Pharmaceutical Lemons: The Effect of Patents and Regulation in the Drug Industry

Ariel Katz

Assistant Professor
University of Toronto, Faculty of Law

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I. Introduction

Before a new drug can be marketed in the US, the Food and Drug Administration (FDA) must approve it.[1] Such approval requires satisfying the FDA that the drug is safe and effective, following a series of costly and lengthy clinical trials.[2] Furthermore, if the new drug is patented—and new drugs often are—the time it takes to get the approval eats into the period of effective patent life (EPL). This happens because US patents are granted for twenty years from the time of filing the application,[3] which usually happens at a very early stage of the development process of a new drug. On average, after getting a patent it takes additional eight years before the FDA approves the drug for marketing.[4] As a result, EPL is much shorter than twenty years.[5]

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[1] Similar regulatory requirements exist in most developed countries and elsewhere.

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[3] 35 U.S.C. §154.

[4] F. M. Scherer, *Pricing, Profits, and Technological-Progress in the Pharmaceutical-Industry,* 7 J. Econ. Persp. 97 (1993) at 99.

[5] A common misconception is to ascribe the entire decrease of EPL to the regulatory process. Since rarely a drug company would have a ready-to-market product upon getting a patent, some delay between getting a patent and marketing a drug is inevitable and independent of the regulatory process. Marcia Angell, The Truth about the Drug Companies, (2004), at 35 notes that the average time of FDA review was sixteen

This is an unfortunate reality for drug companies. Naturally, they would prefer a longer EPL over a shorter one—who wouldn't? But our concern is not with the loss of monopoly profits as such. As a society, we should be concerned that the loss of such monopoly profits (supposed to encourage innovation) would decrease the amount and speed of new drugs available to consumers. We should be worried that as a result of the cost and delay imposed by the process of regulatory approval, thousands of the potential beneficiaries of new drugs would die or unnecessarily suffer.[6] Hence, regulation of new drugs is perceived to negatively affect the incentive effect of patents, with negative consequences not only for drug companies, but to the public at large.

To mitigate such concerns, a few reforms have been made. Some reforms are aimed at speeding-up the regulatory process by restructuring internal processes within the FDA, others at providing more funds to support the process.[7] As a result of such reforms the FDA has moved from being the slowest regulatory drug agency in the developed world to being the fastest.[8] Other reforms sought to compensate drug companies for the shorter EPL, thus restoring the incentive that the patent system promised and regulation, arguably, has not kept.

The proposed compensation can take different forms. The most straightforward one is the extension of patent terms. In the US, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)[9] 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.[10] In Japan, Section 67(2) of the Patent Law provides that "the term of the patent right may be extended by a period

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months in 2002, and in some cases even less that this. It does not mean however that the actual delay or cost caused by regulation is only sixteen weeks (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.

[6] Sam Peltzman, Regulation and the Natural Progress of Opulence, (2005) at 15-16.

[7] Prescription Drug User Fee Act.

[8] Angell *supra* note

[9] Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156 (1984).

[10] *See* H.R. REP. 98-857(II), P.L. 98-417, Drug Price Competition and Patent Term Restoration Act, House Report No. 98-857(II), 3, (Aug. 1, 1984).

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."[11] In the EU, 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.[12] While *de jure* a SPC is not a patent, for practical purposes the instruments are equivalent.[13] The preamble to Regulation 1768/92 provides the following rationale:

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

This paper questions this justification for patent terms extension, and more generally, 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 this industry. I will show that the regulatory framework is not solely a burden imposed on the industry but also a valuable service to the industry—the certification of drug quality. I will argue 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 encourages innovation.

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[11] Patent Law, (Law No. 121 of April 13, 1959, as amended by Law No. 220 of December 22, 1999), art. 67(2), *available at* http://www.wipo.int/clea/docs_new/pdf/en/jp/jp036en.pdf.

[12] Council Regulation EEC No. 1768/92 O.J. L182 1 (1992).

[13] See Edward H. Mazer, *Supplementary Protection Certificates in the European Economic Community,* 48 Food & Drug L. J. 571 (1993).

Consequently, the effect of drug regulation is not antithetical to the patent system, but rather a complement.

This paper has a modest purpose. I do not aim necessarily to defend the current method of drug regulation and every particular aspect of it, nor advocate its inherent superiority over other forms of quality assurance. I simply aim to highlight another aspect of drug regulation often missing from its cost-benefit analysis.

II. The Interplay between Drug Regulation and Patents

The standard justification for regulating new drugs 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, or simply would overstate positive points and understate negative ones in promoting and labeling their products.[14] This market failure results from information imperfection: customers' inability to obtain full information about the benefits and risks of new drugs,[15] which in turn leads firms to take advantage on this imperfection and supply less, and less accurate, information about their products. While such imperfections characterize many consumer products, the potential severe and irreversible threats to human health from the consumption of drugs justify extensive government intervention,[16] beyond the general domains of tort law, or consumer protection law.[17]

Critics of drug regulation would not generally dispute this potential market failure but point out the unfortunate existence of regulatory failure whose costs—in the form lives lost or suffering continued as a result of reduced innovation and delay—are greater than the social cost of the market failure.[18]

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:

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[14] Henry G. Grabowski & John M. Vernon, The Regulation of Pharmaceuticals: Balancing the Benefits and Risks, (1983), at 7.
[15] Id.
[16] Id.
[17]
[18] Grabowski & Vernon *supra* note , Peltzman.

those of industry (through patents) on the one hand, and those of consumers (through drug regulation) on the other. Patent laws, by providing market exclusivity, generate the financial incentives to innovate, whereas drug regulation laws, by keeping unsafe and ineffective drugs off the market, protect consumers, but at the expense of diminished incentives to innovate.

