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## Power to the People or to the Professionals: The Politics of Mature Regulatory Regimes

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## **POWER TO THE PEOPLE OR TO THE PROFESSIONALS? THE POLITICS OF MATURE REGULATORY REGIMES**

R. Shep Melnick\*

RENA STEINZOR AND SIDNEY SHAPIRO, *THE PEOPLE'S AGENTS AND THE BATTLE TO PROTECT THE AMERICAN PUBLIC: SPECIAL INTEREST, GOVERNMENT, AND THE THREATS TO HEALTH, SAFETY, AND THE ENVIRONMENT* (Univ. of Chicago Press 2010). Pp. 272. Cloth. \$45.00.

DANIEL CARPENTER, *REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA* (Princeton Univ. Press 2010). Pp. 856. Cloth. \$78.50. Paperback. \$35.00.

During the 1970s and 1980s regulation was an exciting field to study. This explosion of "social" regulation that began in the late 1960s was unprecedented in its scope, cost, complexity, and capacity to generate controversy. This raised all sorts of fascinating questions for political scientists, historians, economists, and law professors. What caused this massive expansion of government regulation? How would the newly created and reconstituted regulatory bodies behave? How had judges contributed to these changes, and how would they respond to the demand to review a multitude of complicated administrative decisions? How effective would this ambitious regulation be? Would it retard economic growth? Why was it that this remarkable growth of health, safety, consumer, and environmental regulation coincided with often successful attacks on New Deal-style "economic" regulation?

Throughout these decades we were treated to a series of rich, detailed studies of regulatory agencies, including the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the National Highway Traffic Safety Administration (NHTSA), the Federal Trade Administration (FTC), and the Food and Drug Administration (FDA).<sup>1</sup> We came to understand the key role played by policy entrepreneurs in Congress, usually allied with public interest groups and aided by the

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1. Among the most important works are STEPHEN BREYER, *REGULATION AND ITS REFORM* (1982); DANIEL FIORINO, *MAKING ENVIRONMENTAL POLICY* (1995); RICHARD HARRIS & SIDNEY MILKIS, *THE POLITICS OF REGULATORY CHANGE: A TALE OF TWO AGENCIES* (2d ed. 1996); ROBERT A. KATZMANN, *REGULATORY BUREAUCRACY: THE FEDERAL TRADE COMMISSION AND ANTITRUST POLICY* (1980); MARC K. LANDY ET AL., *THE ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS* (1990); JERRY L. MASHAW & DAVID L. HARFST, *THE STRUGGLE FOR AUTO SAFETY* (1990); THOMAS K. MCCRAW, *PROPHETS OF REGULATION* (1984); GRAHAM WILSON, *THE POLITICS OF SAFETY AND HEALTH: OCCUPATIONAL SAFETY AND HEALTH IN THE UNITED STATES AND BRITAIN* (1985). Many of the best studies of regulatory bureaucracies were produced by students of James Q. Wilson. Nine such studies are contained in his edited volume *THE POLITICS OF REGULATION* (James Q. Wilson ed., 1980).

media.<sup>2</sup> We learned how an unlikely alliance of liberal consumer advocates and market-oriented conservatives could bring down regulatory regimes long thought impregnable.<sup>3</sup> Law professors and political scientists collaborated to describe the “Reformation of American Administrative Law” and to explore its consequences.<sup>4</sup> Other works described the counter-mobilization by business in the late 1970s and the development of regulatory review by the Office of Management and Budget (OMB).<sup>5</sup> Cost-benefit analysis and various forms of risk assessment were subject to extensive and probing review. Comparative works showed that the allegedly weak American state was often more aggressive on regulatory issues than were European governments, and that the United States employed a uniquely adversarial and legalistic regulatory style.<sup>6</sup>

By the middle of the 1980s the regulatory blitzkrieg had turned into political trench warfare. Both the pro- and anti-regulation forces were politically potent and well-organized. Given the nature of the American political system, it was easier to play defense than offense. Environmental advocates won a few victories (most notably the 1990 amendments to the Clean Air Act), but the overall picture was one of stasis. Not surprisingly, each side developed its own political narrative, appropriating whatever social science theory suited its purpose. The best work was becoming more technocratic: one could not even begin to study air pollution regulation without mastering the details of NAAQSs, SIPs, BACT, MACT, LAER, PSD, NESHAPS, I&M, TCPS, and much, much more. When I began my teaching career in 1981, “The Politics of Regulation” was my favorite course. By the mid-1990s I no longer offered it. My students found the subject boring, and I found most of the new literature boring as well.

