Regulating by Repute

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Is regulation a hopeless cause? Many thoughtful observers spend a lot of time enumerating all of the reasons why it is doomed to fail. The entire field of public choice, with impeccable logic, posits the likely corruption of every bureaucrat. And if corruption cannot explain the failure of regulation, the atrophy that comes from lack of competition—there is just one government, after all, and it does not have a profit motive—may be just as rich a vein to mine. It could also be that the legal system itself, with its myriad complexities, checks, and procedural requirements, may ossify to the point of strangulation whatever is left of the governance project that capture and incompetence have not already disposed of.

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2. For a discussion by another economics Nobel prizewinner of why bureaucracies generally will be inefficient, see generally F. A. Hayek, The Road to Serfdom 138–56 (50th ann. ed. 1994).

And yet governance, against all these odds, thrives everywhere that markets and people thrive. It is something of a puzzle, really, given all of the excellent reasons why regulation should be nothing more than zero-sum cupidity. Is there some other reason to trust governance, despite the ease with which regulators may be captured by rent-seekers, dulled by monopolization, and stayed by process?

Daniel Carpenter thinks so. His history of the pharmaceutical arm of the Food and Drug Administration ("FDA"), Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA, concerns a classic regulatory enterprise—the government's effort to ensure that its citizens consume safe and effective drugs—that, he argues, went well for decades. His definitive account blends political science theory with a granular retelling of the challenges and achievements of American pharmaceutical regulation. It is meant to be the ur-book on the subject, a reference work that obviates the need for more digging by other scholars into the FDA's pharmaceutical history.

But Reputation and Power is not just about one product line regulated by one agency. I read the book not as a story about drug law (or at least not that the results "largely disconfirm the ossification thesis"). For a broader discussion, see William S. Jordan, III, Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability To Achieve Regulatory Goals Through Informal Rulemaking?, 94 Nw. U. L. Rev. 393, 402 (2000).

4. Or so a number of prominent economists, from both the right and the left, have concluded. See, e.g., Daniel Kaufmann, Governance Redux: The Empirical Challenge (Oct. 2003) (unpublished manuscript), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=541322 (noting "a very high correlation between good governance and key development outcomes across countries"). For a discussion of Kaufmann's work from a legal perspective, see Chantal Thomas, Law and Neoclassical Economic Development in Theory and Practice: Toward an Institutionalist Critique of Institutionalism, 96 CORNELL L. REV. 967, 1010–11 (2011). The so-called "LLSV hypothesis," named for its authors, also suggests that regulation, or at least good governance and strong legal protections, is an important pre-condition to prosperity. See Rafael La Porta, Florencio Lopez-de-Silanes, Andrei Shleifer & Robert W. Vishny, Law and Finance, 106 J. POL. ECON. 1113, 1152 (1998). For a discussion of this hypothesis, see Stephen J. Choi, Law, Finance, and Path Dependence: Developing Strong Securities Markets, 80 TEX. L. REV. 1657, 1727 (2002), and for a critique and another summary, see Claude Ménard & Bertrand du Marais, Can We Rank Legal Systems According to Their Economic Efficiency?, 26 WASH. U. J.L. & POL'y 55, 59 (2008) ("[LLSV] explicitly assumes that there is a close relationship between 'good' institutional design and economic development, and that countries with poor investor protections, either because of their legal system or because of the enforcement rules of this system, severely suffer in their economic dynamics.").

5. This sort of rational choice analysis underlies the elements of positive political theory that have been applied to administrative law. See Matthew D. McCubbins et al., Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies, 75 VA. L. REV. 431, 434–35 (1989) (describing how Congress controls agencies through judicial review or through warning systems designed to facilitate congressional oversight); see also Daniel B. Rodriguez, The Positive Political Dimensions of Regulatory Reform, 72 WASH. U. L.Q. 1, 43 (1994) ("Positive political theory describes regulatory policymaking as a part of a world in which political actors function within institutions rationally and strategically in order to accomplish certain goals." (footnote omitted)).

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only that), but as an identification of a model of governance that could apply not just to medicines, but also to all sorts of consumer products, and perhaps even more broadly to agencies engaged in financial regulation, law enforcement, and other fundamental projects of the administrative state. Carpenter’s history offers insights relevant to agency design, to the importance of image in administration, and, I think, to attempts to justify the regulation of anything.

In particular, Reputation and Power offers two valuable insights to those interested in the progress of the legal enterprise of regulation. First, its central claim—that the good reputation of the FDA was a critical component of its success—offers a chance to evaluate the merits of relying on reputation as the secret sauce that promotes law-abiding behavior. Reputation, sometimes defined variously, is an increasingly popular explanation for legal compliance when a tally of the more immediate and tangible costs and benefits would suggest that noncompliance or shirking is the more rational choice; indeed, a number of scholars have argued that good reputation is the explanation for effective regulation, even in the face of the rent-seeking and overlegalization that would seem bound to stymie it every time. Because Carpenter argues that reputation explains much of the FDA's success, his monograph permits consideration of the complex relationship between reputation and legal compliance.