The relationship between patents and drug regulation are more complicated however. As Rebecca Eisenberg has already noted "[a]lthough 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."[19] On many occasions drug regulation laws support the profitability of new drugs. In some cases drug laws directly provide market exclusivity 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.[20] Developers of pioneering new chemical entities (NCEs) not previously approved may get five years of exclusivity, and the introduction of changes in approved product may qualify for three years of exclusivity.[21] Drug regulation also creates indirect barriers for the entry of competitors. Regulatory approval of generic drugs creates a significant entry barrier despite lower regulatory burdens,[22] and may effectively prevent parallel imports or re-imports of approved drugs even if patent law failed to do the same.[23] But even Eisenberg, in her more nuanced account of how patent laws and drug law intertwine, sees the mere requirement to prove safety and efficacy as a regulatory burden that justifies compensating measures in the form of market exclusivity beyond that granted by patent law.[24]

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[19]Rebecca S. Eisenberg, *The shifting functional balance of patents and drug regulation,* 20 Health Affairs 119 (2001) at 132.
[20] Id, at 123.
[21] Id.
[22] Id, at 121.
[23] Id, at 131.
[24] Id, at 123.

Yet the argument that regulatory approval reduces the expected returns from drug innovation and therefore justifies the extension of patent terms is intuitively appealing but potentially flawed. For the question is not whether or not regulation eats into effective patent life; no doubt it does. 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. To measure the effect of regulatory review 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 the 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, although coupled with reduced EPL, benefits innovation. To illustrate: going to school undoubtedly reduces one's effective 'job-market life'. Yet this tells us nothing about the expected income one earns after graduation. If education improves one's skills—and up to a certain level undoubtedly it does—the delay in entry into the job market increases one's expected income, not reduces it. Similarly, if regulatory review of new drugs increases their value and marketability, regulation—up to a certain level—increases the expected profits from patented drugs and thereby increases the incentive to innovate.

This paper explains why this may be so. Here's the argument in a nutshell: New drugs are 'credence goods'—goods which consumers are never sure about the quality and about to what extent that they actually need them. Severe asymmetry of information exists between drug companies and consumers regarding their safety and efficacy ("quality"). Consequently, in the absence of mechanisms to signal and commit to the quality of drugs, the market for drugs may to become a "market for Lemons"—a smaller market in which only low quality drugs are sold, by non-trustworthy sellers; a market in which Carbolic Smoke Balls[25] and other snake oils are the common cures for diseases.

If so, rather than a burden, regulatory review of new drugs may actually be an effective mechanism for assuring the quality of drugs, one that drug companies would

[25] Carlill v Carbolic Smoke Ball Company [1893] 1 QB 256. [add a brief description of this classic]

have had to establish themselves in order to avoid the lemons problem (for example by establishing some kind of a certifying body). Furthermore, it is possible that the government is even more suitable to perform this function because it is a disinterested third party, which can effectively enforce compliance with the approval process and impose sanctions in the case of attempts to cheat the process (or at least perceived as such by large enough number of consumers). If true, rather than a burden, the requirement for regulatory approval of new drugs is actually a valuable service—probably unintended, but entirely welcome consequence—that increases the expected returns from innovation.

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 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.[26] The quality of a third category, 'credence goods', cannot be evaluated through normal use at all. Their value requires additional costly information. Repair of durable machines or human beings are the classic examples, since most consumers are highly unfamiliar with their intricacies and peculiarities.[27]

The line between experience goods and credence goods may not always be sharp, especially if eventually quality will be discerned through use, but only after the lapse of considerable period of time.[28] Furthermore, most goods possess many attributes; some are learned before purchase, some after purchase and some never.[29] So for example, a potential buyer of canned tuna can know before purchase that she buys a canned product,

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[26] Phillip Nelson, *Information and Consumer Behavior,* 78 Journal of Political Economy 311 (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).
[27] Michael R. Darby & Edi Karni, *Free Competition and Optimal Amount of Fraud,* 16 J. L. & Econ. 67 (1973)at 69.
[28] Darby & Karni *supra* note , id.
[29] ,Jean Tirole, The Theory of Industrial Organization, (1988), at 106

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 does, or does not, contain genetically modified organisms (GMOs), 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.[30] Nevertheless, despite its limitations this classification of search, experience and credence goods is useful for our analysis.

Most drugs can be easily characterized as credence goods, particularly with regard to their most important attributes: their efficacy and safety. Sure, 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 suffering from headache could immediately assess the efficacy of a pain killer, and similarly, most men suffering from erectile dysfunction could easily determine how effective a drug like Viagra is.