The two books under review seek to reverse this trend. Both focus on health, safety, and environmental regulation — Steinzor and Shapiro on the EPA, OSHA, NHTSA, the FDA, the Consumer Product Safety Commission (CPSC); Carpenter on the FDA alone. Beyond that they have little in common. *The People's Agents* is short, engagingly written, directed at the average reader, highly partisan, and deeply flawed. *Reputation and Power* is very long (eight hundred pages), dense with details and political science analysis, intellectually challenging, and a major contribution to our understanding of the power of professionals within government. Steinzor and Shapiro wear their politics not just on their sleeves, but on their dust cover: the very title of their book points to a Manichean battle between “the people” and “special interests.” Carpenter, in contrast, manages to write hundreds of pages without letting us know

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2. See generally JEFFREY M. BERRY, *THE NEW LIBERALISM: THE RISING POWER OF CITIZEN GROUPS* (1999).

3. See generally MARTHA DERTHICK & PAUL J. QUIRK, *THE POLITICS OF DEREGULATION* (1985).

4. See generally Richard Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667 (1975); R. SHEP MELNICK, *REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT* (1983); MARTIN SHAPIRO, *WHO GUARDS THE GUARDIANS? JUDICIAL CONTROL OF ADMINISTRATION* (1988).

5. See generally RICHARD NATHAN, *THE ADMINISTRATIVE PRESIDENCY* (1983); DAVID VOGEL, *FLUCTUATING FORTUNES: THE POLITICAL POWER OF BUSINESS IN AMERICA* (1989).

6. See generally RONALD BRICKMAN ET AL., *CONTROLLING CHEMICALS, THE POLITICS OF REGULATION IN EUROPE AND THE UNITED STATES* (1985); ROBERT A. KAGAN & LEE AXELRAD, *REGULATORY ENCOUNTERS: MULTINATIONAL CORPORATIONS AND AMERICAN ADVERSARIAL LEGALISM* (2000); STEVEN KELMAN, *REGULATING AMERICA, REGULATING SWEDEN: A COMPARATIVE STUDY OF OCCUPATIONAL SAFETY AND HEALTH POLICY* (1981); DAVID VOGEL, *NATIONAL STYLES OF REGULATION: ENVIRONMENTAL POLICY IN GREAT BRITAIN AND THE UNITED STATES* (1986).

whether he considers FDA regulation of pharmaceuticals excessive, insufficient, or just right.

Nevertheless, each book teaches us something important about regulation. Carpenter helps us understand how a relatively small agency can become extremely powerful and autonomous. The answer lies in the way the FDA incorporated the professional norms of clinical pharmacologists into its standard operating procedures and sense of mission, while building a network of like-minded professionals in universities and the regulated industry. Although Carpenter does not emphasize this point, his study presents a major challenge to standard arguments about the power of interest groups. Steinzor and Shapiro offer a one-dimensional picture of the regulatory process, but unwittingly help us understand the political world view of those who consider themselves “public interest” advocates.

The central claim of *The People's Agents* is that “the people” have demanded aggressive health, safety, and environmental regulation, but their “agents” — especially the president and his lackeys in OMB, but also Congress and the federal courts — “have all made decisions that sabotage the five protector agencies’ ability to carry out their statutory mandates.”<sup>7</sup> As a result, all five lie “in shambles.”<sup>8</sup> In fact, the EPA “has been brought to its knees.”<sup>9</sup> If this continues, “lives will be lost, people will be hurt, and natural resources will be squandered.”<sup>10</sup> This is not just bad public policy, but a betrayal of “the people.”

