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# Capture, Accountability, and Regulatory Metrics

Sidney A. Shapiro & Rena Steinzor\*

Aggressive regulation to eliminate threats to health and safety began shortly after the dawn of the twentieth century in the United States, but did not hit its stride for another fifty years. Spurred by the political and cultural changes that the Civil Rights Movement and Vietnam War provoked,<sup>1</sup> Congress and a series of presidents dramatically expanded the regulatory state, making the Food and Drug Administration (FDA) into a powerhouse and, in rapid succession, creating the Environmental Protection Agency (EPA), the Occupational Health and Safety Administration (OSHA), the National Highway Traffic Safety Administration (NHTSA), and the Consumer Product Safety Commission (CPSC).<sup>2</sup> Today, another forty years later, these agencies are in shambles, in some instances suffering catastrophic, highly publicized failures—think Vioxx (FDA) and Chinese toys (CPSC)—and in other instances experiencing lower profile but equally devastating systemic failures in carrying out their core missions—think climate change (EPA) and the dearth of any new controls on workplace exposure to toxic chemicals (OSHA).

Will Congress and the next president ride to the rescue again, revitalizing these agencies as they near forty? Or have we passed the era of expecting government to take action in response to complicated new threats to people and the environment? Bipartisan political rhetoric suggests the second outcome, with every president for the past thirty years declaring that, as Bill Clinton famously put it, “The era of big government is over.”<sup>3</sup>

With respect, we disagree.<sup>4</sup> We favor the resurgence of strong, deterrence-based federal and state enforcement authorities that will focus on

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1. See MICHAEL W. MCCANN, *TAKING REFORM SERIOUSLY: PERSPECTIVES ON PUBLIC INTEREST LIBERALISM* 29–30 (1986) (linking the expansion of regulatory government to the Civil Rights and Vietnam protest movements).

2. See RICHARD J. PIERCE ET AL., *ADMINISTRATIVE LAW AND PROCESS* 32–33 (4th ed. 2004) (documenting FDA’s expansion and the creation of new agencies).

3. President William J. Clinton, Radio Address (Jan. 27, 1996) (transcript available at [http://www.cnn.com/US/9601/budget/01-27/clinton\\_radio](http://www.cnn.com/US/9601/budget/01-27/clinton_radio)).

4. For an elaboration of these views, see generally *A NEW PROGRESSIVE AGENDA FOR PUBLIC HEALTH AND THE ENVIRONMENT: A PROJECT OF THE CENTER FOR PROGRESSIVE REGULATION* (Christopher H. Schroeder & Rena Steinzor eds., 2005) [hereinafter *NEW PROGRESSIVE AGENDA*], which sets forth a progressive agenda. We are member scholars of the Center.

the egregious conduct that has flourished during years of regulatory neglect. Instead of half-hearted recognition of global challenges such as climate change and mercury contamination of seafood, which is invariably accompanied by self-righteous finger-pointing at the developing world, we support aggressive efforts to require American industry to push the envelope of technology-based solutions, making it possible to export this progress to other countries.

We understand that revitalization cannot simply turn the clock back to an earlier era. Instead, efforts to revitalize the administrative state will falter without the adoption of new approaches to the threshold problem that undermines regulatory government: ineffective efforts to hold agencies accountable for failure to accomplish their statutory missions. To respond to this challenge, this Article proposes to harness the power of the World Wide Web with a new version of an old idea: the independent development of rigorous and concise “positive metrics” that would give public notice when health and safety agencies are successful in achieving their statutory missions and when they have failed to do so.

The issue of agency accountability dates back to the 1960s when consumer and environmental advocates were determined to prevent agency capture by regulated interests. They reasoned that the domination of agencies by corporate interests could not long survive if seats were available at the table for the full range of affected constituencies, thereby compelling government to operate in the sunshine. The resulting “reformation” of administrative law, to use Richard Stewart’s famous description,<sup>5</sup> has produced mixed results. The United States has achieved an impressive record of regulatory success since the 1950s in reducing environmental, health, and safety risks.<sup>6</sup> Yet, as noted earlier, the regulatory ship of state is listing to starboard in the water, unable to take bold, effective action to address pressing problems.

As this Article will demonstrate, the procedures wrought by the administrative law reformation have failed to ensure that agencies vigorously and effectively achieve their statutory missions for a number of reasons. Unsympathetic judges have reversed or weakened some of the procedural innovations that earlier courts fashioned to hold agencies accountable for regulatory failures. Environmental and consumer-interest groups lack the resources to fight their business opponents on every important battlefield. Even more important, significant causes of agency failure—acute budget shortfalls in particular—are beyond the scope of procedural accountability.

Beginning in the 1980s, a broad and energetic counterreformation fomented by regulatory critics has also undermined the impact of the

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5. Richard B. Stewart, *The Reformation of Administrative Law*, 88 HARV. L. REV. 1669, 1669 (1975).

6. See NEW PROGRESSIVE AGENDA, *supra* note 4, at 11–14 (describing regulatory achievements).

reformation.<sup>7</sup> The counterreformers were similarly interested in holding government accountable, but their motivations were in diametric contrast to those of the sixties reformers.<sup>8</sup> Rather than sketching the agencies' missions in bold, broad, affirmative strokes (consider President Richard Nixon's declaration, "The Congress, the Administration and the public all share a profound commitment to the rescue of our natural environment."<sup>9</sup>), the counterreformers portrayed their efforts as necessary to rein in government and control spending (consider Senator Roth's assertion, "Reinventing government does not mean creating a host of new programs. . . . If done right, it means better government—more responsiveness at less cost—not bigger government."<sup>10</sup>). Most of the procedures adopted by the counterreformers, particularly the numerous regulatory-impact analyses requirements, operate "below the water line" of activity that attracts any—much less consistent—public attention.<sup>11</sup> A notable exception is the Government Performance and Results Act<sup>12</sup> (GPR), passed with bipartisan support and embraced by then-newly elected President Bill Clinton.<sup>13</sup> This far-reaching law, which requires agencies to compile "strategic plans" that establish goals for evaluating their performance, is a popular subject in the public-management literature,<sup>14</sup> but it has received no attention in the legal literature as an accountability mechanism. Over the last fifteen years, GPR has proved inadequate as a hedge against regulatory failure—but not for the lack of paperwork. Although agencies annually devote thousands of hours to complying with the statute, these efforts have a surreal quality, typically failing to acknowledge the impediments that produce the episodes of regulatory failure that have erupted into front-page news in the last half-decade.

