money for drug companies. It increases the value consumers ascribe to new drugs and translates into an increase in the expected returns for investment in new drugs. Now, if regulatory review of new drugs provides such assurances, it may actually supplement patents in creating incentives to innovate, not detract from such incentives. The justification for patent term extension is thus turned on its head. Instead of decreasing the expected profits secured by drug patents, regulatory review boosts them. Instead of diminishing the incentives to innovate, regulatory review strengthens them. Instead of a burden, one can reconceptualize regulatory review of new drugs as a valuable pro-innovation service the government provides.

In fact, reconceptualizing drug regulation as a service rendered to the drug industry may even justify shortening patent terms for new drugs. A potential argument could be that if the government provides this service through tax revenues,<sup>81</sup> the public may justifiably insist on demanding earlier competitive supply of new drugs. The quid pro quo argument ("you penalize us by demanding prior approval of new drugs and therefore should compensate us") can be used to promote just the opposite result ("we subsidize *you* by assuring the quality of your products and therefore *we* should get in return lower drug prices earlier").<sup>82</sup>

Yet any such polarized views about the relationship between patents, drug regulation, and innovation would be misleading. Before reaching any conclusion about the implications of this insight on public policy, the following should be considered. First, even if regulatory review of drugs benefits the industry in general, it can only be true up to a certain limit. Clearly, if it took nineteen years to approve a new drug it is less likely that one remaining year of EPL would yield enough profit to make the investment worthwhile. Therefore, regulatory review benefits the industry only if an FDA approved drug, sold under patent for a shorter

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81. Although since 1992, with the enactment of PDUFA, drug companies now shoulder part of the financial burden of funding the FDA, such user fees from drug companies only supplement but do not substitute the FDA's annual appropriation for salaries and expenses. See US GAO, *supra* note 15, at 1.

82. Possibly, if forced to choose between regulation with shorter EPL and non-regulation with longer EPL, drug companies may prefer the former option. But because they are not faced with the need to choose, they may assert the first quid pro quo and enjoy the best of both worlds: the benefits of regulation and longer EPL.

period, generates higher profits than a non-approved drug sold under patent for the full patent term. Second, since we do not know what the optimal patent term is, it is still plausible that patents should be extended despite the positive effects of regulation. Third, recognizing the benefits arising from regulatory approval does not imply that the current regulatory framework is optimal and cannot be improved.<sup>83</sup> Such improvements, by reducing the development time of new drugs or otherwise decreasing development costs, may increase the overall incentive from the combination of patents and regulatory review, and bring new (and presumably better) drugs to the market earlier rather than later. Therefore nothing in this Article should be read as discouraging attempts to improve the current system. Lastly, ultimately determining whether regulation is a burden or a benefit requires considering how effective alternative measures for quality assurance can be. In particular, it requires determining whether public regulation inhibits, substitutes, or complements effective market-based, anti-lemon devices.

Nonetheless, the true opportunity cost of regulation is not simply the forgone profits of a shorter EPL, but should also take into account the possibility that in the absence of regulation and the quality signal that it conveys, drug companies would either have to invest in alternative signaling methods and incur the cost and delay associated with these,<sup>84</sup> enter the market earlier but gain less profit, or refrain from entering altogether. Therefore, even if regulation is less efficient compared to self-regulation or other alternative signaling methods, the actual cost of regulation is only the difference between its cost and the cost of its alternatives. The current literature's failure to acknowledge this pro-industry role of regulation thus tends to overstate its negative impact.

The following section discusses what market-based anti-lemon devices might be used and their applicability to new drugs.

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83. See, e.g., Ernst R. Berndt, Adrian H. B. Gottschalk, & Matthew W. Stobek, *Opportunities for Improving the Drug Development Process: Results from a Survey of Industry and the FDA*, (Nat'l Bureau of Econ. Research, Working Paper No. W11425, 2005), available at <http://ssrn.com/abstract=745818>.

84. In some cases, drug companies found it advantageous from a marketing perspective to conduct more Phase III (pre-approval) and Phase IV (post-approval) tests than the FDA required, hoping to improve their competitive position vis-à-vis competing drugs. See F. M. Scherer, "Pharmaceutical Innovation" 20 (John F. Kennedy Sch. of Gov't, Working Paper No. RWP07-004, 2007) available at <http://ssrn.com/abstract=902395>. Scherer also notes that in pharmaceuticals, "substantial risks of total failure persist later in the research and development cycle than in most other industries," whereby about one-third of the molecules brought into Phase III tests failed getting FDA approval. *Id.* at 4. This suggests that drug companies would not be able to credibly commit to quality without conducting clinical trials on their own initiative. Following a successful completion of Phase III tests, it takes on average an additional one to two years until regulatory approval is obtained. *Id.* at 5.

#### IV. ANTI-LEMON DEVICES

Lemonization of markets, of course, is not an inevitable consequence of information asymmetry. Akerlof himself acknowledged that “numerous institutions arise to counteract the effects of quality uncertainty,”<sup>85</sup> and that in some cases, government intervention may increase sellers’ and buyers’ welfare. This Article focuses on government intervention through mandatory regulatory review and its potential anti-lemonizing effects. However, it may be useful to discuss market-based institutions and their potential limitations.

##### *A. Repeat Purchases*

Repeat purchases may sometimes counteract information failures. As consumers’ positive or negative experiences from consuming a product would affect their decision whether to keep buying the product, producers interested in repeat sales would supply quality to induce a positive experience. This is one significant difference between drugs and used cars: a seller of a used car may not expect repeat purchases, whereas a drug manufacturer may. Yet this difference should not be overstated. The efficacy of the mechanism requires two necessary conditions: 1) consumers must learn the quality of the purchased item sufficiently quickly, and 2) they must renew their purchases sufficiently often.<sup>86</sup> As noted earlier, such conditions likely apply to the efficacy attributes of a few drugs, such as pain killers or Viagra, whereby the consumer can easily identify the symptom and verify the result. In such cases, with repeat use and frequent correlation between drug use and symptom relief, the patient may reasonably infer causation. This may explain why, prior to the therapeutic revolution that began in the late 1930s (which coincided with heightened regulation of drugs), most available effective drugs were limited in their function to the immediate relief of common symptoms, not to curing the underlying condition.<sup>87</sup> Yet for many drugs, and especially those treating more serious and less common conditions, repeat purchases may not be frequent enough and ascertaining efficacy requires expertise that consumers do not usually possess. Furthermore, even when repeated use allows consumers to ascertain drugs’ immediate effect and benefit, they are incapable of evaluating their long run safety and potential complications. Therefore, for many drugs, repeat purchases are unlikely to function well as anti-lemon devices.

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85. Akerlof, *supra* note 66, at 499.