Steinzor and Shapiro claim to offer dramatic empirical support for these claims. Indeed, so disturbing is their evidence that “we were shocked when we assembled this data in one place.”<sup>11</sup> What does this assemblage of shocking data show? Oddly enough, their budget figures do not show that funding for the five agencies has seriously eroded. According to their graphs, the FDA’s budget has increased significantly since 1990.<sup>12</sup> Measured in inflation adjusted dollars, the budget of the other four has remained relatively constant.<sup>13</sup> While it is true that their regulatory duties have grown, it is also the case that state governments have taken over some of their enforcement duties and that initiating huge regulatory programs is more resource-intensive than monitoring compliance with existing ones. The authors’ hyperbolic rhetoric does not fit their rather bland data.

But what about their more serious charge that weaker regulation has caused more Americans to be injured and killed each year by pollution and defective products? Not only do they fail to demonstrate that our highways, workplaces, air, and water have become more dangerous, they concede that they have continued to become *safer*. Highway fatalities per vehicle miles travelled have gone down over the past several decades, even in the George W. Bush years. To deflect attention from this inconvenient

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7. RENA STEINZOR & SIDNEY SHAPIRO, *THE PEOPLE'S AGENTS AND THE BATTLE TO PROTECT THE AMERICAN PUBLIC: SPECIAL INTERESTS, GOVERNMENT, AND THREATS TO HEALTH, SAFETY, AND THE ENVIRONMENT* 49 (2010).

8. *Id.* at 4.

9. *Id.* at 5.

10. *Id.* at 38.

11. *Id.*

12. *Id.*

13. *Id.*

fact, they write, “[d]espite this steady progress, traffic fatalities remain the leading cause of death among people ages four through thirty-four . . . and NHTSA has been unable to make much progress in achieving its goal of further reducing deaths by vehicle miles traveled.”<sup>14</sup> A major culprit, they point out, is consumer preference for SUVs. In other words, things have gotten better, but not as much as many of us would wish. They apply a similar logic to OSHA. After citing Bureau of Labor Statistics figures that show workplace fatalities falling from eighteen fatalities per 100,000 workers in 1970 to thirteen in 1980, nine in 1990, 4.3 in 2000, and 4.0 in 2006, they try to minimize the importance of this progress by claiming that many injuries go unreported.<sup>15</sup> Huh? Is underreporting really more severe now than in 1970? How does one get away with failing to report a death? Compounding the problem, in describing the danger of work in the meatpacking industry, they cite a GAO report that injury and illness rates were cut in half between 1992 and 2001. Does this indicate the continuing vitality of OSHA regulation? Of course not — because “the rate was still among the highest of any industry.”<sup>16</sup> True, but a non sequitur. Steinzor and Shapiro don’t even try to claim that the quality of our environment has declined since there is so much evidence that it continues to improve. In short, while they claim to rely on systematic data rather than anecdote, almost all of their evidence indicates that things have gotten better, but problems remain. They always do.

This book is guided not by statistics, but by a near-religious belief that the benefits of well-intentioned health, safety, and environmental regulation always exceeds its cost. As scientific evidence rolls in, they claim, it invariably shows that the risks posed by chemicals “was much worse than originally thought.”<sup>17</sup> “In fact,” they assert, “it is possible to count on one hand the number of times that hazards addressed by the five agencies turned out to be negligible. The overwhelming record . . . is that those hazards turn out to be worse than originally thought and delays in taking action cost us dearly.”<sup>18</sup> Later they add, “the more we learn, the more we realize that the chemicals [we have regulated] are even more hazardous than we first imagine[d].”<sup>19</sup> One looks in vain for even a single footnote to support these assertions. What about Superfund, which was based on a massive exaggeration of the dangers of waste sites?<sup>20</sup> The same is true of asbestos in school buildings. Those who want more examples should consult Justice Stephen Breyer’s *Breaking the Vicious Circle: Toward Effective Risk Regulation*.<sup>21</sup> He provides many more examples than one can count on one hand. Breyer also points out that removing one risky item from the market or the environment can increase other risks. Removing a drug from the market because it has serious side-effects can reduce doctors’ ability to treat a disease. Banning a sugar substitute could lead to the

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14. *Id.* at 12.

15. *Id.* at 18.

16. *Id.* at 23.

17. *Id.*

18. *Id.*

19. *Id.* at 83.

20. LANDY, *supra* note 1, at 133-72.

21. STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 3-29 (1993).

consumption of more sugar, thus increasing obesity, one of the nation's most serious health problems. Where Breyer sees competing risks that need to be compared with one another, Steinzor and Shapiro see a battle between good and evil, with the lives of children at stake.

