FIVE

# Confidence Games: How Does Regulation Constitute Markets?[1]

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We live in an information-rich, highly networked world, one saturated with information and choice alternatives – some trustworthy, some not. In such a society, the confidence of citizens in the marketplace is a key goal of any economic and political institution. Increasingly, our entire political system, our society, and our economy are built upon expectations – expectations of fairness, of safe and fraud-free transactions, of known risks (but also transparent, finite, and reasonable risks), of reasonable and equitable treatment (the absence of pervasive price discrimination and ethnic and racial discrimination). Effective regulation helps to maintain a structure of beliefs that make prosperity and liberty possible (or appreciably more likely). Regulation, in other words, in some sense creates the very possibility of marketplaces.[2]

In this chapter I advance a particular version of this argument, focusing on institutions of entry regulation and approval regulation. I define approval regulation as that form of regulation in which the state must confer particular rights upon a producer or a consumer for an economic transaction to take place, where the rights are conferred at the discretion of the state and only upon the completion of a submission process in which the producer may test the product. Various forms of entry regulation can be considered as special cases of this genre. The emblematic case I have in mind is that of national pharmaceutical regulation, as carried out by the

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[2] Related arguments about the market-making capacities of regulation appear in the essays of Neil Fligstein and Joseph Stiglitz in this volume.

U.S. Food and Drug Administration (FDA) and the European Medicines Evaluation Agency (EMEA). In these institutions, firms can market pharmaceutical products and other therapeutic commodities (medical devices, vaccines, diagnostics) only after express registration of the product by a national agency. Approval occurs at the discretion of this regulator (the FDA, the EMEA), and only after the completion of required experimentation with the drug. This discretionary feature of approval regulation, combined with experimentation hurdles, renders its institutions quite different from those of "fee for entry" licensure, which is practiced by many national and local governments worldwide (Djankov et al. 2002). Fee for entry licensure does not often compel research and development benchmarks for initiation of the approval process, and approval is discretionary in the sense that a firm's fee payment does not compel the regulator to allow market entry. In addition to therapeutic commodities, this model of governance applies to many forms of grant-making, wetlands, and some construction permitting, and professional and occupational licensure (where the state mandates educational requirements and examinations).

Other forms of health and safety regulation such as occupational safety regimes (Kelman 1981, Huber 2007) and public health regulations are related but do not contain the experimentation and veto properties of approval regulation. The arguments expressed here may or may not apply to these areas. I focus here upon approval regulation because it represents a case of strong state power, namely the veto capacity of a government agency over research and development, and the related requirement for private actors to engage in greater R&D than they would otherwise in order to gain marketing rights.

In this chapter I advance four arguments that lie at the interstices of social science disciplines.

- Institutions of approval regulation have been chosen worldwide by republican polities through democratic processes and have been continually legitimated by societies with embedded rule of law. The emergence of these institutions continually defies capture-based explanations.
- Evidence from the most rigorous and historically contextual studies suggests that institutions of entry and approval regulation have arisen in markets characterized by learning constraints, including credence good markets and markets with appreciable information asymmetries. In the absence of regulation, as well as in the presence of weak regulation, these markets are characterized by equilibrium fraud and "lemons

problems" (Akerlof 1970) – consumers will repeatedly purchase and use inferior commodities, human agents will repeatedly choose products that reduce their welfare relative to lesser known alternatives, and more cheaply developed "bad" products will drive out more expensively developed "good" ones.

- Institutions of approval regulation may serve to produce more information, and higher-quality information, than would be provided in their absence. By raising the returns to research and development, institutions of approval regulation also induce the production of superior and lower-variance commodities. In this way, the markets constituted by approval and entry regulation are fundamentally different from those that would appear in the absence of these institutions, and the products in these markets are qualitatively different from those that would appear in the absence of these institutions. *Approval regulation actually makes new and more sophisticated markets.*
- The restrictions of institutions of approval regulation and entry regulation, combined with this information provision, can and often do materially improve human welfare in the setting of advanced republican polities, where the occasional drawbacks of these regulatory policies can be detected and reformed through legislation and other mechanisms of revision.

The chapter's initial section advances these four arguments as theoretical claims, drawing on mathematical, philosophical, and historical considerations where appropriate.

## I. The Republican Origins of Regulatory Institutions

A proper theoretical account of any political or economic institution begins with the institution itself. Many theories of regulation start not with institutions but with an institutional vacuum (an unregulated market) and then proceed to deduce the set of market failures that would justify their creation. Although this approach can foster illuminating thinking about regulation, it cannot serve alone as a theoretical or policy guide. It commits first the fallacy of assuming that institutions of governance arise for reasons primarily related to our normative theories used to rationalize them. Unless accompanied by a careful analysis of the institutions themselves (and their development and variance), such market failure thinking often generates unscientific, functionalist accounts of institutions that have more complex and nuanced histories. It further presupposes, as the essays in this volume by

Table 5.1. *Institutions of approval regulation for pharmaceuticals, by government and year of appearance*

| Nation/State | Year of first state regulatory body for drugs | Year of compulsory premarket review (approval regulation) |
|---|---|---|
| Norway | 1928 | 1928 |
| Sweden | 1934 | 1934 |
| United States | 1906/1927 | 1938 |
| United Kingdom | 1963/1971 | 1963 |
| France | 1978 | 1945 |
| Germany/W. Germany | 1961 | 1961 |
| Japan | 1962 | 1948 |
| India | 1940 | |
| Canada | n/a | 1963 |
| Australia | 1963 | 1963 |
| European Union | 1995 | 1995 |
| China | 1979 | 1985 |
| South Korea | 1953 | |

Marc Eisner and Joseph Stiglitz both observe, that societies could somehow generate vibrant markets in the absence of webs of supporting institutions.

In this treatment, then, I start with the regulatory institutions themselves, not as an add-on to the market but as a basic institution whose institutions need better understanding.

The institutions of pharmaceutical approval furnish a useful place to begin. Table 5.1 displays the year that twelve nation states and the European Union first created regulatory bodies for pharmaceuticals and the year in which those same bodies instituted a compulsory premarket approval process. Most other nations did not create such formal processes until the 1980s. In general, these moves occurred only under conditions of general democratization. Thus Germany under National Socialism did not possess a system of premarket approval, whereas the United States and several Scandinavian nations already did. The Nazi *Stopverordnung* in fact prohibited the production of and research into many therapeutic medicines. South Korea created institutions of approval regulation in 1953; North Korea still has yet to do so. The Soviet Union never created a system of drug approval regulation, despite a nontrivial level of pharmaceutical production. India began a system of pharmaceutical regulation in 1940 and is now home to a large clinical trials industry; Communist China, meanwhile, has yet to nationalize its system of regulation, and as its export sector has grown, the global press has recently highlighted the weaknesses of its food and drug regulations.