GPR has failed to promote effective regulatory government because it has a fundamental flaw: Its major goal is to ferret out waste, fraud, and abuse

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7. See generally Sidney A. Shapiro, *Administrative Law After the Counter-Reformation: Restoring Faith in Pragmatic Government*, 48 U. KAN. L. REV. 689, 706–20 (2000) (describing the counterreformation).

8. See generally *id.* at 692–720 (contrasting the two movements).

9. Special Message to the Congress About Reorganization Plans to Establish the Environmental Protection Agency and the National Oceanic and Atmospheric Administration, 1 PUB. PAPERS 586 (July 9, 1970).

10. 139 CONG. REC. 17,974 (1993) (statement of Sen. Roth).

11. See Shapiro, *supra* note 7, at 706–14 (noting that counterreformation initiatives such as impact statements require agencies to get expert cost–benefit analysis prior to taking public action).

12. Pub. L. No. 103-62, 107 Stat. 285 (codified in scattered sections of 5 U.S.C. and 31 U.S.C.).

13. Remarks on Signing the Government Performance and Results Act of 1993 and an Exchange with Reporters, 2 PUB. PAPERS 1310 (Aug. 3, 1993) [hereinafter Remarks on Signing GPR].

14. See generally, e.g., DAVID G. FREDERICKSON & H. GEORGE FREDERICKSON, *MEASURING THE PERFORMANCE OF THE HOLLOW STATE* (2006) (evaluating and discussing several aspects of GPR, including, among other things, its implementation and impact on confidence in government).

in government performance,<sup>15</sup> and agencies can expect to be punished for such underperformance with reduced budgets. Predictably, agencies try to protect themselves by devising euphemistic performance goals in order to ensure that they can “pass” their own grading criteria.<sup>16</sup> The upshot is a sunny set of invented statistics designed to reassure their overseers that they are doing fine, ending any possibility that the real causes of regulatory failure—such as underfunding, inadequate legal authority, political interference, or lack of bureaucratic will—can be discovered, much less addressed.

The concept underlying GPRA—basing accountability on agency performance—is unassailable. But performance must be measured on the basis of positive metrics that invite a diagnosis of the real problems that prevent agencies from achieving their statutory missions. The regulatory metrics that we propose would be designed to attract maximum public attention to both agency successes *and* shortcomings. Whatever the causes of regulatory failure, positive metrics should produce early warnings and motivate searches for potential solutions.

Our proposal differs from GPRA in another fundamental way. While the elaborate paperwork that GRPA has generated is easy to recover from the World Wide Web, one has to be an involved party or, at the very least, a political-science or public-management graduate student to get any satisfaction out of reading these arcane narratives. Both the content and context of these documents represent the essence of “inside baseball,” making them unintelligible even to public interest advocates whose job it is to track such developments. By comparison, a system of positive metrics would be sufficiently concise, accessible, independent, and objective such that the metrics would become a topic of interest to both regulatory insiders and outsiders, including the media and the public.

We do not underestimate the challenge of boiling down the existing morass of information about agency performance and propose merely to begin the process of accomplishing that goal in this Article. We also wish to stress the distinction between identifying regulatory gaps and failures and actually addressing the causes of these problems. It will take a sea change in attitudes toward government for the spirit and not just the letter of positive metrics to work as it should. Nevertheless, this Article will explain why the use of positive metrics has a realistic chance of jump-starting a political dynamic that would make it possible to root out the causes of regulatory failure and act to correct those deficiencies.

The first Part of this Article is focused on “procedural accountability.” It describes the administrative procedures adopted in the 1960s and 1970s to

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15. Government Performance and Results Act of 1993 § 2.

16. *See, e.g., infra* notes 138–45 and accompanying text (discussing how EPA’s self-assessment completely ignored a major shortcoming of the agency: its inadequate funding of Superfund projects).

address regulatory capture and explains why they have not prevented regulatory failure. The second Part examines “performance accountability,” comparing GPRA in theory and practice. The third Part endorses the concept of performance accountability and proposes an alternative method of achieving it. We recommend criteria for positive metrics and demonstrate how positive metrics would work, using an example drawn from the Clean Water Act. The final Part discusses how positive metrics can jump-start a political process that would address the real reasons for regulatory failure.

### I. Procedural Accountability

Ralph Nader and other sixties activists shared with their Progressive Era and New Deal predecessors the faith that effective government was necessary to regulate corporate behavior that threatened people and the environment, but they were not prepared to trust the regulators.<sup>17</sup> They were particularly worried that regulated industries would blunt reforms by “capturing” the bureaucracy.<sup>18</sup> This concern was based in part on a series of reports published at the time by Nader and teams of young investigators (“Nader’s Raiders”) documenting the overly cozy relationships between regulators and the regulated as the primary reason for the faltering performance of older regulatory agencies, such as the Federal Trade Commission.<sup>19</sup> Nader and his allies also had considerable confidence in their ability to serve as watchdogs for agency capture, so long as they were ensured a seat at the table where any significant decision was made and had the right to appeal unfavorable decisions to the generally liberal judges on the federal bench at the time.<sup>20</sup>

Three developments have thwarted this vision of procedural accountability. First, the reformers overestimated their capacity to keep track of the burgeoning agencies.<sup>21</sup> This expansion of the government was the most ambitious attempted since President Franklin Roosevelt’s New Deal, and the sheer scope of the government’s activities has made it difficult for public interest groups struggling to overcome collective-action problems to

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17. Shapiro, *supra* note 7, at 696.

18. *See id.* at 693 (“[R]eformers attributed the failure of what regulatory programs did exist to their ‘capture’ by the business community.”).

19. *See* JAMES MARTIN, NADER: CRUSADER, SPOILER, ICON 81–84 (2002) (recounting the optimism and ambitious reform plans of Nader and his supporters).

