The Impact of Regulation on Innovation in the United States: A Cross-Industry Literature Review*

Luke A. Stewart, Information Technology & Innovation Foundation, June 2010

This paper was commissioned by the Institute of Medicine Committee on Patient Safety and Health IT, whose report can be found at www.iom.edu/hitsafety.

The debate over the impact of government regulation on innovation in the United States is framed in the context of the gradual decline of economic regulation since the 1960s, and the gradual increase in social welfare regulation over the same period. Fueling much of the economic deregulation movement has been classical economic theory, which holds that regulation imposes a cost burden on firms, causing them to reallocate their spending away from investments in innovation. On the other side, the environmental movement along with greater public concern about social health and safety has fueled arguments that economic efficiency is a necessary sacrifice for improved social welfare. The "Porter Hypothesis" goes even further, arguing that environmental, health, and safety regulation regularly induces innovation and may even enhance the competitiveness of the regulated industry.

With this context in mind, the purpose of this paper is to conduct a high-level review of the relevant literature and to extract those concepts from which a general inference can be made about the impact of different regulatory regimes on innovation in the private sector. The first section outlines the theory and develops a taxonomy of the regulatory attributes that affect innovation. These attributes pertain to regulatory stringency, flexibility, and market information. In the second section, the taxonomy is applied of a review of the existing literature on the impact of regulation on innovation across multiple industries, including manufacturing, pharmaceuticals, automobiles, chemicals, energy, healthcare, telecommunications and agriculture. The third section briefly discusses the findings of the literature review, and serves as a starting point for the analysis of the innovation impact of proposed regulation.

Theory and Taxonomy

This paper employs the definition of "innovation" described by Joseph Schumpeter (1942). Schumpeter distinguished innovation, the commercially successful application of an idea, from invention, the initial development of a new idea, and from diffusion, the widespread adoption of the innovation (Ashford and Heaton, 1981, p. 110).[1] Based on this Schumpeterian definition of

[1] According to Jaffe et al. (2002, p. 43), "A firm can innovate without ever inventing, if it identifies a previously existing technical idea that was never commercialized, and brings a product or process based on that idea to the market"; however, for simplicity, this paper assumes that innovations are preceded by invention. Note also that this paper frequently substitutes the term "innovative activity" for "invention"; that is, innovative activity can result in invention but not innovation if the invention is not commercially successful.

innovation, at the highest level of analysis, there are two competing ways in which government regulation impacts innovation. First, regulation places a *compliance burden* on firms, which can cause them to divert time and money from innovative activities to compliance efforts. For example, financial reporting regulation may cause a firm to redirect resources from its R&D division to its internal auditing division.[2] Counter to this, and second, firms may be unable to achieve compliance with existing products and processes and thus, assuming the firms do not shut down, regulation may spur either compliance innovation or circumventive innovation. *Circumventive innovation* occurs when the scope of the regulation is narrow and the resulting innovation allows the firms to escape the regulatory constraints. For example, the regulation of a financial product, such as checks, may cause a bank to develop new financial products, such as electronic funds transfer, that are outside the scope of the regulation of checks. *Compliance innovation* occurs when the scope of the regulation is broad and the resulting product or process innovations remain within the scope of the regulation. For example, vehicle emissions targets resulted in vehicle innovations that were still bound by the regulation but that were now in compliance. In general, the literature reviewed in this paper focuses on the wide-scope regulation of industries and thus on compliance innovation almost exclusively.

For any regulation that requires at least some innovation for compliance, there are these two opposing forces, and, in general, whichever one is stronger will in large part determine whether the regulation stifles or stimulates innovation (Figure 1). It is important to note, however, that simply requiring innovation for compliance is no guarantee that the resulting innovative activity will meet the Schumpeterian definition of innovation by creating a commercial success. The innovative activity can result in "dud" products or processes, and thus, even when it demands compliance innovation, regulation can still stifle innovation in the end.

Not all innovation is alike, of course. One common distinction is whether innovation is incrementally or radically new. *Incremental innovation* occurs when firms make relatively minor improvements to existing products and processes, improving preexisting attributes in order to meet the minimum standards for compliance. In contrast, *radical innovation* replaces existing products or processes. At the extreme, radical innovation may usher in new technological paradigms, greatly benefitting the innovator or society at large. Very generally, radical innovation yields greater benefits than incremental innovation yet is also significantly more costly and risky. Radical innovation is often the pursuit of "unknown unknowns," whereas incremental innovation travels a more certain path, and thus attempts to radically innovate are more likely to produce *"dud" inventions*—or, in extreme cases, no invention at all. For this reason, incremental innovation is often more attractive to firms as a means to comply with regulation, despite the benefits of successful radical innovation.

[2] Note that due to heterogeneous marginal costs, the burden of regulation is almost never borne equally among firms. Various factors can affect firms' marginal cost curves; for example, firm size is a common factor.

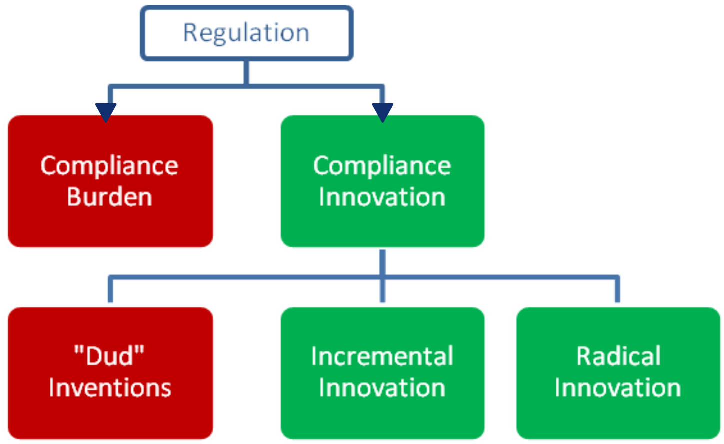

Figure 1. Regulation imposes a compliance burden but may also require innovation for compliance. Assuming the regulated firms do not shut down, regulation that requires compliance innovation will result in incrementally new innovation, radically new innovation, or “dud” inventions with no commercial viability.

In summary, regulations that are most effective at stimulating innovation will tend to require compliance innovation and, at the same time, will minimize the compliance burden and mitigate the risks of producing “dud” inventions. Furthermore, radical innovation can yield more benefits than incremental innovation, yet comes at a higher cost and a higher risk of producing “dud” inventions.

The Three “Innovation Dimensions” of Regulation

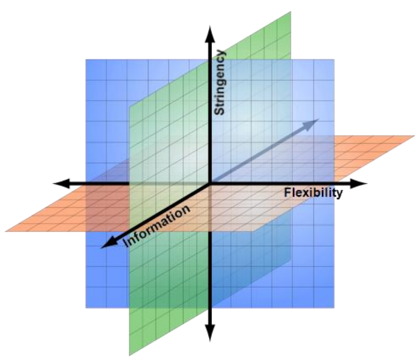

Figure 2. Regulation can change along three “innovation dimensions”: stringency, flexibility, and information.[3]

Relative to the prior regulatory regime, new regulation can change along three dimensions related to innovation—flexibility, information, and stringency (Figure 2)—although not all regulations will change along all three. *Flexibility* describes the number of implementation paths firms have available for compliance. *Information* measures whether a regulation promotes more or less complete information in the market. *Stringency* measures the degree to which a regulation requires compliance innovation and imposes a compliance burden on a firm, industry or market. Each dimension plays a large role in determining the impact of regulation on innovation. Greater flexibility and more complete information generally aid innovation; with stringency, there is a trade-off between the compliance burden and the type of innovation desired, as more radical innovation will generally come at a higher cost.

Before a regulation is implemented along one or more of these dimensions, it is typically preceded by uncertainty. *Policy uncertainty* occurs when a firm or industry anticipates the

[3] Adapted from Wikimedia Commons, Sakurambo, http://commons.wikimedia.org/wiki/File:3D_coordinate_system.svg.

enactment of a regulation at some time in the future.[4] Policy uncertainty has a mixed effect on innovation, although often it will precipitate the effects of the innovation dimensions of the regulation itself, regardless of whether the regulation is eventually enacted or not. For example, if firms expect a change in the stringency of a regulation to require compliance innovation, then policy uncertainty may spur innovation prior to the regulation being enacted. Likewise, the compliance burden may affect firms prior to enactment if, in anticipation, they begin diverting resources toward compliance. That said, this behavior assumes that the degree of policy uncertainty is not so large as to discourage business decision making entirely. If policy uncertainty is high and the optimal decisions with and without the regulation are contradictory, then firms may suspend investment in innovation until a policy uncertainty is reduced to a more comfortable level (Ishii and Yan, 2004).

Stringency

Ashford et al. (1985, p. 426) call stringency "the most important factor influencing technological innovation." A regulation's *stringency* is the degree of change required for compliance innovation or of the change in the "essential" compliance burden of the regulation—the minimal compliance burden necessary to achieve the desired outcome of the regulation. For example, a stringent performance or specification standard may require a "significant" change in technology. Or a stringent price control may require a significant change in a product's price, thereby imposing a high compliance burden (Ashford, 1985, p. 426). Often, the degree of compliance innovation and the degree of compliance burden required go hand-in-hand—in other words, compliance innovation is positively correlated with compliance burden. (Many studies use compliance costs are a proxy for regulatory stringency.)

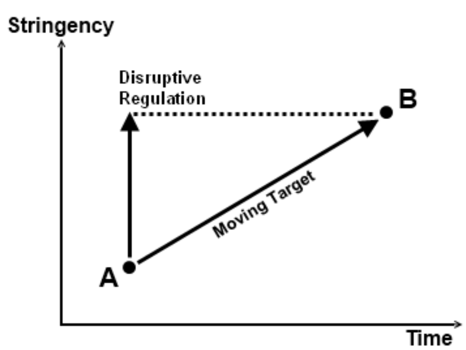

Figure 3. To achieve regulatory outcome B, regulators can employ a "moving target" to increase stringency gradually, or they can enact "disruptive regulation" and fully increase stringency all at once.