The lesson of these data, I would argue, is that institutions of approval regulation appear in the context of mature republican (representative) and constitutional democracies. Authoritarian regimes, communist nations, and otherwise "institutionally backward" countries are not likely to generate such institutions, even though they may have large state sectors, heavy government intrusion into national and regional economies, and rather robust scientific programs.[3]

Of equal importance, the democratic legislative processes that generated bureaucratic approval regulation of food and drugs do not offer evidence of industry control over political decision making. Capture, in other words, did not drive the creation of agencies like the FDA. Carpenter (2001), Law (2002), and Law and Libecap (2005) examine the Progressive Era creation of food and drug regulation in the United States. In all three quantitative studies, tests of producer capture hypothesis produce null or negative (evidence contradicting the producer capture hypothesis) results. More recently, Carpenter and Sin (2007) have examined the passage of the Food, Drug and Cosmetic Act of 1938 and have adduced evidence from roll calls and legislative histories that directly contradicts the predictions of producer capture theory. Table 5.2 displays relevant evidence from Carpenter and Sin (2007). The votes for S.5 reconsideration were votes to strengthen the FDA's power over pharmaceuticals; a gatekeeping provision did not appear until after the sulfanilamide tragedy of 1937, after these votes took place. In particular, legislators representing those firms that stood most to gain from stronger government regulation (representatives of the United Medicine Manufacturers' Association) were less likely, not more likely, to vote for FDA-strengthening legislation in the middle 1930s (see the coefficient estimates for the variable entitled "Number of UMMA firms in state," the last row of coefficient estimates). This legislation remained unaltered until the 1937 sulfanilamide tragedy, in which a drug suspended in a diethylene glycol solution caused more than one hundred deaths. In the months following that episode, the FDA's parent bureaucracy, the U.S. Department of Agriculture, responded immediately by introducing legislation with a premarket approval requirement. Congress enacted the USDA's proposal into a law a few months later (Jackson 1970, Carpenter and Sin 2007).

[3] One could make the point statistically by regressing the existence or duration of such institutions upon some numerical indicator of democratization and/or representation. I would regard such an exercise as having little value-added, because it would simply reproduce what one can view from the table and from examining the data with intuition. (Most nations do not possess independent institutions of approval regulation for pharmaceuticals, so most of the data would be null observations.) From a statistical vantage, there is also massive cross-unit dependence in the data, as most countries have copied American (and to a lesser extent, European) arrangements in the genesis of their national institutions.

Table 5.2. *Probit analyses of three votes on S. 5 (Senate votes, 74th congress)*

| | [Senate votes, 74th congress] | | |
|---|---|---|---|
| Variable | S. 5 Amendment reconsideration [4/1/1935] | S. 5 Amendment reconsideration [4/2/1935] | Bailey amendment [4/8/1935] |
| Consent | 1.8371 (1.5636) | 3.8839 (1.8262) | −1.7690 (1.4917) |
| D-NOMINATE 1-D | −2.0944 (0.8531)) | 2.6960 (1.0643) | 1.8166 (0.8019) |
| D-NOMINATE 2-D | −1.3916 (0.8194) | 0.3583 (1.1096) | 0.3844 (0.8613) |
| Party {Democrat = 1) | −0.7572 (0.6857) | 1.3627 (0.8369) | 1.0947 (0.6750)) |
| Percentage of State Vote for FDR, 1932 | −0.0041 (0.0206) | 0.0169 (0.0250) | 0.0081 (0.0185) |
| Change in % of State for FDR, 1932–1936 | −0.0103(0.0321) | −0.0471 (0.0386) | −0.0177 (0.0250) |
| % of State Population African-American | 0.0 445 (0. 0396) | −0.0429 (0.0492) | 0.0153 (0.0377) |
| % of State Population Illiterate | −0.1166 (0.0790) | −0.2109 (0.0924) | 0.1061 (0.0818) |
| % of State Population Educated | −0.0879 (0.0494) | 0.2119 (0.0683) | 0.0370 (0.0469) |
| % of State "Gainful Workers" Unemployed | 0.4181 (0.1327) | 0.5893(0.1736) | −0.0815 (0.1134) |
| Retail Sales as % of Wholesale | −0.0010 (0.0026) | −0.0009 (0.0028) | −0.0007 (0.0025) |
| South | 2.1259 (0.9639) | 1.1556 (1.5649) | −0.8767 (0.8770) |
| Number of Proprietary Association Firms in State | 0.0375 (0.0215) | 0.0311 (0.0245) | 0.0179 (0.0178) |
| Number of UMMA Firms in State | 0.2596 (0.0829) | −0.2888 (0.0929) | 0.0882 (0.0541) |
| *N*(df) | 83 (69) | 75(61) | 81 (67) |
| LLF | −43.512 | −33.796 | −49.307 |
| Pseudo-$R^2$ | 0.2417 | 0.3396 | 0.1139 |

*Notes:* Asymptotic standard errors in parentheses. Bold coefficient estimate implies statistical significance at $p < 0.05$ (two-tailed test). UMMA firms and PA firms variables correlated at 0.5598. Removal of UMMA firms variable results in negative but insignificant coefficient estimate for PA firms variable.

The sulfanilamide tragedy, then, crystallized common public opinion about two facts: (1) the capacity of an administrative and regulatory agency to protect consumers and impose minimal order and standardization upon a therapeutic market, and (2) the perils of an unregulated market for therapeutics. The public character of the deliberation reduced (although it did not eliminate) the influence of particularistic interest organizations. Here one sees a powerful example of a crisis situation reducing the capacity of even well-connected interest groups to influence legislative decision making, much as David Moss and Mary Oey's essay describes for the Voting Rights Act, the passage of Medicare, and the creation of the EPA's Superfund program.

Whether in cross-national perspective or in the details of particular statutes, then, institutions of drug approval regulation have arisen by legislative choice in republican and constitutional democracies, in a manner inconsistent with rent-seeking accounts. This conclusion, of course, is not equivalent to the claim that such laws always reflect the public interest in all of their details. It is the correlation of market-constituting regulation with core political and philosophical concerns of the republican political tradition that concerns me here. These concerns animated the American founding, not least as voiced by Alexander Hamilton, but also by other scholars of political economy such as Montesquieu and John Adams. Although appreciable differences separate the sorts of institutions created in modern pharmaceutical regulation from the regulatory institutions of early and mid-modern republican governments, there is also considerable overlap, not least in public health regulations, hazard regulations, the regulation of finance and other policies (Novak 2000; Balleisen 2001; Wood 1967).[4]

*The Debility of Capture Theory and its Rules of Evidence.* It is worth pausing at this point to note that the account presented here starkly diverges from capture and rent-seeking theories that have long held sway in economics and political science. Despite capture theory's successes in the academy, the account leaves some very large holes, a point also emphasized by Jessica Leight and Donald Wittman in their contributions to this collection. Perhaps the most enduring problem in modern capture theory is that it relies on a set of rules of evidence that fall well short of rigor. The core empirical method of the theory of economic regulation was elaborated by Stigler in the 1970s. "The theory tells us to look," Stigler then explained, "as precisely and carefully as we can, at who gains and who loses, and how much, when we seek to explain a regulatory policy." Thus if regulation is inefficient and its benefits flow to large producers, analysts should assume it to have been designed with these effects in mind. Stigler's moral is lucid and he rehearses it unapologetically: protection implies capture. "The announced goals of a policy," he insisted, "are sometimes unrelated or perversely related to its actual effects, and the truly intended effects should be deduced from the actual effects." If a given regulation bestows advantages on a specific firm of industry, scholars ought to infer producer capture regardless of the stated purposes of the law.[5]