*The People's Agents* assumes that "the people" agree with its conclusions. To be sure, many polls show that large majorities believe we should do everything possible to protect the environment "regardless of cost." But if you change the polling question to ask if respondents would be willing to pay significantly higher gas prices or electric rates to curb global warming or to reduce smog, their response is an overwhelming "No!" Price is no object — as long as someone else is footing the bill. Similarly, the public may love "government efforts to save lives," but it hates "bureaucracy," "red tape," and rules that hobble small business and entrepreneurs. Steinzor and Shapiro's failure to acknowledge these two faces of public opinion is either naïve or deeply cynical.

*The People's Agents* often falls back on the argument that in the 1970s Congress frequently included "health-only" standards in federal legislation, most notably the Clean Air Act. Agencies, they insist, must follow these congressional commands. One problem with this approach is that it is based on a health "thresholds" understanding of risk that seldom holds up under close scrutiny. (A House report at the time conceded that thresholds were a "myth"<sup>22</sup>). Moreover, if agencies were to take this command seriously, they would establish pollution standards at or below natural background levels — meaning, for example, that auto traffic should be banned in major cities. Few administrators are foolish enough to do that. So they wink and nod and bring in cost through the backdoor. Meanwhile environmental advocates pontificate about how regulators have left some people at risk.

The real demon in *The People's Agents's* story is OMB, or more precisely, regulatory review by its Office of Information and Regulatory Affairs (OIRA). The book works hard to associate OIRA with the Bush Administration's arguments about the "unitary executive," an example of both guilt by association and the now common debating technique of *reducto ad Bushium*. They acknowledge that such regulatory review was used by Reagan, skipping lightly over the fact that it has been employed by every president since the advent of social regulation in the 1970s — including Carter, Clinton, and Obama. It is unlikely that the present head of OIRA, Cass Sunstein, relies on Bush-era theories of the "unitary executive."

No assault on OIRA would be complete without an attack on cost-benefit analysis (CBA). There are many problems with a highly quantitative approach to CBA, and the authors point out most of them. Then they proceed to throw out the baby with the bathwater. Their wholesale rejection of CBA combines demagoguery with sloppy thinking. For example, they criticize an analysis by former OIRA director John Graham because it assumes that "an intervention that saves the life of an older person is less worthy than one that would save a younger person or, to put it more bluntly, society benefits less when it saves the life of a middle-aged or elderly person."<sup>23</sup> How horrible! How age-ist! How undeniably reasonable! If you had to choose between saving the life

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22. MELNICK, *supra* note 4, at 252-55.

23. STEINZOR & SHAPIRO, *supra* note 7, at 83.

of a three-year-old and an octogenarian, would you be indifferent? I hope not. If you had a million dollars to spend, would you spend it on reducing a risk in a nursing home rather than a similar risk in an elementary school?

After charging — no doubt correctly — that industry always exaggerates the cost of regulation, the authors demonstrate their willingness to go very far in the opposite direction. The argument that regulation is too expensive, they maintain, is based on “persistent confusion about how much this aspect of government actually costs. Far too many people are confused about the difference between the inflated estimates of the compliance costs businesses must pay to reduce hazards and *the money we actually spend on the five agencies.*”<sup>24</sup> The government, they explain, only spends about \$10 billion per year on all five agencies, a drop in the bucket. True, but completely irrelevant. As anyone who has thought about regulation for five minutes knows, only a tiny fraction of the social cost of regulation is borne by government. That is the essential feature of this form of policymaking. Governments do not pay for scrubbers or clean coal or catalytic converters — consumers do. In Steinzor and Shapiro’s analysis, these costs mysteriously disappear.

The authors initially present themselves as defenders of Congress — the “first” branch of government — against executive usurpation. But we later learn that Congress is deeply dysfunctional.<sup>25</sup> Not only is it unable to act because of super-majoritarian requirements and polarized parties, but it has a bad habit of attaching anti-regulatory riders to annual appropriations bills. One could argue that one phase of the congressional process, the enactment of authorizing legislation, reflects the public’s demand for protection against various risks, while the restrictions placed on regulators by riders and other budgetary constraints are a response to shifting public moods on whether the federal government is too costly and intrusive. But this would require them to rethink their dogma about what “the people” want. Thus when a Democratic Congress passed landmark environmental regulation in the 1970s, it reflected the wishes of the people. When Republicans took over, it became dysfunctional.