Second, by delving into what the agency did once it was given the authority to permit or reject the sale of drugs in the American market, Carpenter offers an account of what happens in agencies after administrative law stops its usual inquiry—or, at least, after it did so in the case of the FDA. The lawyers sorted out what the agency could do; Carpenter’s history of the FDA evaluates what the agency did— he studies the ordinary governance of drug approvals that ensued after Congress’s direction was interpreted and after the courts decided to defer to the scientists in the agency. These postlitigation bureaucratic processes often go beyond the scrutiny of administrative lawyers interested in the judicial supervision of agencies, but sorting out what agencies actually do with their powers is critical to any useful understanding of the purpose of judicial and legislative oversight. Carpenter’s account takes the legal authority that Congress gave to the FDA as a precondition to understanding it, rather than as the end of the analysis.


8. See Richard A. Merrill, The Architecture of Government Regulation of Medical Products, 82 VA. L. REV. 1753, 1775 n.68 (1996) (“To bring a successful challenge to the terms FDA set the sponsor would have to convince a court that the agency had acted arbitrarily or without factual basis. This has proved nearly impossible.” (citations omitted)). Courts have been much less deferential to the FDA's labeling and marketing supervision, to say nothing of the food safety division of the agency. See, e.g., Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 74 (D.D.C. 1998), amended sub nom. Wash. Legal Found. v. Henney, 56 F. Supp. 2d 81, 88 (D.D.C. 1999), vacated in part, 202 F.3d 331 (D.C. Cir. 2000) (invalidating the FDA's effort to restrict pharmaceutical companies from discussing off-label uses of drugs).
In this Review, I first discuss Carpenter's story about the way that reputation and power interacted to the benefit of the FDA's regulatory mission. In Part II, I consider the merits of reputation as a governance tool, which I believe are real but limited. Carpenter is right to recognize that reputation gets agencies breathing room from courts and Congress, and motivates employees—if anything, it is important to recognize that there are many other nonpecuniary reasons why regulators might perform their jobs well, and that reputation should not stand in for all of them. In Part III, I offer some other criticisms of the Carpenter book, which focus chiefly on its doorstop ambitions. Part IV offers some thoughts about the relationship between the ordinary governance that is the subject of his history and the sort of governance that lawyers study. A richer understanding of the incentives of regulators, and an awareness of the sheer quantity of work that they do outside of the courts, underscores some of the limitations of the naively cynical story about the doomed governance project. Regulation is hardly perfect, but, really, it is a lot like work in any large organization: it is capable of triumphs and failures, and it can—if designed well, to meet a need—be made effective.

I. REPUTATION AND POWER AT THE FDA

In the first decades of the twentieth century, Americans consumed aggressively-marketed medicines that did not cure anything, and evaluated these medicines through strategies of self-help and personal experimentation. Today, the FDA only permits medicines that are proven to be safe and effective to be sold; the fly-by-night patent medicine outfits are gone, and health care is provided by doctors and scientists. Life expectancy, in the meantime, has skyrocketed, and intractable diseases, ranging from tuberculosis to polio to AIDS, have been made tractable. By mediating the relationship between therapeutic drugs and their potential consumers, the FDA has played a critical role in this remarkable evolution in drugs, science, health, and business. It famously kept thalidomide out of the American market, saving the country from the tragic deformed births in Germany and Australia, where the drug was widely prescribed to mitigate morning sickness. It kept the ineffective cancer therapy Laetrile from American shelves in the face of a great deal of public pressure to approve the drug. And it evinced flexibility in the face of AIDS, which looked like

9. Chapter 4. The cover of Carpenter’s book depicts Frances Kelsey, the FDA official famous for rejecting the application to use the morning sickness drug in the American market.

10. Pp. 410–28. In United States v. Rutherford, 442 U.S. 544, 551 (1979), the Supreme Court ruled that terminal cancer patients had no right to use Laetrile absent FDA approval, a victory for the agency, which had to endure a great deal of public pressure to legalize the drug—including from actor Steve McQueen. McQueen took a course of Laetrile in Mexico and claimed that he was happy with the results; he later died of cancer in 1980. Pp. 424–25. For a discussion of the McQueen case and the Laetrile controversy, see Jerry Menikoff, Beyond Abigail Alliance: The Reality Behind the Right To Get Experimental Drugs, 56 U. KAN. L. REV. 1045, 1046–47 (2008). According to Carpenter, “In resisting the most popular alterna-
it would be a death sentence for hundreds of thousands of Americans and ruination for the agency's careful but slow approval process (Chapter Six). How did it manage all of these accomplishments?