An entire cottage industry in the economic analysis of regulation has adopted Stigler's logic as something of a universal method. At its core,

[4] See for instance Novak, *The People's Welfare*; Wood, *The Creation of the American Republic*; Pettit, *Republicanism: A Philosophy of Freedom and Government.*

[5] Stigler, *The Citizen and the State*, 140.

the rules of inference in the modern economic theory of regulation are simple. If econometricians can demonstrate the incidence of a regulation or measures of its effects to be partially associated with the presence or strength of an organized interest, then they reject a public interest account in favor of a capture or rent-seeking explanation. Thus if weight limits on four- and six-wheel trucks were less severe (higher) in those states where the share of trucks in farming and the average length of a railroad haul were higher, Stigler inferred capture and rent-seeking from these associations, even though farming and freight haul length both connote less urbanization and infrastructure development. Urbanization (population density) and infrastructure (bridges, tunnels) create conditions that may induce safety-conscious legislators to place weight limits on trucks. Hence the associations observed by Stigler could easily and probably have arisen for reasons having nothing to do with capture or interest group politics at all. In other studies, adherents of capture theory have observed that the arrival of occupational safety regulation, environmental regulation, and pharmaceutical regulation all coincide with retarded entry and reduced product innovation by small firms. These scholars cite such reductions in firm entry as evidence for capture, despite the fact that they might have happened even if the regulation had never emerged, and despite the fact that even a legally neutral scheme of regulation would impose heavier costs upon smaller and newer firms in an industry. More generally, numerous statistical studies have shown evidence of a correlation between measures of regulatory policy or agency behavior and indicators of the presence or strength of a certain interest, which their authors then interpret as evidence for capture and rent-seeking accounts, implicitly discounting the possibility that such correlations might have arisen under a regulatory regime that was neutral or designed with noncapture purposes in mind.[6]

The fundamental flaw of capture and rent-seeking accounts concerns causality and the rules for establishing and inferring it. Capture accounts using the Stigler method generally fail to consider other explanations that may account for the patterns observed. The problem in statistics is known

[6] The statistical analyses of trucking weight limits are undertaken in Stigler, "The Theory of Economic Regulation"; *The Citizen and the State*, 120–24. Despite obvious flaws in Stigler's research design and his inferences, it would seem that few if any scholars in economics or related disciplines have revisited his assertions. On environmental regulation, see Peter Pashigian, "Environmental Regulation: Whose Self-Interests Are Being Protected?" *Economic Inquiry* 23 (4) 551–84. For other examples, see Bartel and Thomas, "Predation through Regulation"; Lacy Glenn Thomas, "Regulation and Firm Size: FDA Impacts on Innovation," *RAND Journal of Economics* 21 (4) (Winter 1990) 497–517.

as one of "observational equivalence." If two theories or causal mechanisms potentially lead to the same pattern of evidence, then the evidence in question cannot be used to distinguish between the theories. If a scholar conducting a statistical analysis finds that regulation is more stringent where certain interest groups are more prevalent, or where government is more autocratic, what exactly does this prove? The presence of an interest group and the autocracy of government may be correlated with other factors such as urbanization, education, a legacy of colonialism and slavery, and other factors that capture-based analyses fail to consider.

The influence of capture theory in academic scholarship, I am convinced, has resulted in part from the weakness of its dominant alternative: public interest theory. Indeed, it would appear that "the public interest theory" of regulation persists in part as an artificial alternative to capture theory. The simple dichotomy between "public interest" and "public choice" persists for several reasons. One is the simplicity of the world it presents. Another is the rhetorical skills of some of capture theory's innovators and votaries, in particular George Stigler. Yet a crucial and disturbing feature of the public-interest versus public-choice dichotomy is that it often stacks the deck in favor of capture. At their extremes, capture arguments prop up public interest as a sort of straw man competitor. The slightest empirical departure from the public interest model ostensibly justifies the capture or rent-seeking view. In a world with just two theories, one response to evidence that is inconsistent with one theory is to favor its alternative. But a more compelling path may be to admit that there are still other possible theories and to look for them.[7]

An oft-cited cross-country study published by Simeon Djankov and colleagues in 2002 ("The Regulation of Entry") exemplifies this tendency, committing the all-too-common errors of assuming that protection implies capture and otherwise stacking the deck in favor of capture-based accounts of regulatory action. The authors report that entry regulation (measured

[7] Numerous papers in economics, history, political science, and sociology make this inference. In the study of pharmaceutical regulation, scholars have taken business involvement in the writing of regulatory statutes and rules as prima facie evidence of rent-seeking. See Harry Marks, "'The Origins of Compulsory Prescriptions' Revisited," *American Journal of Public Health*, 85 (1) (1995) 109. Clayton A. Coppin and Jack High make a similar inference, concluding that Harvey Wiley's involvement with business interests in the writing of the 1906 Pure Food and Drug Act is evidence for a form of rent-seeking. *The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy* (Ann Arbor: University of Michigan Press, 1999). In fact the evidence suggests that Wiley was consulting with business interests for information on how to write and specify more appropriate and effective regulations, and in part to build a broad and credible coalition behind his reforms. James Harvey Young, *Pure Food* (Princeton: Princeton University Press, 1990); Carpenter, *The Forging of Bureaucratic Autonomy*, Chapter 8.

as the number of procedures required to start a business in a country) is not associated with superior social outcomes (reduced pollution, reduced accidental deaths, a smaller unofficial economy). Instead, they find that entry regulation is higher where countries are poorer and governments are less transparent and more autocratic. These associations, the authors claim, are "inconsistent with public interest theories of regulation, but support the public choice view that entry regulation benefits politicians and bureaucrats." In this instance, the study's findings are skewed by a heavy presence of African countries in the sample, and (probably) by the lack of a control for education; if these researchers had restricted their analysis to countries in Europe and North America, the findings would disappear. Moreover, certain forms of regulation that decidedly affect entry and that are more common in wealthier countries – such as environmental regulation and occupational safety regulation undertaken by national governments – are excluded entirely from the authors' measure. This exclusion almost certainly inflates the authors' findings and creates an odd situation in which well-known social democratic governments such as Sweden, Germany, Norway, and Canada appear far less stringent than countries such as Singapore, Taiwan, and South Korea. Finally, the inference that poorer countries with more severe health and environmental problems adopt more entry regulation may well suggest that countries with more traditional religious and social cultures regulate entry more heavily (as in, for example, countries governed by more conservative versions of religious law such as Islamic *sharia*). Hence the incidence of entry regulation may have little to do with grabbing hands and much more to do with features of national, ethnic, and religious culture.