In order to achieve a particular outcome, a regulator can tighten the stringency of regulations in two ways. One option is to gradually increase the stringency of a regulation over time, which typically manifests as "*moving target*" regulation (Stewart, 1981, pp. 1271-1272) (Figure 3). Often, as soon as the firm or industry is in compliance, the regulators will tighten the stringency of the regulation further. Moving target regulation is more apt to result in incremental innovation, if only because it does not demand radical innovation, so firms tend to take the least costly and risky path. Although moving target innovation minimizes the compliance burden imposed on firms, the resulting incremental innovation does not typically afford the large benefit gains of radical innovation. Another disadvantage of moving target regulation is that it may actually disincentivize innovative activity if firms know that as soon as they comply with the regulation, the regulators will simply tighten the regulation again.

[4] Policy uncertainty is often termed "regulatory uncertainty" in the literature. This paper uses the term "policy uncertainty" to more clearly differentiate it from the "compliance uncertainty" described below.

The second option for regulators is to increase the stringency of the regulation to meet the desired outcome all at once. The primary innovation advantage of this approach is that it can encourage radical innovation by, in essence, simply demanding that it occur. Because of this, static stringency is akin to *disruptive regulation*, in that it disrupts the existing products and processes of firms and industries and forces them to undergo radical reengineering. The main disadvantage of disruptive regulation is that it imposes a high compliance burden on firms. Moreover, because disruptive regulation can drastically shift production away from a preexisting market equilibrium, any resulting products and processes will face uncertain commercial viability, and thus disruptive regulation can increase the likelihood of "dud" inventions.

Flexibility

The flexibility of a regulation can determine the cost burden and the probability of producing "dud" inventions. One classification of flexibility is the authority structure of the regulation. *Command-and-control regulations* are behavioral obligations. A firm may be obligated to lower the price of its output, for example. Or it may be required to reduce pollution emissions. On the other hand, *incentives-based regulations* make a particular behavior more profitable for a firm to pursue. The firm can weigh the regulatory incentives for the encouraged behavior against other market incentives and then decide to what degree (or when) to behave as desired by the regulator. On an industry-wide level, the greater flexibility afforded by incentives-based regulation can minimize the compliance burden for the industry as a whole, because those firms for which behavioral compliance is relatively less costly will assume more of the burden of the regulation, instead of the burden being evenly distributed across all firms, including those with higher compliance costs.[5] In environmental economics, a classic example of incentives-based regulation is a system of tradable permits for emissions, whereby the total emissions are capped, the total allowed emissions are allocated among firms, and then those firms that lower emissions below their allocation—typically those with the lowest reduction costs—can trade their permits to those that exceed their allocation—those with higher reduction costs.[6]

Another measure of flexibility pertains to the stage the specificity of the regulation. *Specification standards* or *technical standards* govern the material composition or the technical configuration of a product or process. For example, the Clean Air Act requires some firms to use the "best available technology" to control pollutant emissions from plants and vehicles. On the other hand, *performance standards* set a benchmark for the performance of the product or process. They are more flexible than specification standards in that they allow firms to choose their own path to compliance. Not only can this reduce the compliance burden, but it can also directly reduce the probability that the firm will produce a "dud" invention, assuming, in both cases, that the firm is a more effective decision maker than the regulator. Emissions standards are a classic example of a performance standard.

[5] There are many caveats to this simple analysis. For example, incentives-based regimes may be less suited to more stringent regulations. See, for example, Hahn and Stavins (1992) and Harrington and Morgenstern (2007).

[6] Marginal costs. That said, the lower cost burden of incentives-based regulation is, again, a generalization; the precise impact of command-and-control versus incentives-based regulation is, as always, case specific. Although outside the scope of this paper, another popular example of an incentives-based regime is Pigovian taxation. See Baumol (1972).

Information

Regulation can promote more complete information about products and processes in the marketplace. Regulation can also induce uncertainty. Each affects the compliance burden of a regulation and the probability that compliance innovation will result in "dud" inventions. In general, more complete information aids innovation. One example is regulation that reduces information asymmetry. Information asymmetry occurs when one side of the market—typically the consumer side—has less information about a product than the producer side. When information asymmetry is present, regulation that helps alleviate the asymmetry may offset its own compliance burden somewhat. An important case is when regulation promotes more complete information by acting as a certification of the quality of the product for consumers, thereby *adding compliance value* for producers. For example, preapproval screening of drugs by the Food and Drug Administration (FDA) may act as a certification of the quality and efficacy of new drugs, thereby raising their value on the market, increasing firms' return on investment, and thus reducing the compliance burden of the preapproval screening requirement. Although not a reduction of information asymmetry per se, regulation may also add compliance value by improving information on the producer side of the market. In this case, the higher compliance bar set by the regulation ensures that the invention is of a particular quality and thus more apt to become a commercial success, thereby reducing the number of "dud" inventions. The strong assumption here is, of course, that the standards for compliance accurately reflect consumer demand, although value can be also added simply by knowledgeable regulators providing useful feedback during the innovation process. It is doubtful, however, that either effect would fully offset compliance burden of the regulation (Katz, 2007; Norberg-Bohm, 1999).

Uncertainty occurs in the absence of complete information. Uncertainty caused by an existing regulation is *compliance uncertainty*, which can take two forms. In the first, a firm may be uncertain as to whether a product or process will comply with preexisting regulation. For example, a pharmaceutical company may be uncertain whether the FDA will approve a new drug. This first form can also occur when the details of the regulation are unclear or difficult to interpret. In the second form, a firm may be uncertain about the length of the delay before a product complies with regulation in order to reach the market—otherwise known as "regulatory delay" (Braeutigam, 1981, p. 99). In this case, the pharmaceutical company may be unsure whether approval for the new drug will take two years or ten years. In both forms, a regulation creates uncertainty about a return on investment, thereby increasing its compliance burden (Table 1).[7]

Regulation	Compliance Burden	Compliance Innovation	
		"Dud" Inventions	Innovation
Flexibility			
Command and control	Higher	–	–

[7] Interestingly, with regulatory delay, uncertainty may lower the compliance burden if the firm underestimates the length of the lag before compliance—for example, a pharmaceutical company may be less likely to invest in drug R&D if it is certain that a drug trial will take ten years, versus a case where the company, under compliance uncertainty, (incorrectly) expected the trial to take five years.

Incentives-based	Lower	–	–
Specification standards	Higher	More	–
Performance standards	Lower	Less	–
Information			
Compliance value added	Lower	Lower	–
Compliance uncertainty	Higher	–	–
Stringency			
Moving target	Lower	Less	None/Incremental
Disruptive regulation	Higher	More	Radical

Table 1. Selected attributes of regulations and their theoretical impacts on innovation.

Classifications of Regulation and Innovation

To conduct a high-level analysis on the impact of regulation on innovation, it is necessary to not only look at specific attributes, but also to classify both regulation and innovation broadly. Regulation differs broadly in its intent, which has a significant effect on whether innovation occurs and also on determining the beneficiaries of the innovation. And distinguishing between the beneficiaries of innovation highlights the changes in the nature of innovation than can occur within a firm or industry once regulation is imposed.

Intent

In textbook economics, government regulation is divided into two broad categories based upon the regulation's intent: economic regulation and social regulation. *Economic regulation* sets market conditions. Some examples of economic regulation are price controls, market entry conditions, production obligations, the regulation of contract terms, and most regulations governing the finance industry. Often, the application of economic regulation changes the allocative and dynamic efficiency of a market; it may also affect market equality and fairness. For example, a primary function of the Federal Communications Commission (FCC) is to allocate radio spectrum among telecommunications providers; that is, the FCC decides what firms can enter the wireless telecommunications market. The Securities and Exchange Commission (SEC) regulates securities transactions to maintain fair and efficient securities markets. *Social regulation* is the imposition of requirements on firms to protect the welfare of society or the environment. Typically, social regulation seeks to correct a market externality. Some examples of social regulation are environmental controls, health and safety regulations, and the regulation of advertising and labeling. The FDA engages in social regulation through functions such as the enforcement of drug safety screening and product labeling requirements. The Environmental Protection Agency (EPA) seeks to mitigate pollution, a market externality.

Beneficiaries of Innovation

Classified by its beneficiaries, there are two types of innovation: market innovation and social innovation. Stewart (1981, p. 1279) defines *market innovation* as "product or process innovations that create benefits that firms can capture through the sale of goods and services in the market." Market innovation typically benefits producers, consumers and society at large, although there are cases where it may only benefit producers at the expense of social welfare.[8] *Social innovation* refers to "product and process innovations that create social benefits, such as cleaner air, that firms cannot directly capture through market sales." Although firms do not directly capture the benefits of social innovation, the Schumpeterian definition of innovation still applies in that the innovation must be commercially successful.[9] The distinction between market innovation and social innovation is important because regulation often impacts each sort differently. For example, environmental regulation may spur a firm to develop a new, cleaner technology—a positive impact on social innovation—yet may divert resources from potentially more profitable innovations—a negative impact on market innovation. Indeed, there is a wide collection of literature that focuses solely on the impact of regulation on environmental innovation, while often paying little attention to the regulation's impact on market innovation.