In Carpenter's view, the agency benefitted from the initial grant of strong legal authority—especially the authority to serve as a gatekeeper over new drugs (p. 16). But that power was critically enhanced by the agency's growing reputation for effectiveness, which it built by transforming its drug approval process into something that looked like state-of-the-art scientific research. Over the course of the forty years following World War II, the agency required randomized controlled experiments—three-stage and, in some cases, five-stage testing processes—and, at least in theory, continued surveillance of drugs after approval to be sure that they were working as intended (Chapter Nine).

The FDA also built a strong reputation. Reputation can be defined capa-
ciously, and Carpenter embraces that capaciousness, for better and for worse. Sometimes, reputation affects public reliance on agency work, and sometimes reputation affects what experts in the field, from journalists to advocates to scientists to businesspeople, think about an agency's work (pp. 33–34). In the former cases, reputation leads to support in the political arena; in the latter, to acquiescence to agency decisions by the relevant stakeholders (pp. 45–60). Reputation also appears to have had an effect on the courts too—they have adopted a multidecade record of deference to the FDA's pharmaceutical decisions, lasting from the quiescent 1950s through the activist 1970s to today (pp. 45–60).

But if reputation contains multitudes, the idea, for each of these audi-
ences, is that the agency's legal strength may be paired with an extralegal fillip that turns mere authority into something worthy of respect. Reputation can lead to virtuous circles of ever-better regulation: the agency itself became motivated to meet high scientific and safety standards because such standards were expected and relied on by everyone else (pp. 55–56). This account might be characterized as something of an exercise in constructivist political science—the idea that ideas and intangibles can shape other tangible facts, like power and resources.11

Carpenter begins his book with an account of the gradual evolution of the FDA between the 1938 Food, Drug, and Cosmetic Act's creation of its gatekeeper role, to its 1961 triumph in banning thalidomide from the American market, followed quickly by 1962 legislation institutionalizing and expanding

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11. Although I associate the constructivist element of political science mostly with a strand of international relations heterodoxy, see, e.g., James Fearon & Alexander Wendt, Rationalism v. Constructivism: A Skeptical View, in HANDBOOK OF INTERNATIONAL RELATIONS 52 (Walter Carlsnaes, Thomas Risse & Beth A. Simmons eds., 2004), it has found its way into the international legal literature as well, see Ryan Goodman & Derek Jinks, How To Influence States: Socialization and International Human Rights Law, 54 DUKE L.J. 621 (2004).
its watchdog status (pp. 238–60). The approach is historiographical. While others see a sharp break between a quiescent agency before the thalidomide decision and the 1962 amendments and a fearsome agency after them, Carpenter argues that the FDA’s adoption in the 1940s and 1950s of best scientific practices regarding the clinical evaluation of new medicines made the difficult decision to ban a popular drug like thalidomide possible.

In this telling, a necessary, but not sufficient, initial step in building the FDA’s reputation turned on the power that Congress gave the agency (pp. 74–75). Before 1938, the FDA could remove only demonstrably dangerous medicines from the shelves, and, although the New Deal was a good time for agencies to receive broad grants of authority from Congress, the FDA’s acquisition of a power to pass on the dangerousness of medicines before they were marketed to consumers was no sure thing (pp. 80–85). As is often the case with regulatory reform, it was a disaster that won the agency its broad new responsibilities—specifically, the deaths of at least seventy Americans to an antifreeze-laced patent medicine produced by the Massengill Company of Tennessee. The resulting legislation turned the FDA’s veto power into an assent requirement, and it also changed the mood of pharmaceutical regulation. The deferential decision by the Supreme Court in United States v. Dotterweich affirmed that the agency and the Department of Justice could broadly sanction drugmakers found to produce adulterated or dangerous products. Accordingly, although the importance of reputation for regulatory effectiveness animates Carpenter’s account, the legal powers that the 1938 Act granted came first.

That power was confirmed between World War II and 1962; the FDA almost never lost in court during that period (p. 362). The result was the creation of something of an almighty agency, with little supervision by the courts, Congress, or, apparently, the rest of the executive branch.

One can imagine disastrous or happy outcomes ensuing from such liberty, but Carpenter’s account does not explain why the agency, given its legal power to regulate in any of a number of different ways, chose to

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13. Carpenter argues that the critical moment in the empowerment of the FDA occurred not between 1960 and 1962, when the FDA banned thalidomide and received new authority in the 1962 Kefauver-Harris Amendments to its governing statute, but rather more gradually before then as the agency engaged in increasingly scientific practices for drug evaluations, an evolving postwar trend that stemmed from the critical gatekeeping role for new drugs that it assumed in 1938. Pp. 119–23.