Besides its lack of rigor, the deeper problem with the Djankov study (and others like it) is its lack of institutional depth. All sorts of regulations create barriers to entry, but this fact does not imply the restrictions lend themselves to a common scale or metric. If poor and unstable African countries have institutions that smell of rent-seeking and also have high "fee for entry" barriers, does this fact tell us much – does it tell us *anything* – about entry regulation in other settings? Probably not. A superior approach would be to examine the incidence of the regulations themselves, where researchers can draw meaning and inferences directly from particular statutes or administrative/legal institutions.

## II. Credence Goods and Placebo Economies

A second consideration in examining institutions of approval regulation involves the sorts of commodities typically governed by such arrangements.

Here I claim that approval regulation institutions govern commodities that are characterized by severe learning problems for those using the product. As a result of self-remitting disease patterns and placebo effects, as well as the interaction between these dynamics (Carpenter 2005b), drugs are types of credence goods, whose quality consumers can assess neither through inspection (as for "inspection goods" like a tomato) nor experience (as for experience goods like a job). Such goods, social scientists have demonstrated both theoretically and empirically, create "lemons problems." Because of informational shortcomings, consumers will continually purchase or consume inferior products when superior alternatives are available, whereas the presence of more cheaply produced inferior goods leads to a "crowd out" of superior products with greater development costs.

Before I partially elaborate this claim, a caveat is in order. To say that institutions of approval regulation help to solve particular problems is not to say that they were created for this purpose. Nor is it to render the regulation in question consistent with a public interest account. It is instead to say that the many (possibly unintentional) purposes served by such institutions possibly include the creation of better access to good information, and hence the manufacture of public confidence.

The argument that information asymmetry between producer and consumer can create "lemons problems" to the benefit of inferior goods, which drive out good ones, has been a staple conclusion of informational economics for several decades (Akerlof 1970, Leland 1974). These models are powerful but also limited by the *a priori* status of credence goods. What makes quality unknowable, and what makes information about quality asymmetric? Mathematical models of lemons and credence good markets do not provide a theoretical answer.

In the therapeutic marketplace, several mechanisms exist to confound proper learning, mechanisms that may or may not be applicable to other markets. In the pharmaceutical example, Carpenter (2005a) considers a model of dynamic utilization (a "multi-armed bandit" model) where the human agent uses Bayes's rule to update on drug quality from a history that is (unknowingly) affected by the agent's own expectations. As a rolling example, consider the influenza patient who learns about the quality of a therapeutic product ("Dr. Cure's Magic Thera-Pee") by conducting a simple "before-versus-after" comparison of his experience with it. If the consumer purchases and takes the product and his condition improves, he infers that the product worked. If the consumer takes the product and his condition does not improve, then he infers that the product did not work and begins a search for another therapy.

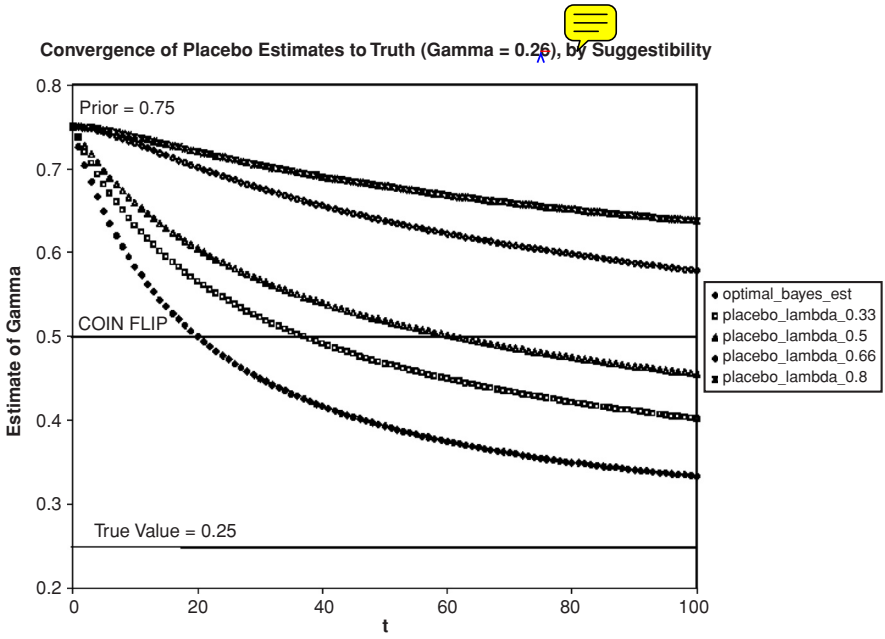


Figure 5.1. Convergence of placebo estimates to truth (Gamma = 0.26), by suggestibility.

In many ways, this hypothetical consumer is behaving rationally, even somewhat scientifically, comparing his experience with the product (after) with his experience without the product (before). The problem is that the "evidence" in this scenario (the consumer's felt health state) is influenced by his own expectations about the quality of the product. It is well known from a half-century of research in medicine, psychology, and neuroscience that patients' mere expectations of a product's healing power will influence their own physiological reaction to it. To magnify problems, the patient's condition – influenza in this example, but also true with migrane or depression – would have subsided anyway. The human agent conflates improvements that are generated pharmacologically and improvements that are generated by placebo effects. Under very simple assumptions, a minimal amount of suggestibility (the enhancement of experienced health by the agent's own prior expectations of the quality of the therapy) will lead to inefficient Bayesian estimation of product quality, exacerbated by the dynamics of word-of-mouth advertising, in turn generating patterns of equilibrium fraud whereby consumers durably opt for an inferior product when a cheaper one (or no treatment at all) would serve them as well.

Figure 5.1 is taken from a simulation in which the true curing probability associated with a drug is 0.25 but the patient starts with optimistic

prior beliefs of 0.75. Under regular Bayesian estimation (the lowest curve), the human agent's estimate follows the law of large numbers and returns appropriately to the true value. But wherever the agent's experienced health is contaminated by his own expectations, the human estimate converges progressively more slowly to the truth. In the example above, a medium level of suggestibility (0.5, where the parameter lies on the unit interval 0–1) leads to a tripling of the time required for the Bayes estimate to cross the "coin-flip" threshold.

This point is interesting enough, but when one adds the fact that many health conditions (as well as other utility states such as mood and health-affected utility) are cyclic, the problem gets worse, not better. When self-remitting conditions (mood, hypertension, stress, muscle injury, influenza) are added to the model, the agent can conflate the pharmacological power of the drug, the probability of self-healing, and the curing power of the patient's own expectations. The following figure shows that a medium amount of remission (probability = 0.5) can lead to asymptotically inconsistent estimates of the curing probability of the treatment (continuing the previous example, the prior is 0.75 and the "true" is 0.25).