Porter Hypothesis

Whether or not social regulation stimulates market innovation as opposed to solely social innovation (or any innovation at all) is the central theme of the debate surrounding the Porter Hypothesis. Put forward by Michael Porter in the early 1990s, the Porter Hypothesis posits that social regulations—and environmental regulation in particular—not only induce innovation but also often enhance the competitiveness of the regulated firms and industries by increasing the "resource efficiency" of production or by increasing the quality of the products. Furthermore, Porter argues that early regulation that spurs compliance innovation can provide the regulated industry with a first-mover advantage, thereby capturing market share from competitors that are regulated later market (Porter, 1991; Porter and van der Linde 1995b; Ashford and Hall, 2011). The Porter Hypothesis is controversial, however. For example, the EPA is currently seeking to impose more stringent regulation on greenhouse gas emissions and ground-level pollutants such as mercury. But many in Congress and industry have argued that the regulations would "devastate U.S. competitiveness" and are seeking to block the EPA from taking action (Barrett, 2011). The following literature review will, in part, seek to enlighten the Porter Hypothesis debate with an overview of the empirical evidence.

Literature Review

This section examines the empirical evidence on the impact of government regulation on innovation. The review is organized by industry for readability, as the analysis and narrative is generally similar within industries. In every case examined, the essential attributes from the taxonomy that are present are highlighted and explained. Nearly all cases are classified as either economic or social regulation, and the innovative benefits are classified as market or social innovation.[10] For simplicity, the focus is on administrative law with the exclusion of antitrust, patent law and adjudication, which operate in very different regulatory environments. Also, an

[8] For example, see Warren (2008).
[9] Although social innovation is less profitable for firms, if it is accepted by both the producers and the consumers, then it is a commercial success.
[10] In cases that involve changes in regulatory stringency, nearly all focus on increasing rather than decreasing stringency. The reason for this is to narrow the focus of this paper to the impact of regulation, rather than the impact of deregulation. Moreover, although reduced stringency is often deemed "deregulation" in the literature, deregulation is an imprecise term that can take many forms outside the scope of this paper.

overriding assumption is that regulation is exogenous—in other words, factors that affect regulation, such as political influence, are not assessed. Importantly, the review does not evaluate the accuracy or the merit of each work, as such an effort is inherently subjective and risks introducing bias into the analysis. Instead, the review covers a broad range of literature in order to provide a relatively unbiased overview of the subject.[11] That said, there is certainly selection bias inherent to the body of literature as a whole: topics that are of greater relevance to social and political discussion receive greater attention from experts than have those on the periphery of social discussion. For example, the impact of environmental regulation has received an abundance of attention, while the impact of economic regulation on social innovation has hardly been explored at all.

Manufacturing

Jaffe and Palmer (1996) use regression analysis to analyze the relationship between the stringency of environmental regulations and innovation in U.S. manufacturing industries, and their results are mixed. While they find no relationship between environmental compliance costs (as a proxy for static stringency) and patent counts, they do find a statistically significant relationship between compliance costs and R&D expenditures. Noting that these results are somewhat contradictory, and the difficulty in classifying patent data by industry, the authors warn that their results cannot be considered conclusive. Furthermore, the authors cannot distinguish whether the increase in R&D activity is an indicator of market innovation or social innovation—they are unable to discern whether the regulation has caused firms to "wake up and think in new and creative ways about their products and processes," or whether firms are increasing R&D to comply with regulation at the expense other, potentially more profitable R&D investments (p. 18).

Pickman (1998) performs a test similar to that of Jaffe and Palmer (1996) and finds that social regulation causes firms to change the direction of innovation, from market innovation to social innovation. She employs a more complex regression analysis and limits her innovation proxy to environmental patents—thus she focuses exclusively on "environmental innovation." Pickman finds a statistically significant positive relationship between environmental compliance costs and environmental patenting, indicating that regulation does indeed spur environmental innovation. Her findings may go some way toward answering the question posed by Jaffe and Palmer (1996): to comply with social regulation, firms tend to divert R&D expenditures from market-oriented innovation to compliance-oriented social innovation.

Like Pickman (1998), Brunnermeier and Cohen (2003) also examine the impact of environmental regulation on environmental innovation, but they also include the degree of enforcement as an explanatory variable. They find a small but statistically significant effect of compliance costs on environmental innovation, as measured by environmental patent activity. (It is certainly small: a 0.04 percent increase in patents per $1 million in compliance expenditures.) They also test enforcement's effect on innovation using pollution inspection data from the EPA, but they find no significant relationship between enforcement and innovation.

[11] Note that the accuracy of various proxies for innovation—such as patents or R&D expenditure—varies widely. For example, patent counts may be subject to biases in patent law across countries, as regulatory incentives for patenting may skew patent counts may skew patent counts in favor of certain nations, regardless of the actual location of the innovative activity.

Pharmaceutical and Biotechnology Manufacturing

Hauptman and Roberts (1987) use regression models to examine the effect of increased stringency of social regulation on young firms in the biotechnology industry, and they find that the resulting compliance uncertainty reduced market innovation—especially that of advanced technology products—but that innovation rebounded after several years. The regulation they examined was a 1976 FDA amendment that increased the preapproval scrutiny of medical devices. Following the amendment, Hauptman and Roberts observe a sharp drop in production. After four years, however, the trend was reversed, leading the authors to hypothesize that the firms' management adapted their processes to operate effectively in the more stringent regulatory environment. Wrubel et al. (1997) also observe this rebound effect in a study of the impact of social regulation on the market innovation of genetically engineered microorganisms (GEMs), but they attribute the recovery of innovation to adaptation not by firms, but rather by regulators. They assert that early GEM innovators suffered from both regulatory stringency and compliance uncertainty due to unclear regulatory requirements, but, as the industry matured and regulators gained more experience with GEM products, regulations were clarified and streamlined, thereby easing the burden on innovation.

Grabowski and Vernon (1977) employ a regression model to analyze the effects of social regulation on the pharmaceutical industry. They find that increased stringency and compliance uncertainty due to regulatory delay resulted in a decrease in the market innovation of new drugs. In essence, regulation caused drug innovation to concentrate in larger, multinational firms that were better able to deal with the regulatory costs, which reduced competition in the pharmaceutical industry, resulting in less market innovation and thus a decline in the supply of new drugs. Grabowski et al. (1978) come to a similar conclusion when they compare changes in productivity following increased regulatory stringency in the United States and the United Kingdom, finding that the 1962 Kefauver-Harris Amendments, which increased the rigor of new drug screening, caused the costs of a "new chemical entity" in the United States to double, reducing market innovation. Like Grabowski et al. (1978), Thomas (1990) uses a regression analysis to examine the gradually increasing stringency of FDA regulations from 1962, using the United Kingdom as a baseline for regulatory stringency. He finds that market innovation fell substantially in smaller pharmaceutical firms but larger firms were unaffected. Moreover, the larger firms gained market share at the expense of the smaller firms; thus, increased stringency may have in fact been beneficial for large pharmaceutical firms, although it is unclear whether this translated to higher innovative activity.

On the other side of the debate, both Katz (2007) and Eisenberg (2007) posit that social regulation that promotes more complete information in a market can stimulate market innovation by adding compliance value. Katz argues that stringent FDA regulations, such as preapproval screening and post-approval warnings, serve as "anti-lemon devices," whereby the certification of drug safety and effectiveness increases the value of drugs that make it to the market, thus increasing their expected returns and incentivizing innovation. It is uncertain, however, whether this added value would outweigh the value lost due to the higher compliance burden. Munos (2009) frames this argument in an international context of the Porter Hypothesis when he asserts that, by reducing the number of lemon drugs produced by domestic firms, stringent social regulation of pharmaceuticals may increase the value of U.S. drugs overseas, further augmenting market innovation within U.S. pharmaceutical firms. Gastineau (2004) reviews regulation of the blood cell manufacturing industry and, while warning against the negative effects of compliance uncertainty caused by preapproval screening, he lauds the “helpful advice and comments” from regulators (p. 780). This is evidence of compliance value being added through the promotion of more complete information on the producer side of the market.

Employing a regression model to analyze cross-country data on the 20 largest pharmaceutical companies, Vernon (2003) finds that economic regulation in the form of drug price controls would have a negative impact on the market innovation of new drugs. His analysis shows that if the United States implemented a price control policy that was identical to the average degree of price regulation in pharmaceutical markets overseas, then industry R&D intensity would decline by 36.1 to 47.5 percent, although he cautions that, owing to the heterogeneity of price controls across countries, this is certainly an oversimplification. Moreover, the standard errors in his analysis are large, and thus the degree by which R&D intensity would decline is highly variable.

Along with similar technical caveats, Vernon (2005) reinforces these findings using a similar regression model under different assumptions. Instead of assuming that the U.S. policy uses the worldwide average degree of price regulation, Vernon (2005) assumes that “the new policy will cause U.S. pharmaceutical prices to be regulated in such a manner as to make U.S. pharmaceutical profit margins equal, on average, to non-U.S. pharmaceutical profit margins” (p. 9), although it is unclear whether this assumption implies a more or less stringent regulatory regime than Vernon (2003). He finds that industry R&D intensity would decline by 23.4 to 32.7 percent. Golec and Vernon (2010) estimate that if the United States had implemented price controls between 1986 and 2004, they would have led to 117 fewer new drugs reaching the market. Vernon et al. (2006) include the effect of drug importation regulation in their analysis, and they too find that economic regulation would reduce market innovation. Golec and Vernon (2010) and Vernon et al. (2006) also introduce an important caveat to their analysis: they concede that their paper does not answer the question of whether or not regulated drug prices in the U.S. … “will, on net, improve social welfare” (Vernon et al., 2006, p. 175). In other words, their analysis focused on the regulatory impact on market innovation; the harder-to-measure impact on social innovation, if any, is not assessed.[12]

Golec et al. (2005) show that policy uncertainty surrounding price controls can reduce market innovation well before the regulation is in effect. They also show that regulation may not reduce market innovation per se, but rather it may change the nature of innovation. Their study uses the Clinton Administration’s proposed 1993 Health Security Act (HSA) as a natural experiment to study the effect of proposed drug price controls on biotech and pharmaceutical firms. They find that the mere proposal of the HSA reduced firm R&D spending by about $1 billion and caused firms to cut back on clinical trials; however, they find that the number of patent filings rose sharply. To explain this contradiction, they conjecture that firms used patents—which are relatively less expensive than R&D and clinical trials—to show investors that they were still active. This would imply that firms shifted resources from developing expensive breakthrough drugs to “cheaper-to-develop supplemental … drugs and improved manufacturing”—both patentable innovations that do not require heavy R&D investment (pp. 20-21).