15. 320 U.S. 277 (1943) (upholding strict liability against corporate executives, namely, the president of a firm found to have mislabeled drugs); see also pp. 116–17 (citing Dotterweich, 320 U.S. 277).
adopt best scientific practices for drug approval. In addition to the thalidomide success, though, the implementation of the 1938 legislation resulted in a growth in the scientificness—and burdensomeness—of FDA approvals. Randomized control trials were required. Data were expected to be shared. Three-phase experiments including clinical trials and human subject tests became the sine qua non of what the FDA did. To Carpenter, the important historiographical fact about these innovations is that they were instituted before the banning of thalidomide—that is, the FDA became the modern and effective agency he admires not because it happened to make a right choice on a dangerous drug in 1961, but rather because it adopted best scientific practices to inform the implementation of the authority given it in 1938.

After the thalidomide episode, a heyday of the FDA ensued, one that lasted between 1963 and approximately 1986, a period in which, despite debates over whether the agency was slowing the introduction of new therapeutic pharmaceuticals, its word was respected law and all but judicially irreversible. As Carpenter observes, the FDA's approach to pharmaceutical approval "became normal, as authority was converted into patterns of protocol, expectation, and practice, and as everyday life in the modern pharmaceutical world was restructured" (p. 299). During this period, the FDA approved a universe of controversial drugs, including contraceptives such as the Pill, without rousing the ire of the public or suspicions of politicization (pp. 185–88). Aggrieved stakeholders, if they wished to reverse an agency decision, were forced to adopt a rather strange, generally ineffective set of arguments that turned on the process of approval or denial, rather than on the basic science behind the drugs (pp. 465–68). Moreover, they usually had to make this case to the agency itself, rather than to the courts, which, if it led to anything, led only to a further elaboration of the protocols required before a manufacturer could hope to win approval of a new drug (pp. 359–62).

In Carpenter's view, the period following the apogee of the agency's power has been marked by increasingly vigorous debates about how that power has been deployed. Part of this debate has been a straightforward conversation about the efficacy of government oversight, one increased during antiregulatory ferment in the Bush Administration—this often took the form of handwringing over the amount of time taken by the agency to approve new drugs (p. 741). But somewhat more subtly, the combination of reputation and gatekeeping power has led to a focus on the question of approval, to the detriment of postapproval monitoring to see if the drugs have actually worked (pp. 586–87). Accordingly, "[s]ince the 1960s at latest, critics and observers of U.S. pharmaceutical regulation have targeted the post-market surveillance system for complaints. And their conclusions, while varied in some respects, have often revisited the perceived conflict between pre-market and post-market processes" (pp. 588–89). The postmarket critique now has a poster drug in Vioxx, the heart disease medication

16. P. 229. For another discussion of the evolution of the new drug approval system after 1982, see Merrill, supra note 8, at 1768–1800.
that, effective as it was, was not safe for all patients, as it turned out after the FDA approved it (pp. 737–43). For Vioxx, it was the tort system, rather than the FDA, that performed much of the critical postmarket regulatory work. And so the FDA's reputation has grown more contested, even as its legal authority remains unchanged. To Carpenter, this suggests that the overall effectiveness of the agency, which depends both on power and reputation, could now be threatened.

II. REPUTATION AS A LEGAL MATTER

In Carpenter's view, the reasons for the FDA's successful record are rooted in the reputational incentives of the regulators who worked for it, the respect its reputation engendered in other stakeholders in pharmaceutical regulation, and the institutional decision to place the agency as the gatekeeper through which all new drugs must pass before going to market. While lawyers understand the implications of gatekeeping authority well, Carpenter's emphasis on reputation is different precisely because it does not depend on legal authority—although reputation can, in his understanding, affect that authority. Reputation incentivizes regulators to pursue their mission against pushback from the industry and criticism from Congress, and to do so emboldened by the support that the public can provide to a technocratic, jargon-ridden institution. Moreover, reputation, in the view of Carpenter and others, can create virtuous circles: regulators want to be seen as doing a good job, and the more plausible the story about why they may be doing a good job, the more likely that the agency's work will be met with respect. This dynamic encourages successful regulatory interventions, followed by increasing respect from the players in the political or regulatory process. For the FDA, the happy reputation story was grounded in an approach to regulation that turned on scientific best practices that were overseen and administered by good scientists. Indeed, Carpenter even suggests that FDA regulators became willing to trade leisure and the lucre of

17. For a critical evaluation of the FDA's role in the Vioxx controversy, see David A. Kessler & David C. Vladeck, A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims, 96 Geo. L.J. 461, 465 (2008) (“Recent regulatory failures, such as the agency's ineffectual response to Vioxx, have demonstrated the FDA's shortcomings . . . .