However, for many drugs whose expected effect is not immediate or immediately observable, or whose use is combined with other drugs or treatments, assessing how effective a drug is can be extremely difficult. First, as 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, it can relate to other characteristics such as the method of administration (oral, injectible, or topical) and the dosage required.[31] Even more difficult for most consumers is knowing what the expected long term effect of the drug are, or what the possible complications, reactions with other substances and side effects are.[32] Moreover, since combining different drugs may be ineffective, or even worse—lethal, consumers cannot simply try every drug and every cure until they find the one that works

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[30] Giovanni Anania & Rosanna Nistico, *Public Rregulation as a Substitute for Trust in Quality Food arkets: What if the Trust Substitute cannot be Fully Trusted?,* 160 Journal of Institutional and Theoretical Economics-Zeitschrift fur Die Gesamte Staatswissenschaft 681 (2004), at 682.
[31] Peter Temin, Taking Your Medicine: Drug Regulation in the United States, (1980), 9.
[32] Id, 9-10.

(even if they are affluent enough to do so); they need to know before they commit to a specific drug that it is likely to work.

Second, 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.[33] Epidemiological research is not only beyond the reach of consumers, but also beyond the reach of most practicing physicians[34] or pharmacists.

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. And when the information held by sellers and buyers is asymmetric the market may fail, as Goerge Akerlof showed in his groundbreaking "lemons market" paper.[35]

In this paper 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 what buyers are willing to buy. In this 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 good as a higher-quality one. The buyer, however, takes this incentive into consideration, and discounts all sellers' quality claims, so that for any price only the average quality will be considered. As a result, sellers who offer higher-than-average quality will be driven out of the market. Unless credible guarantees to the quality of the good exit, this mechanism, in which the

[33] Id. 10.
[34] Id.
[35]George A. Akerlof, *The Market for Lemons - Quality Uncertainty and Market Mechanism,* 84 Quarterly Journal of Economics 488 (1970) Note, though 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. So that in Akerloff's example of cars, there is no asymmetry of information about a whether a specific new car is good or 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.

low-quality products drives out the high-quality, repeats itself until a no-trade equilibrium is reached.

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, employers' reluctance to hire members of minority groups, or the dearth of formal credit markets in underdeveloped countries. Nineteenth century drug markets,[36] or contemporary dietary supplement markets[37] 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 transaction decreases in comparison to what it would be if the available information were perfect, or if "anti-lemon devices"—mechanisms to credibly assure the quality of products—were available.[38]

Note, however, that the Akerlovian failure differs from the informational failure described above as the commonly perceived basis for drug regulation. In the 'traditional' failure, self-interested sellers refrain from acquiring and providing information to consumers, knowing that market imperfection would allow them to get away. Government intervention designed to increase the information available to consumers operates against such sellers' self interest; as much as consumers would cherish it, producers would loath it. In contrast, in the Akelovian scenario honest sellers of high quality credence goods are interested in providing enough accurate information to consumers, yet they cannot credibly do so. Their problem is to persuade consumers that the information provided by them is indeed sufficient and accurate, given consumers' inability to distinguish between honest and dishonest ones. Such sellers would welcome, just as consumers would, any measure (including regulatory ones) that would allow them to credibly signal their quality.

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[36] See infra,
[37] See infra,
[38] Tirole *supra* note at 109.

B. The implications for pharmaceuticals

The implications for pharmaceuticals are clear. Without mechanisms capable of credibly assuring the quality of drugs, drug markets for drugs would perform badly. 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 to 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 subtract from them. The justification for patent term extension thus turns 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, regulatory review of new drugs can therefore be re-conceptualized as a valuable pro-innovation service provided by the government.

In fact, re-conceptualizing of 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—especially if funded by taxpayers' money—the public may justifiably insist in 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 further 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").

Yet any of such polarized views about the relationship between patents, drug regulation and innovation would be misleading, and before reaching any conclusion about the implications of our insight on public policy, the following should be considered.

First, even if in general, regulatory review of drugs benefits the industry, 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 a remaining one 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 period generates higher profits than a non-approved drug sold under patent for the full patent term. Second, recognizing the benefits arising from regulatory approval does not imply that the current regulatory framework is optimal and cannot be improved.[39] Such improvements, which may reduce the development time of new drugs or otherwise decrease development costs, may increase the overall incentive from the combination of patents and regulatory review, and of course bring new (and presumably better) drugs to the market earlier rather than later. Therefore nothing in this paper should discourage attempts to improve the current system. Third, 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 substitutes or complements equally effective market-based anti-lemon devices.