20. *See, e.g., infra* section I(A)(2) and accompanying text (explaining that while proponents of stringent regulations initially favored hard look review, today opponents of strict regulation have capitalized on hard look review to prevent agencies from adopting more stringent regulations that the rulemaking record justifies).

21. *See infra* subpart I(B) and accompanying text (documenting the advantage of business over public interest groups in their abilities to participate in environmental lobbying, rulemaking, and rule commenting).

make successful use of their own procedural model.<sup>22</sup> Second, judges have moderated the reformers' procedural protections by, among other things, limiting access to the courts.<sup>23</sup> Last but not least, counterreformers have successfully imposed new burdens on rulemaking, making it more difficult for agencies to take affirmative action.<sup>24</sup>

With the benefit of hindsight, one overriding conclusion emerges: the sixties reformers did not pay sufficient attention to building up the capacity of agencies to fulfill their ambitious regulatory missions. Although many who were influenced by the environmental and consumer movements entered the civil service during the 1960s and 1970s, including the two authors of this Article, these movements did not give sufficient credence to the possibility that a committed and responsible bureaucracy is a bulwark against capture and, consequently, regulatory failure. Instead of building up the resources available to agencies and defending their independent expertise, the reformation focused too much on fomenting aggressive regulation and enforcement from without.

#### A. *The Fraying of the Reformation*

During the reformation, the courts expanded rulemaking notice requirements, established a strong presumption that agency action and inaction were subject to judicial review, liberalized standing requirements for citizens' groups that sought judicial review, empowered public interest groups to represent statutory beneficiaries in federal court, and required agencies to have "adequate" explanations for their actions.<sup>25</sup> For its part, Congress passed the Freedom of Information Act<sup>26</sup> (FOIA), the Federal Advisory Committee Act<sup>27</sup> (FACA), and the National Environmental Policy Act of 1969<sup>28</sup> (NEPA), which were intended to make it difficult for agencies to adopt industry-friendly policies behind closed doors.<sup>29</sup>

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22. *Cf. infra* notes 57–69 and accompanying text (arguing that businesses can organize much more easily than private individuals).

23. *See infra* notes 32–44 and accompanying text.

24. *See infra* notes 45–54 and accompanying text.

25. *See Shapiro, supra* note 7, at 694–95 (documenting these developments).

26. Pub. L. No. 89-487, 80 Stat. 250 (1966) (codified as amended at 5 U.S.C. § 552 (2000)).

27. Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified as amended at 5 U.S.C. app. §§ 1–16 (2000)).

28. Pub. L. No. 91-190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. §§ 4321–4370f (2000)). NEPA requires agencies to analyze and disclose to the public the potential environmental impacts of their actions, and authorizes the courts to review agency compliance with these requirements. *Id.* § 4332(2)(C). Like the open-government laws, NEPA made it easier for environmental advocates to monitor agencies that were perceived by them to be hostile to their interests because the agencies were excessively friendly to corporate and business interests.

29. *See Shapiro, supra* note 7, at 695–96 (noting that open-government legislation made it easier for public interest groups to monitor agencies they perceive as excessively friendly to industry interests).

Environmental and public interest groups still use the reforms generated during the reformation to hold agencies accountable for the failure to abide by their statutory mandates.<sup>30</sup> Over time, however, the political mood in the country changed, and the election of Republican presidents produced a judiciary that has limited the effectiveness of many of these procedural reforms.<sup>31</sup>

The Supreme Court has weakened the presumption that agency action is subject to judicial review,<sup>32</sup> defined “ripeness” in a manner that excludes some types of agency action from appeal to the courts,<sup>33</sup> and made it more difficult for public interest groups to obtain standing to challenge final decisions.<sup>34</sup> Lower federal courts have narrowed the open-government provisions of FOIA and FACA.<sup>35</sup> Although these trends have played a significant role in undercutting judicial review as the safety net for regulatory failure envisioned by Nader and his allies, two additional developments have done as much to undermine procedural accountability as these other changes combined: the courts have proven unwilling to compel agencies to act in the absence of very specific statutory mandates and many judges have turned

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30. See, e.g., *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008) (vacating an EPA rule that delisted “mercury” as a hazardous air pollutant under § 112 of the Clean Air Act without following statutory prerequisites for such a decision). See generally Sidney A. Shapiro, *Pragmatic Administrative Law*, ISSUES IN LEGAL SCHOLARSHIP, Mar. 2005, art. 1, at 6–7 (2005), available at <http://www.bepress.com/ils/iss6/art1> (establishing that procedural innovations have assisted public interest groups in holding agencies accountable).

31. See Shapiro, *supra* note 7, at 697 (arguing that the counterreformation was in full bloom when Reagan took office and declared that “government is not the solution to our problem . . . [g]overnment is the problem”).

32. See, e.g., *Heckler v. Chaney*, 470 U.S. 821, 837–38 (1985) (limiting judicial review of agency decisions not to engage in enforcement actions).

33. See, e.g., *Ohio Forestry Ass’n, Inc. v. Sierra Club*, 523 U.S. 726, 738 (1998) (holding that legal challenges to overall land-planning decisions must await the agency’s issuance of a permit to conduct specific activities).

34. See, e.g., *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 105 (1998) (holding that the environmental group’s complaint failed the third test of standing—redressability—because the violations had already ceased before commencement of the suit); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 (1992) (holding that an environmental organization whose members had visited an area prior to the commencement of an agency’s project there, and had indefinite plans to return, lacked standing to challenge the agency’s action); *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 889 (1990) (holding that an affidavit offered by a member of an environmental group, claiming occasional use of unspecified portions of an immense tract of territory on which mining activity could occur by virtue of government action, was not sufficient to confer standing and survive a motion for summary judgment). However, standing doctrine is in flux, as some recent Supreme Court cases have adopted a more liberal position on standing. See, e.g., *Massachusetts v. EPA*, 127 S. Ct. 1438, 1454–55 (2007) (conferring standing because Massachusetts has a “well-founded desire to preserve its sovereign territory”); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 187–88 (2000) (rejecting the application of *Steel Co.* to deny standing when a complaint seeks penalties for actions that are ongoing at time of the complaint).