18. It is worth noting that this gatekeeping function is relatively rare in administrative agencies. The branch of the FDA regulating food does not sit in judgment of novel foodstuffs before they may be marketed to consumers, nor does the medical device supervisor. See Merrill, supra note 8, at 1800–35 (discussing the fact that the FDA does not have stringent premarket regulations for medical devices). And financial regulators, to take another example, have no such gatekeeping oversight over new financial products, even after the Dodd-Frank Act's creation of a consumer protection regulator that might, in theory, be able to take on such a job. Schan Duff, Consumer Financial Protection After Dodd-Frank (Dec. 21, 2010) (unpublished manuscript) (on file with author).

the revolving door for those reputational benefits. He thinks that this reputation for effectiveness and mission control characterized the FDA from the 1930s until at least the 1990s.

Reputation is a common recourse of rationally inclined legal theorists who wish to explain why legal projects work, even in the face of public choice reasons why they should not. Andrew Guzman has argued that reputation is the reason why states comply with international law, even when noncompliance would be in keeping with their short-term interests. Jeffrey Lax has argued that reputation-building explains some of the strategic voting in which justices engage when making certiorari decisions. Securities and Exchange Commission ("SEC") officials tout reputation as one of the reasons why capital market intermediaries are likely to comply with the agency's regulations. And, of course, reputation fuels Carpenter's domestic administrative law story.

Is reputation the secret sauce that explains why governance works where short-term interests or pure public choice analyses would doom it to failure? In my view, if reputation is defined parsimoniously, the way that many

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20. P. 66 ("[O]nce recognized, officials with authority in an organization may take measured steps to protect, maintain, and enhance [the organization’s reputation]. This reputation-protection imperative has governed and animated the FDA’s behavior in pharmaceutical regulation for much of the last half-century."). For a discussion of how Carpenter’s vision of reputation might affect these sorts of internal motivations, see Steven Teles, Brains on Drugs, WASH. MONTHLY, May/June 2010, at 48–52 (reviewing Reputation and Power). Carpenter made similar arguments in his first book, where he argued that bureaucratic autonomy is “forged” when agency leaders are able to nurture reputations for effectiveness that suggest that they have unique organizational capabilities. DANIEL P. CARPENTER, THE FORGING OF BUREAUCRATIC AUTONOMY 353 (2001) (arguing that autonomy arises “when agency leaders build reputations for their organizations—reputations for efficacy, for uniqueness of service, for moral protection, and for expertise”).

21. In the aftermath of the Vioxx withdrawal, however, “the U.S. Food and Drug Administration . . . lost some of its scientific and consumer protection luster.” P 738.


24. Paul F. Roye, the former director of the SEC Division of Investment Management, argued as follows:

A compliance failure can lead to bad publicity and embarrassment, which can permanently damage a firm’s reputation and ultimately lead to an erosion of its client base. The end result will be lower profitability and private lawsuits. In short, a weak and ineffective compliance system can spell disaster for an adviser.

Paul F. Roye, Meeting the Compliance Challenge, Remarks Before the Investment Counsel Association of America (Apr. 23, 1999), available at http://www.sec.gov/news/speech/speecharchive/1999/spch271.htm. For a discussion of the importance of reputation to the SEC's compliance efforts, see H. Lowell Brown, The Corporate Director's Compliance Oversight Responsibility in the Post Caremark Era, 26 DEL. J. CORP. L. 1 (2001); James Rathz, Compliance as the Competitive Differentiator, 12 DUQ. BUS. L.J. 13, 24–25 (2009) ("If a particular compliance metric included in the compliance story line were to deteriorate to vulnerability or deficiency status, the public message could be significantly marginalized, thereby introducing increased reputation risk to the firm.") (footnote omitted)).
aficionados do with rational choice stories about the government, then reputation alone cannot explain all the useful regulatory achievements in the face of the usual self-interested incentives to shirk, seek rents, and so on. It cannot serve as a shorthand for all the difficult-to-capture reasons why anyone might choose to perform his or her job capably or comply with legal obligations, although that would seem to be the implication of a rational choice paradigm in administrative law that seeks to explain everything through the lens of self-interest, how ever broadly characterized. People—even government bureaucrats—do not simply seek to win the approval of others, pay, or leisure from their jobs. Regulators often perform ably for nonreputational reasons too—because it gives them a sense of self-worth, because they are interested in the subject matter of what they do, or because they feel a kinship with those whom their agency is meant to protect. But the new enthusiasm for reputation as a way out of the rational choice/public choice trap for regulatory enterprises elides these other perfectly plausible non-self-maximizing welfarist reasons that might secure a competent regulatory effort by a responsible government.