[12] Santerre and Vernon (2006) explore this issue and find that the consumer welfare gains due to price controls would not offset the welfare losses due to the reduced supply of new drugs. Hughes et al. (2002) come to a similar conclusion.

Automobile Manufacturing

Atkinson and Garner (1987) find that social regulation had a positive impact on both market innovation and social innovation in the U.S. automobile industry. They study the impact of the flexible performance-standards-based regulatory regimes that were implemented in the 1960s and 1970s, including the introduction of stringent emissions standards with the Clean Air Act Amendments of 1970, the corporate average fuel economy (CAFE) standards enacted by the Energy Policy and Conservation Act of 1975, and the stringent safety standards implemented by the National Traffic and Motor Vehicle Safety Act of 1966. Importantly, Atkinson and Garner argue that these disruptive environmental standards brought the American auto industry more in line with customer demand for lighter, more fuel-efficient automobiles, helping it compete with already-efficient Japanese vehicles, which began arriving on the domestic market in the 1960s. Hence, Atkinson and Garner argue, not only did the environmental performance standards bring about social innovation in the form of reduced emissions in the short term, but those same innovations also allowed U.S. automakers to retain market share, and thus, over the long term as the regulations became integrated into the global market, those social innovations evolved into market innovations.[13] The stringent regulations also forced automobile firms to spend less on money on annual style changes:

> From the perspective of the American paradigm, such a result was clearly negative; the more styles and options available, the higher sales and profits. However, if viewed from the global paradigm, such a result was clearly beneficial. It coincided with a shift toward more utilitarian styles and more emphasis on the engineering components of the car. (p. 365)

Nevertheless, Atkinson and Garner emphasize that the success of these social regulations very much depended upon the nature of the auto industry at the time—for example, the regulations came at a time when the vehicle market was experiencing a pronounced change in customer demand combined with increased competiveness due to globalization—social regulation implemented through performance standards is certainly not unequivocally advantageous.

Gerard and Lave (2005) examine the same disruptive performance standards as Atkinson and Garner (1987) but find that their success at promoting social innovation was mixed and quite costly for the automobile industry. They explain that U.S. automobile firms succeeded in developing moderately radical catalytic converter technology to reduce hydrocarbon and carbon monoxide emissions, but by 1977, they had not yet met the stringent standards of the Clean Air Act Amendments. Moreover, nitrogen oxides emissions remained more than twice as high as their target. Meeting the stringent standards required the development of three-way catalyst technology, but this required even more radical engine and technology improvements, and thus a heavy R&D investment. In fact, after the development of the catalytic converter, Gerard and Lave find that both industry R&D intensity and patenting dropped sharply in 1975, although the authors are uncertain as to whether this was due to severe economic pressure or because firms sensed that the enforcement of further emissions reductions did not have political support. Congress was faced with the possibility of an industry-wide shutdown and instead chose to reduce the stringency of the standards by lowering the emissions targets and allowing for waivers. Technology to meet the standards was finally introduced in 1981, although not without

[13] Sperling et al. (2004) agree that the standards forced automakers to move from their "lethargic behavior of the 1960s," but argue that they also allowed Japanese automakers to more easily enter the U.S. market (p. 17).

some difficulty: GM recalled every single vehicle it produced in 1981 and 1982. According to the authors, "A longer phase-in of the technology would have saved the company considerable expense," indicating that perhaps moving-target-style regulations would have been more efficient (p. 774).

Goldberg (1998) performs a regression analysis to examine the impact of the CAFE performance standards in 1989 and finds that they were successful at spurring social innovation. Interestingly, she tests whether the downward pressure on fuel consumption due to the standards was offset by two effects: a "utilization" effect, whereby consumers increase the mileage driven in fuel efficient cars; and a "compositional" effect, in which consumers switch to less fuel efficient models. She finds no evidence of the former and little evidence of the latter, suggesting that social innovation did occur. She also finds that the cost burden of the regulation was borne solely by the automobile companies and not by consumers, suggesting "that CAFE may not fare that badly from a welfare point of view" (p. 31).

Pilkington and Dyerson (2006) examine the development of electric vehicle technologies and find that while emissions regulations effectively promoted incremental social innovation in internal combustion engine vehicles, they did not produce the radical innovations required for the commercialization of electric vehicles; they produced "duds." The authors use international patent data as a proxy for innovation and recognize a correlation between regulatory stringency and technological capability. They speculate that regulation to promote zero-emissions vehicles (such as the electric car) failed because the stringency of the mandates were reduced after several years, thereby eliminating "any protected niche market to allow the nurturing of the new technology to a performance level that challenges the existing dominant design" (p. 89).

Chemical Manufacturing

Ashford and Heaton (1983) conduct a detailed qualitative analysis of the impact of social regulation, including the 1976 Toxic Substances Control Act (TSCA), on market innovation in the chemical industry, and their findings are mixed. They divide the regulations they examine into preapproval screening regulations and end-of-pipe regulations (the regulation of existing products and processes). They find that the compliance uncertainty caused by premarket screening regulations tend to negatively impact market innovation in small and new firms, while positively impacting market innovation in larger, more established firms. They suggest several possible causes, including the fact that new firms tend to introduce new products, which are then subject to the approval process, and also that larger firms are better able to cope with the compliance burden. That said, they also find evidence that compliance value added by premarket screening may aid market innovation: in this case, the more rigorous R&D required to ensure approval leads the firm itself to gain more knowledge about potential applications of the product, which in turn leads to more innovation within every class of firm. With respect to the regulation of existing products and processes, the authors find that more stringent regulations tend to spur market innovations, although they may also delay the development of compliance technologies.

Davies (1983) finds that the TSCA had a somewhat negative effect on market innovation but a positive effect on social innovation. After savaging the conclusions of several previous studies that found a significant fall in market innovation, he asserts that the negative impact on market innovation is small and likely due to compliance uncertainty, in that many small manufacturers misinterpret the law's premanufacturing reporting requirements. He also asserts that the TSCA stimulated social innovation and perhaps market innovation through both process and product innovations, such as the recycling of material that was previously discharged into the environment. He argues, however, that "health and safety regulation must be justified on the grounds of improved health and safety, not as an obscure and indirect way of stimulating innovation" (p. 57).

Ollinger and Fernandez-Cornejo (1998) use regression analysis to study the effect of environmental regulation on the innovation of pesticides between 1972 and 1991 and find that increasing regulatory costs decreased the number of pesticides brought to the market. But, they also find that the regulation encouraged firms to develop less toxic pesticides, suggesting that regulation resulted in an increase in social innovation. However, social innovation did not increase by enough to offset the decrease in market innovation, and thus the overall innovation of pesticides was reduced.

Porter and van der Linde (1995a, 1995b) provide several anecdotal examples of environmental regulation stimulating market innovation in the chemical industry. In 1987, regulators called for Dow Chemical California to close wastewater evaporation ponds. This forced the company to redesign its production process, which resulted in an annual cost savings for the company of over $2.4 million. In another example, regulations forced Ciba-Geigy Corporation to reengineer their wastewater streams at their dye plant in New Jersey, providing annual savings of $740,000—although, the authors note, that part of the plant was ultimately closed.

Other Manufacturing Industries

In the consumer appliance industry, Newell et al. (1999) find that social regulation had a modest positive effect on social innovation. Specifically, the authors use regression analysis to investigate the impact of the performance standards established by the National Appliance Energy Conservation Act (NAECA) of 1987 on the energy efficiency of room air conditioners, central air conditions and gas water heaters (along with impact of exogenous price changes). NAECA mandated that minimum energy efficiency targets be met by 1990. During this period, the authors find that the energy efficiency of room air conditioners and gas water heaters improved by about 2 percent per year faster than they otherwise would have. That said, the authors also note that a "substantial portion of the overall change in energy efficiency for all three products cannot be associated with either prices changes or government regulations" (p. 970).

Norberg-Bohm and Rossi (1998) study environmental regulation of the pulp and paper industry and find that although it promotes social innovation, the innovation is largely incremental. They also find two cases where policy uncertainty precipitated the effects of expected future regulation. The regulations they examine are a series of EPA water quality standards that regulated discharges of the highly carcinogenic chemical dioxin, beginning in 1984. Nearly all of the firms in the study developed incremental innovations, such as chemical substitution, to comply with the regulation. Only two firms developed more radical technologies. Norberg-Bohm and Rossi conjecture that the radical innovators faced resource constraints that were not faced by the incremental innovators, and thus radical innovation presented the most cost-effective path to compliance. Furthermore, both radical innovators developed their technologies in response to preexisting regulatory requirements, and thus both were responding to policy uncertainty, positioning for more stringent regulatory requirements in the future. The most simple explanation, however, is that the incremental innovators were able to comply with the regulation through incremental innovation. Although the regulation achieved the desired compliance outcome, it was not sufficiently stringent to demand radical innovation throughout the industry.