86. TIROLE, *supra* note 59, at 112.

87. TEMIN, *supra* note 37, at 36.

### B. Warranties

Sellers may use warranties to signal quality. By committing themselves to some self-imposed penalty enforceable by consumers if they fail to stand for the claimed quality of a product, sellers signal that the product's quality is indeed high.<sup>88</sup> Yet the signaling effect of warranties may work better in the case of experience goods than in the case of credence goods. Warranties' effectiveness depends on their enforceability, which, in turn, depends on the ability to verify quality. This is why the Carboloc Smoke Ball Company<sup>89</sup> could easily have promised to pay £100 for anyone who contracted influenza after using the carboloc smoke ball even though the ball would not prevent or cure the flu. Failing to anticipate that its own actions would change the law, it assumed that under then-existing contract law such a promise would not be enforceable, even if the fallacy of its promise was easily observable *ex post*. Following the legal change, the company no longer offered the same reward.<sup>90</sup> But even if such promises can be enforced as a matter of contract law doctrine, the inherent difficulty in assessing most drugs' quality in any particular case would make it extremely difficult for a court to verify whether the drug failed to stand for its claimed quality.<sup>91</sup>

### C. Branding and Advertising

Branding and advertising may signal quality in a number of ways and function as anti-lemon devices. First, drug companies may use advertisements to supply information about the quality of their drugs.<sup>92</sup> The problem, of course, is that consumers would not necessarily believe them and may discount the claims altogether. However, the quality signal may not lie in the content of advertising, but rather in the information conveyed by the fact of expenditure on advertising and brand building, even

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88. Sanford J. Grossman, *The Informational Role of Warranties and Private Disclosure about Product Quality*, 24 J. LAW ECON. 461, 470–77 (1981). Akerlof makes a brief early statement of signal theory, which explains warranties as information provided to consumers by manufacturers to inform them of the reliability of a product. *See* Akerlof, *supra* note 66, at 499; Elise Golan et al., *Economics of Food Labeling*, 24 J. CONSUMER POL'Y 117, 128 (2001) (similarly applying warranties and voluntary labeling to food products).

89. *See, e.g.*, *Carlill v. Carboloc Smoke Ball Co.*, [1892] 1 Q.B. 256 (A.C.).

90. *See* Simpson, *supra* note 2, at 371. For a brief period after losing the case, the Carboloc Smoke Ball Co. continued to offer a reward, but only a single one, and subject to "conditions to be obtained on application, a duplicate of which must be signed and deposited with the Company in London by the applicant before commencing the treatment . . ." *Id.* The offer itself remained open for a limited period. *Id.* In later advertisements, the company did not cease to make remarkable claims about the curative qualities of the Smoke Ball, but it stopped offering the reward. *Id.*

91. *See supra* Part III.B.

92. I ignore current regulatory restrictions on drug advertisements.

if such advertising contains no substantive information. Such apparently wasteful expenditures signal quality because they are sunk costs that would not make economic sense unless the firm plans to stay long enough in the market to recover them. Since high quality products are likely to have longer life than low quality ones, large advertising and brand building expenditures signal their quality.<sup>93</sup>

In addition, in those cases in which the advertisement does make claims about the quality of the product and those claims later turn out to be false, the firm risks reputational damage and future liability under false advertising or product liability laws. Therefore, advertising claims about product quality is a risky venture, which a rational firm might not take unless it genuinely believed that the product is as good as advertised.

But these considerations also demonstrate the limits of advertising as a quality signal for credence goods such as drugs. In order to function, the low quality of advertised low quality products should be promptly discovered. Although it is not unreasonable to expect that such information would eventually surface, in the interim, a sufficient number of consumers may insufficiently discount the quality claim and purchase the product to allow recovery of the sunk cost of deceptive advertising. Therefore, in order for ex post discovery of deceptive advertising to provide an ex ante incentive to supply quality, low quality should be able to surface early enough. However, in the case of drugs, this may not happen.<sup>94</sup> In addition, if the injury caused by the low quality drug is very large, the seller may not have the resources to pay a very large damages judgment,<sup>95</sup> and may not face adequate incentives to advertise accurate information. If the injury is too small (e.g., a drug relatively is safe but ineffective), individual victims may not find it worthwhile to sue,<sup>96</sup> and even a class action may not be highly attractive if the damages collectible were small.

Because of such imperfections, some dishonest sellers may find it worthwhile to invest in advertising and branding and free-ride on the reputation of honest sellers. Consumers may respond by discounting the authenticity of all sellers' quality signal.<sup>97</sup> If the number of dishonest

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93. See Benjamin Klein & Keith B. Leffler, *The Role of Market Forces in Assuring Contractual Performance*, 89 J. POL. ECON. 615, 630–33 (1981).

94. The long period that it takes to conduct clinical trials and get FDA approval may indicate that the therapeutic effect of drugs and their safety are not immediately evident.

95. See, e.g., RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 383–84 (6th ed. 2003).

96. *Id.*

97. See *Cal. Dental Ass'n v. FTC* 526 U.S. 756 (1999). In this case, the U.S. Supreme Court, relying on a "lemons" theory, refused to condemn as facially anti-competitive a professional association's rules limiting its members' advertising. The Court noted that "in a market for professional services, in which advertising is relatively rare and the comparability of service

sellers is large enough, and the discount serious enough, lemonization may ensue. Therefore, these devices' effectiveness in preventing lemonization depends on honest sellers' ability to distinguish themselves from dishonest ones, perhaps by investing even more heavily in advertising and branding. Even if this may ultimately weed out dishonest sellers, this may not come without cost. Such sunk costs may increase the entry barriers into the relevant markets, and the reduced competition may cause social losses from an increase in prices or decrease in innovation (although under some conditions such decrease in competition may augment patents leading to increase in innovation).<sup>98</sup>

Drug companies' behavior is consistent with the above, at least where direct-to-consumer advertising is allowed.<sup>99</sup> Drug companies spend heavily on advertising and branding. Historically, this practice began with the discovery of antibiotics, which led to the therapeutic revolution and the emergence of research-based drug companies, as opposed to earlier symptomatic drug companies.<sup>100</sup> Since information asymmetry is greater in the case of therapeutic drugs, the growth and importance of advertising and branding is consistent with their function as anti-lemon devices. Whether advertising and branding would render drug regulation superfluous is difficult to ascertain because, historically, the trend towards advertising and branding coincided with the growth of drug regulation. Thus, while the ability to commit to quality through advertising and branding may support a claim that drug regulation is superfluous, it may also be that by weeding out the dishonest sellers, drug regulation supplements the signal created by advertising and branding and allows the more honest sellers to supply a clearer, and more trustworthy, signal. If that is the case, without drug regulation, drug companies would either have to invest even more in advertising and branding, or might find it impossible to credibly commit to quality through branding. Alternatively, it is also possible that while the signaling effects of regulation and advertising are equivalent, government certification provides a more direct and cost-effective signal.

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packages is not easily established, the difficulty for customers or potential competitors to get and verify information about the price and availability of services magnifies the dangers to competition associated with misleading advertising." *Id.* at 772.

98. It has been debated whether reduced competition induces or inhibits innovation. See, e.g., Philippe Aghion et al., *Competition and Innovation: An Inverted U Relationship*, 120 Q.J. ECON. 701 (2005). I do not intend to solve this debate here. For the purposes of the point made it is enough that, under some conditions, reduced competition inhibits innovation.

99. Currently, among OECD countries, only the United States and New Zealand permit direct-to-consumer advertising of drugs. See Greg Finlayson & Ross Mullner, *Direct-to-Consumer Advertising of Prescription Drugs: Help or Hindrance to the Public's Health?* 22 J. CONSUMER MARKETING 429, 429-31 (2005).

100. TEMIN, *supra* note 37, at 58-87.

#### D. Reputation Economies of Scale

The informational effect of branding can expand if the firm applies the same brand to more than one product. A portfolio of many products associated with a single seller signals the quality of all of its products. This may mitigate some of the deficiencies of branding, advertising, and repeat sales described in the previous paragraphs. As the firm increases the number of products for which it claims high quality, the probability of consumers eventually detecting a false claim made by the firm increases as well. As a result, the risk for the firm of damaging its brand's reputation increases as well, and this reduces the firm's incentive to cheat in the first place.<sup>101</sup> If credibly committing to quality requires a portfolio of drugs, such portfolios may increase the barriers to entry to the industry, and result in the same problems described in the previous section.