Their assessment of judicial review is similarly partisan. They criticize federal courts for placing excessive evidentiary demands on the five agencies. When the Supreme Court required in 1980 that OSHA demonstrate that the risks it addresses are “significant,” the agency “was devastated” and “has never recovered.”<sup>26</sup> Sounding positively Frankfurterian, they repeatedly call for judicial deference to agency expertise.<sup>27</sup> So it comes as a surprise to learn that they object to recent Supreme Court decisions narrowing standing in regulatory cases. Isn’t raising the bar for standing a good way to protect agency discretion and expertise? So devoted are they to the assumption that public interest groups are good and business bad that they do not even seem to notice the contradiction. Requiring an agency to provide substantial evidence in support of their rules constitutes judicial “overreaching,” but requiring the EPA to promulgate regulations to address global warming — likely to become one of the most extensive

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24. *Id.* at 222 (emphasis added).

25. *Id.* at 97-121.

26. *Id.* at 150.

27. *Id.* at 147-48, 162-65.

regulatory programs in history — is not.

After wading through these multiple contradictions, it becomes apparent that what the authors want is to hand over regulation to scientists and other civil servants in their five agencies, telling them to do everything possible to protect the public against all kinds of risks. Theirs is a technocratic model of regulation, albeit one that slights economic analysis. They conclude their book by encouraging agencies to regain the “brashness” and “swagger” evidenced by a former chief counsel of the FDA who bragged about intimidating drug manufacturers in this fashion: “I would go in there and say ‘My name is Peter Barton Hutt and I represent the agency that protects small children and pregnant women. Do you have any questions?’”<sup>28</sup>

Those were the days, my friend. But what did they produce? The authors praise two EPA reports issued in the late 1980s that they claim demonstrate administrators’ capacity for clear thinking. These are indeed thoughtful studies. What these reports conclude, though, is that the regulatory regime was terrible at setting rational priorities and assessing competing risks:

For the past 20 years, [the] EPA has been basically a “reactive” agency. . . . [T]he Agency has made little effort to compare the relative seriousness of different problems. Moreover the Agency has made very little effort to anticipate environmental problems or to take preemptive actions that reduce the likelihood of an environmental problem occurring.<sup>29</sup>

In other words, the good old days just were not that good, and the present just is not that bad. “The people” are inconsistent, wanting protection as long as it does not cost them anything. Congress reflects their ambivalence. Steinzor and Shapiro want to install people who think like them in the bureaucracy, protecting them from interference from OMB, hostile congressional committees, and reviewing courts — but still allow public interest groups to use the courts to force them to toe the line. To get a sense of how such an arrangement might work, we can turn to Dan Carpenter’s description of the Food and Drug Administration.

It is difficult to do justice to Carpenter’s long and complex book even in an extended review. I have chosen to say little about his “reputational” theory of bureaucratic autonomy in order to focus on his more specific arguments about the FDA. I do this reluctantly because his examination of reputation is intriguing, if still somewhat underdeveloped. His reputational approach emphasizes that an agency must appeal to a variety of constituencies. Even more importantly, successful administrators realize that reputations take a long time to build but a short time to tarnish. The risk aversion one finds in many agencies, Carpenter argues, “is something more. It is aversion to

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28. STEINZOR & SHAPIRO, *supra* note 7, at 230.

29. Science Advisory Board A-101, United States EPA, SAB-EC-90-021, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (Sept. 1990), quoted in STEINZOR & SHAPIRO, *supra* note 7, at 186-87. The other report is United States EPA, *Unfinished Business: A Comparative Assessment of Environmental Problems Overview Report*, 000R87901 (Feb. 1987). For particularly astute assessments of this problem, see LANDY, *supra* note 1, and BREYER, *supra* note 21.

reputational damage.”<sup>30</sup> His work points to an escape route for those who have grown weary of standard social science models of policymaking.