A second simulation from the Carpenter model, shown in the following, suggests that different levels of self-remission can generate more optimistic estimates of treatment efficacy that are retained asymptotically.[8]

The upshot of these models is that otherwise rational consumers will, under placebo learning from diseases with self-remission or other forms of cyclicity, consistently overestimate the therapeutic effect of the treatments they try first. They will either fail to rationally abandon a bad medicine, or they will abandon the therapy eventually, but too slowly. This serves as a brute but effective metaphor for the continued profitability of quack treatments and methods in therapeutic markets, particularly unregulated and less regulated therapeutic markets. As shown in many historical examinations of the subject, the market for patent medicines in the United States was immensely profitable, especially among well-educated and literate sectors of the population. Although it is far short of an empirical demonstration of the theory, it is worth noting that similar patterns hold for many nutritional supplements today. The enduring marketing strategies pursued by the purveyors of health scams further bear out these theoretical ruminations, dependent as they often are on heartfelt personal testimonials.

[8] Thanks to Justin Grimmer, a graduate student in the Department of Government, for the necessary programming and the code. I harbor full responsibility for use and misuse of the demonstration here.

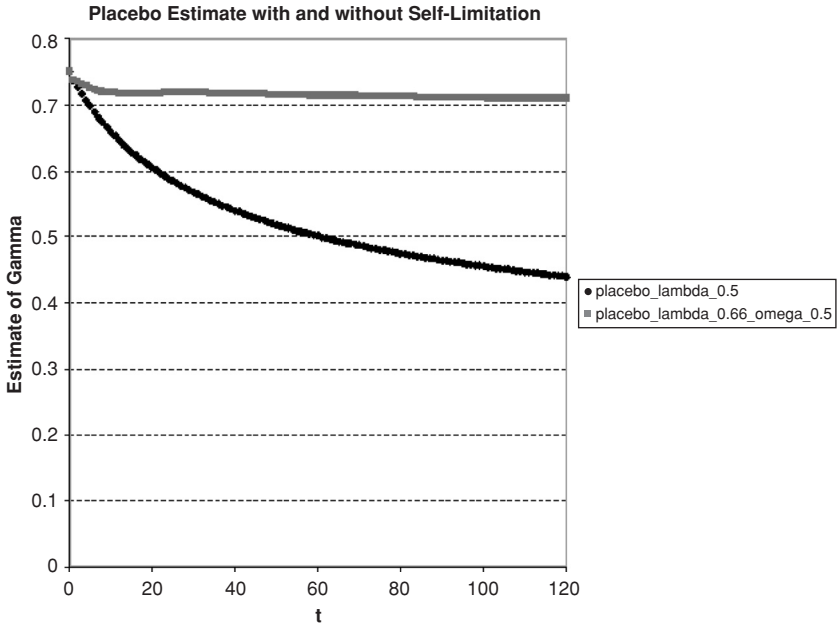


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Figure 5.2. Placebo estimate with and without self-limitation.

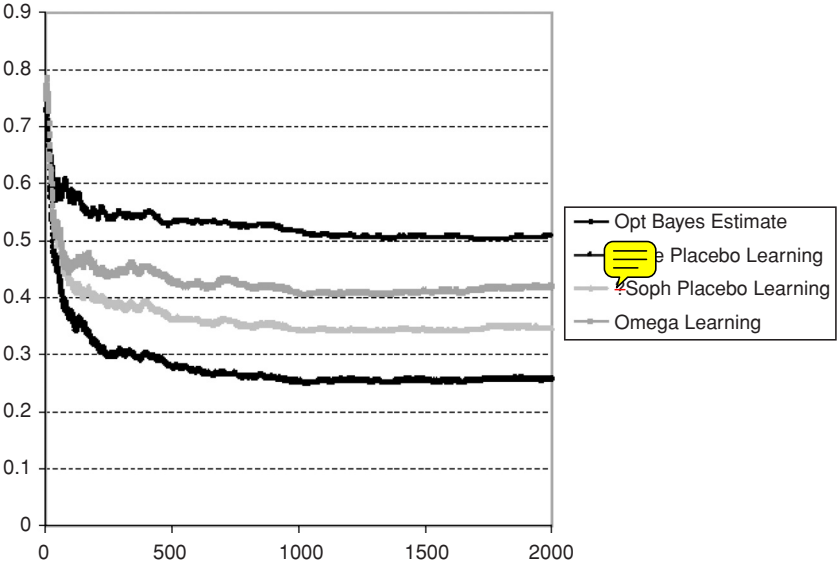


Figure 5.3. Placebo estimate with and without self-limitation.

Theoretically, it is but a brief step from these results – which essentially endogenize the credence good properties of drugs and other therapeutic commodities (that is, explained through assumptions internal to the nature of those goods) – to the analyses of Akerlof (1970) and Leland (1979). When consumers consistently choose inferior products, then cheaply developed bad products drive out good alternatives, and the induced distribution of product quality is less than would be the case in the absence of placebo- and remission-based learning constraints.

Speaking more practically, learning constraints in therapeutic markets generate at least two additional thorny problems. First, therapeutic sponsors no longer invest in areas where the bad drugs take up space. This is the Akerlof "crowd out" hypothesis, and it is directly testable in the pharmaceutical arena. Second, consumers (patients) get stuck on the bad drugs and suffer worse health outcomes. Evidence for this claim comes from Jishnu Das's study of the market for physicians in India (2001).

A more detailed logic of this model essentially elaborates upon the difficulty of decentralized, market-based learning about efficacy. When medical conditions are either self-remitting or cyclic (following a natural history), the impact of placebo effects upon human learning is multiplied. Such situations frustrate decentralized learning about product quality in therapeutic markets; even markets characterized by many consumers and many products will end up with long-term (asymptotic) bias. In other words, no matter how many people take the products, and no matter how long they take them, the true quality of the products will never be accurately revealed to anyone, much less to the whole of society. This general pattern underscores the factual nature of the kind of "economic irrationality" discussed by Joseph Stiglitz in his essay for this volume, and its strong presence in the pharmaceutical and therapeutic marketplace.

From this point the standard "lemons" arguments of Akerlof and others apply. Either uncertain consumers will not sign up for the pharmaceutical "lottery" and will forgo superior treatments that would have been good for them, or they will continually choose inferior treatments that will drive more expensive and superior alternatives out of the market.

## III. Approval Regulation Institutions Induce Markets with Higher Rates of Experimentation and Superior Product Quality

Given the previous portrait of "credence good" marketplaces, or placebo economies, we can now consider some of the effects and possible desirability of regulation. Approval regulation sharply truncates the array of products

that the consumer faces. Speaking in mathematical concepts, if a consumer (a patient, or that patient's physician) is uncertain about a product, such that she faces a nondegenerate distribution of efficacy (a range of potential outcomes), then an entry restriction can be welfare improving if it dampens the "lower tail" of the distribution (or restricts the especially problematic cases). In even more precise mathematical language, entry regulation must induce a product quality distribution that first-order stochastically dominates the original distribution, in which the likelihood of getting a product that works dramatically improves over the situation prior to the introduction of regulation. In other words, the regulator must be able to separate good from bad products, even if brutally and inefficiently. Notice that this argument is about welfare; nothing about the preceding argument implies that regulation is efficient or the best way of obtaining improvements in patient welfare.