Historically, the drug industry has become increasingly more concentrated, and this trend is correlated to the increase in drug regulation.<sup>102</sup> Whether large drug portfolios would suffice to prevent lemonization and render regulation superfluous, or whether regulation supports the ability of firms with smaller portfolios to remain competitive, is a difficult question to answer.

#### E. Rivalry

Market rivalry may give competitors incentives to reveal information about the quality of their rivals' products. If firm *A* provides inadequate information about the quality of its drug, competitor firm *B* may inform consumers that *A*'s drug is not as efficacious and safe as advertised. *B*, for that matter, may not necessarily be a competing drug company, but may equally be a provider of a competing service whose sales decrease when *A*'s drug sales increase. For example, if the use of antidepressant drugs reduces the demand for psychotherapy, practicing psychologists or psychiatrists may seek to inform the public about the ineffectiveness or dangers associated with antidepressants.<sup>103</sup>

However, the role of rivalry in assuring quality of drugs is limited. First, firms may not have sufficient information about the quality of their rivals' drugs, especially in an unregulated market, because there is no requirement to produce such information.<sup>104</sup> Second, even if they do have

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101. See Thomas Liebi, *Trusting Labels: A Matter of Numbers?*, (Univ. of Bern Dep't of Econ. Working Paper No. 0102, 2002), available at <http://ssrn.com/abstract=307080>.

102. TEMIN, *supra* note 37, at 58–87.

103. See, e.g., FROM PLACEBO TO PANACEA: PUTTING PSYCHIATRIC DRUGS TO THE TEST (Seymour Fisher & Roger P. Greenberg eds., 1997) (arguing that there is inadequate scientific information to conclude that psychoactive drugs are substantially more effective than placebos).

104. Even under the existing regulation there is no requirement to disclose the data submitted to the FDA. The pharmaceutical industry has taken the position, which has been

it, the problem inherent with credence goods is that consumers lack the capacity to evaluate each of the competing sides' claim and may discount both sides' claims altogether, unless they have good reason to believe that some claims (for example, if supported by independent scientific research) are more credible than others. If not, suggesting a danger in *A*'s drug may render the consumer suspicious of all drugs or treatments of the same category, including *B*'s. An FDA approval may provide more credibility for *B*. Third, firm *B* may fail to find it beneficial to disclose its knowledge that *A*'s drug is ineffective or dangerous if *B* can profit from selling an equally bad treatment until its futility is ultimately discovered.<sup>105</sup>

#### F. Complementarity

A similar mechanism may develop if drugs complement other products or services. In such cases, the low quality of a drug may impose a negative externality on the suppliers of the complement good, particularly if the consumer cannot ascertain which component of the combined treatment was harmful or ineffective. The supply of drugs and medical care demonstrates such complementarity. Physicians clearly benefit when they can provide their patients with high quality drugs (if the two are complements rather than substitutes), and may face lower demand for their services if only quack medicines are available.<sup>106</sup>

Two observations follow. First, drug companies may not bear the full cost of low-quality drugs and therefore may have a less-than-perfect incentive to supply high quality. Second, physicians may seek to minimize this negative externality by demanding verifiable information about drugs' quality claims. However, physicians are numerous and dispersed and may not individually find it beneficial or possible to exert pressure on drug companies, although several mechanisms and institutions allow physicians to overcome this collective action problem. For example, as early as 1905, the American Medical Association (AMA) decided to ban advertisements of ineffective nostrums in its *Journal of the American Medical Association*. The AMA established the Council on Pharmacy and Chemistry to test the proprietary medicines and determine which, if any, could substantiate their curative claims. The results would then be

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supported by the FDA, that the data are trade secrets belonging to the submitting firm. Eisenberg, *supra* note 41, at 380.

105. See, e.g., Trudo Lemmens, *Piercing the Veil of Corporate Secrecy about Clinical Trials*, 34 HASTINGS CENT. REP. 14, 15 (2004) ("Competitors will not challenge a company's claim that anxiety, shyness, premenstrual dysphoric disorder, and post-traumatic stress disorder are endemic and have to be aggressively treated with medication.").

106. The reverse is probably true as well: drug companies may benefit from high quality medical profession.



published in the *Journal*.<sup>107</sup> Publicly-funded research, carried out by physician-researchers may be another example of a mechanism that alleviates this collective action problem. On the other hand, it will not always be in physicians' and their organizations' best interest to disclose negative information on drugs. In some cases, realizing that the dissemination of negative information would hurt the demand for their services, physicians and other medical institutions may decide to conceal such information.<sup>108</sup>

Another complication comes from yet another direction. Even when exerting pressure on drug companies to supply high-quality drugs is in the best interest of physicians, the collective action problem described above implies that only collective pressure would be effective. Such collective pressure would inevitably involve a risk of allegations of illegal boycotting and potential antitrust liability. In *Wilk v. AMA*,<sup>109</sup> for example, the Court of Appeals for the Seventh Circuit affirmed the lower court's decision that a rule promulgated by the AMA Committee on Quackery, which made it unethical for physicians to professionally associate with chiropractors, violated section 1 of the Sherman Act. The court rejected the AMA's argument that the boycott was pro-competitive because it was a response to a market failure caused by information asymmetry. The AMA advanced a lemons story arguing that because the market for medical services is one in which consumers lack sufficient information to evaluate the quality of medical services, consumers would avoid necessary treatment for fear of fraud and accept treatment with no expectation of quality. According to the AMA, its conduct ensured that

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107. Letter from the Council on Pharmacy and Chemistry, American Medical Association, to the Manufacturing Pharmacists and Chemists of the United States and to Others Concerned, 44 J. AM. MED. ASS'N 719 (1905). See also YOUNG, *supra* note 9, at 187–88. Dependency on advertising revenue, however, seems to have prevailed. In the early 1950s, concerns about advertising revenues led the AMA to stop publishing lists of fraudulent and useless drugs in its publications. See Trudo Lemmens, *Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene*, 32 J.L. MED. & ETHICS 641, 646 n.60 (2004), (citing PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 127 (2003)). Similarly, the *New England Journal of Medicine* recently announced that it would not always enforce a rule requiring the disclosure of authors' financial interests, as it has become increasingly difficult to find researchers who do not have financial links with producers or competitors. *Id.* at 646.

108. See Lemmens, *supra* note 105 (explaining how various financial interests affect research or the disclosure of its result by non-industry actors who otherwise would have an interest in obtaining and disseminating such information). See also TEMIN, *supra* note 37, at 29 (noting that the AMA decision from 1905 to eliminate nostrum ads from *JAMA* was dropped by the following year). Temin also reports that in 1929, the AMA reinstated such a program (the "Seal of Acceptance" program), only to drop it in the mid-1950s. According to Temin, the primary reason for the policy change was AMA's need for cash, which unrestricted advertising could—and did—generate. *Id.* at 85–86.