Energy

Cohen (1979) and Marcus (1988) each study the effect of regulation on social innovation in the nuclear power industry. Marcus finds that flexibility helps promote social innovation. Through examining the safety regulations implemented by the Nuclear Regulatory Commission (NRC) following the 1979 Three Mile Island accident, he finds that regulations affected plants differently depending upon their prior safety records. The NRC took a less flexible approach to plants that had a poor safety record before the accident, while it took a more flexible approach to those with good safety records. By regressing human error events on the compliance implementation strategy undertaken by each plant, Marcus finds that poor safety records resulted in less flexible regulation, which restricted plants' implementation choices, and this in fact perpetuated poor safety performance in the future. On the other hand, a good safety record allowed for a "zone of discretion" in implementation, which resulted in continued strong safety performance. Marcus goes on to note, "If poor performers are given more autonomy, … their safety record is likely to improve" (p. 249). Cohen (1979) reviews NRC power plant licensing procedures and finds that they negatively impact market innovation through compliance uncertainty due to regulatory delay, although she suggests that this may be worth the social benefit of improved safety and quality.

Lyon (1996) finds that compliance uncertainty caused by economic regulation has a negative impact on market innovation. He examines the regulatory "hindsight reviews" that were adopted by regulators in the 1980s in response to a series of poor investments made by electric utilities. Hindsight reviews assess whether a utility's investment was "used and useful" and is a cost-effective source of power, from which the regulator determines whether the utility's investment should be disallowed. Lyon runs a simulation using data from coal-burning steam plants and finds that hindsight reviews can cause a utility to forgo investing in risky innovation and instead utilize more costly conventional technologies. Furthermore, utilities may cease making technological investments at all and instead switch to purchasing power from third-party producers.

Sickles and Streitwieser (1991) use statistical analysis to examine the impact of the Natural Gas Policy Act of 1978, which altered existing well-head price controls such that gas prices could rise more rapidly to curtail shortages in the wake of the 1973 oil price shock. Sickles and Streitwieser find that both the technical efficiency and the productivity of gas transmission firms fell over the period 1977-1985, which is indicative of flagging innovative activity. They attribute these results to a lack of flexibility in economic regulations that "could neither anticipate changing market conditions nor rapidly adjust to those changes" (p. 1).

Bellas (1998) finds evidence that the moving target of continuously revised social regulations is not conducive to market innovation in the energy industry. Using cost data as a proxy for innovation, he performs a regression analysis to examine whether the desulfurization (scrubbing) units utilized by coal power plants underwent technological improvement during the regulatory regimes specified by the environmental performance standards of the Clean Air Act and the Powerplant and Industrial Fuel Act of 1978—importantly, the stringency of sulfur emissions regulation is subject to increase as soon as costs fall. Bellas finds little evidence that the cost of scrubber units fell since their introduction, indicating that there had been little technological progress. Importantly, he observes that the market innovation of scrubbers is greater when power plants are subject to regulations that do not change in response to innovation, rather than moving-target regulations that increase in stringency as soon as costs fall.

Lange and Bellas (2005) apply the model of Bellas (1998) to the system of tradable permits established by the 1990 Clean Air Act Amendments and find more flexible incentives-based regulation to be somewhat more effective at inducing market innovation than the previous command-and-control regulatory regime. The amendments established a system of tradable permits for sulfur dioxide emissions. The authors' results show a significant drop in the cost of scrubber units following the legislation; however, when they looked at the rate of change in costs over time, it was no different than the rate before the regulation. In other words, the tradable permit system induced a sudden flurry of innovation, but the innovation then subsided, occurring at a lower rate than it did prior to the system, offsetting the increased innovation from the sudden flurry. The authors suggest that market-based policies may be useful for inducing sudden breakthrough innovation, but less suited for stimulating incremental innovation over time, although they offer little explanation for this theory.

Instead of cost data, Popp (2003) examines scrubber innovation using patent counts. Through estimating a regression model, he finds that, contrary to Lange and Bellas (2005), the level of market innovation decreased following the incentives-based social regulation of the 1990 Clean Air Act Amendments, but that social innovation increased:

> Prior to 1990, most new plants were required to install a scrubber with a 90 percent [sulfur] removal efficiency rating. As a result, there were no incentives for R&D that would increase the ability of scrubbers to control pollution. However, there were incentives to perform R&D to lower the costs of operating these scrubbers, and thus lower the costs of complying with the regulation. In contrast, the [sulfur dioxide] permit market established by the 1990 Clean Air Act provided incentives to install scrubbers with higher removal efficiencies, and thus led to more R&D designed to improve the removal efficiency of scrubbers. (p. 658)

Hence, although innovative activity still occurred, the benefits of the innovative activity were redirected from the firm to society and the environment.

Taylor et al. (2005) take a more qualitative look at the Clean Air Act's effect on the market innovation of scrubber units. Using patent counts as well as R&D investment figures and expert interviews, they find that government regulation precipitated by policy uncertainty can stimulate market innovation.[14] And, contrary to Popp (2003), they find that the incentive-based standards of 1990 did not lead to more innovation than the prior regime of performance standards. However, this does not refute incentives-based regimes in general, they argue; rather, the incentives system simply came too late in the maturation of scrubber technology to have an effect.

[14] Ishii and Yan (2004) find that policy uncertainty reduces capital expenditure in the energy industry, although capital expenditure is a relatively poor proxy for innovation. These results could be extrapolated to innovation, however, and may provide some evidence that policy uncertainty stifles innovation in the energy industry.

Through regression analysis, Majumdar and Marcus (2001) find that incentives-based regulation of electric utilities leads to higher productivity—a proxy for market innovation—compared to command-and-control regulation. They analyze the time period around the 1990 Clean Air Act Amendments, which established the system of tradable permits for pollution control. Their productivity measure includes total sales and energy disposition as outputs, and total production, transmission, distribution, employees, and purchasing power as inputs. Their results show that the productivity of electric utilities was lower during the prior command-and-control regime. Additionally, their results indicate that regulations that are stringent but flexible in terms of the firm's path to implementation are more effective at promoting market innovation.

Popp (2006) employs a regression model with patent data from the United States, Japan, and Germany to measure the impact of sulfur dioxide and nitrogen oxide emissions standards on pollution control innovations among electric utilities. He finds that more stringent U.S. emissions standards resulted in greater innovation in the United States but had no effect on innovation in Japan and Germany. Popp concludes that U.S. firms innovate in response to domestic regulations, but not foreign regulations. Furthermore, he finds that domestic firms innovate even for technologies that have already experienced significant innovative activity abroad, although his results also show that earlier foreign patents serve as an important building block for U.S. nitrous oxide emissions innovations.

Johnstone et al. (2008) examine the effect of various economic regulations on the market innovation of renewable energy technologies in OECD countries, and they find that the effect of different regulatory regimes varies across energy sources.[15] Their regression models specify a relationship between renewable energy patent counts, as a proxy for innovation, and policy instruments, including public R&D support, investment incentives, tax incentives, voluntary programs, quantity obligations, and tradable permits. Regressing the patent counts for each renewable on an aggregate policy variable representing the effect of regulation in general, they find that, in general, economic regulation has a positive effect on the innovation of all energy sources. Regressing an aggregate patent count representing all renewables on each policy instrument, they find that only tax incentives, quantity obligations, and tradable certificates have a positive effect on renewable energy innovation overall. Then, they regress each energy source on each policy instrument. These estimations show that investment incentives stimulate innovation on solar and waste-to-energy technologies, that tariff structures spur biomass energy innovation, and that production obligations (often linked to tradable certificates) support wind technology innovation. Only tax incentives stimulated innovation for a wide range of renewable energy sources. Because the study uses a wide array of patent data, it is unclear whether their results indicated market innovation or social innovation.

Healthcare

There has been little empirical research on the impact of regulation on innovation in hospitals, hospices, nursing homes, and the like. One possible explanation for the dearth of literature is that many of the innovative products employed by the healthcare industry are produced by other industries, such as manufacturing, pharmaceuticals, and biotechnology. Motivated by the lack of

[15] Although the regulation of renewable energy is ultimately geared toward the welfare of the environment, the regulations discussed here are economic, not social regulations, because they do not require the renewable firms to protect the welfare of environment. Rather, they manipulate the conditions of the market in order to aid renewable energy firms, typically at the economic expense of nonrenewable energy firms.

research on the subject, Walshe and Shortell (2004) conducted a study on the impact of social regulation on healthcare organizations' performance. They find that social regulation of healthcare organizations had a generally positive effect on social innovation but a generally negative effect on market innovation. Throughout 2001 and 2002, they interviewed leading researchers, governmental and nongovernmental regulators, executives of regulated healthcare organizations, and others involved in the healthcare field. Unremarkably, they find that regulators tend to have a positive view of the effects of regulation, while those inside the healthcare industry are more ambivalent. Some interviewees lauded the moving-target approach to regulation, whereby continuously revised standards caused sustained process improvements. Other interviewees viewed regulations as an impediment that prevented them from progressing with desirable innovations and complained that they distorted the priorities of the healthcare organization. Assuming that market innovations are generally a higher priority for a firm and that social innovations are of a lower priority, the survey responses signal that market innovation suffered under regulatory scrutiny, while social innovation was spurred.

Telecommunications

Prieger (2002) studies a period of decreased stringency in the economic regulation of telecommunications providers and finds that reduced compliance uncertainty allowed market innovation to increase by 60 to 99 percent. The regulation Prieger studies is the requirement that large telecommunications carriers—those that control local telephone networks—submit "comparably efficient interconnection" (CEI) plans to the FCC whenever they introduce a new telephony service. The CEI plans theoretically allow smaller rivals to offer similar services on the local networks. Between 1992 and 1995, the FCC did not require firms to submit CEI plans, and Prieger uses this as a natural experiment to study effect of stringency on telecommunications innovation. He develops a regression model that tests the effect of regulatory delay on the introduction of new services. Overall, his results indicate that telecommunications firms would have introduced 62 percent more services during his analysis period had the more stringent CEI regulation not been in effect.