IV. The Evidence So Far

The 1962 Amendments to Food and Drug Act have fundamentally changed the process of introducing new drugs into the American market. Under the previous legislation a new drug would be automatically approved unless the FDA objected to its marketing within 180 days.[40] The new legislation required prior approval before marketing.[41] The second major change was requiring firms seeking to introduce new drugs to demonstrate that the drug is not only safe but also effective for the purpose to which it would be sold.[42] The third major change was requiring drug developers to

[39] *See e.g.,* Ernst R. Berndt, Adrian H. B. Gottschalk, & Matthew W. Stobeck, Opportunities for Improving the Drug Development Process: Results from a Survey of Industry and the FDA, (2005) .
[40] Check whether 180 or 60 (according to Kitch it's 180, and according to Grabowski & Vernon it's 60).
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obtain FDA approval before conducting any tests on human subjects.[43] Following the enactment of the 1962 amendments the number of New Chemical Entity (NCE) approvals declined substantially relative to pre-amendment levels, a trend which continued throughout most of the 1970s.[44] Between 1963 and 1969 the number of NCE approvals was 13.6 per year, and 13.7 NCEs per year in the 1970s,[45] compared to over 50 per year in the late 1950s.[46]

Grabowski et. al. cite five hypotheses that were advanced for explaining this trend: (1) tighter regulation of the industry by the FDA following the amendments; (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.[47] However, several studies that were undertaken during the 1970s concluded that the first cause, the enactment of the 1962 amendments, is the primary reason for the decline in NCEs in the US.[48]

The decline in the approvals of NCEs has changed its course since the 1980s, however. 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.[49] More recently there has again been a downturn.[50] The turnaround in NCEs since the 1980s has been explained by

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[44] Joseph A. Dimasi, *New drug innovation and pharmaceutical industry structure: Trends in the output of pharmaceutical firms,* 34 Drug Information Journal 1169 (2000), at 1172.

[45] Id.

[46] Grabowski & Vernon *supra* note , at 29. According to Grabowski and Vernon, the post-amendment average number had been 17.

[47] Henry G. Grabowski et al., *Estimating Effects of Regulation on Innovation - International Comparative Analysis of Pharmaceutical Industry,* 21 J. L. & Econ. 133 (1978), at 19.

[48] Id. See also, Peltzman.

[49] Dimasi *supra* note 44.

[50] ,F. M. Scherer, *The Pharmaceutical Industry - Prices and Progress,* 351 New England Journal of Medicine 927 (2004).

adaptation of drug companies to the new regulatory regime,[51] as well as new discovery opportunities resulting from breakthroughs in biochemistry, enzymology, molecular biology,[52] and genetic engineering.[53] Nevertheless, this turnaround, while potentially undermining the effect ascribed to the 1962 amendments, may not necessarily do so, since the reforms that the regulatory regime has undergone since the 1980s have allowed firms to increase the expected return to their R&D by extending patent terms, shortening the time that it takes to approve new drugs, and other means. Yet another possibility, to which, with one exception,[54] I have found no reference in the literature, is that the 1962 amendments have increased the confidence of consumers in the quality of drugs, thus increasing the demand for new drugs.

Although this evidence from the more recent history suggests ambiguous effects of drug regulation, looking back at the history of the drug industry in the era that preceded regulation can provide additional insights. [add historic account of the pre-regulation era and finish with a caveat that it isn't necessary that regulation was the only solution to what seemed to me lemon markets. It is possible that the market would have developed its own mechanisms.]

V. Anti-Lemon Devices

Lemonization of markets, of course, is not an inevitable consequence of information asymmetry. Akerlof himself acknowledged that "numerous institutions may arise to counteract the effects of quality uncertainty"[55] and that in some cases government intervention may increase sellers' and buyers' welfare. This paper focuses on government intervention—mandatory regulatory review—and its potential anti-lemon effects, but it may be useful to discuss the market-based institutions and their potential limitations.

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[51] Dimasi *supra* note 44.
[52] Id.
[53] ,Scherer *supra* note , at 100.
[54] Peltzman (at 121) indeed raised this hypothesis yet quickly dismissed it, as it would imply an increase in the number of NCEs, whereas the figures available at that time indicated a marked decline.
[55] *Id*. at 499.

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 positive experience. But for this mechanism to work two conditions are necessary. One, consumers must learn the quality of the purchased item sufficiently quickly, and two, they must renew their purchases sufficiently often.[56] As noted earlier, such conditions 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. Indeed, prior to the therapeutic revolution that began in the late 1930s (which coincided with the more 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.[57] Yet for many drugs, ascertaining efficacy requires expertise that consumers do not usually possess. Furthermore, even when repeated use allows consumers to ascertain drugs' effect, they are incapable of evaluating their safety and their potential complications. Therefore, for many drugs repeat purchases are unlikely to function well as anti-lemon devices.

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[56] ,Tirole *supra* note , at 112.
[57] Temin *supra* note 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.[58] 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 the ability to verify quality, a precondition for enforcing the commitment. The renowned *Carbolic Smoke Ball* case[59] demonstrates the last point. The Carbolic Smoke Ball Company could easily promise to pay £100 for anyone who contracted influenza after using the Carbolic Smoke Ball, since it assumed that under then-existing contract law such promise would not be enforceable, and did not anticipate that its own actions would change the law. Following the legal change, the company no longer offered the same reward.[60] But even if such promises can be enforceable as a matter of contract law doctrine, the inherent difficulty of assessing drugs' quality[61] would make it extremely difficult for a court to verify whether the drug failed to stand for its claimed quality.