109. *Wilk v. Am. Med. Ass'n*, 895 F.2d 352 (7th Cir. 1990), *cert. denied*, 498 U.S. 982 (1990).

physicians acquired a reputation for quality, in part by not associating with chiropractors, which the AMA regarded as “unscientific cultists.”<sup>110</sup> It also allowed consumers to be assured that physicians would use only scientifically valid treatment. The court rejected the argument, noting that while “[g]etting needed information to the market is a fine goal . . . the AMA was not motivated solely by such altruistic concerns . . . [and] intended to ‘destroy a competitor,’ namely, chiropractors.”<sup>111</sup> The AMA also failed to show that its measures to address concerns for patient care could not be achieved “in a manner less restrictive of competition.”<sup>112</sup> While eliminating antitrust liability may enhance professional groups’ ability to self-regulate, such a move may not always be desirable. Because the group seeks to maximize its members’ net gain, and extra profits may be achieved at a lower level of total output, the quality standard chosen by professional groups may exceed the socially optimal level.<sup>113</sup>

### G. Information Intermediaries

Because consumers cannot observe credence qualities even after consumption, sellers and buyers can only partially rely on the above mentioned mechanisms to signal quality. This is when quality assurances supplied by third parties, who act as information intermediaries, may be used. There are three types of information intermediation: advice, certification, and licensing.

#### 1. Advice: Physicians and Pharmacists

Consumers can hire advisers whose training, talent, or investment of time and effort in collecting information allows them to know more about credence goods’ quality. Physicians and pharmacists can fulfill this function regarding drugs by acting as disinterested experts, or learned informational intermediaries, to alleviate some of the problems that re-

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110. *Id.* at 361.

111. *Id.*

112. *Id.* at 363.

113. Hayne E. Leland, *Quacks, Lemons, and Licensing: A Theory of Minimum Quality Standards*, 87 J. POL. ECON. 1328, 1339 (1979). In the context of physicians and drugs, the concern could be that physicians would adopt excessive quality standards to boycott safe and effective drugs that could reduce the demand for their services. This is why the majority opinion in *California Dental Association*, 526 U.S. 756, to the extent that it limits antitrust scrutiny of self-regulation, is troublesome. As Professor Hovenkamp explains, the Court erred not in finding that the market for dental services is prone to lemonization but in concluding that “the dentists themselves were worthy policemen to protect [consumers].” Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 22 (2004).

sult from information asymmetry.<sup>114</sup> Arguably, physicians who prescribe drugs (as well as the pharmacists that fill the prescriptions) have access to extensive information regarding the properties of the drugs. Physicians also have extensive medical training and continually update this information through medical literature and professional seminars that can be drawn upon to brief the patient regarding the consequences of the drug.<sup>115</sup> A similar rationale stood behind the Federal Food, Drug, and Cosmetic Act of 1938, which introduced, among other things, the prescription-only regulation, which assumed that consumers are not competent to make informed decisions regarding drugs, and that physicians should make the choice in their stead.<sup>116</sup>

However, using advisers is an imperfect anti-lemon device. First, they may have less-than-optimal incentives to invest in gathering information because it is a public good.<sup>117</sup> Second, just as with the quality of drugs, verifying the quality of the services rendered by information intermediaries is costly because such services are credence goods themselves. This may explain why physicians and pharmacists are themselves subject to licensing requirements and ongoing regulation by governments or by the professions' self-regulatory bodies, and why they have developed norms that value trust relationships with patients and an ethos of priority of the patient's welfare over the physician's profit-maximization.<sup>118</sup>

Third, while physicians and pharmacists are better positioned than their patients to evaluate drugs' quality claims, they cannot fill their patients' information gap until a drug has been utilized long enough to allow gathering, processing, and communication of sufficient information about its safety and efficacy. However, in the case of *new* drugs, a physician will be only slightly better positioned than the consumer regarding efficacy

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114. W. K. Viscusi, *Efficacy of Labeling of Foods and Pharmaceuticals*, 15 ANN. REV. PUB. HEALTH 325, 327 (1994).

115. *Id.*

116. TEMIN, *supra* note 37, at 54. The prescription-only regulation presents another interesting effect of drug regulation, which complements, rather than undermining the patent system. As Temin explains, when a drug is sold only under prescription, the demand for the drug becomes much less elastic because the prescribing doctor is insensitive to the price and the patient (or the insurer) cannot purchase an alternative drug, even if she prefers to. As a result, drug companies could charge much higher prices for their products. In most cases the drug company decides whether to designate a drug as "prescription only," and drug companies failed to oppose this aspect of regulation. *Id.* at 52–54.

117. GRABOWSKI & VERNON, *supra* note 27, at 67.

118. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 966 (1963).

and safety.<sup>119</sup> The physician may be able to identify whether some claims make sense, but she does not have any meaningful information about side effects, interactions with other drugs, and efficacy of treatment until they are tested. But even in the case of drugs already on the market, assessing their quality is beyond the professional capability of any individual physician or pharmacist. Not only is the concept of effectiveness itself vague, however dramatic the effect of a drug on one person may be, meaningful information on drugs' quality can be obtained only by looking at large samples and carefully applying statistical methods.<sup>120</sup> This type of research is beyond the ordinary skills of most practicing physicians and pharmacists, and even if they had the skills, writing prescriptions or dispensing drugs may not allow enough time for applying them.<sup>121</sup> Of course, physicians and pharmacists do not necessarily have to conduct research on their own, and theoretically they can rely on research done by others if such information exists and is made available to them. However, practicing physicians are notoriously incapable of gathering and processing enough information about new and existing drugs and treatments, and as a result tend to exhibit strong habit persistence in their treatment decisions.<sup>122</sup>

Similarly to their patients, physicians will average the claims regarding new drugs in the absence of credible quality assurance. Regulatory review, therefore, may provide the critical mass of credible evidence necessary to persuade physicians to start or continue prescribing a drug. Once they start prescribing the new drug, they could gather more information and make it available to other physicians.<sup>123</sup> Therefore, even in the absence of mandatory regulation, given the risk aversion of many physicians and their tendency to follow habit,<sup>124</sup> drug companies that seek to rely on them as intermediaries would have to conduct lengthy

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119. See Avorn, *supra* note 64, at 72 (claiming that even with FDA approval, "when a new drug is first marketed, little is known about its safety and efficacy compared to existing alternatives, and the situation is often no clearer years or decades later.").

120. TEMIN, *supra* note 37, at 9–10.

121. Bernstein & Bernstein, *supra* note 50, at 616 (discussing the danger of information overload affecting physicians).

122. See generally Ramkumar Janakirnam et al., *Physicians' Persistence and its Implications for their Response to Promotion of Prescription Drugs*, MANAGEMENT SCIENCE (forthcoming 2007), available at <http://ssrn.com/abstract=1016602> (reviewing the literature on physicians' persistence and finding empirical support for its magnitude). See also Avorn, *supra* note 64, at 270–71.

123. Physicians are allowed to prescribe and pharmacists are allowed to dispense drugs for "off label" use, i.e., purposes other than those approved by the FDA, as long as the off-label use was generally recognized as acceptable in the scientific community. The general rules governing their professional liability would apply.