Accordingly, the recent affection for reputation among scholars might be most useful as a gateway drug for reputation’s consumers in the rational choice community, a bridge to take them from self-interest alone toward more nuanced appreciations for social and personal value that bolster legal compliance in a world in which self-interest alone inevitably dictates shirking, noncompliance, and corruption.

Moreover, a strong regulatory reputation should not be viewed as a panacea—other agencies have enjoyed elite-level reputations only to make elite-level mistakes. Consider financial regulation, which has a history of terrible errors made by highly reputed regulators. Liaquat Ahamed’s Pulitzer Prize–winning Lords of Finance: The Bankers Who Broke the World is about the failed efforts of four central banks to provide stability to the Western economy before the Great Depression. Ahamed observes:

In the 1920s, a group of high financial officials, ... dubbed by the press the “Most Exclusive Club in the World,” ... sought to manage the international financial system. But, instead of averting a catastrophe and saving the world, the committee from the 1920s ended up presiding over the greatest collapse that the global economy has ever seen.

I view Carpenter’s valuation of reputation to be something that regime designers might consider in other contexts, but historical experience suggests caveats. The work done by Ahamed’s central bankers represented one of the first efforts to create a cross-border regulatory enterprise, and the story of how central bank coordination developed in the early part of the twentieth century still matters today. Their sort of informal regulatory cooperation, given its uneven legal support, might seem to be a strong candidate

26. Id. at 506–07.
for looking to foster its reputation to enhance its compliance pull. But esprit de corps in the past meant the overcommitment by smart, independent, and respected central bankers to a ruinous ideal—strong currencies, backed by gold—in the face of mounting evidence that the gold standard was harming economic growth.27

The reputation won by the FDA in Carpenter’s account led it to enjoy a substantial degree of autonomy. But checks on autonomy have their advantages; there are risks to groupthink, and if reputation clears the field of dissent, then a regulatory project can go as wrong as did the project to defend the gold standard.

Reputation may thus be a regulatory tool best deployed for limited purposes. While it may usefully stiffen the spines of enforcement-oriented regulators, it does not clarify a mission or assist much in the making of good policy decisions. Reputation is, at best, an enhancement of regulation, rather than a guarantee of the quality of the ends to which that reputation is put.

III. Cavils and Criticisms

Carpenter has written a definitive, but methodologically eclectic book: the account is historical and the constructed reputation story would not look outlandish to literature scholars, but the storytelling is also accompanied by quantitative research.28

It is all keenly observed, but it errs on the side of overexhaustiveness. There are so many facts! In the service of providing the prospective consumer with a sense of the feel of the book, I used a random number generator to pick out five pages from which I extracted representative sentences, which might then be divided into categories. There are insightful, if not central, observations; minute details that tend to be too comprehensive; and occasionally an entertaining mixture of both. For example, Carpenter observes that by “delegating [research protocol inspections] to the [Institutional Review Boards], a resource-poor agency was able to effect a vast expansion in its governance of medical research while effecting minimal direct intrusion into clinical settings” (p. 567). That observation is an important window into not just pharmaceutical approval, but also a shift in the nature of oversight of academic research itself. Similarly, Carpenter provides this interesting observation about nothing less than the weltanschauung of the average American over time: “The transformation of ‘citizen’ to ‘consumer’ as the primary identity for the American individual and family had been under way since the late 1800s, but it accelerated during the years following the Second World War” (p. 341). Are citizens now

27. Id. at 13.
28. Carpenter tracks the time it took for the agency to render decisions on new drugs, pp. 495–503, counts the references to phased clinical studies in Western medical literature, p. 293, conducts an event study in which he examines changes in pharmaceutical manufacturers’ stock prices following news from the FDA, p. 583, and engages in other counting exercises that pack the book with information without resorting to highly complex models, see pp. 675–85.
nothing more than consumers? The implications, as well as the timing of the transformation, are provocative.

Reputation and Power also contains plenty of details that could only be interesting to an extremely small number of experts. The cast of characters in Carpenter's story, ranging across borders and decades, and including regulators, researchers, and businesspeople, is enormous. For example, regarding Britain's approach to drug regulation, Carpenter takes a deep immersion into the weeds of the timing of change in that country: "Dunlop made these arguments defensively, as the 1968 changes had come in part from dissatisfaction with his Committee's operations after 1964" (p. 699). The rest of the page delves into similarly narrow nuances in the debate over how to reform pharmaceutical oversight in that country (p. 699). Carpenter provides more comparative bureaucratic history, this time involving the European Community: "It would take two decades more—and the International Conference of Harmonization—for European regulators to fully embrace individual case reports as part of the Common Technical Document, but the Community's preference had been clearly stated" (p. 703). The moment at which these international shifts occurred on minor matters of pharmaceutical regulation did not engage me.