Carpenter’s central question is “How did the FDA become such a powerful agency?” As the “gatekeeper of the American pharmaceutical marketplace,” the FDA commands:

[T]he power to limit advertising and product claims, the power to govern drug manufacturing, the power to enable drug firms to generate vast riches and the power to chase those same firms from the marketplace, the power to sculpt medical and scientific concepts, and ultimately the power to influence the lives and deaths of citizens.<sup>31</sup>

The FDA’s power is not limited to the United States. Given its prestige and the size of the U.S. industry, it “rules the entire global pharmaceutical market.”<sup>32</sup> Other countries have copied our regulatory regime, but none have created so powerful a bureaucracy. Rare are agencies such as the FDA that “have created entire new industries and have fundamentally refashioned scientific disciplines.”<sup>33</sup>

The FDA enhanced its influence and established its autonomy not by relying heavily on what Carpenter calls its “directive power” (its ability to issue enforceable commands), but primarily through its “gatekeeping power” — that is, its ability to keep drugs off the market and to block experimentation with new drugs — and its “conceptual power,” its capacity to shape the way virtually everyone thinks about what constitutes a “safe and effective” drug and a “well-controlled investigation” of new drugs.<sup>34</sup> With little guidance from Congress, long-serving administrator/scientists at the FDA equated “well-controlled investigations” with randomized, double-blind clinical trials using placebos and conducted by pharmacologists who had earned the respect of their fellow scientists within the Administration. The norms of the emerging field of clinical pharmacology — a specialty nurtured and shaped by the FDA — became the controlling norms of the entire organization, indeed of an extended regulatory regime that stretched into laboratories of leading universities and the most successful pharmaceutical companies. Carpenter provides not just vivid portraits of these scientist/administrators — especially the heroine of the thalidomide saga, Dr. Frances Kelsey — but a detailed explanation of how they create a network of respected pharmacologists throughout the country. Drug companies that embraced their approach to research (such as Merck) were trusted and rewarded with relatively quick approvals. Those that did not (such as Merrill Pharmaceutical, the company whose application to distribute thalidomide in the U.S. was so wisely delayed by Kelsey) were subject to much more skeptical review. Of course, winning the trust of the FDA meant *not* pushing applications of questionable merit, which required companies like Merck to scuttle many products early in the application

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30. DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 67 (2010).

31. *Id.* at 1.

32. *Id.*

33. *Id.* at 18.

34. *Id.* at 15.

process. Thus did the law of anticipated reactions increase the power of the FDA. More subtly, the fact that everyone in the extended system took for granted the FDA's elaborate three-phase drug development scheme indicated the extent of its "conceptual" power.

Carpenter provides multiple examples of how the FDA's power spread from drug approval to supervision of experimental design, and then to review of the qualifications of experimenters and to determination of what constitutes "informed consent" by the subjects of clinical trials. To enforce its "informed consent" rules, it required all research institutions to create Internal Review Boards (IRBs). It then used its considerable clout to turn these IRBs into "satellite regulators of early phase clinical trials."<sup>35</sup> By "implicitly delegating" to the 5000 IRBs spread throughout the country the task of reviewing all individual research protocols, "a resource-poor agency was able to effect a vast expansion in its governance of medical research."<sup>36</sup> This "empowerment of the IRBs," he notes, "projected the Administration's veto power to universities, institutes, [and] contract research organizations."<sup>37</sup> The FDA then encouraged the IRBs to be tough on applicants by reviewing only approvals — and never taking a look at denials. If the FDA became dissatisfied with an IRB, it could disqualify it, thereby prevent the entire university or research institution from receiving federal funds or support from pharmaceutical firms. This death threat convinced IRBs to pay very close attention to the wishes of the Administration.