124. Janakirnam et al., *supra* note 122. See also Scherer, *supra* note 14, at 101.

and costly trials to produce enough evidence to convince physicians to prescribe new drugs.<sup>125</sup>

## 2. Certification

Similarly to advisers, trusted third parties may alleviate the market failures that result from information asymmetry by certifying the quality of credence goods. Unlike advisers, usually retained by the consumer, the clients of the certifying entity are the sellers. Firms commonly use voluntary third-party quality certificates to assure the quality of products, especially to signal the quality of their experience or credence attributes. Examples are abundant. The International Organization for Standardization's ISO 9000 is widely used to certify "quality management," or in ISO's language, it aims to "fulfill[] the customer's quality requirements, and applicable regulatory requirements, while aiming to enhance customer satisfaction, and achieve continual improvement of its performance in pursuit of these objectives."<sup>126</sup> As consumers are increasingly interested in the environmental impact of firms' production processes, a credence property, ISO has begun issuing its ISO 14000, primarily concerned with "environmental management."<sup>127</sup> ISO 14000 certifies "what the organization does to[] minimize harmful effects on the environment caused by its activities, and to achieve continual improvement of its environmental performance."<sup>128</sup> The range of credence quality certificates includes the ancient Kosher certification in Jewish communities,<sup>129</sup> environmental certificates, organic products, socially conscious "Fair Trade" labels,<sup>130</sup> and the recently proposed "Fair Employment Mark" that companies can apply to their products and services to indicate that they have promised not to discriminate on the basis of sexual orientation.<sup>131</sup>

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125. Some may regard this prediction as naïve and may argue that instead of investing more in scientifically establishing the quality of their drugs, drug manufacturers will invest in bribing physicians through lavish promotional expenditures in the guise of "educational" activities. See, e.g., ANGELL, *supra* note 15, at 141–43.

126. See International Organization for Standardization, ISO 9000 and ISO 14000, [http://www.iso.org/iso/iso\\_catalogue/management\\_standards/iso\\_9000\\_iso\\_14000.htm](http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000.htm) (last visited Nov. 3, 2007).

127. *Id.*

128. *Id.*

129. See, e.g., Shayna M. Sigman, *Kosher Without Law: The Role of Nonlegal Sanctions in Overcoming Fraud Within the Kosher Food Industry*, 31 FLA. ST. U. L. REV. 509 (2004) (discussing the Kosher industry).

130. See Maria L. Loureiro & Justus Lotade, *Do Fair Trade and Eco-Labels in Coffee Wake Up the Consumer Conscience?*, 53 ECOLOGICAL ECON. 129, 129–30 (2005) (describing the origins and meaning of fair trade labels).

131. See IAN AYRES & JENNIFER GERARDA BROWN, STRAIGHTFORWARD: HOW TO MOBILIZE HETEROSEXUAL SUPPORT FOR GAY RIGHTS 79–94 (2005).

While certification may alleviate some concerns about quality, it suffers from several drawbacks. First, certification itself is a credence good, hence the eternal question remains: *quis custodiet ipsos custodies?*<sup>132</sup> Second, if with regard to a certain attribute more than one certifying body exists, each employing different standards, the signals provided may become blurred. Third, consumers may suspect a certifying body that financially depends on its clients. Certifying bodies would therefore need effective quality assurance mechanisms as well, which may not work perfectly.

### 3. Licensing

In the case of licensing, a third party, such as the government, determines which product or seller may enter the market. Unlike certifying, which is voluntary, licensing is mandatory and requires the state's involvement.<sup>133</sup> Licensing may assure quality by directly regulating the product through output regulation, or indirectly, by setting minimum requirements for firms in the industry through input regulation.<sup>134</sup> Current drug regulation is an example of the former. It requires a license to market every drug. Occupational licensing, which is common in medical, legal, and other professions is an example of the latter.<sup>135</sup> It does not directly regulate the quality of the service but instead seeks to ensure "that professionals engage in a minimum level of human capital investment."<sup>136</sup>

It is by no means suggested here that licensing may not be susceptible to failures of its own. Asking *quis custodiet ipsos custodies* may be appropriate to the licensing agency as well. The FDA, for example, has been criticized for being inherently over-cautious because the institutional incentives confronting its officials lead them to concentrate on avoiding Type-I errors, approving drugs that are not safe and effective, and ignoring Type-II errors, keeping off the market safe and effective drugs.<sup>137</sup> Regulatory capture, which may lead to too lax regulation, is

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132. Who shall guard the guardians?

133. An industry may also determine which products will be sold and by which sellers. Such attempts, however, without endorsement by the government, may run afoul the antitrust laws.

134. See Carl Shapiro, *Investment, Moral Hazard, and Occupational Licensing*, 53 REV. ECON. STUD. 843, 844 (1986).

135. It is conceivable to imagine a different model of drug regulation under which the FDA would set minimum testing and manufacturing standards to which all drug companies would have to adhere and debar those companies with a negative track record.

136. Shapiro, *supra* note 134, at 844.

137. GRABOWSKI & VERNON, *supra* note 27, at 10 (explaining that FDA officials committing Type-II errors may bear heavy personal costs because the effects of such errors can be highly visible and are one for which both the FDA and the official are held politically accountable, whereas the effect of Type-I errors are much less visible and are borne largely by

another concern.<sup>138</sup> Moreover, licensing may be an excessive solution to the lemons problem. In the used cars example, the problem arises because sellers of good cars cannot differentiate themselves from sellers of bad cars and cannot exact a price that will keep them in the market. But while the quality of used cars varies, so too do the preferences and risk tolerance of consumers. Even bad cars, if sold at a sufficient discount, may be a bargain for some consumers. If a credible signal for each quality type can be communicated, so that buyers can choose from a menu of different price/quality matches, total exclusion of bad cars makes no sense. The same is true for drugs. The current licensing structure only allows sales of new drugs which meet a certain threshold of efficacy and safety. Yet even a banned drug can be the best available drug for some consumers for several reasons. First, the FDA approves only new drugs whose average therapeutic effect is higher than the average therapeutic effect of a placebo, but merely because the drug's average effect fell below the average for the entire sampled population does not mean that it is ineffective to members of some non-identified sub-groups or individuals.<sup>139</sup> Second, different drug users may have different safety/efficacy preferences. For example, a patient whose odds of remaining untreated are even worse may be willing to take an effective but dangerous drug, or may be rationally willing to spend money on long shots, even when he knows that they are no more than long shots.

#### H. *Ex post Liability*

Legal liability may also supply direct and indirect incentives for quality. Tort law may eliminate the marketing of harmful products and the negligent provision of services. Contract law and consumer protection laws may hold sellers liable for false quality claims. Such laws, which may be reinforced by criminal liability, directly decrease the sale of low quality products by making their sale more costly. They also indirectly promote quality by making it easier for sellers credibly to commit to quality. Procedural instruments, such as class actions, may make the

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outside parties (drug companies and sick patients)); see also RICHARD A. EPSTEIN, *OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION* 116–18 (2006).

138. For the classic statement of capture, see George Stigler, *The Theory of Economic Regulation*, 2 *BELL J. ECON. & MGMT. SCI.* 3 (1971) (explaining that regulators sometimes serve the interests of the regulated rather than the public interest).

139. EPSTEIN, *supra* note 137, at 120 (citing Anup Malani & Feifang Hu, *The Option Value of New Therapeutics* 1 (October 25, 2004) (unpublished manuscript)). The new science of “pharmacogenomics” might remedy this problem by connecting variations in drug receptivity to differences in recipients’ DNA sequences, thus optimizing drug therapy to ensure maximum efficacy with minimal adverse effects, and making clinical trials more precise and possibly less costly. See Scherer, *supra* note 84, at 11–12.

former more effective by aggregating small claims that otherwise would be too costly to litigate and by overcoming problems of collective action among many victims. Regulatory agencies, even if not engaged in licensing or certification, may enhance adherence to higher quality by using their coercive powers to obtain information, by exploiting increasing returns to scales to gather information on products' less observable qualities, and by bringing lawsuits against sellers making false claims or selling products of a quality below prescribed standards.