Finally, in the third category, I place Carpenter's view of the decline of the agency's reputation during the Bush Administration, which comes not merely with examples but also with historical context. The random page generation offers this nugget: "Bush appointees to the FDA came from two institutions that had served as homes of criticism and resistance to the Administration in the 1970s: M. D. Anderson Hospital and the American Enterprise Institute in Washington" (p. 741). It may be more detail than is strictly necessary in this case, but it is interesting detail nonetheless. I cannot assure the reader that this was the case in each of the other 801 pages of the book.

Carpenter presents his detailed analysis with long, fact-packed sentences and huge paragraphs—on the five randomly generated pages, there were six paragraph breaks in total. The detail, in short, is not for the faint of heart, although since Carpenter is telling a story with a large number of moving parts—there are a large number of audiences that have to be convinced of the agency's reputation, in his view—one hopes that each of these stories contributes to the full picture of a set of ultimately acquiescent stakeholders to the FDA's decisions.\footnote{See pp. 302–14 (providing examples of Carpenter's exhaustive detail regarding all relevant stakeholders).}

There were also portions of the book that seemed misguided. Agency derring-do does not only come from its esprit de corps, even when bolstered with a powerful gatekeeping role. There is also the question of funding, and for what it is worth, here Carpenter expresses concern that the FDA is now partly funded by levies on drug manufacturers, which essentially pay for their approvals (pp. 734–35). Some observers have argued that such funding should be banned entirely in light of the risk of corruption by binding the
agency budget to regulated industry. At best, Carpenter suggests, the pharma-pays model adopted in the Hatch-Waxman Amendments of 1996 has distorted the agency, which now has a huge new drug-approval arm and a rather small postapproval surveillance arm; the FDA has not benefitted from the fees for approvals and may have been collaterally defunded by them.

But the ability to fund oneself, even if those funds come from regulated industry, is often the foremost way to obtain independence as an administrative agency. Observers of financial regulation might tut-tut about the dependence of banking regulators on fees from the banks that they regulate. But few scholars seem unhappy that the Federal Reserve can make monetary policy decisions without being jerked around by congressional purse strings. And they also bemoan the dependence of other agencies, such as the SEC, on appropriations, sensitive to the fact that regulation can fail not just because of a lack of authority but also because of a lack of resources. Indeed, in the aftermath of the recent financial crisis, Congress created the Consumer Financial Protection Bureau (“CFPB”) with a funding mechanism that would make it immune to the risk of starvation by insufficient congressional appropriations. There are advantages to funding by regulated entities. Indeed, law firms engaged to advise clients about compliance, and even law professors engaged to grade the students whose tuition pays their salaries, take this approach to funding.

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31. Pp. 736–38. This would occur if Congress reduced funding to the agency as fee revenue—directed exclusively to approvals—increased, as some observers have suggested might be the case.

32. Dain C. Donelson & David Zaring, Requiem for a Regulator: The Office of Thrift Supervision’s Performance During the Financial Crisis, 89 N.C. L. Rev. 1777, 1792 (2011) (noting the critique that financial regulators are “dependent . . . on fees from charter holders”).


IV. JUDICIAL AND ORDINARY GOVERNANCE

Most lawyers who practice before the FDA—and there is an entire bar that does only that—will never appear before the Court of Appeals for the District of Columbia (“D.C. Circuit”). Nonetheless, most of the scholarship in administrative law is premised on the idea that lawsuits will end up before that august court, and possibly also the Supreme Court, and that these lawsuits will provide agencies with the guidance they need to perform the delegations of power that Congress granted them. But really, only some agencies set their clocks to judicial review. The sorts of regulation that exist in the United States can usefully be divided into three categories, where the relationship with the judiciary is a dividing point. The best-known regulations are those supervised by the courts and subject to the rules of the Administrative Procedure Act (“APA”).\(^\text{37}\) The Environmental Protection Agency (“EPA”) and SEC, with their consumer protection–oriented missions, are examples of such agencies. These agencies have an adversarial relationship with regulated industry and often face challenges from active and energetic consumer advocates or other nongovernmental organizations.\(^\text{38}\) Litigation is common, so the applicable content of rules will ultimately depend on judicial decisionmaking. It could be called the paradigmatic model of administrative law.