Likewise, Prieger (2007) uses a regression model to examine the effect of compliance uncertainty due to regulatory delay and finds that reduced regulatory delay increased market innovation. His analysis focuses on state telecommunications regulations in Illinois, Indiana, Ohio and Wisconsin. As a proxy for innovation, he uses introduction dates of innovations by the firm Ameritech (now part of AT&T). The introduction of a new service required Ameritech to petition the public utility commission in each state, which resulted in regulatory delay. Prieger finds that the reduction of the average length of regulatory delay in the late 1990s contributed to faster introduction of new products from Ameritech.

Ai and Sappington (2002) study the impact of the change in the economic regulation of telecommunications firms from rate-of-return regulation to more flexible incentive-based regulations and find that it resulted in an increase in market innovation. Beginning in the late 1980s, telecommunications regulators began switching from rate-of-return regulation of carriers, in which firms are required to charge a price equal to their cost of capital plus some specified rate of return, to incentive-based regulations, such as earnings sharing regulation, which requires the firm to share earnings with its customers. Ai and Sappington's regression analysis indicates that the change in regulatory regimes contributed to increased network modernization and process improvements measured by lower operating costs. Similarly, Schmalensee and Rholfs

(1992) and Tardiff and Taylor (1993) both find that the change in regulatory regimes resulted in an increase in total factor productivity, a measure of technological innovation. On the other hand, Shin and Ying (1993) find that service costs increased under incentive regulation, indicating that market innovation may not have occurred (Kridel et al., 1996).

Kahn et al. (1999) look at the Telecommunications Act of 1996 and argue that the economic regulatory overhaul, designed to promote competition among telecommunications carriers, created barriers to market innovation. First, they argue that the previous, less flexible rate-of-return system actually offered greater incentives for market innovation, because carriers could incorporate their R&D expenditures in their capital costs. This allowed them to undertake large-scale and risky R&D activities—that is, radical innovative activities—that are harder to justify in a highly competitive market. Second, Kahn et al. attack the stringent regulation that requires larger regional carriers to share their local wired telephone networks with local competitors. The authors label the notion that regional carriers will continue to invest in risky innovation when they then have to share them with their competitors an "anti-patent system" and, "quite simply, ludicrous" (pp. 347-349).

Finance and Banking

There are few empirical studies on the impact of regulation on innovation in the financial sector. In searching for literature on how to determine an optimal level of regulation of the financial industry, Jackson (2007) discovered that "no such literature or guidance exists" (p. 253). One problem is that the financial industry in the United States has undergone a sustained period of deregulation over the past several decades, and thus, until the global financial crisis of 2007-2009, the subject of regulation (or re-regulation) captured few researchers' interest. Moreover, the majority of literature on financial regulation assumes financial innovation to be an exogenous factor, and, while many analyze the indirect interaction of regulation and innovation, the direct impact of regulation on innovation itself is routinely ignored.

Nevertheless, it has long been the conventional wisdom that a significant portion of financial innovation is driven not by productivity gains but by circumventive innovation (Silber, 1983). Kane lists various market innovations, such as electronic funds transfer systems, that were substituted for other products, such as checks, as they became more heavily regulated. Likewise, Baer and Pavel (1988) use regression analysis to find that increased stringency of bank regulation, including capital taxes and reserve requirements, explains a significant portion of the growth of market innovations, such as Eurodollar deposits and standby letters of credit. The role of circumventive innovation is far from certain, however, as other studies show that regulation has less of an innovation impact. Silber (1983) conducts a simple qualitative analysis of financial innovations and finds that less than 30 percent were induced by regulation.[16] Jagtiani et al. (1995) perform a regression analysis on the effect of increased stringency of bank capital requirements and found that there was no effect on the adoption of various market innovations.

Warren (2008) suggests that the inflexibility of some economic regulations hinders the sort of market innovation that is most beneficial to consumers. For example, she cites the Truth in Lending Act, which requires the disclosure of pertinent loan information, for being overly specific in its requirements, including the size of the typeface that must be used. "The specificity

[16] According to Silber (1983), other factors that induce financial innovation are inflation, interest rates, general price level, tax effects, volatility, technology, and globalization.

of these laws works against their effectiveness, inhibiting some beneficial innovations (e.g., new ways of informing consumers) while failing to regulate dangerous innovations (e.g. no discussion of negative amortization" (p. 456).

Agriculture

Unnevehr and Jensen (1996) examine the USDA specification standard requiring Hazard Analysis Critical Control Point (HACCP) safety inspection in the meat industry. Going against the conventional economic wisdom, they regard this command-and-control regime as more efficient than potential incentive-based regimes due to inherent information asymmetry in the meat market. In other words, incentive standards would require that quality information about the safety of products is conveyed to consumers such that they can make purchasing choices. In the case of meat products, effectively conveying this information to consumers would be both costly and difficult. On the other hand, Henson and Caswell (1999) argue that command-and-control regulations tend "to restrict the freedom of [food] suppliers to control food safety in a manner that is most appropriate for their operations, hampering efficiency and innovation" (p. 596).

Aerni (2004) studies the effect of increasing regulatory stringency and policy uncertainty on fisheries and finds that they tend to respond to social regulation with market innovation in both products and processes. He asserts that the evolution of the industry from small-scale fish catching to large-scale fish catching to fish farming and fish breeding was partly in response to more stringent policies regarding high sea fishing, as well as policy incentives to promote fish farming. He also finds that many of the innovations—including aquatic biotechnology and transgenic fish breeding—were stimulated by the policy uncertainty caused by the threat of future regulation. One consequence of innovation, he notes, is that "the amount of feed used for growing salmon in 2003 is 44 percent of what it was in 1972" (p. 331).

Cross-Industry Studies

Lanjouw and Mody (1996) examine general trends of environmental innovation in response to the increasing environmental regulations in the United States, Germany, and Japan, from 1972 to 1986. They find that there is a correlation between regulatory compliance costs (as a proxy for stringency) and environmental patenting, although they do not control for other factors that would also affect environmental innovation. Nameroff et al. (2004) look at "green chemistry" patenting across all sectors in the United States, where green chemistry is defined as "chemical products and processes to reduce or eliminate the use and generation of hazardous substances" (p. 960). They find that an increase in the ratio of green chemistry patents to other chemistry patents is correlated with an increase in environmental regulation in the 1980s and early 1990s, although most of the green chemistry patenting activity is concentrated in the chemical industry.

Bargeron et al. (2010) use regression analysis to measure the impact of the more stringent and less flexible regulations of the Sarbanes-Oxley Act (SOX) on corporate risk taking, and they show that SOX had a negative impact on market innovation. Their results match their hypothesis that two provisions in particular—the requirement of an increased role for independent directors with expanded liability for corporate misdeeds, and the requirement that firms evaluate their internal control over financial reporting—increase the costs of compliance and thus the cost of investment, and thereby reduce the incentive for firms to take risks. Using data for public corporations in the United States, United Kingdom, and Canada, the authors regress firm-level

R&D expenditure on a binary variable pre- and post-SOX variable (among other control variables). They find that R&D expenditure decreased significantly among U.S. firms in the post-SOX period, while it increased significantly for U.K. and Canadian firms.[17] They also find that large firms reduced R&D expenditure significantly more than small firms, which supports the view that the cost of complying with SOX is higher for firms with greater complexity.

Findings

Although the precise impact of regulation on innovation is highly variable and case-specific, it is possible to broad patterns from the literature. Overall, these patterns roughly conform to the theory outlined in this paper. Hence, the results and guidelines presented should serve only as a starting point for evaluating the impact of proposed regulation on innovation in the private sector.

Policy uncertainty does appear to precipitate the both the negative and positive effects of expected future regulation, as shown by Golec (2005), Taylor et al. (2005), and Aerni (2004). Nevertheless, classical theory holds that policy uncertainty causes businesses to delay investment decisions, and the evidence presented here does not refute this. Most likely, the behavior of firms under policy uncertainty depends upon the level of uncertainty and the profitability of the available actions given the range of expected regulatory alternatives. Higher uncertainty and larger differences in the expected profitability of innovation investments will tend to stifle innovation.[18] Hence, as a general rule, regulators would do well to minimize policy uncertainty. However, in cases where the future regulation would demand compliance innovation, a moderate level of uncertainty might be useful as an early catalyst, while also allowing firms more time to adapt to compliance, especially in the case of disruptive regulation.

Flexible regulations, including incentives-based regulation and performance standards, tend to aid both market and social innovation by maximizing the implementation leeway available to firms, allowing the market to dictate cost efficient and commercially viable solutions. One important exception is the study by Kahn et al. (1999), which finds that incentive-based pricing regulation reduced radical innovation in the telecommunications industry. In this case, the previous command-and-control regime had provided incumbent telecommunications companies with monopoly-like price protection, allowing them to invest in more risky innovations with little fear of market repercussions. Incentives-based regulation removed this protection, in effect making the industry more competitive and reducing the incentive for incumbent firms to take risks. Regulators should be mindful of this result when their desired regulatory outcome is to promote more radical, not incremental, innovation.

Regulation that promotes more complete market information also aids both types of innovation. In particular, compliance value, added by reducing information asymmetry on the consumer side or by aiding development on the producer side, is unequivocally beneficial for innovation. Therefore, regulators should jump at opportunities to enact regulation or tweak proposed regulation such that information in the marketplace may be enhanced. Likewise, compliance

[17] These results complement those of Cohen et al. (2009), who also show that SOX disincentivizes corporate risk-taking. However, Cohen et al. aggregate R&D expenditure with other potentially risky investments that do not correlate as strongly with innovative activity, such as capital expenditure and acquisitions.

[18] For example, see Ishii and Yan (2004) and Hoffmann et al. (2008).

uncertainty is unequivocally detrimental to innovation, and thus regulators should, of course, seek to minimize regulatory delay but also to enhance the clarity and coherence of regulation—for example, by avoiding overlapping authority across regulatory agencies.