However, relying on ex post liability to assure effective ex ante incentives to supply quality drugs depends on the ability of a court to verify ex post that quality claims were false or that the drugs were harmful. But in the case of credence goods, whose quality is inherently difficult to ascertain, even in retrospect, courts may only suboptimally impose liability, potentially leading to under- or over-deterrence.<sup>140</sup> Theoretically, under-deterrence may be corrected by increasing the penalty, criminal or civil, but this may provide only partial solutions and may create its own distortions.<sup>141</sup> Paradoxically, increased liability may even lead drug companies to keep bad products on the market and avoid gathering information about the effects of their products, or doing anything else that might signal bad quality. A drug company may fear that the public would view such actions as a "confession" that the drug is harmful and invite an eruption of lawsuits which, given the information asymmetry, would otherwise be unlikely.<sup>142</sup> Over-deterrence may occur when courts or juries are overly sympathetic to plaintiffs' claims, especially when an individual plaintiff person sues a deep-pocket pharmaceutical corporation. Over-deterrence may be just as serious a social problem as under-deterrence. Both would reduce the number of available quality drugs. From the point of view of solving the lemons problem, however, the respective effects are not symmetric. Under-deterrence may cause lemonization, whereas over-deterrence may solve it, although perhaps excessively.

These two possible distortions suggest that relying solely on ex post litigation initiated by individuals would not be the best way to deal with such complex issues, and that some form of regulatory oversight by an administrative agency may be desirable. As even Richard Epstein—not

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140. Leland, *supra* note 113, at 1330 (noting that making sellers liable for poor quality products or services may only be useful when product failure is readily observable ex post, whereas "it may be difficult or impossible to ascertain product failure in cases where the effect is long, delayed and partial").

141. See generally STEVEN SHAVELL, *FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW* (2004).

142. Omri Ben-Shahar, *The (Legal) Pains of Vioxx: Why Product Liability Can Make Products More Dangerous*, 3 *THE ECONOMISTS' VOICE* 1, 2–3 (June 2006), available at <http://www.bepress.com/ev/vol3/iss6/art6>.



known for his fondness of centralized government control—has noted: “Administrative review has the unfortunate feature of centralized control, which is difficult to correct. But whereas the tort system privileges extreme outcomes, the administrative system, suitably capped, is less likely to run off the rails.”<sup>143</sup>

## V. PUBLIC VS. SELF-REGULATION

I noted earlier that many suppliers of credence goods, other than pharmaceuticals, find it in their best interest to signal quality by using third-party certifiers. This suggests two things. First, that signaling achieved by other market mechanisms such as repeat purchasers, warranties, and advertising may fail to solve fully the problem of information asymmetry in such industries. Second, that government regulation may function as a substitute for similar forms of third-party certification that drug companies would otherwise have to set up. The cost and delay associated with such certification may simply represent the inherent costs of selling credence goods. Therefore, the view that regulation is in fact a valuable service may replace the notion that new-drug regulation is a burden imposed on the industry. Yet merely recognizing that regulation by the government may substitute for forms of self-regulation fails to tell us which type of regulation is preferable. It only tells us that it is plausible that government regulation would be preferable. Answering this question requires comparing the relative costs and benefits of each method.

One immediate benefit that the industry may derive from public regulation would be the erection of barriers to entry and other benefits associated with regulatory capture.<sup>144</sup> This benefit to the industry counsels against such forms of regulation, unless such benefits to the industry translate into a higher expected return on its R&D, thus complementing the patent system in another manner. I raise this potential negative regulatory effect but will now set it aside, not because it is unimportant, but because I would like to focus on the under-researched way in which publicly-supplied drug regulation benefits the industry in a way that *is* aligned with the public interest. The focus is on the ability of drug regulation and

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143. EPSTEIN, *supra* note 137, at 236.

144. See Stigler, *supra* note 138. Cf. Daniel Carpenter, *Protection Without Capture: Product Approval by a Politically Responsive, Learning Regulator*, 98 AM. POL. SCI. REV. 613, 626–27 (2004) (considering capture theory as it relates to the FDA and arguing that while capture may exist, it does not necessarily fully explain evidence of barriers to entry and large firm advantage in regulated markets).

approval to remedy information asymmetry and save the drug markets from the fate of lemonization.

#### A. *Some Advantages of Public Regulation*

Despite its well-documented shortcomings, public regulation may present several advantageous features not easily available to self-regulators. First, public regulation may be doing a better job in aligning the various interests of the public, the industry, and individuals such as managers. Avoiding the failures that result from information gaps is in the interest of both industry and consumers, yet assuring quality is a public good. Once a quality assurance mechanism has been set up, each firm faces an incentive to cheat and free-ride on the reputation of the industry. Similarly, managers may face an incentive to cheat in order to gain short-term profits and a short-term increase in the firm's valuation without internalizing the longer term damage to the reputation of the firm and the industry.

Under either type of regulation some firms may seek to free-ride on the reputation of the regulated firms. They may do so by failing to opt into the regulatory scheme either entirely or selectively. For example, they may not submit any drug for certification or submit some, but not all. Other forms of cheating may include obtaining approval by submitting false or incomplete information, concealing negative information after approval was granted, continuing to market a drug even if it becomes known ex post that the approval should not have been granted, or bribing the certifying entity or its officials. But while the incentives to cheat exist under either type of regulation, self-regulation schemes may be less effective in preventing it. For example, self-regulators would not generally have the ability to exclude such drugs from the market. Of course, they may seek to mitigate these problems by incorporating appropriate elaborate terms in the relevant governing contracts, or by boycotting defiant members or third parties. However, executing such provisions and boycotts may be highly ineffective or extremely costly, and could also involve the entities in antitrust<sup>145</sup> and other legal difficulties.<sup>146</sup> In addition, how effective certification schemes are depends on how well consumers can distinguish between certified and non-certified drugs and recognize the differences between the certified and the non-certified, or between different variants of certification.

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145. *See supra* Part IV.F.

146. For example, the tort of wrongful interference with an economic relationship. *See generally* Louis Altman & Malla Pollack, 2 CALLMANN ON UNFAIR COMPETITION, TRADEMARKS, AND MONOPOLIES § 10:28 (4th ed. 2007).

In contrast, by harnessing state power, licensing through a public regulatory scheme may do a better job in preventing these kinds of cheating. First, as opposed to voluntary licensing or voluntary certification, a regime of mandatory licensing that applies to all drugs prevents free-riding by opting out as described above. Second, to discourage cheating by falsifying information, the FDA may demand information, inspect and enter manufacturers' facilities,<sup>147</sup> withdraw marketing approval if approval was granted based on bribery, fraud, or similar act, or if the drug maker "repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce."<sup>148</sup>

In addition, penalties ranging from civil sanctions to criminal fines and imprisonment, as well as excluding non-compliant individuals or firms from the market, may assist in reducing the incentives to cheat in a manner that would not be at the disposal of private certifiers. Even if self-regulators could effectively prevent cheating, the inherent potential for anti-competitive abuse may make self-regulation less attractive than it otherwise would seem.<sup>149</sup>

Moreover, if an important benefit of regulation is not only excluding dangerous or ineffective drugs from the market, but also providing quality assurance to consumers with regard to the drugs that are marketed, then public regulation may possess advantages over self-regulation if consumers trust a public regulatory agency more than they would a private entity, particularly one that is funded by or financially dependent on drug producers.<sup>150</sup> Indeed, the FDA ranks high in public trust. In a 2000 survey by the Pew Research Center and Princeton Survey Research Associates, the FDA received an overall favorable rating of over eighty percent, more than twice the approval rate of the entire government and higher than other federal agencies studied.<sup>151</sup> While public trust in the

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147. 21 U.S.C. § 374 (2004).