About half Carpenter's book offers a detailed history of the regulation of pharmaceuticals by the FDA.<sup>38</sup> The conventional wisdom holds that the Administration was shaped by a series of external shocks: the public outcry over adulterated food sparked by Upton Sinclair's *The Jungle*; the sulfanilamide tragedy that led to the pivotal Food, Drug, and Cosmetics Act of 1938; the thalidomide crisis, which produced the equally important amendments of 1962; and the AIDS epidemic, which forced the Administration to revise its conservative approach to drug approval for patients facing a terminal disease. Carpenter shows that this standard story is wrong. Key players within the FDA used highly publicized events to extend and legitimate policies they had long advocated. This was most evident in passage of key legislation in 1938 and 1962. The FDA consciously and cleverly used the sulfanilamide incident to push legislation that had become hopelessly stalled in Congress. Among the more interesting details is the way in which the FDA reframed the story so it focused not on African-American men who had used sulfanilamide to treat venereal disease — by far the most numerous victims of "Dr. Massengill's elixir" — but on the death of a photogenic young white girl from Oklahoma. With the help of Secretary of Agriculture Henry Wallace, the FDA used the tragedy to promote its reputation as a vigorous protector of public health and to wrest additional regulatory authority from Congress.

Just as convincingly, Carpenter demonstrates that the thalidomide incident did not shake up the FDA or change its direction, but rather empowered it to move more quickly

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35. CARPENTER, *supra* note 30, at 557.

36. *Id.* at 567.

37. *Id.*

38. *Id.* at 73-461.

to establish the regulatory regime envisioned by its clinical pharmacologists. Frances Kelsey had been placed in her position and had been backed up by her superiors precisely because she represented the type of tough, well-trained clinical pharmacologist favored by the Administration. Carpenter also shows that the 1962 Amendments' grant of authority to review "efficacy" as well as "safety" merely legitimated an expansion of power that had already taken place. In its formal statements and informal practices, the Administration had previously explained that it could not separate safety from "intended use," and an "intended use" could only be one found effective in treating a specific disease or condition. Here, too, we see how reformers shaped news stories: the famous *Washington Post* story that made Frances Kelsey an international celebrity was not the result of investigative journalism, but was spoon-fed to a reporter by congressional staffers promoting the FDA's legislation.<sup>39</sup>

The AIDS epidemic of the 1980s produced unprecedented condemnations of the FDA. But Carpenter shows that these attacks were really aimed more at the policies of the Reagan Administration than at the FDA itself, and that these often hysterical criticisms ignored the extent to which the agency *had* recognized the extraordinary problem and reacted with unusual flexibility. The AIDS story is just one part of a long-term development that has threatened the autonomy and power of the FDA: the formation of a plethora of politicized patient advocacy organizations allied with medical specialists. This first became apparent in the flap over an alleged anti-cancer drug, laetrile. The FDA later faced a more formidable challenge from the National Cancer Institute, a research arm of the federal government that believed the FDA was placing too many restraints on investigation of new cancer treatments. Although Carpenter does not develop the argument, he hints that the steady growth of the medical-industrial complex — now nearly one sixth of the American economy — creates a political environment that is increasingly difficult for the FDA to manage.

*Reputation and Power* is filled with insights about the power of professionals and professional norms within public bureaucracies. For example, Carpenter shows how the administrative forms scientists were required to fill out in order to move to the next stage of clinical trials shaped the entire regulatory process. These forms, which were seldom subject to rulemaking procedures or judicial review, were often more important than regulations subject to public scrutiny and to notice-and-comment rulemaking under the Administrative Procedures Act. Another example is the way in which widely shared professional norms shifted policymaking within the FDA downward, empowering long-term civil servants and weakening the authority of political executives.

Perhaps the most important feature of this highly professionalized regulatory regime, though, was the way it focused attention almost exclusively on the approval of new drugs. The FDA's standard operating procedures, its sense of mission, and its defense of its reputation all led it to emphasize its gatekeeping function and to be uncharacteristically lackadaisical about post-approval monitoring of these drugs' safety and efficacy. Clinical pharmacologists dominated the agency. They did what they knew best: evaluating the evidence produced by well-designed clinical trials. Just as importantly, once they had staked their reputation on a drug, they were highly reluctant

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39. *Id.* at 258.

to admit that they had made a mistake. The FDA's data on drug use, in contrast, was incomplete, unreliable, and largely out of the Administration's control. Post-approval monitoring was conducted by an office staffed by epidemiologists, a distinctly inferior medical specialty in the eyes of the Administration's leaders. One particularly vocal FDA epidemiologist complained that the clinical pharmacologist in the Office of New Drugs come to view a drug as their "own child" after approval, and this "typically proves to be the single greatest obstacle to effectively dealing with serious drug safety issues."<sup>40</sup> Rather than risk its reputation by recalling a drug, the Office of New Drugs prefers to tweak labeling requirements.