35. See Sidney A. Shapiro & Rena I. Steinzor, *The People’s Agent: Executive Branch Secrecy and Accountability in an Age of Terrorism*, 69 LAW & CONTEMP. PROBS. 99, 117, 119–21 (2006) (describing cases restricting the open-government provisions of FOIA and FACA).



“hard look” review on its head, using it to block regulation that they believe is too stringent.

1. *Judicial Reluctance to Police Failure to Act.*—Although the previous restrictions have reduced incentives for agencies to respond to public interest group concerns, perhaps the most telling problem is judicial reluctance to police the failure of an agency to act. For the most part, the courts have disqualified themselves from any role in solving a major problem that was given short shrift by the sixties reformers: with growing frequency, agencies sit on their hands, refusing to address compelling threats to health and safety.<sup>36</sup> If an agency rejects a petition to commence a rulemaking, the courts review the denial under a highly deferential standard of review.<sup>37</sup> This deference is probably inevitable because judges usually lack a rulemaking record to scrutinize in this context, which deprives public interest groups of the opportunity to build an evidentiary case for regulatory action. If an agency fails to respond to a rulemaking petition, the Administrative Procedure Act (APA) authorizes the courts to compel an answer after an unreasonable delay,<sup>38</sup> but judges have been reluctant to second-guess such omissions, preferring instead to defer to agency agenda-setting.<sup>39</sup> An agency’s assertion that it has not had time to respond becomes less convincing as the years pass, but it is unusual for the courts to force a response before the expiration of at least several years.<sup>40</sup> Even when a court decides that the delay is excessive, it typically solicits a timetable from the agency concerning when it can respond, thereby adding additional delay.<sup>41</sup>

2. *Anti-regulatory Hard Look Review.*—Environmental and consumer interest groups have not only had difficulty compelling agencies to act, but

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36. See Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEXAS L. REV. 525, 529 (1997) (offering explanations for the phenomenon of agency inaction).

37. See, e.g., *Nat’l Customs Brokers & Forwarders Ass’n of Am., Inc. v. United States*, 883 F.2d 93, 96 (D.C. Cir. 1989) (noting that while failure by an agency to promulgate a rule is subject to judicial review, such review should be extremely limited and highly deferential); *WWHT, Inc. v. FCC*, 656 F.2d 807, 818 (D.C. Cir. 1981) (contrasting the broad discretionary power that agencies possess when deciding whether to promulgate rules with the narrow scope of judicial review of such decisions).

38. The APA requires agencies to give “prompt notice” of the denial of a petition to commence a rulemaking, accompanied by a “brief statement of the grounds for denial.” 5 U.S.C. § 555(e) (2000). The courts are authorized to “compel agency action unlawfully withheld or unreasonably delayed.” *Id.* § 706(1).

39. See *PIERCE ET AL.*, *supra* note 2, at 218 (“A court can know only a small fraction of elements that must enter into an agency’s process of setting its agenda and allocating its resources among competing tasks.”).

40. See, e.g., *Pub. Citizen Health Research Group v. Chao*, 314 F.3d 143, 151–59 (3d Cir. 2002) (finding OSHA’s nine-year delay in responding to a rulemaking request to be excessive).

41. See Sidney A. Shapiro & Robert L. Glicksman, *Congress, the Supreme Court, and the Quiet Revolution in Administrative Law*, 1988 DUKE L.J. 819, 834–35 (discussing and providing examples of timetable solicitation and deadline enforcement by courts).

they have also lost ground in defending stringent regulation when it actually occurs. Opponents of strict regulation have been able to capitalize on hard look review, originally conceived as a way for judges to stymie agency adoption of weak regulations in the face of strong opposition by public interest groups.<sup>42</sup> Today, judges employ hard look review to address the possibility that agencies have adopted a more stringent regulation than the rulemaking record justifies. Like their more liberal predecessors, today's more conservative judges consider, often in painstaking detail, an agency's factual predicate, its analytical methodology, and its chain of reasoning.<sup>43</sup> Even if agencies survive such judicial review, it has played a major role in ossifying the rulemaking process—an adverse effect unanticipated by the 1970s reformers who supported its adoption.<sup>44</sup>

3. *The Impact of Counterreforms.*—By the 1990s, broad coalitions of regulated industries succeeded in persuading the White House and Congress to implement a series of procedural initiatives that hinder affirmative regulation. Exhibit A is Office of Management and Budget (OMB) review of proposed regulations, originally conceived by the Reagan Administration, used by every subsequent administration, and expanded to a new level of

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42. The phrase “hard look” review originated in 1970 with Judge Harold Leventhal, who observed that a judge’s supervisory function required a court to determine whether an “agency has not really taken a ‘hard look’ at the salient problems, and has not generally engaged in reasoned decisionmaking.” *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970). In a law-review article, Leventhal explained that the function of hard look review was to ensure that agencies did not shirk their statutory responsibilities to protect the environment, particularly in cases where the agency had to balance environmental concerns with other social and economic objectives. Harold Leventhal, *Environmental Decisionmaking and the Role of the Courts*, 122 U. PA. L. REV. 509, 555 (1974).

43. See, e.g., *Corrosion Proof Fittings, Inc. v. EPA*, 947 F.2d 1201, 1216–17 (5th Cir. 1991) (rejecting EPA’s methodology in calculating risks associated with asbestos); *Int’l Union, UAW v. OSHA*, 938 F.2d 1310, 1322 (D.C. Cir. 1991) (finding fault with OSHA’s logic and risk-assessment in promulgating a lockout regulation); *Gulf S. Insulation v. Consumer Prod. Safety Comm’n*, 701 F.2d 1137, 1146–47 (5th Cir. 1983) (revisiting a Consumer Product Safety Commission ban on urea-formaldehyde foam insulation in schools, and criticizing the agency’s data collection for, among other things, using too few rats in its cancer studies); *CPC Int’l, Inc. v. Train*, 515 F.2d 1032, 1047–49 (8th Cir. 1975) (analyzing in detail the factual record and finding it insufficient to support an EPA Administrator’s determination that deep-bed filtration technology would be efficient in the corn wet-milling industry).