How exactly does approval regulation bring about this improvement in quality? Until recently, students of regulatory institutions were without models to account for this process. In a recent chapter devoted to the study of regulatory error in political science, Carpenter and Ting (2007) advance a model that can be used as a metaphor for approval regulation institutions. Their model posits two-sided uncertainty – both the firm and the regulator (both singular in the model) are uncertain about product quality, but the firm's estimates are more precise than those of the regulator. The regulator, in addition, has a higher quality standard for market admissibility than does the firm for product launching. The essential logic of the model is that the regulator's higher standards, combined with the firm's incentives in bringing the drug to market, induce the firm to engage in more experimentation than it would otherwise. Figure 5.4 shows the stages of play for the firm and the regulator, given that the firm's product is of a given type. In each of the first two periods, the firm can submit (S) its product to the regulator for possible approval (A) or rejection (R), can experiment (E) further (in the sense of taking a draw from a Bernoulli distribution with Beta-distributed priors or it can withdraw (W) the product entirely.[9] The most compelling

[9] For a rolling example, suppose I was handed a bent or warped coin and wanted to know whether it was "fair" in the sense that it returned "heads" with the same probability that it returned "tails." One way of testing the assumption of fairness would be to toss the bent coin ten times. If the coin returned five heads and five tails after ten tosses, I would have some evidence that the hypothesis of fairness (heads probability = 0.5) was supported. If I tossed the coin one hundred times and saw fifty tails and fifty heads I would have even better evidence. If on the other hand I tossed the coin ten times (or one hundred times) and saw "all tails" then I would begin to wonder. In my wondering, I would be updating on a Beta distribution (deciding where between 0 and 1 to place my probability estimate) using Bernoulli trials (coin tosses, or "experiments" where the outcome is of two sorts).

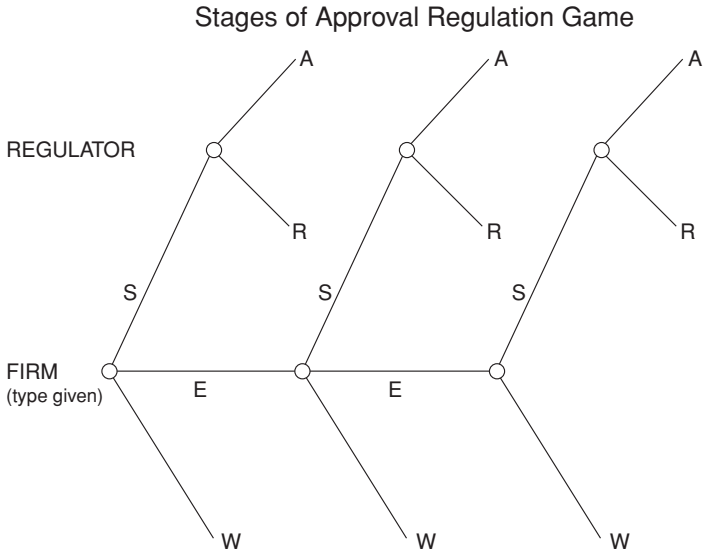


Figure 5.4. Stages of approval regulation game.

equilibria of the model are those in which the regulator adopts the mixed strategy that deters firms from submitting poor products, encourages information acquisition for (and then submission of) "good" products, and leaves firms indifferent between submitting and withdrawing "just-below-standard" products (Carpenter and Ting 2007, Figure 5.1, p. 841).

This approval regulation model and its associated veto metaphor, of course, shoehorn a nuanced and complicated bureaucratic process into a simpler, binary set of outcomes. The model nonetheless conveys important intuition about how these institutions function. Even though the government does not conduct most experiments with therapeutic products – testing is largely funded by private industry, with government science agencies and academia also playing an appreciable role – its veto power over market entry induces greater experimentation than would otherwise prevail. My point is not that more experimentation always redounds to the benefit of society, but that a simple veto power of the government over therapeutic product development has wide-ranging impacts on corporate behavior.

The model also suggests that depictions of approval regulation as "intervention" into the market are seriously misleading. Approval regulation institutions do not intervene in existing marketplaces but create new markets altogether. This characterization much more sensibly fits the evidence

about developments in the post-World War II European and American pharmaceutical industries, especially if one conceives of governmental action broadly. The randomized, placebo-controlled trial did not originate in industry, but rather in academic and government science (Marks 1997). By the same token, the requirement for controlled studies of therapeutic products did not emerge as a market-based mechanism – instead, governments imposed that requirement upon the pharmaceutical industry, responding to the findings of academic and government scientists, and their bureaucratic and legislative allies. These requirements brought forth a new commercial world. They created a "scientific" demand for new instrumentation and new research capacity. More importantly, they generated a far broader and deeper demand for pharmaceutical goods, in part because of the way that government certification then triggered insurance coverage. A similar story can be told for the American market for "generic" drugs, which took off only after the FDA and Congress established common standards for the "bioequivalence" of generic drugs to the pioneer molecules they were trying to copy.[10]

## IV. Improvements in Human Welfare and Liberty

Institutions of approval regulation not only create new markets, they create markets that are plausibly superior in many respects to those that were (historically) and are (counterfactually) displaced by these institutions. There are many dimensions on which one can compare institutions of approval regulation with other arrangements, but I am concerned here with three especially trenchant comparisons. First, effective approval regulations create a market with better products, in part through the direct effect of screening, in part through by indirectly encouraging private abandonment and "crowd out" of quack products. Second, even if the characteristics of the products in the market do not change, approval regulation may generate better information about the products that exist. Third, in a particular way, approval regulation may protect a vital form of liberty, emancipating citizens from unjust subjection to the whims and capricious decisions of producers.

[10] This argument has some relation to Professor Yohai Benkler's paper in this volume. Benkler's claim is that in many contexts, the dynamics of social cooperation can produce significant innovations, and that these innovations in turn can create platforms and networks for new kinds of commercial activity. The point here is that in some contexts, like clinical trials for drugs, governmental action can create a reputational mechanism that extends the impact of those socially produced innovations.

Formally and conceptually, a minimum quality standard can create a market with higher average quality, where the quality effects are sufficient to outweigh the changes in equilibrium price (Leland 1979). This result can occur either because the standard is sufficiently high as to induce a higher quality distribution (Leland), or because its existence deters the one-time makers of low-quality products from even attempting to pass the necessary hurdles for market entry (which is akin to a costly signaling mechanism) (Carpenter and Ting 2007). Hence even with the possible price rises that entry restrictions might entail, equilibrium consumption might rise under such a scenario.[11]

Studies of markets with quality standards suggest that such effects are plausible. In a skillful analysis of state pure food laws in the late nineteenth and early twentieth century, Law (2003) shows that capture mechanisms poorly account for those laws, whereas increases in food consumption did correlate with passage of such legislation. Zhin and Leslie (2003) show that disclosure regulation, related to though distinct from approval regulation, induced superior health outcomes at Los Angeles restaurants, and Hsu, Roberts and Swaminathan (2007) have demonstrated that markets with quality standards generally experience reduced commodity price variability.[12]

In part because the confidence effects of pharmaceutical regulation have been so little theorized academically, no empirical studies of these phenomena exist. Yet there is suggestive evidence from the decades before and after the 1962 Kefauver-Harris Drug Amendments. Those amendments mandated that all new drugs demonstrate effectiveness for their treated conditions as well as safety, and they charged the FDA with creating a new system of experimentation in which the best evidence of safety and effectiveness would be produced through controlled clinical trials that were prospectively designed (in other words, where the hypotheses and research design were established before the start of the experiment). As is well known among social scientists who study the FDA, those amendments coincided with a decline in the introduction of New Molecular Entities (NMEs – essentially newly concocted chemical compounds that have some medicinal value) to the marketplace, as the FDA began to siphon good from bad products and

[11] More formally, one would wish to prove that the imposition of regulation induces a quality distribution that has first-order stochastic dominance (FOSD) and possibly second-order stochastic dominance (SOSD) over that of no approval regulation. This result emerges quite readily from the Carpenter and Ting (2007) model.