148. *Id.* § 335(c)(a).

149. See *supra* Part IV.F. Of course, public regulation is not immune to successful attempts by the regulated industry to obtain regulation that advances its anti-competitive agenda. See, e.g., Richard A. Posner, *Theories of Economic Regulation*, 5 BELL J. ECON. & MGMT. SCI. 335 (1974).

150. TIROLE, *supra* note 59, at 110 n.19; Peltzman, *supra* note 31, at 1052 n.1.

151. Pew Research Center for the People & the Press, *Performance and Purpose; Constituents Rate Government Agencies* (April 12, 2000), <http://people-press.org/reports/display.php3?ReportID=41>. Spam e-mails provide more anecdotal evidence for consumers' valuation of the regulatory process. Attempting to sell fake medicines, many spammers falsely state that those drugs are "FDA APPROVED," thus indicating their belief in the promotional power of such FDA designation. Accordingly, spam filters often include the term "FDA APPROVED" in their lists of suspicious terms. Examples of such spam e-mails are on file with the author.

FDA has deteriorated recently, trust in the pharmaceutical industry has declined even further.<sup>152</sup>

As mentioned earlier, the FDA is inherently over-cautious, focusing on avoiding Type-I errors (approving drugs that are not safe and effective) and ignoring Type-II errors (rejecting safe and effective drugs).<sup>153</sup> Notwithstanding the social costs arising from this tendency, one benefit accruing to the manufacturers of those drugs that are approved is a stronger signal about their quality. If consumers recognize the FDA's tendency to be overcautious, their confidence in the quality of *approved* drugs increases.

### B. Regulation's Real Effects vs. Placebo Effects

In the previous sections I have suggested why regulation of new drugs may function as an anti-lemon device and why it may do a better job in assuring new drugs' quality compared to market-based devices. Whether the FDA or equivalent regulators in other countries actually function better than the market, requires additional studies beyond the scope of this Article. However, in evaluating the impact of drug regulation on social welfare, such studies should consider not only the objective effects of the regulation, but also their "placebo effects," or the way regulation manipulates the subjective beliefs of consumers and other market participants about the effect of regulation.<sup>154</sup> The important fact here is not whether, objectively, the FDA does a better job than private market-based institutions in distinguishing between high- and low-quality drugs. What is important are consumers' subjective beliefs about the trustworthiness of such institutions. If consumers trust the FDA more than they would trust a self-regulatory body, they will discount the quality assurance of the private entity and would be willing to pay less for such drugs even if objectively the private entity would do a better job. If this is the case, public regulation would be preferable over self-regulation from both the consumers' and the drug companies' points of view.

Commentators have often pointed out that the main reforms in drug regulation followed widely publicized scandals, the Elixir Sulfanilamide scandal in 1937, and the Thalidomide scandal in 1961.<sup>155</sup> Some have re-

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152. Carpenter, *supra* note 51, at W5-470.

153. GRABOWSKI & VERNON, *supra* note 27, at 10; *see also* EPSTEIN, *supra* note 137, at 116-18.

154. *See generally* Amitai Aviram, *The Placebo Effect of Law: Law's Role in Manipulating Perceptions*, 75 GEO. WASH. L. REV. 54 (2006).

155. *See, e.g.*, Paul J. Quirk, *Food and Drug Administration*, in *THE POLITICS OF REGULATION* 191, 196, 199 (James Q. Wilson ed. 1980); GRABOWSKI & VERNON, *supra* note 27, at 2-3.

marked that the actual reforms adopted covered much broader ground than was necessary to prevent these incidents.<sup>156</sup> However, the argument may actually indicate a placebo effect of drug regulation. Both the Elixir Sulfanilamide and Thalidomide incidents were highly publicized and involved highly visible tragedies, including 107 deaths of mostly children in the case of Elixir Sulfanilamide, and birth defects in the case of Thalidomide. These may have caused the exact three forms of cognitive biases which, according to Aviram may cause the public to overestimate risks: availability bias, vividness bias, and social amplification.<sup>157</sup> Thus, the reforms might have overreacted when considering the objective risk of new drugs, but that overreaction might have been necessary to de-bias the public's perception of the risk.<sup>158</sup>

## VI. FINAL NOTE

So far, the possibility that drug regulation prevents the lemonization of the pharmaceutical industry and benefits drug innovation has been largely ignored by the scholarly literature on the industry, which was predominantly influenced by Peltzman's early 1970s studies. However, one of the few who did think about this possibility was Peltzman himself.<sup>159</sup> In a footnote he raised the possibility that the 1962 Amendments provided a "public good" for the drug industry, in the form of independent evaluation

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156. See, e.g., TEMIN, *supra* note 37, at 43 (tangentially-related legislation being enacted after the elixir sulfanilamide tragedy); *id.* at 123–26 (arguing that the bill for the 1962 Amendments then pending in the Senate would have done little to prevent the thalidomide tragedy and actually reflected the FDA's concerns, not the public's).

157. Aviram, *supra* note 154, at 71–75. The availability bias causes people to "assess the frequency of a class or the probability of an event by the ease with which instances or occurrence [sic] can be brought to mind." *Id.* at 71 (quoting Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty—Heuristics and Biases*, 185 SCI. 1124, 1127 (1974)). The vividness bias "causes individuals to place more weight on concrete, emotionally interesting information than on more probative abstract data." *Id.* at 73 (quoting Harry S. Gerla, *The "Reasonableness" Standard in the Law of Negligence: Can Abstract Values Receive Their Due?*, 15 U. DAYTON L. REV. 199, 210 (1990)). Additionally,

Social amplification is a heuristic by which an individual relies on others' beliefs when the individual has little independent knowledge of the matter. This reliance causes people to perceive as more probable those risks that also concern others. As a result, highly visible, dramatic events that capture media attention generate immense public concern that is disproportionate to the actual risk.

*Id.* at 74–75.

158. In fact, as mentioned earlier, the literature has recognized the public's and the physicians' reluctance to consume and prescribe new drugs following the thalidomide incident as a cause for the decline in new drug introductions. It appears that even the 1962 Amendments were not fully or immediately effective in de-biasing the perception of risk.