The Vioxx case offers a useful contrast between Carpenter's analysis and that of Steinzor and Shapiro. Vioxx was a much-heralded arthritis drug produced by the most prestigious of all pharmaceutical companies, Merck. After approving Vioxx, the FDA responded cautiously to studies that showed a rise of heart attack by those who had taken it. The evidence on coronary risk mounted until Merck lost a \$5 billion tort suit and the FDA finally withdrew its approval. For Steinzor and Shapiro this is another example of the "hollowing out" of the FDA through budget cuts.<sup>41</sup> Carpenter tells a more complex story. Within the FDA "[t]he dispute over Vioxx quickly became a debate about the relative value of pharmacology versus epidemiology, and the value of randomized controlled trials versus observational studies in drug regulation."<sup>42</sup> This debate "pitted drug reviewing medical officers . . . symbolically and structurally against post-marketing surveillance officers."<sup>43</sup> In other words, the problem was not that nefarious outside forces had weakened the Administration, but that the very features of the Administration that had made it so powerful and effective sometimes proved to be its Achilles heel.

Given the fact that the first 729 pages of *Reputation and Power* are devoted to explaining how the FDA became and remained so powerful, it is a bit of a surprise to learn on page 730 that by 2010 "the reputation and the power" of the FDA had "waned appreciably."<sup>44</sup> Carpenter devotes less than 20 pages to an examination of "the FDA's decline," concluding that the topic "demands a book or two in its own right."<sup>45</sup> It is hard to attribute this shift simply to an anti-regulatory mood in Congress or the courts since Congress has recently (and at long last) given the Administration authority to regulate tobacco products, and the Supreme Court has allowed state tort law to impose a new level of regulation on top of that of the FDA. Moreover, some of the key changes noted by Carpenter came during the tenure of David Kessler, a Clinton appointee and a determined advocate of aggressive regulation.

Carpenter very briefly mentions several possible suspects, but does little more to address the mystery. It could have been the Republican take-over of Congress in 1994, the indirect effect of making the FDA dependent on a user-fee paid by the drug industry, political executives appointed by George W. Bush, or the proliferation of patient advocacy groups allied with medical specialists. The final pages of the book read like the

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40. CARPENTER, *supra* note 30, at 630 (internal quotation marks and citation omitted).

41. STEINZOR & SHAPIRO, *supra* note 7, at 26-27.

42. CARPENTER, *supra* note 30, at 738.

43. *Id.*

44. *Id.* at 730.

45. *Id.*

end of a best-seller mystery, the type that comes with the first chapter of the author's newest thriller appended. Having solved one mystery (Why has the FDA been so powerful for so long?), Carpenter introduces a new one (Why did this regime come to an end?). The good news is that he may be in the process of writing another outstanding book. The bad news is that it is hard to see how his "reputational" approach answers his new question.

Carpenter may be in the same situation Martha Derthick found herself in when she completed her magisterial book, *Policymaking for Social Security*<sup>46</sup> in 1979. The Social Security Administration (SSA) was the most powerful and autonomous federal administrative agency during the half-century following the New Deal — significantly more so than the FDA. Derthick noted that the foundations of its influence were disintegrating in the late 1970s. Her next book, *Agency under Stress*<sup>47</sup>, explained how the new tasks undertaken by the SSA and its more complicated political environment contributed to its fall from grace. She noted that a similar fate had befallen other powerful, well respected agencies, including the IRS, the FBI, and the Forest Service. Carpenter's book brilliantly explores the inner working of the FDA and explains how it managed to maintain its reputation among many audiences. It says little about how the audiences in its political environment were changing. This admittedly would be no easy job because the number of repeat players and the conflict among them has grown so significantly in recent decades. It sounds like a job for a scholar with the tenacity, balance, and insight of Dan Carpenter.

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46. See generally MARTHA DERTHICK, *POLICYMAKING FOR SOCIAL SECURITY* (1979).

47. See generally MARTHA DERTHICK, *AGENCY UNDER STRESS: THE SOCIAL SECURITY ADMINISTRATION IN AMERICAN GOVERNMENT* (1990).