The second type of administrative law regime is a more coordinated model—that is, coordinated with the stakeholders involved in the agencies’ remit. This might be called a constituency, or interest group representation, approach.\(^\text{39}\) The Department of Housing and Urban Development (“HUD”) and the federal government’s welfare administration may be examples of this model, where states and cities, as well as tenants and builders, participate in the policymaking and funding decisions of the agencies quite informally or through a procurement process that rarely sees the light of judicial day.\(^\text{40}\)

Other agencies ignore the traditional administrative structure altogether. Their often critical roles in the government proceed without much supervision by the judiciary or the Office of Management and Budget (“OMB”). These institutions include those whose regulatory mission does not easily fit

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\(^{38}\) See, e.g., NetCoalition v. SEC, 615 F.3d 525 (D.C. Cir. 2010) (petitioning for review of an SEC order); Our Children’s Earth Found. v. EPA, 527 F.3d 842 (9th Cir. 2008) (alleging that the EPA failed to comply with the Clean Water Act).


in a model of consumer protection or interest group representation. They include the pre-APA Departments of State, Defense, and the Treasury.41

The interesting thing about the FDA is that it, like the EPA and SEC, has a consumer protection mission, but its technical expertise has for decades kept it away from the strong oversight that the other consumer protection agencies receive from the courts. It would seem to belong in the paradigm of classic administrative law agencies; however, it has not had to set its policymaking by reference to the D.C. Circuit, as have other agencies such as the National Highway Transportation Safety Administration, which Jerry Mashaw and David Harfst has famously suggested was hamstrung by litigation, and eventually transformed into an inefficient, reactive recall institution rather than a proactive rulemaker.42

If the FDA exemplifies a way that an agency might win discretion for itself, despite being in the consumer protection business and overseeing a well-lawyered industry, it might be worth concluding with an observation of just how much an agency does that is foreign to courts, considering their concern with procedural regularity over reevaluations of the substance of the agency’s decisions. The FDA has devised a drug approval process that turns not only on what its own scientists and reviewers find, but one that also relies on pharmaceutical manufacturers to perform the trials required to obtain new drug approval, and on advisory commissions of leading pharmaceutical researchers for guidance throughout the process.43

In addition to being a scientific and technical enterprise, then, drug approvals are partly privatized affairs. And this critical component of FDA procedure lies outside the traditional focus of administrative law—that is, judicial review of government decisions, usually performed by the D.C. Circuit. In other words, the FDA has, possibly through reputation, and probably also through technical decisionmaking, moved itself from the consumer protection category of judge-supervised agencies into the less supervised category—like State, Treasury, and the older departments—partly because so much of its important work consists of the kinds of decisions that courts are not willing to scrutinize.

41. See David Zaring, Administration by Treasury, 95 MINN. L. REV. 187, 193–94, 238 (2010) (discussing how the Treasury Department’s administration differs from the strictures of the APA and noting that “older agencies like the Departments of State and Defense” also “do things differently” than APA-regulated agencies).


44. Zaring, supra note 41, at 238 (“There are other agencies like Treasury, agencies that play important roles in the government without playing important roles in the judicial (or OMB) administration of the executive branch and administrative state. These departments include the pre-APA agencies, and those whose regulatory mission does not comfortably fit in a model of consumer protection or interest group representation.”)
The scholarly gaps in the study of the sort of regulation that drug regulation represents may be a reasonable delegation of authority by administrative law scholars—it could be that it makes sense to leave the explanation of the FDA’s approval process to public health, political science, and medical school academics.

But lawyers are involved in the process of developing and obtaining approval for new drugs at every turn. Law firms devote practice groups to managing it. Legal scholars should probably be able to make some sense of it. One of the signal achievements of Carpenter’s account is that it offers a paradigm that does make sense of pharmaceutical regulation, one that may be transferrable to other governance contexts. If the drug process was characterized for decades by a consensual deferral to the FDA’s reputation for competent decisionmaking, then lawyers and institution builders may wish to think carefully about how the preconditions for reputation can be built into agencies—and maybe about whether the grant of strong legal authority to act is a precondition or a result of that power.

CONCLUSION

Reputation and Power is a comprehensive (at times extremely comprehensive) retelling of the challenges of American pharmaceutical regulation in the twentieth century and the government’s response to those challenges. Because those challenges were met again and again with successful regulatory responses, Carpenter’s book is a rebuke to those who assume that public administration is doomed to failure, not just because that is his inclination, but also because of the book’s sheer breadth. Given all the carefully recounted interventions made by the FDA after 1938, during a golden age of public health, it is hard to view the agency as a pure drag on the public welfare. While no study of a single agency can definitively prove that the agency did a good job (compared to what, one must ask), the evidence that Carpenter assembles is massive; his success mechanism—legal power plus extralegal reputation—is intuitive, if not definitive; and his attention to agency outcomes as well as agency procedure is refreshing. Stories like his may prove that there is something to the administrative state, and to careful studies of how it has operated.