159. See also Law, *supra* note 9; Carpenter, *supra* note 51.

and certifications, but was quick to dismiss the argument by noting that if “private underproduction of new drug evaluations is corrected by the Amendments, the demand price of new drugs would be increased more than the costs of complying with the amendments, and new-drug output would rise.”<sup>160</sup> But because he observed a marked decline in new drug output, which he attributed to the Amendments, he quickly rejected the hypothesis.<sup>161</sup>

Yet a broader historical perspective on the pharmaceutical industry may give greater credence to the beneficial effects of drug regulation. When one examines nineteenth-century drug markets, as described in the introduction, one observes the quintessential example of a lemons market. Historically, the pharmaceutical industry’s transformation from its lemon state to its current highly scientific nature coincided with the introduction and expansion of drug regulation. Moreover, the decline in NCEs introduced during the 1960s and 1970s, which engendered the antinomy between regulation and innovation, has changed its course since the 1980s. During the 1980s, the number of approvals per year increased 35% to 18.5. In the 1990s, the approvals grew an additional 48% to 27.4.<sup>162</sup> The turnaround in NCEs since the 1980s has been explained by adaptation of drug companies to the new regulatory regime,<sup>163</sup> as well as new discovery opportunities from breakthroughs in biochemistry, enzymology, molecular biology,<sup>164</sup> and genetic engineering.<sup>165</sup> More recently there has again been a downturn.<sup>166</sup> Overall, the average number of approved NCEs per year in the 1970–2005 period was 21.4 “with a statistically significant upward trend.”<sup>167</sup>

Prudence counsels against immediately concluding from this observation that the transformation of the pharmaceutical industry’s dismal state in the nineteenth century to its current nature is attributable to the anti-lemon role of drug regulation. Clearly, other factors determining the quality of drugs did not remain constant. Many institutions such as contract law, tort law, consumer protection laws, and class actions, necessary to support market-based lemon devices, such as those described above,

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160. Peltzman, *supra* note 31, at 1052 n.1.

161. *Id.* at 1052. Peltzman’s quick dismissal of the hypothesis may also be explained by the fact that at the time he wrote his paper, economic analysis of markets with information asymmetries was a newly emerging field of economic research. Akerlof’s lemons paper was published in 1970 and Peltzman’s in 1973.

162. Dimasi, *supra* note 38, at 1172.

163. *Id.*

164. *Id.*

165. Scherer, *supra* note 14, at 100.

166. Scherer, *supra* note 38, at 927.

167. Scherer, *supra* note 84, at 3 (excluding 1995 and 1996 from the average due to an unusually high upward trend).

have developed as well. And above all, the scientific basis for medical care and pharmaceutical development and production has grown profoundly since the days Mrs. Carlill purchased her carbolic smoke ball and contracted the flu. Arguably, life sciences and pharmacology would have advanced regardless of drug regulation, and as Peltzman argues, the “natural progress of opulence”<sup>168</sup> could mask the negative effects of regulation and allows it to survive politically because “[m]edical progress of all kinds continues. Beneficial new drugs, however delayed, ultimately do make it to market.”<sup>169</sup> Yet, assuming that science advances “naturally” seems a bit naïve. “Academic science is transformed into [beneficial new drugs] through richly interconnected networks.”<sup>170</sup> Commercial prospects drive at least some scientific endeavors, whether such research occurs within the laboratories of drug companies, with their financial support, or even in publicly funded research institutions. If we observe tremendous medical progress, it is likely that the present institutions are conducive to such progress. Of course, observation tells us nothing about the effect of any particular institution, only that their aggregate effect is conducive to medical progress. Therefore, Peltzman’s point that without regulation progress would be even greater is, while non-falsifiable, still entirely plausible. However, I believe that the Akerlovian insights suggested in this Article, combined with a broader historical perspective on the development of the industry, allow us to give more credit to the beneficial aspects of drug regulation than that given by most economists who have studied the area. At least, these insights allow us to acknowledge the complexity of the issues.

## VII. CONCLUSION

Current literature predominantly treats the regulation of drugs as a drag on innovation: while patents are expected to encourage investment in research and development of new drugs, the cost and delay caused by new drug regulation reduces the expected return on such investment and thereby reduces the incentive to innovate. On the basis of this argument, drug companies have successfully lobbied legislators in the United States, Japan, the European Union, and other countries for laws permitting the extension of patent terms. This Article has shown that new drug regulation may serve as an anti-lemon device, thus providing a valuable service for the industry and consumers alike. Counter to common wisdom, regulation in fact may supplement the role of patents in

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168. Peltzman, *supra* note 17, at 16.

169. *Id.*

170. Scherer, *supra* note 84, at 15.

encouraging innovation. Whether this anti-lemon role outweighs the cost and delay caused by regulation requires further study. Therefore, while this Article may be understood as a defense of drug regulation, at most it is only a defense of the general idea of drug regulation, not of any specific form thereof. Nor does this Article deny that many critics of the current system, even if they ignored its anti-lemonization role, have still identified some serious flaws in its operation. The simple point made is that any cost-benefit evaluation of the current system and any proposal to reform it may be incomplete without considering this under-studied role of the regulatory framework.

Similarly, the insights of this Article do not necessarily imply that laws permitting patent term extensions have been wrongly enacted. It is still possible that effective patent life of twelve years leads to suboptimal level of investment in innovating despite the positive effect of regulation. In other words, even if in an unregulated world, in which the effective patent life lasted the entire patent term, the flow of innovative drugs would have been lower compared to the present world, this would not tell us anything about how far from optimal the current patent system is. It is still possible that current patent terms are suboptimally short. In the same vein, even if increasing consumers' confidence in regulation increases the rewards from innovation for successful drugs, it is theoretically possible that because only fewer drugs are allowed to enter the market, the total reward available for developers of new drugs is smaller, and over-rewarding the successful ones (so as to achieve a normal rate of return over the entire portfolio of costly research) corrects the ex ante incentives to innovate.<sup>171</sup> However, the decision whether to extend current patent terms or not should depend on correctly assessing all the relevant factors, including the possibility that drug regulation positively affects the incentive to innovate. However, the justification for patent term extension has relied thus far on the perceived dichotomy between the effects of patents and those of regulation. This dichotomy has created the fairness argument: "you, the Government, give us patents with one hand but then reduce their effective life through lengthy regulation," and as such touches upon entrenched notions of equality ("if inventors in other industries can enjoy a full twenty years of effective patent life, why should the pharmaceutical industry be singled out and have de facto shorter patents?"). The use of the terms "restoration" in the American legislation and "penalize" in European legislation represent this fairness approach.

Using this fairness argument makes strategic sense as a matter of advocacy. Relying only on economic data and arguments to convince

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171. I thank Bruce Chapman for this point.



legislators and voters that current patent terms are too short may be a losing strategy. Not only do such arguments tend to be complex and boring (at least for many), they would often be countered by other studies. The fairness argument is significantly less assailable. Strategically, then, the patent/regulation dichotomy and the resulting fairness argument may prove to be much more powerful tools. But this is unfortunate. If drug regulation actually complements the patent system, the fairness argument should be taken off the table. Policy decisions about patent terms should be made on the basis of economic data and theory. However “treacherous . . . the path to an optimal patent policy” may be,<sup>172</sup> if patents are granted to stimulate R&D, their terms should be determined on the basis of their effect on R&D.

The insights of this Article may also be relevant in assessing proposals to relax or tighten the regulatory process. Under the patent/regulation dichotomy, relaxing the regulatory process should have the same effect as extending patent terms as both can increase the effective patent life or otherwise increase the reward derived from the patent. In the short-run, both options can increase the introduction of NCEs. But in the long-run, relaxing the regulatory process can have a devastating effect on the industry if doing so would lead to its lemonization. But as long as the patent/regulation dichotomy dominates the discourse, lobbying for such relaxation could be fully rational. It may increase the market value of existing firms and the compensation for current managers, but if that would lemonize the industry sometime in the future, it would then be someone else’s problem. Again, nothing said here implies that the current regulatory framework is optimal; only that ignoring its anti-lemon role may be counterproductive.

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172. EPSTEIN, *supra* note 137, at 61.