44. See McGarity, *supra* note 36, at 557 (“[E]valuative substantive review can chew up agency resources as the agencies attempt to fill rulemaking records with studies and to rebut all of the criticisms that blunderbuss attacks produce. This inevitably reduces the agency’s capacity to issue rules, and . . . effectively reduces the scope of federal regulation.”). Administrative-law scholars have debated whether hard look review also has a benefit of stimulating agencies to think more carefully about proposed rules. See, e.g., Mark Seidenfeld, *Demystifying Ossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEXAS L. REV. 483, 486 (1997) (“[Hard look] review encourages an agency to perform more thorough analyses than it otherwise might.”). This Article is not the place to enter into this debate. We note only that hard look review is implicated in the failure of agencies to be more effective in carrying out their statutory missions.

intrusiveness by the George W. Bush Administration.<sup>45</sup> Although proponents of OMB review contend that it operates on a neutral basis,<sup>46</sup> the legal literature contains considerable evidence that it has the overall and significant impact of reducing the stringency of proposed regulations.<sup>47</sup> Review proponents attempt to counter by pointing to examples of OMB's seeking stronger regulation,<sup>48</sup> but almost all of these accounts are disputed.<sup>49</sup>

OMB review is among a multiplicity of analytical requirements that the White House and Congress have imposed, each mandate potentially requiring some form of analysis before an agency can propose a regulation.<sup>50</sup> This duplication and overlap has suggested to public interest advocates that skeptics of government regulation are more interested in "paralysis by analysis" than actually improving decision making.<sup>51</sup> As one of the authors has noted previously, this charge gains credibility from the fact that neither Congress nor the White House, which as institutions consistently claim an overriding interest in government efficiency, has made any real effort to consolidate the various requirements and end the duplication and overlap that exists.<sup>52</sup>

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45. See Shapiro, *supra* note 7, at 707–08 (documenting these developments). President Bush initially adopted the executive order on OMB review promulgated by President Clinton, but he later extended the requirement of assessing cost and benefits to significant agency guidance documents. Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007).

46. See generally, e.g., John D. Graham, *The Evolving Role of the U.S. Office of Management and Budget in Regulatory Policy*, 1 REV. ENVTL. ECON. & POL'Y 171 (2007), available at <http://reep.oxfordjournals.org/cgi/content/short/1/2/171> (explaining the application of neutral economic analysis to regulatory proposals).

47. See Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 49–50, 75 (2006) (finding that, based on interviews of top political officials at EPA during the George H.W. Bush and Clinton Administrations, the Office of Information and Regulatory Policy (OIRA) "regularly skew[ed] rulemaking in a deregulatory direction" and that OIRA "may [have used] cost-benefit analysis to impose its own normative preference for deregulation"); Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 858–60, 877 (2003) (finding no statistical correlation between whether a rule was changed—or approved by OIRA without change—and written submissions by various types of interest groups, but finding that politically controversial rules are usually changed in the OMB review process, and arguing that this contradicts the claim that OMB review is purely technocratic). See generally David M. Driesen, *Is Cost-Benefit Neutral?*, 77 COLO. L. REV. 335, 354–64 (2006) (discussing how OMB sought changes that would have reduced regulatory protections in twenty-four of twenty-five proposed significant rules between June 2001 and July 2002, and that the remaining changes had a neutral impact).

48. See, e.g., Richard D. Morgenstern & Mare K. Landy, *Economic Analysis: Benefits, Costs, and Implications*, in ECONOMIC ANALYSIS AT EPA: ASSESSING REGULATORY IMPACT 458 (Richard D. Morgenstern ed., 1997) (noting instances where OMB has prompted agencies to take action).

49. See, e.g., Driesen, *supra* note 47, at 365 (rebutting the claim that OMB's influence promotes regulatory intervention).

50. See Mark Seidenfeld, *A Table of Requirements for Administrative Rulemaking*, 27 FLA. ST. U. L. REV. 533, 536–37 (2000) (establishing that agencies are subject to 111 potential analytical steps before proposing a regulation).

51. See Thomas O. McGarity & Sidney A. Shapiro, *OSHA's Critics and Regulatory Reform*, 31 WAKE FOREST L. REV. 587, 626 (1996) (discussing "paralysis by analysis").

52. Shapiro, *supra* note 30, at 16.

One potential solution to all of these developments, which have undermined procedural accountability, is to curtail the duplicative analytical requirements that have become such major impediments to affirmative regulatory responses to the problems mentioned at the outset of this Article.<sup>53</sup> Another is to curtail judicial hard look review.<sup>54</sup> While these reforms will undoubtedly be necessary over the long term to accomplish the goal of revitalizing the regulatory state, positive metrics have the distinct advantage of making the case for why such revitalization is crucial in the first place, as we explain further in the third Part of this Article.

### B. *Pluralism's High Costs*

Environmental and consumer activists had counted on the fact that procedural protections guaranteeing access to the courts and information would give agencies adequate incentives to heed their concerns.<sup>55</sup> That threshold assumption was predicated on their ability to participate actively in rulemakings across the government, despite the multiplication of agencies that their success had produced. As it turned out, the available evidence indicates that business interests have a significant resource advantage when it comes to lobbying agencies and filing rulemaking comments.<sup>56</sup> While this advantage does not always translate into pro-business administrative decisions, the superior funding of the business community appears to be another reason why procedural accountability has failed to promote effective regulation.

The early public-choice literature predicted that business groups would be more successful in organizing to influence government than individual citizens,<sup>57</sup> which led to a prediction that regulatory agencies would be captured by the entities that they were supposed to regulate.<sup>58</sup> Prominent

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53. For a discussion of such reforms, see NEW PROGRESSIVE AGENDA, *supra* note 4, at 98–99, which argues that Congress should simplify and reduce regulatory analysis requirements faced by agencies.

54. *See id.* at 99–100 (stating that courts should defer to congressional choice when reviewing the level of precaution in agency regulations rather than taking a hard look approach).

55. *See supra* text accompanying note 20.