[12] This may speak to the second-order stochastic dominance criterion discussed in notes 8 and 10.

as the costs of pharmaceutical R&D increased. As Temin and Hilts have noticed, however, this decline began precipitously at least five years before Congress enacted the 1962 amendments. Most of the statistical studies have involved very brute annual time-series regressions (and hence very small N), so the evidence here is not good for causal inference as to the effects of the 1962 law.

Other intriguing post-1962 changes in the drug markets have attracted much less scholarly attention. A full empirical examination of the effects of FDA regulation on consumer confidence and pharmaceutical consumption and confidence effects lies beyond the scope of this chapter. But I will note some key dimensions of that apparent impact.

One key point is that the decline in the number of new drugs was not accompanied by a rise in pharmaceutical prices. Instead, prices actually fell in the decade following the Kefauver-Harris Amendments, and those price declines look even more substantial once total CPI is taken into account.[13] The substantial fall in the cost of prescription pharmaceuticals in the 1960s and 1970s remains an anomaly in the policy literature on the 1962 amendments (Carpenter 2005b). If regulation restricted entry but had no other effects upon consumption, we should have witnessed a substantial rise in equilibrium price. Yet precisely at the time when inflation elsewhere in the U.S. economy was raging, prescription drug prices stayed flat. This finding suggests that either other unmeasured factors contributed to the price decline, or that the regulatory reforms had effects beyond simply reducing the number of NMEs entering the market. All of this deserves much more investigation than we can give it here.[14]

At the same time that drug prices fell, per-NCE (new chemical entity) sales rose significantly. Furthermore, the pharmaceutical markets became much more predictable, at least in prices, consistent with the idea that regulation created greater certainty in patient and physician utilization of pharmaceuticals. It is possible – and the hypothesis deserves further investigation – that federal regulation accomplished these effects through standardization pathways. The dissemination of drug trial findings, combined with their interpretation upon common metrics that were scientifically established,

[13] Statistics taken from Bureau of Labor Statistics industry-specific CPI aggregates, also the *Drug Development and Marketing* volume. There are other possible sources for this argument.

[14] I realize that all of this falls a light-year short of an empirical demonstration that FDA regulation enhances consumer and physician confidence in drugs by reducing uncertainty about the efficacy and safety. Again, a genuine investigation would require a book-length treatment. Yet this hypothesis has been maintained, and brute price and sales statistics from the decades before and after the 1962 amendments are consistent with the account.

plausibly permitted the establishment of insurance formularies in which physicians and insurers had greater confidence.[15]

These correlations and inferences, of course, do not establish causation; but they do suggest causal possibilities that deserve rigorous academic investigation. This evidence is certainly consistent with the hypothesis that pharmaceutical markets (particularly prescription and utilization) were characterized by greater stability and certainty after the 1962 amendments.

Second, it is plausible (though perhaps hard to assess empirically) that institutions of approval regulation produce superior information about the products in the marketplace, and that this additional information can have desirable effects as well. In the case of national pharmaceutical markets, one might look for evidence that drugs in existence before the 1962 amendments were prescribed by doctors and used by patients more often and more effectively after the amendments relative to their use before the transformation in the regulatory process.

Third, approval regulation may actually generate more republican liberty – or "freedom from domination" – in the sense that modern theorists of republicanism have used the term (Pettit 1997, 2005). As Pettit and others have argued, one of the tasks of modern democratic government is to impose institutional constraints upon centers of power. From the colonial period through the nineteenth century, a great deal of regulatory activity by American governments reflected this republican approach to politics and political economy (Novak 2000, Balleisen 2001). The underlying mechanisms linking approval regulation to personal liberty have at least two dimensions. By reducing the ability of producers to defraud consumers, approval regulation dramatically improves the capacity of individuals to

[15] For evidence on increasing per-drug sales, see Balter (1975: 37–43) and Schwartzman (1975: 68–69). Per-drug data on prescription patterns are unavailable, but the variance of prescription pharmaceutical prices dropped heavily after the 1962 regulations. In the twelve years before the 1962 amendments the variance of the pharmaceutical CPI was 18.7 CPI points, whereas the variance in the twelve years following the Amendments was 6.1, less than one-third of its pre-1962 value. The level of the prescription pharmaceutical CPI also fell continuously during the 1960s, from 51.4 in 1961 to 46.9 in 1970, and reached its preregulation peak only in 1976. All data are from Consumer Price Indices as calculated by the Bureau of Labor Statistics, U.S. Department of Labor. The decline of prescription pharmaceutical prices in the decades following the 1962 amendments is something of an anomaly in the study of pharmaceutical regulation, one that deserves continued study. If the 1962 regulations increased the cost of entry and had no other effects upon the market, we would expect to witness a sharp increase in prices as entry and supply were restricted. The long-term decline in pharmaceutical prices during this very period, at the same time that inflation was raging, suggests either that other factors were driving the price of drugs or that the new regulatory regime had impacts on more than innovation alone.

make informed decisions about crucial dimensions of their lives. Compared to a similar individual living in 1960, an individual living in 1975 with a chronic fungal infection or with heart disease had a much enhanced capacity to choose among treatment options. She and her physician could refer to clinical trials in which the different drugs available to her had been tested, and many of the results of these trials were now readily in the medical literature, in patient package brochures, and even in physician advertisements. Moreover, many inefficacious treatments for this patient's diseases had been removed from the market by 1975, either voluntarily or by virtue of the DESI review. In addition, by constraining the ability of powerful producers unilaterally to set the terms of market interactions (as in antitrust), institutions of approval regulation may serve as a countervailing force to concentrations of economic power. The dependence of companies such as Pfizer or Merck on the FDA – these companies must, if they are to remain profitable, continually introduce new products and gain the FDA's clearance of their marketability – and this dependence functions as a partial constraint on their behavior. Current firm behavior must anticipate the necessity of appearing and reappearing before the regulator in the future for purposes of drug approval.[16]

## V. Research Agendas

The argument here, although speculative, rests upon a broader and emerging literature on the effects of regulatory institutions. It rests upon formal theories of market operations (Akerlof 1970, Leland 1979, Das 2001, Carpenter 2005a), formal theories of regulatory dynamics (Carpenter 2004, Carpenter and Ting 2007), and historical and empirical accounts of regulatory operation (Law 2003, Hilts 2003, Law and Libecap 2006, Carpenter and Sin 2007). In concluding I sketch several research agendas that would expand our grasp of the larger concepts and theories discussed here.