C. Branding and Advertising

Branding and advertising may function as anti-lemon devices. Branding and advertising may signal quality in a number of ways. First of all, drug companies could simply use advertisements to supply information about the quality of their drugs.[62] The problem, of course, is that consumers would not necessarily believe them and may discount the claims altogether. Therefore the quality signal may not lie in the content of

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[60] For a brief period after losing the case the Carbolic Smoke Ball Co. continued offering a reward, but only a single one, and subject to small print which made the reward 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 …". The offer itself remained open for a limited period. 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, *see* A. W. B. Simpson, *Quackery and Contract Law - the Case of the Carbolic Smoke Ball,* 14 J. Legal Stud. 345 (1985), at 371.

[61] See *supra* Part III. B.

[62] I ignore now regulatory restrictions on drug advertisements.

advertising but rather in the information conveyed by the mere fact of expenditure spent on advertising and brand building. 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 live longer than low quality ones, large advertising and brand building expenditures signal their quality.[63]

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 laws. Therefore advertising claims about the quality of a product is a risky proposition, which a rational firm might not take, unless it believes that the product is as good as advertised so that the risk is small.

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. It is not unreasonable to expect that such information would eventually surface, but only eventually. In the meanwhile, sufficient number of consumers may insufficiently discount the quality claim and purchase the product nonetheless to allow recovery of the sunk cost of advertising. In order for *ex post* discovery for deceptive advertising to provide *ex ante* incentive to supply quality, low quality should be able to surface early enough, which in the case of drugs, may not happen.[64] 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,[65] and may not face the proper incentive to advertise accurate information. If the injury is too small (e.g., a drug is safe but ineffective), individual victims may not find it worthwhile

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[63] *See* Benjamin Klein & Keith B. Leffler, *The Role of Market Forces in Assuring Contractual Performance,* 89 Journal of Political Economy 615 (1981)
[64] The long period that it takes to get an FDA approval may indicate that the therapeutic effect of drug and their safety are not immediately evident.
[65] *See. e.g,* Richard A. Posner, Economic Analysis of Law, 6th (2003) at 383-84.

to sue,[66] and even a class action may not be highly attractive as the damages collectable would be 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, as a result, may respond by discounting the authenticity of all sellers' quality signal, and if the number of dishonest sellers is large enough and the discount serious enough, lemonization may ensue. Therefore, how effective these devices would be in preventing lemonization depends on honest sellers' ability to distinguish themselves from dishonest ones, for example, 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 resulting from increase in prices or decrease in innovation.[67]

Drug companies' behavior is consistent with the above. Drug companies spend heavily on advertising and branding, and historically this practice began with the discovery of antibiotics which lead to the therapeutic revolution and the emergence of research-based drug companies as opposed to symptomatic drugs that existed before.[68] 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, since historically, the trend towards advertising and branding coincided with the growth of drug regulation. So while the ability to commit to quality through advertising and branding may support a claim that drug regulation is superfluous, it may also be the case that drug regulation supplements the signal created by advertising and branding, by weeding out the dishonest sellers and allowing the honest ones to supply a clearer, and more trustworthy, signal through advertising and branding. If that is

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[66] Id.
[67] It has been debated whether reduced competition induces or inhibits innovation, *see e.g.,*___. I do not intend to solve this debate here. For the purposes of the point made it is enough that under some condition reduced competition inhibits innovation.
[68] Temin *supra* note , Ch. 4.

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.

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, and 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; this reduces the firm's incentive to cheat in the first place.[69] The same problems arising from higher barriers to entry described in the previous paragraph would apply here too.

As in the previous paragraph, historically, the drug industry has become increasingly more concentrated and this trend it correlated with the increase in drug regulation.[70] 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, firm *B*, a competitor, may inform consumers that *A*'s drug is not as good as advertised. *B* for that matter may not necessarily be a competing drug company, but may equally be a competing service provider whose sales decrease when *A*'s drug sales increase. For example, if the use of antidepressant drugs reduces the demand for

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[69] *See* Thomas Liebi, Trusting Labels: A Matter of Numbers?, (2002)
[70] Temin *supra* note , Ch. 4.

psychotherapy, practicing psychologists or psychiatrists may seek to inform the public about the ineffectiveness or dangers associated with antidepressants use.[71]

The problem with credence goods, however, is that consumers lack the capacity to evaluate each side's claim and may discount both sides' claims altogether, unless it has good reason to believe that some claims (for example, if supported by independent scientific research) are more credible than others. Moreover, firm *B* may not necessarily find it in its best interest to disclose its knowledge that *A*'s drug is ineffective or dangerous. In some cases it can jump on the bandwagon and sell an equally bad treatment too.[72]

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. An obvious example of such complementarity is the supply of drugs and medical care. Physicians clearly benefit when they can provide their patients 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.[73]

Two observations follow. One, drug companies may not bear the full cost of low-quality drugs and therefore may only have 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. An immediate difficulty

[71] *See e.g.,* Fisher & Greenberg, From Placebo to Panacea : Putting Psychiatric Drugs to the Test (arguing that there is inadequate scientific information to conclude that psychoactive drugs are substantially more effective than placebos).