The analysis of stringency provides the most interesting results. There is a clear divide between the effects of economic regulation and the effects of social regulation: economic regulation tends to stifle market innovation; social regulation tends to stimulate social innovation; and the impact of social regulation on market innovation is mixed.[19] This result is intuitive: social regulations are more likely to require compliance innovation in order to correct externalities; economic regulations are often less focused on innovation and more concerned with economic allocation and fairness. When economic regulation does impact regulation, it is typically circumventive as opposed to compliance oriented, as with the financial industry. Cases where social regulation does indeed promote market innovation, such as in the works of Porter and van der Linde (1995a, 1995b), Atkinson and Garner (1987), and Aerni (2004), seem to support the Porter Hypothesis, in that firms' competitiveness was enhanced through improved resource efficiency and product quality. In the latter two cases, regulation forced the industries out of an innovation "rut," leading them to successfully catch a shifting wave of consumer demand. Nevertheless, in the majority of cases, social regulation in fact stifles market innovation or at least negates the producer benefits while still benefitting the environment and society (Table 2).

	Market Innovation	Social Innovation
Economic Regulation	Less	–
Social Regulation	Mixed	More

Table 2. The impact of stringent regulation on innovation.

With social regulation, there is some evidence that more stringent and disruptive regulation—when successful—tends to promote more radical innovation, whereas the moving target approach of gradually increasing stringency over time is more apt to result in incremental innovation. For example, Pilkington and Dyerson (2006) lament that the relaxation of the stringency of zero-emissions vehicle regulations resulted in only incremental technological developments, as opposed to the radical changes needed for commercial viability. Norberg-Bohm and Rossi (1998) show that regulation that is insufficiently stringent results in incremental, not radical, innovation. Gerard and Lave (2005) demonstrate that stringent regulation can result in commercial viable technology, as with the automobile catalytic converter, but also highlight the risks of stringent regulation producing commercial "duds," as with General Motor's recall of its 1981 and 1982 vehicle models.[20]

The lesson here is that stringent economic regulation, being largely detrimental to innovation, should be implemented through the moving target approach in order to minimize the compliance burden and thus its negative impact on innovation. This same lesson applies to social regulation that does not require compliance innovation. On the other hand, when crafting social regulation that will require compliance innovation, regulators should first decide what sort of innovation—

[19] There is insufficient evidence to draw a conclusion about the impact of economic regulation on social innovation.
[20] Nevertheless, the majority of cases do not explicitly differentiate between incremental and radical innovations.

incremental or radical—will be needed to achieve the desired outcome. If that outcome calls for radical innovation, then regulators should weigh the benefits of successful radical innovation against both the compliance burden of the regulation and the risk that the innovative activity would be futile or result in commercial "duds." That said, given the high level of uncertainty surrounding radical innovation, conducting an accurate assessment of the probability of commercial success is difficult. Therefore, the benefits of radical innovation should be high—a social or environmental imperative—in order safely compensate for both the cost and the risk.

Conclusion

Regulation that does not require innovation for compliance will generally stifle innovation, although it may spur circumventive innovation if the firm or industry can find a path to escape the regulatory constraints. For regulation that does require compliance innovation, the impact on innovation is nuanced. Faced with this sort of regulation, firms reallocate funding from other business activities toward the innovative activity that will bring them into compliance. Yet these other business activities may also include investments in other potential innovations—those that the firm preferred prior to the imposition of the regulation. This is evident in many cases where social regulation causes social innovation to increase but causes market innovation to decrease. Hence, the net impact of this sort of regulation on innovation is unclear; there is no way to know whether the resulting social innovation is more valuable to society than the market innovation that was forgone. Nor is it clear whether regulation that requires compliance innovation will enhance firm or industry competitiveness. On occasion, the Porter Hypothesis is borne out by the evidence: there are several cases in which social regulation does indeed improve the competitiveness of firms and industries. Nevertheless, in the majority of cases there is an apparent trade-off between market innovation that benefits the firms and that which serves only to meet the compliance standards of regulation.

What is clear is that regulators can design regulation such that it minimizes the compliance burden on firms while maximizing the probability that the compliance innovation will be successful. Regulation should be flexible, allowing the firm and the market to decide the optimal path to implementation. Regulation should also be expedient—both in its implementation and execution—and unambiguous, minimizing the uncertainty facing firms when bringing new products or processes to the market. Regulators should also jump at opportunities to reduce information asymmetry in the market, or even to provide expert knowledge in collaboration with industry in order to aid the innovation process. And regulators should be cognizant of the trade-offs between the sudden enactment of stringent regulation versus the gradual increase of stringency over time. The most elementary lesson, however, is that, regardless the impact of regulation on innovation in general, if regulators simply place innovation at the forefront of their policy analysis along with distributional, fairness, and environmental concerns, then the United States will undoubtedly see a marked and sustained improvement in its innovative potential.

References

Aerni, P. 2004. Risk, Regulation and Innovation: The Case of Aquaculture and Transgenic Fish. *Aquatic Science* 66(3): 327-341.

Ai, C., and D. E. Sappington. 2002. The Impact of State Incentive Regulation on the U.S. Telecommunications Industry. *Journal of Regulatory Economics* 22(2): 133-160.

Ashford, A. A., and G. R. Heaton. 1983. Regulation and Technological Innovation in the Chemical Industry. *Law and Contemporary Problems* 46(3): 109-157.

Ashford, A. A., C. Ayers, and R. E. Stone. 1985. Using Regulation to Change the Market for Innovation. *Harvard Environmental Law Review* 9(2): 419-466.

Ashford, A. A., and R. P. Hall. The Importance of Regulation-Induced Innovation for Sustainable Development. *Sustainability* 3(1): 270-292.

Atkinson, R. D., and L. Garner. 1987. Regulation as Industrial Policy: A Case Study of the U.S. Auto Industry. *Economic Development Quarterly* 1(4): 358-373.

Baer, H. L., and C. A. Pavel. 1988. *Does Regulation Drive Innovation?* Working Paper. Federal Reserve Bank of Chicago.

Bargeron, L. L., K. M. Lehn, and C. J. Zutter. 2010. Sarbanes-Oxley and Corporate Risk-Taking. *Journal of Accounting and Economics* 49(1-2): 34-52.

Barrett, P. M. 2011. The Price of Clean Air. Bloomberg Businessweek, June 2, http://www.businessweek.com/magazine/content/11_24/b4232010130946.htm.

Baumol, W. J. 1972. On Taxation and the Control of Externalities. *American Economic Review* 62(3): 307-322.

Bellas, A. S. 1998. Empirical Evidence of Advances in Scrubber Technology. *Resources and Energy* 20(4): 327-343.

Braeutigam, R. R. 1981. The Effect of Uncertainty in Regulatory Delay on the Rate of Innovation. *Law and Contemporary Problems* 43(1): 98-111.

Brunnermeier, S. B., and M. A. Cohen. 2003. Determinants of Environmental Innovation in US Manufacturing Industries. *Journal of Environmental Economics and Management* 45(2): 278-293.

Cohen, D. A., A. Dey, and T. Z. Lys. 2009. *The Sarbanes Oxley Act of 2002: Implications for Compensation Contracts and Managerial Risk-Taking*. Working Paper. Stern School of Business, New York University.

Cohen, L. 1979. Innovation and Atomic Energy: Nuclear Power Regulation, 1966-Present. *Law and Contemporary Problems* 43(1): 67-97.

Davies, J. C. 1983. The Effects of Federal Regulation on Chemical Industry Innovation. *Law and Contemporary Problems* 46(3): 41-58.

Eisenberg, R. S. 2007. The Role of the FDA in Innovation Policy. *Michigan Telecommunications and Technology Law Review* 13(2): 345-388.

Gastineau, D. A. 2004. Will Regulation Be the Death of Cell Therapy in the United States? *Bone Marrow Transplantation* 33(8): 777-780.

Gerard, D., and L. B. Lave. 2005. Implementing Technology-forcing Policies: The 1970 Clean Air Act Amendments and the Introduction of Advanced Automotive Emissions Controls in the United States. *Technological Forecasting and Social Change* 72(7): 761-778.

Goldberg, P. K. 1998. The Effects of Corporate Average Fuel Efficiency Standards in the US. *Journal of Industrial Economics* 46(1): 1-33.

Golec, J., and J. A. Vernon. 2010. Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms. *Pharmacoeconomics* 28(8): 615-628.

Golec, J., S. Hegde, and J. Vernon. 2005. *Pharmaceutical R&D Spending and Threats of Price Regulation*. Working Paper. National Bureau of Economic Research, Cambridge, MA.

Grabowski, H. G., and J. M. Vernon. 1977. Consumer Protection Regulation in Ethical Drugs. *American Economic Review* 67(1): 359-364.

Grabowski, H. G., J. M. Vernon, and L. G. Thomas. 1978. Estimating the Effects of Regulation on Innovation: An International Comparative Analysis. *Journal of Law and Economics* 21(1): 133-163.

Hahn, R. W., and R. N. Stavins. 1992. Economic Incentives for Environmental Protection: Integrating Theory and Practice. *American Economic Review* 82(2): 464-468.

Harrington, W., and R. D. Morgenstern. 2007. Economic Incentives Versus Command and Control: What's the Best Approach for Solving Environmental Problems? In *Acid in the Environment*, edited by G. R. Visgilio and D. M. Whitelaw. New York: Springer. Pp. 233-240.

Hauptman, O., and E. B. Roberts. 1987. FDA Regulation of Product Risk and Its Impact Upon Young Biomedical Firms. *Journal of Product Innovation Management* 4(2): 138-148.