56. *See* Scott R. Furlong, *Businesses and the Environment: Influencing Agency Policymaking, in* BUSINESSES AND ENVIRONMENTAL POLICY: CORPORATE INTERESTS IN THE AMERICAN POLITICAL SYSTEM 155, 167 (Michael E. Kraft & Sheldon Kamieniecki eds., 2007) (“Many of these studies comment on the role of business interests and what appears to be their advantage in the rulemaking process.”).

57. *See generally, e.g.*, Mancur Olson Jr., THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS 16–33 (1965) (presenting the traditional theory on group formation and noting the difficulties encountered in small-group formation).

58. *See, e.g.*, Sam Peltzman, *Toward A More General Theory of Regulation*, 19 J.L. & ECON. 211, 211 (1976) (“The creeping recognition that regulation seemed seldom to actually work this way, and that it may have even engendered more resource misallocation than it cured, forced attention to the influence [that] regulatory powers . . . could have . . . on allocative efficiency.”); Richard A. Posner, *The Social Costs of Monopoly & Regulation*, 83 J. POL. ECON. 807, 809–12

environmental and consumer interest groups routinely overcome collective-action constraints. Public interest groups have been able to organize and maintain themselves by finding sponsors, reducing the transaction costs of reaching out to potential members, and offering tangible economic benefits that can only be obtained by joining.<sup>59</sup> Their achievements also rebut the contention that individuals respond only to the profit motive and demonstrate that people also respond to such noneconomic incentives as solidarity and purposive benefits, especially when led by what James Q. Wilson calls a “skilled entrepreneur who can mobilize latent public sentiment (by revealing a scandal or capitalizing on a crisis).”<sup>60</sup> Former Vice President Al Gore’s activism on global warming is an excellent recent example of this phenomenon.<sup>61</sup>

While these factors explain the existence of and important successes of national environmental and consumer organizations, the business community’s funding advantage most often translates into superior influence over administrative decision making. A 1977 Senate committee report found that large regulated parties had a significantly greater presence in agency decision-making processes than did public interest groups and outside parties.<sup>62</sup> More recent evidence suggests that the situation has not changed.<sup>63</sup>

Scott Furlong’s study of registrations required by the Lobbying Disclosure Act indicates that many more business groups lobby the Executive Branch than public interest groups.<sup>64</sup> Examining lobbying reports

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(1975) (asserting that obtaining a monopoly from a regulatory agency is a competitive activity in which vast amounts of resources are spent by the competing firms); George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 3 (1971) (“A central thesis of this paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit.”).

59. Jack L. Walker, *The Origins and Maintenance of Interest Groups in America*, 77 AM. POL. SCI. REV. 390, 398 (1983).

60. James Q. Wilson, *The Politics of Regulation*, in THE POLITICS OF REGULATION 357, 370 (James Q. Wilson ed., 1980). Solidarity benefits are socially derived, intangible benefits that arise from association with other people, such as fun, status, camaraderie, or prestige. Allan J. Cigler & Burdett A. Loomis, *Introduction. The Changing Nature of Interest Group Politics*, in INTEREST GROUP POLITICS 1, 8 (Allan J. Cigler & Burdett A. Loomis eds., 7th ed. 2007). Expressive or purposive benefits are the intangible rewards someone gets from contributing to a group because of its stated goals. *Id.* Moreover, some people will simply join an organization out of altruistic motivations.

61. After his movie on climate change, *An Inconvenient Truth*, received an Academy Award, Vice President Gore was awarded the Nobel Peace Prize. Sarah Lyall, *Gore Urges Bold Moves in Nobel Speech*, N.Y. TIMES, Dec. 11, 2007, at A1.

62. STAFF OF S. COMM. ON GOVERNMENTAL AFFAIRS, 96TH CONG., PRINCIPAL RECOMMENDATIONS AND FINDINGS OF THE STUDY ON FEDERAL REGULATION 25 (Comm. Print 1979).

63. See Steven P. Croley, *Theories of Regulation. Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 129 (1998) (finding that more recent evidence has reached “comparable conclusions”).

64. Scott R. Furlong, *Exploring Interest Group Participation in Executive Branch Policymaking*, in THE INTEREST GROUP CONNECTION 282, 290–91 (Paul S. Herrmson et al. eds., 2d ed. 2005).

for 1996, Furlong identified registrants who indicated that they sought to influence environmental and natural-resource issues and that they lobbied both Congress and the Executive Branch.<sup>65</sup> Over 94% of these registrants were business or trade associations, while only about 3% of the registrants were public interest groups.<sup>66</sup> Furlong found a similar situation when he looked at the clients of lobbying firms. Over 73% of the clients listed were business interests as compared to about 6% who were public interest groups.<sup>67</sup>

This dominance translates into higher rates of participation in rulemakings. A survey of Washington-based interest groups by Furlong and Neal Kerwin found that individual businesses participated in over twice the number of rulemakings as other types of organizations.<sup>68</sup> An earlier survey by Furlong found that business interests submitted many more comments on proposed regulations than other interests did.<sup>69</sup>

These results are consistent with studies that examine who files rulemaking comments. Jason Webb Yackee and Susan Webb Yackee, who studied forty rules promulgated by four agencies from 1994 to 2001, found business interests filed 57% of the comments; governmental interests filed 19% of the comments; and nonbusiness, nongovernmental interests submitted 22% of the comments.<sup>70</sup> Public-interest-group comments constituted only 6% of the total of comments submitted by nonbusiness, nongovernmental interests.<sup>71</sup> Melissa Golden, who examined comments filed on eleven proposed regulations at three agencies, found the same business dominance.<sup>72</sup> The dominance was greatest for the eight rules proposed by EPA and NHTSA. Corporations, public utilities, and trade associations filed between 66.7% and 100% of the comments concerning these rules, and neither EPA nor NHTSA received any comments from public interest groups concerning five of the eight rules.<sup>73</sup> Cary Coglianese, who studied twenty-five

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65. Furlong, *supra* note 56, at 174.

66. *Id.*

67. *Id.* at 175.

68. Scott R. Furlong & Cornelius M. Kerwin, *Interest Group Participation in Rulemaking: A Decade of Change*, 15 J. PUB. ADMIN. RES. & THEORY 353, 361 (2005).