[72] *See e.g.,* Trudo Lemmens, *Piercing the Veil of Corporate Secrecy about Clinical Trials,* 34 Hastings Center Report 14 (2004), at X ("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.")

[73] The reverse is probably true as well. Drug companies may benefit from high quality medical profession.

comes to mind. Physicians are numerous and dispersed and may not individually find it beneficial or possible to exert such pressure on drug companies. However, several mechanisms and institutions allow physicians to overcome this collective action problem. For example, as early as 1905 the American Medical Association decided to ban advertisements of ineffective nostrums in its *Journal of the American Medical Association*. The Association 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 published in the *Journal*.[74] Publicly-funded research, carried by physicians-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' 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, rather than disclose it.[75]

Whether 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 inevitably would involve a risk of allegations of illegal boycotting and potential antitrust liability.[76] In

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[74] (1905) 44 J Amer Med Assoc 719-21. See also Y*oung, Pure Food, supra,* at 187-8. 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 Journal of Law Medicine & Ethics 641 (2004) at 646, n60, *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.

[75] Lemmens *supra* note (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 , 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 AMA reinstated such a program (the "Seal of Acceptance" program), only to drop it in the mid-1950s. According to Temin, the main reason for the policy change was AMA's need for cash, which unrestricted advertising could—and did—generate, *id.* at 85-86.

[76] *See e.g.,* Wilk v. American Medical Ass'n, 895 F.2d 352 (7th. Cir. 1990) *cert. denied* 498 U.S. 982 (affirming a lower court decision that a rule promulgated by the AMA Committee on Quackery that made it unethical for physicians to professionally associate with chiropractors violated § 1 of the Sherman Act.

Wilk v. AMA, for example, the 7th Circuit affirmed the lower court's decision that a rule promulgated by the AMA Committee on Quackery that made it unethical for physicians to professionally associate with chiropractors violated § 1 of the Sherman Act. The court rejected AMA's argument that the boycott was pre-competitive because it was a response to a market failure caused by information asymmetry. AMA argued that because the market for medical services is one where consumers lack sufficient information needed 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 AMA, its conduct ensured that physicians acquired reputation for quality, in part by not associating with chiropractors, which AMA regarded as "unscientific cultists," and allowed consumers to be assured that physicians would use only scientifically valid treatment. The court rejected the argument, noting that while getting needed information to the market is a fine goal … AMA was not motivated solely by such altruistic concerns [and] intented to "destroy a competitor," namely, chiropractors."

G. Information intermediaries

Since consumers cannot observe credence qualities even after consumption, sellers and buyers can only partially rely on the abovementioned 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.

i. 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 with respect to drugs, by acting as disinterested experts, or learned informational intermediaries, alleviating some of the

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The court also rejected AMA's argument that the boycott was pre-competitive because it was a response to a market failure caused by information asymmetry.

problems resulting from information asymmetry.[77] 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 both through the medical literature and professional seminars that can be drawn upon to brief the patient regarding the consequences of the drug.[78] A similar rationale stood behind the Federal Food, Drug, and Cosmetic Act of 1938, which introduced, among other things, the prescription-only regulation, assuming that consumers are not competent to make informed decisions with respect to drugs, and that physicians should make the choice in their stead.[79]

Using advisers is an imperfect anti-lemon device, however. First, since the information that they gather is a public good, they may have less-than-optimal incentive to invest in gathering it.[80] Second, just like the quality of drugs, verifying the quality of the services rendered by information intermediaries is costly; such services are credence goods for themselves. It is not surprising then that physicians and pharmacists themselves are subject to licensing requirements and ongoing regulation by the state of by the professions' self-regulatory bodies, and that such professions have developed norms that cherish trust relationships with patients and an ethos of priority of the patient's welfare over the physician's profit maximization.[81]

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 for a substantial enough period 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 and safety. The physician may be able to tell that some claims don't make any sense and that some may make some sense, but she doesn't have any

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[77] W. K. Viscusi, *Efficacy of Labeling of Foods and Pharmaceuticals,* 15 Annual Review of Public Health 325 (1994) at 327.
[78] Viscusi *supra* note at 327.
[79] ,Temin *supra* note , 54
[80] Grabowski & Vernon *supra* note
[81] Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care,* 53 Am. Econ. Rev. 941 (1963), at 26.

meaningful information about side effects, interactions with other drugs and efficacy of treatment until those have been tested to some degree. But more importantly, even in the case of drugs already on the market, assessing their quality is beyond the professional capability of any individual physician or pharmacist. As I already mentioned, not only the concept of effectiveness is 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.[82] This type of research is not only beyond the ordinary skills of most practicing physicians or pharmacists, even if they had the skills, diagnosing and treating patients, writing prescriptions or dispensing drugs cannot allow enough time for applying them. True, physicians and pharmacists do not necessarily have to conduct such research on their own; instead they can rely on research done by others if such information exists and made available to them. Interestingly, however, as Temin has shown, the information available to physicians about the relative quality of drugs is rather limited.[83] According to Temin, "Doctors do not and cannot exhibit instrumental behavior when prescribing drugs. They act instead in the customary mode."[84]