### A. Formal and Mathematical Research Agendas

I direct the remarks in this section to those who are interested in the mathematical modeling of regulation, regulatory behavior, and regulated industries. The mathematical theory of regulation has concentrated heavily for three decades on the issue of information asymmetry, but almost entirely

[16] This argument is currently rather opaque.

with respect to cost information and price regulation. The related literatures on mechanism design and cost revelation (Baron and Myerson 1982, Baron and Besanko 1984a, 1984b) are well known. Yet in thinking about empirical and historical forms of regulation – occupational licensing and pharmaceutical and medical technology regulation, to name two common forms – mathematical theorists have until recently (Carpenter 2004, Carpenter and Ting 2007) made little progress in the analysis of these institutions.

Laffont and Tirole (1993) have provided the most comprehensive investigation of these forays into the mathematical conceptualization of regulation. Yet even they lack a model where both the firm (or firms) *and* the regulator are uninformed, much less models that incorporate explicit experimentation. These conditions – dual (possibly asymmetric) uncertainty and experimentation – would seem to characterize a large number of markets, so there is no empirical basis for the exclusion of these components from further formal models. One set of research agendas, then, would be the formal development of models that analyze credence good economies, regulations for credence good and placebo economies, and institutions of approval regulation.[17]

### **B.** Empirical and Policy Research Agendas – the Case of the Drug Efficacy Study

One obvious context to explore the more tangible impact of regulation on expectations is pharmaceutical policy. For institutions of approval regulation, like the FDA, I would wager that cost-benefit analysis of major regulatory changes should focus on the very long term (as in Greenstone's work on the impact of environmental initiatives (Chay and Greenstone 2005), rather than Peltzman's work on pharmaceutical regulation (1973).[18]

More particularly, the analysis of pharmaceutical regulation in the United States has been complicated by issues of multiple simultaneous causes of the outcomes one would wish to examine and the very blunt nature of the data used. Numerous scholars (starting with Peltzman 1972) have attempted to

[17] Another area deserving of attention concerns how regulation affects beliefs. At the core of markets lies a set of expectations. The mathematical theory of expectations (e.g., Billingsley 1979, 1999) relies upon integrals, which rely upon probability measures and in turn, upon countable and co-countable spaces. As a conjecture, consider: Does regulation render essential outcomes in certain markets more countable, more integrable, more measurable, furnishing more people access to credible and relevant information that otherwise might not exist?

[18] A related point concerns the statistical quantity of interest in empirical studies of regulation. Scholars should examine not only the mean effects of government regulation but the variance effects (see Hsu et al. 2007 for a recent exception).

examine the "effects" of the 1962 drug amendments upon different measurable policy outcomes, but all of these attempts have incorporated fatal flaws, usually related to the fact that the "intervention" or "treatment" in question was a highly aggregated and time-dependent change in institutions. Put differently, a great many changes occurred simultaneously at the time of the 1938 and 1962 statutes, significantly complicating efforts to link consequences to causes.

Although I am very skeptical of the existence of informative "natural experiments," I do think that a move toward more finely grained data is in order, and that the Drug Efficacy Study Initiative (DESI) of the 1960s and the 1970s may provide a quasi-experiment that merits close analysis. The DESI project was occasioned by the 1962 law's requirement that the FDA examine the effectiveness of drugs approved from 1938 to 1962. Where a national advisory panel concluded that a previously approved drug lacked evidence of efficacy, the FDA was charged with removal of the drug by substantive administrative rule making. Scholars have assessed this episode in regulatory history largely for its influence upon administrative law and for its effect upon clinical trial standards – it was here where the FDA began to mandate randomized, controlled clinical studies as the "gold standard" of evidence for drug efficacy – but its larger social, economic, and health effects have so far escaped careful examination.

Using data from the National Archives, one can examine the exact timing of market withdrawals for hundreds of medications from 1969 to 1975. A (possibly asymmetric) panel data set can then be created that uses Federal Register listings as a proxy for market withdrawals in a therapeutic class. If we can trust the DESI process, then the timing of the market removal would constitute a quasi-experimental treatment in approval regulation that varied by therapeutic class, by disease, and over time. Although the overall "exogeneity" of this intervention may be difficult to establish (I am generally dubious of such claims), it would be useful to estimate the association between these removals and subsequent economic and health outcomes, including (in all cases for therapeutic classes in which the FDA revoked licenses to make and sell particular drugs (a) subsequent levels of pharmaceutical use, (b) subsequent prices and price variability, (c) subsequent research and development and pharmaceutical innovation,[19] and (d) and subsequent health outcomes. After this statistical analysis is complete, we would then be in a position to ask important questions such as: Did investment in new therapies increase in those areas where DESI pulled drugs off the market? Did therapeutic outcomes improve?

[19] A brute test of Akerlof ("bad products crowd out good ones") may be possible here.

The upshot of these empirical hypotheses is that DESI and its associated institutions – the randomized, controlled trial (RCT) as a technology for quality assessment in pharmaceuticals – did not merely intervene into an existing market, but created a new market altogether. It is difficult to imagine therapeutic markets today without the presence of an RCT standard, not to mention other, less well-known regulatory standards such as bioavailability, bioequivalence, and others.

### C. Historical Research Agendas

Other research agendas suggest themselves for historians and other social scientists interested in the temporal development and evolution of regulatory institutions and markets. Inquiries into the confidence mechanisms of regulation points toward a larger need for all social scientists to examine the origins and patterns of consumer and citizen beliefs about markets, and in particular the effect of regulation upon these beliefs. So too, social scientists such as sociologists, political scientists, and historians should examine the variable credibility of regulatory institutions. Insofar as the confidence and market-constituting effects of regulation depend in some respects on the confidence that citizens and consumers have in regulatory arrangements themselves, this area beckons as a central subject of inquiry. It matters greatly whether citizens trust what the bureaucratic agencies operating in their name are doing. Again, though, beyond broad analyses of "institutional trust," "trust in government," and "trust in physicians," there is little or no empirical or historical scholarship on these vital questions.

## CONCLUSION

By imposing a rigorous entry structure upon the pharmaceutical industry, regulation has generated a technological future, kept bad products from the marketplace, stabilized expectations in the pharmaceutical market, and, ultimately, supported liberty. Libertarian theorists view this sort of entry restriction as inevitably destructive. The standard view of pharmaceutical regulation sees exactly this debilitating dynamic, as the 1962 amendments ostensibly produced a steep decline in the number of "new chemical entities." But "the Tobin view" sees something else going on: the FDA was wedding bad products from the marketplace, buttressing "consumer" (physician, pharmacist, and patient) beliefs in the quality of available drugs. This essay considers the pharmaceutical example as a metaphor for a whole host of related institutions. My hunch is that these institutions can be approached

through common theoretical lenses, common strategies of empirical and historical research, and ultimately through renewed normative appreciation of their presence in American and global society.

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