Henson, S., and J. Caswell. 1999. Food Safety Regulation: An Overview of Contemporary Issues. *Food Policy* 24(6): 589-603.

Hoffmann, V. H., T. Trautmann, and M. Schneider. 2008. A Taxonomy for Regulatory Uncertainty—Application to the European Emission Trading Scheme. *Environmental Science & Policy* 11(8): 712-722.

Hughes, J. W., M. J. Moore, and E. A. Snyder. 2002. *"Napsterizing" Pharmaceuticals: Access, Innovation and Consumer Welfare*. Working Paper. National Bureau of Economic Research, Cambridge, MA.

Ishii, J., and J. Yan. 2004. *Investment under Regulatory Uncertainty: U.S. Electricity Generation Investment since 1996*. Working Paper. Center for the Study of Energy Markets, Berkeley, CA.

Jackson, H. E. 2007. Variation in the Intensity of Financial Regulation: Preliminary Evidence and Potential Implications. *Yale Journal on Regulation* 24(2): 253-291.

Jaffe, A. B., and K. Palmer. 1996. *Environmental Regulation and Innovation: A Panel Data Study*. Working Paper. National Bureau of Economic Research, Cambridge, MA.

Jaffe, A. B., R. G. Newell, and R. N. Stavins. 2002. Environmental Policy and Technological Change. *Environmental and Resource Economics* 22(1-2): 41-69.

Jagtiani, J., A. Saunders, and G. Udell. 1995. The Effect of Bank Capital Requirements on Bank Off-Balance Sheet Financial Innovations. *Journal of Banking and Finance* 19(3-4): 647-658.

Johnstone, N., I. Hascic, and D. Popp. 2008. *Renewable Energy Policies and Technological Innovation: Evidence based on Patent Counts*. Working Paper. National Bureau of Economic Research, Cambridge, MA.

Kahn, A. E., T. J. Tardiff, and D. L. Weisman. 1999. The Telecommunications Act at Three Years: An Economic Evaluation of Its Implementation by the Federal Communications Commission. *Information Economics and Policy* 11(4): 319-365.

Kane, E. J. 1981. *Accelerating Inflation, Technological Innovation, and the Decreasing Effectiveness of Banking Regulation*. Working Paper. National Bureau of Economic Research, Cambridge, MA.

Katz, A. 2007. Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry. *Michigan Telecommunications and Technology Law Review* 14(1): 1-41.

Kridel, D. J., D. E. M. Sappington, and D. L. Weisman. 1996. The Effects of Incentive Regulation in the Telecommunications Industry: A Survey. *Journal of Regulatory Economics* 9(3): 269-306.

Lange, I., and A. Bellas. 2005. Technological Change for Sulfur Dioxide Scrubbers under Market-Based Regulation. *Land Economics* 81(4): 546-556.

Lanjouw, J. O., and A. Mody. 1996. Innovation and the International Diffusion of Environmentally Responsive Technology. *Research Policy* 25(4): 549-571.

Lyon, T. P. 1995. Regulatory Hindsight Review and Innovation by Electric Utilities. *Journal of Regulatory Economics* 7(3): 233-254.

Majumdar, S. K., and A. A. Marcus. 2001. Rules versus Discretion: The Productivity of Flexible Regulation. *Academy of Management Journal* 44(1): 170-179.

Malloy, T., and P. Sinsheimer. 2004. Innovation, Regulation and the Selection Environment. *Rutgers Law Review* 57: 183-233.

Marcus, A. A. 1988. Implementing Induced Innovations: A Comparison of Rule-Bound and Autonomous Approaches. *Academy of Management Journal* 31(2): 235-256.

Munos, B. 2009. Lessons from 60 Years of Pharmaceutical Innovation. *Nature Reviews Drug Discovery* 8(12): 959-968.

Nameroff, T. J., R. J. Garant, and M. B. Albert. 2004. Adoption of Green Chemistry: An Analysis based on US Patents. *Research Policy* 33(6-7): 959-974.

Newell, R. G., A. B. Jaffe, and R. N. Stavins. 1999. The Induced Innovation Hypothesis and Energy-Saving Technological Change. *Quarterly Journal of Economics* 114(3): 941-975.

Norberg-Bohm, V. 1999. Stimulating 'Green' Technological Innovation: An Analysis of Alternative Policy Mechanisms. *Policy Sciences* 32(1): 13-38.

Norberg-Bohm, V., and M. Rossi. 1998. The Power of Incrementalism: Environmental Regulation and Technological Change in Pulp and Paper Bleaching in the US. *Technology Analysis and Strategic Management* 10(2): 225-245.

Ollinger, M., and J. Fernandez-Cornejo. 1998. Innovation and Regulation in the Pesticide Industry. *Agricultural and Resource Economics Review* 27: 15-27.

Pickman, H. A. 1998. The Effect of Environmental Regulation on Environmental Innovation. *Business Strategy and the Environment* 7(4): 223-233.

Pilkington, A., and R. Dyerson. 2006. Innovation in Disruptive Regulatory Environments: A Patent Study of Electric Vehicle Technology Development. *European Journal of Innovation Management* 9(1): 79-91.

Popp, D. 2002. Induced Innovation and Energy Prices. *American Economic Review* 92(1): 160-180.

Popp, D. 2003. Pollution Control Innovations and the Clean Air Act of 1990. *Journal of Policy Analysis and Management* 22(4): 641-660.

Popp, D. 2006. International Innovation and Diffusion of Air Pollution Control Technologies: The Effects of NO_x and SO_2 Regulation in the US, Japan, and Germany. *Journal of Environmental Economics and Management* 51(1): 46-71.

Porter, M. E. 1991. America's Green Strategy. *Scientific American* 264(4): 168.

Porter, M. E., and C. van der Linde. 1995a. Green and Competitive: Ending the Stalemate. *Harvard Business Review*, September 1, http://hbr.org/product/green-and-competitive-ending-the-stalemate/an/95507-PDF-ENG.

Porter, M. E., and C. van der Linde. 1995b. Toward a New Conception of the Environment-Competitiveness Relationship. *Journal of Economic Perspectives* 9(4): 97-118.

Prieger, J. E. 2002. Regulation, Innovation, and the Introduction of New Telecommunications Services. *Review of Economics and Statistics* 84(4): 704-715.

Prieger, J. E. 2007. Regulatory Delay and the Timing of Product Innovation. *International Journal of Industrial Organization* 25(2):219-236.

Rothenberg, J. 1979. The Impact on Regulation on an Exhaustive Resource Industry: A Methodological Approach and a Model. *Law and Contemporary Problems* 43(1): 112-149.

Rothwell, R. 1981. Some Indirect Impacts of Government Regulation on Industrial Innovation in the United States. *Technological Forecasting and Social Change* 19(1): 57-80.

Santerre, R. E., and J. A. Vernon. 2006. Assessing Consumer Gains from a Drug Price Control Policy in the United States. *Southern Economic Journal* 73(1): 233-245.

Schmalensee, R., and J. Rohlfs. 1992. *Productivity Gains Resulting from Interstate Price Caps for AT&T*. New York: National Economic Research Associates. Center for Economic Studies, U.S. Census Bureau.

Schumpeter, J. 1942. *Capitalism, Socialism and Democracy*. New York: Harper.

Shin, R., and J. Ying. 1993. *Efficiency in Regulatory Regimes: Evidence from Price Caps*. Presented at the Twenty-First Annual Telecommunications Policy Research Conference, Solomons, MD.

Sickes, R. C., and M. L. Streitweiser. 1991. *Technical Inefficiency and Productive Decline in the U.S. Interstate Natural Gas Pipeline Industry under the Natural Gas Policy Act*. Discussion Paper.

Silber, W. L. 1983. The Process of Financial Innovation. *American Economic Review* 73(2): 89-95.

Sperling, D., E. Abeles, D. Bunch, A. Burke, B. Chen, K. Kurani, and T. Turrentine. 2004. The Price of Regulation. *Access* (25): 9-17.

Stewart, R. B. 1981. Regulation, Innovation, and Administrative Law: A Conceptual Framework. *California Law Review* 69(5): 1256-1377.

Tardiff, T., and W. Taylor. 1993. *Telephone Company Performance under Alternative Forms of Regulation in the U.S.* New York: National Economic Research Associates.

Taylor, M. R., E. S. Rubin, and D. A. Hounshell. 2005. Control of SO_2 Emissions from Power Plants: A Case of Induced Technological Innovation in the U.S. *Technological Forecasting and Social Change* 72(6): 697-718.

Thomas, L. G. 1990. Regulation and Firm Size: FDA Impacts on Innovation. *RAND Journal of Economics* 21(4): 497-517.

Unnevehr, L. J., and H. H. Jensen. 1996. HACCP as a Regulatory Innovation to Improve Food Safety in the Meat Industry. *American Journal of Agricultural Economics* 78(3): 764-769.

Vernon, J. A. 2003. Drug Research and Price Controls. *Regulation* 25(4):22-25.

Vernon, J. A. 2005. Examining the Link between Price Regulation and Pharmaceutical R&D Investment. *Health Economics* 14(1): 1-16.

Vernon, J. A., J. H. Golec, and W. K. Hughen. 2006. The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate. *American Journal of Law and Medicine* 32(2-3): 175-192.

Walshe, K., and S. M. Shortell. 2004. Social Regulation of Healthcare Organizations in the United States: Developing a Framework for Evaluation. *Health Services Management Research* 17(2): 79-99.

Warren, E. 2008. Product Safety Regulation as a Model for Financial Services Regulation. *Journal of Consumer Affairs* 42(3): 452-460.

Wrubel, R. P., S. Krimsky, and M. D. Anderson. 1997. Regulatory Oversight of Genetically Engineered Microorganisms: Has Regulation Inhibited Innovation? *Environmental Management* 21(4): 571-586.