This implies that just like their patients, physicians will average the claims regarding new drugs in the absence of assurances of quality. Regulatory review, therefore, may provide a critical mass of credible evidence necessary to persuade physicians to start prescribing them. Once they do, more information is gathered on which information intermediaries may start relying.[85] It seems that even in the absence of mandatory regulation, given the risk aversion of many physicians and their tendency of sticking to habit,[86] drug companies seeking to rely on them as intermediaries, would have

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[82] Id. 10.
[83] Temin *supra* note , Ch. 5.
[84] Id. at 106. In Temin's terminology, *instrumental* behavior is the economist's rational behavior of the *homo economicus*, whereas people acing in the *customary* or traditional mode do today more or less what they did yesterday, *id.* at 12-13.
[85] Note that 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.
[86] Scherer *supra* note , at 101.

to conduct lengthy and costly trials to produce enough evidence to convince physicians to prescribe new drugs.

[add discussion on the prescription-only regulation; how it was not opposed by the drug industry and how it actually benefited it in two ways: one, by channeling choice through doctors who aren't sensitive to price (Temin); and two, by providing consumers quality assurance.]

ii. Certification

Just like advisers, trusted third parties may alleviate the market failures resulting 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 "what the organization does to enhance customer satisfaction by meeting customer and applicable regulatory requirements and continually to improve its performance in this regard."[87] As consumers increasingly are interested in the environmental impact of firms' production processes—truly a credence property—ISO has begun issuing its ISO 14000 "primarily concerned with "environmental management". … [W]hat the organization does to minimize harmful effects on the environment caused by its activities, and continually to improve its environmental performance."[88] The types of credence quality certificates now range from the ancient Kosher certification in Jewish communities,[89] to environmental certificates, to organic products, to socially conscious "Fair Trade"

[87] See International Organization for Standardization, Overview of the ISO system (2005), online: http://www.iso.org/iso/en/aboutiso/introduction/index.html#twelve
[88] *Id.*
[89] For a case study of the Kosher industry see ,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).

labels,[90] or to 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.[91]

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?*—who shall guard the guardians? Moreover, consumers may suspect a certifying body that financially depends on its clients—the certified firms. Certifying bodies would therefore need effective quality assurance mechanisms as well, which may not work perfectly.

iii. Licensing

In the case licensing, a third party—usually 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.[92] Licensing may assure quality by directly regulating the product (output regulation), or indirectly, by setting minimum requirements for firms in the industry (input regulation).[93] Drug regulation is an example of the first. It requires a license to market every drug. Occupational licensing, such as common in the medical and legal professions is an example of the second. It does not directly regulate the quality of the service but instead seeks to assure that professionals engage in a minimum level of human capital investment.[94]

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.

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[90] *See* Maria L. Loureiro & Justus Lotade, *Do Fair Trade and Eco-Labels in Coffee Wake Up the Consumer Conscience?,* 53 Ecological Economics 129 (2005).
[91] *See* Ian Ayres & Jennifer G. Brown, Straightforward: How to Mobilize Heterosexual Support for Gay Rights, (2005), Ch. 4.
[92] An industry may also determine which products will be sold and by which sellers. Such attempts, however, without endorsement by the state, may run afoul the antitrust laws.
[93] See Carl Shapiro, *Investment, Moral Hazard, and Occupational Licensing,* 53 Review of Economic Studies 843 (1986), at 844.
[94] Id.

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, and indirectly promote quality, by making it easier for sellers credibly to commit to quality. Procedural instruments such as class actions may make the former more effective by aggregating small claims that otherwise would be too costly to litigate and 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 the state power and exploiting increasing returns to scales to gather information on products' less observable qualities and bring lawsuits against sellers making false claims or selling 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. The resulting probabilistic under-deterrence may be corrected by increasing the penalty (whether criminal or civil, e.g., treble damages) but this may create its own distortions. [expand]

VI. Public vs. Self Regulation

The fact that many suppliers of credence goods other than pharmaceuticals find it in their best interest to signal quality by using third-parties suggests two things: one, that signaling achieved by other market mechanisms such as repeat purchasers, warranties and advertising, may not fully solve the problems of information asymmetry in such industries. Second, that government regulation may function as a substitute for similar forms of self-regulation that drug companies would have set up in its absence. Therefore, the notion that new-drug regulation is a burden imposed on the industry may be replaced with the view that regulation is in fact a valuable service provided to it. Yet that regulation by the government may substitute forms of self regulation does not 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.[95] This benefit to the industry, of course, counsels against such form of regulation, unless such benefits to the industry translate into higher expected return on its R&D, thus complementing the patent system. I raise this potential effect of regulation but will now set it aside, not because it is not important but because I would like to focus on the understudied 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 approval to remedy information asymmetry and save the drug markets from the ill fate of lemonization.

A. Some Advantages of Public Regulation

Public regulation may be preferable to self regulation for several reasons. 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 resulting 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 short term increase in the firm's valuation without internalizing the longer term damage to the reputation of the firm and the industry.

Under voluntary self-regulation some firms may seek to free-ride on the reputation of others. They may do so by failing to opt-in to the regulatory scheme either entirely or selectively. 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,

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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. Self-regulation schemes may not be capable of effectively preventing such forms of cheating. For example, they would not generally have the ability to exclude such drugs from the market. Of course, self-regulatory certification schemes may seek to counter such forms of cheating by incorporating appropriate elaborate terms in the relevant governing contracts, or by boycotting defiant members or third parties. However, executing such provisions may be highly ineffective or extremely costly, and could also get the entities involved into antitrust troubles.[96] In addition, how effective such certification schemes are depends on how well consumers can distinguish between certified and non-certified drugs and apprehend the differences between the certified and the non-certified or between different variants of certifications.

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,[97] withdraw a marketing approval if approval was granted based on bribery, fraud or other 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.[98]

In addition, penalties ranging from civil sanctions to criminal fines and imprisonment, as well as debarment of non-compliant individual or firms, may assist in reducing the incentives to cheat, in a manner that would not be at the disposal of private certifiers.

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[96] See *supra* Part __.
[97] 21 U.S.C. §374.
[98] Id, §335(c)(a).

In addition, 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 be advantageous compared to 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.[99] 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 80 percent, more than twice the approval rate of the entire government and higher than other federal agencies studied.[100]

Some critics have pointed out that the FDA is inherently over-cautious, because the institutional incentives confronting its officials lead them to tend avoiding Type 2 errors (approving drugs that are not safe and effective) and ignore Type 1 errors (rejecting safe and effective drugs).[101] Notwithstanding the inefficiencies resulting 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 in fact the FDA or equivalent regulators in other countries function better compared to the market requires separate

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[99] Tirole *supra* note , at 110 n19; Sam Peltzman, *Evaluation of Consumer Protection Legislation - 1962 Drug Amendments,* 81 Journal of Political Economy 1049 (1973) at 1052 n1.

[100] Pew Research Center for the People & the Press, Performance and Purpose; Constituents Rate Government Agencies (April 12, 2000), at http://people-press.org/reports/display.php3?ReportID=41. Spam e-mails provide another 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.

[101] Grabowski & Vernon *supra* note , at 10 (explaining that FDA officials committing Type 2 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 1 errors are much less visible and are borne largely by outside parties (drug companies and sick patients)).

studies beyond the scope of this paper. 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"—the way regulation manipulates the subjective beliefs of consumers (or other market participants) about the effect of regulation.[102] The important fact here is not whether the FDA indeed does a better job compared to private market-based institutions in distinguishing between high- and low-quality drugs. What matters 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, not only from the point of view of consumers, but also from this of drug companies.

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 US, Japan, the EU and other countries for laws permitting the extension of patent terms. This paper has shown that new drug regulation may serve as an anti-lemon device, thus providing a valuable service for the industry. Counter to common wisdom, regulation in fact may supplement the role of patents in encouraging innovation. Whether this anti-lemon role outweighs the cost and delay caused by regulation requires further study.

The insights of this paper 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

[102] Amitai Aviram, The Placebo Effect of Law, (2005) *available at* http://ssrn.com/abstract=784646

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. However, the decision whether to extend current patent terms or not should depend on assessing correctly all the relevant factors, including the possibility that drug regulation positively affects the incentive to innovate. So far, however, the justification for patent term extension relied on the perceived dichotomy between the effects of patents and those of regulation. This dichotomy has created the fairness argument: "you 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 the "penalize" in the European well represent this fairness approach.

Using this fairness argument makes a lot of sense as a matter of advocating strategy. Convincing legislators and voters that current patent terms are suboptimal by using only economic data and arguments may be a losing strategy. Not only such arguments tend to be complex and boring (and least for many), they would often be countered by other studies. The fairness argument is significantly less assailable. Strategically, though, the patent/regulation dichotomy and the resulting fairness argument may prove to be much more powerful tools. But this should not be so. If drug regulation actually complements the patent system, the fairness argument should be cleared off the table. Policy decision about patent terms should be made on the basis of economic data and theory. It is more difficult—surely—but 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 paper 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 increase the effective patent life. In the short run, both options can increase the introduction of NCEs. But in the longer run, relaxing the regulatory process can have 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 will then be someone else's problem. Again, nothing said here implies that the current regulatory framework is optimal, it only means that ignoring its anti-lemon role may be counterproductive.

Another indirect implication regards the role that information intermediaries play. For example, the intended purpose of the Bayh-Dole Act of 1980 has been to promote innovation by allowing publicly funded research institutions to obtain patents on their inventions and then to ally with business partners in commercializing such inventions. While the Act has been successful in encouraging this type of innovation, concerns have been raised that such newly created alliances between researchers in universities and hospitals have weakened their incentives to monitor the safety and efficacy of commercial products.[103] Since such researchers in universities and hospitals function as information intermediaries mediating the information gap between drug producers and consumers, a weakening of this function may in the long run turn out to be counterproductive.

[103] Lemmens *supra* note