69. Furlong, *supra* note 64, at 289.

70. Jason Webb Yackee & Susan Webb Yackee, *A Bias Towards Business? Assessing Interest Group Influence on the U.S. Bureaucracy*, 68 J. POL. 128, 133 (2006). The four agencies were OSHA, the Employment Standards Administration (ESA), the Federal Railroad Administration (FRA), and the Federal Highway Administration (FHA). *Id.* at 131. The study selected all rules receiving fewer than two hundred comments but more than one comment. *Id.*; see *infra* note 80 and accompanying text (discussing the impact of this methodological choice).

71. Yackee & Yackee, *supra* note 70, at 133.

72. Marissa Martino Golden, *Interest Groups in the Rulemaking Process: Who Participates? Whose Voices Get Heard?*, 8 J. PUB. ADMIN. RES. & THEORY 245, 250, 252 (1998). The three agencies were EPA, NHTSA, and the Department of Housing and Urban Development (HUD). *Id.* at 250.

73. *Id.* at 252–53.

significant EPA rules promulgated under the Resource Conservation and Recovery Act (RCRA) between 1989 and 1991, found that business interests participated 95% of the time, national trade associations participated 80% of the time, and citizen groups participated 12% of the time.<sup>74</sup> Groups representing regulated industries constituted 59% of all participants, and groups representing environmental and citizen groups constituted 4%.<sup>75</sup>

These findings are consistent with overall disparities between the resources available to business interests and those available to public interest organizations in most arenas. Environmental advocacy groups have proliferated at the federal, state, and local levels and wield considerable political power.<sup>76</sup> Outside the environmental arena, a significantly smaller group of consumer organizations participate in rulemakings on a regular basis at agencies such as NHTSA and FDA.<sup>77</sup> With the decline of unionization, business interests have a greater advantage at OSHA as well.<sup>78</sup>

Evidence that the business community has more lobbyists and participates more frequently in filing rulemaking comments does not establish that business interests always prevail in the administrative process. The limited available evidence is mixed on whether such a connection exists. Three studies have failed to find that business dominance in filing rulemaking comments produces a pro-business regulatory decision.<sup>79</sup> But Jason Webb Yackee and Susan Webb Yackee have found statistical evidence that “agencies appear to alter final rules to suit the expressed desires of business

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74. Croley, *supra* note 63, at 129 (citing Cary Coglianese, *Challenging the Rules: Litigation and Bargaining in the Administrative Process* 46–47 tbl.2-x (1994) (unpublished Ph.D. dissertation, University of Michigan)).

75. *Id.*

76. See JEFFREY M. BERRY, *THE NEW LIBERALISM: THE RISING POWER OF CITIZEN GROUPS* 144–45 (1999) (describing the increasingly broad and large memberships of various environmental advocacy groups).

77. See Croley, *supra* note 63, at 127–29 (referencing low participation rates in the FDA rulemaking process by public interest groups relative to large regulated parties); Golden, *supra* note 72, at 254 (illustrating the low level of participation by consumer organizations in NHTSA rulemaking by comparing the number of comments submitted by consumer organizations to those submitted by business interests).

78. See Cynthia Estlund, *Rebuilding the Law of the Workplace in an Era of Self-Regulation*, 105 COLUM. L. REV. 319, 321–22 (2005) (arguing that employers have achieved increasing freedom to self-regulate from agencies like OSHA since the decline of the collective-bargaining system).

79. See Golden, *supra* note 72, at 260–61 (finding no evidence of “agency capture” in the changes made to ten proposed rules at EPA, NHTSA, and HUD); see also WESLEY A. MAGAT ET AL., *RULES IN THE MAKING: A STATISTICAL ANALYSIS OF REGULATORY AGENCY BEHAVIOR* 143–45, 157 (1986) (finding no statistically significant empirical support for the hypothesis that active participation in federal rulemaking by firms results in weaker regulatory standards for those firms); Maureen L. Cropper et al., *The Determinants of Pesticide Regulation: A Statistical Analysis of EPA Decision Making*, 100 J. POL. ECON. 175, 192, 194–95 (1992) (finding rulemaking input from environmental groups on the cancellation of federal pesticide-use registration to have twice the impact on the likelihood of cancellation as input from commercial growers).

commenters” when there is a higher proportion of business comments submitted during the public comment period.<sup>80</sup>

Regulated industries are especially likely to have disproportionate influence when regulatory proposals are of low political salience and high technological complexity.<sup>81</sup> Today’s environmental, health, and safety legislation was passed during a period (1968–1978) when Congress was reacting to public outrage over a number of highly visible environmental and safety disasters.<sup>82</sup> As the implementation of these broad mandates requires ever more technical inquiries, their prominence in the news has declined precipitously. Voters do not follow, let alone understand, the myriad of policy issues decided by regulators. Because solutions depend on analyses of complex scientific and technical information, even if public interest groups are able to participate, they have great difficulty eliciting media attention that would educate voters about regulatory issues. Taking advantage of the situation, the business community and its political allies have devised a number of low-visibility tools to throw sand in the gears of regulatory government.<sup>83</sup>

Conversely, public interest groups have more opportunity to prevail over strong business opposition when there is a highly visible problem that achieves prominence through the media, presenting the risk that the outcome of the debate could influence electoral politics.<sup>84</sup> Two contemporary examples of this phenomenon include the strengthening of FDA authority by an otherwise partisan and gridlocked Congress in the wake of the Vioxx and related scandals,<sup>85</sup> and Congress’s apparent willingness to consider analogous reform of the CPSC in the wake of the Chinese toy dangers exposed in 2007.<sup>86</sup> Unfortunately, this level of public concern is seldom generated by

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80. Yackee & Yackee, *supra* note 70, at 135–36. The study was limited to low-saliency rules and does not indicate whether business interests have the same disproportionate influence concerning high-saliency rules. *Id.* at 137.

81. See Michael E. Levine & Jennifer L. Forrence, *Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis*, 6 J.L. ECON. & ORG. (SPECIAL ISSUE) 167, 173–74 (1990) (observing that monitoring costs influence the likelihood that agencies will act in the public interest).

82. SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH 3–4 (2003).

83. See generally DAVID BOLLIER, THOMAS MCGARITY & SIDNEY A. SHAPIRO, SOPHISTICATED SABOTAGE: THE INTELLECTUAL GAMES THAT INDUSTRIES PLAY TO SUBVERT RESPONSIBLE REGULATION (2004) (identifying and explaining low-visibility ways the business community has been able to subvert regulation).

84. In this situation, legislators understand that voters are likely to hold them accountable for a failure to act. This visibility also makes it easier for a legislator’s election opponent to point out that the legislator failed to act in the constituents’ best interest. See Wilson, *supra* note 60, at 370–71 (describing visible scandals leading to the passage of drug and safety laws).

85. See *infra* subpart II(C).

86. See, e.g., CPSC Reform Act of 2007, S. 2045, 110th Cong. § 23 (2007) (reforming prohibitions on the sale of toys containing lead); Consumer Product Safety Modernization Act, H.R.



the daily activities of the regulatory state. When public attention—or the threat of publicity—is unlikely, the procedural remedies installed by the sixties reformers may be overmatched as a deterrent to capture.

Again, a major advantage of the positive metrics we propose in the third Part of this Article is their capacity to lift the most important issues on the health and safety agenda from the first, low-saliency category to the second, high-visibility one. By compelling disclosure of the reality behind agency claims regarding their efforts to solve these problems, the public (and public interest groups) will have a better opportunity to leverage their limited resources in demanding change.

### *C. Oversight Versus Capacity Building*

The sixties reformation has languished on the shoals of unfriendly—or at least unhelpful—judicial developments, burdens on rulemaking imposed by the counterreformers, and greater financial capacity of business interests to lobby agencies and file rulemaking comments. The goals of procedural accountability have remained elusive for one more reason: Agencies lack the financial wherewithal to fulfill the ambitious missions assigned by Congress. This defunding of government is the product of the swing of the political pendulum from left to right, of deficit spending, and of a steady drumbeat of disdain for the civil service fostered by conservatives from Ronald Reagan on down.<sup>87</sup> Although the sixties reformers can hardly be blamed for failing to foresee these developments, they inadvertently prepared the ground for it by focusing their efforts on regulatory capture and spending less time and effort building the capacity of agencies to fulfill their statutory mandates.

Ronald Reagan was elected president only a decade after the expansion of FDA and the creation of EPA, OSHA, NHTSA, and CPSC. He was unabashedly antagonistic toward government and bureaucrats.<sup>88</sup> His brand of conservative ideology created a negative atmosphere at the White House just as the new agencies were beginning to flex their regulatory authority.<sup>89</sup> Some of the most prominent health and safety agencies were literally occupied by political appointees who had well-established records opposing the agencies' core missions.<sup>90</sup> In this, as in so many other contexts, EPA was the poster child for hostile takeover, freeing itself only after one of its leaders

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4040, 110th Cong. § 107 (2007) (requiring CPSC to conduct a study on the effectiveness of safety standards for toys).

87. See JOAN CLAYBROOK & THE STAFF OF PUB. CITIZEN, *RETREAT FROM SAFETY: REAGAN'S ATTACK ON AMERICA'S HEALTH*, at xxii–xxv (1984) (describing the budget cuts instituted by the Reagan Administration's deregulators).

88. See *id.* at xxxi (describing President Reagan's election on a platform of "getting the government off our backs").

89. See *id.* at 117–19 (noting that the Reagan Administration began cutting EPA resources just as the Agency was beginning to institute the Clean Water Act and the amended Clean Air Act).

90. See, e.g., *id.* at 120–21 (listing top-level EPA appointees with anti-environmental records).

was sentenced to jail for corruption<sup>91</sup> and another driven out of Washington in disgrace after picking a fight over executive privilege to prove fealty to her White House masters.<sup>92</sup>

Reagan's ridicule of officious bureaucrats gradually produced a pivot in public opinion that continues to this day. Opinion polls show that Americans distrust their government at the same time that they expect it to keep them safe.<sup>93</sup> This cognitive disconnect has produced even harder times for regulatory agencies. The agencies face withering, even vicious disparagement by members of Congress. Consider, for example, the dreary period when then House Majority Leader Tom DeLay compared EPA to the Gestapo.<sup>94</sup> Yet the agencies are also blamed if they do not move full-steam ahead to achieve their statutory mandates. Such deep-seated ambivalence has taken its toll in myriad ways, contributing to the conditions for the widespread failure of regulatory government that we see today.

Agencies struggle—and have always struggled—with inadequacies in the design of regulatory legislation<sup>95</sup> and the unavailability of scientific and technical information that they need to analyze and devise remedies for threats to people and the environment.<sup>96</sup> Government service is plagued by the same quotient of incompetent personnel as the private sector—some would say more. These immutable challenges would be difficult to surmount in the best of times, but as mentioned earlier, agencies are also compelled to labor under a growing burden of analytic requirements imposed by both the White House and Congress.<sup>97</sup>

As onerous as these analytical requirements have become, they are not the most damaging legacy of the Reagan, Bush I, Clinton, and Bush II

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91. See JONATHAN LASH ET AL., *A SEASON OF SPOILS: THE REAGAN ADMINISTRATION'S ATTACK ON THE ENVIRONMENT* 67 (1984) (describing the perjury conviction of Rita Lavelle, an assistant administrator and Reagan appointee).

92. See *id.* at 79–81 (describing how EPA Administrator Anne Gorsuch invoked executive privilege despite her belief that it had no legal basis, leading to her resignation).

93. See RENA I. STEINZOR, *MOTHER EARTH AND UNCLE SAM: HOW POLLUTION AND HOLLOW GOVERNMENT HURT OUR KIDS* 177–78, 182–83 (2008) (discussing public-opinion polling showing strong support for environmental protection and strong distrust of government).

94. Spencer Michels, *What's Next for the EPA?*, *ONLINE NEWSHOUR*, Dec. 21, 1995, [http://www.pbs.org/newshour/bb/environment/epa\\_12-21.html](http://www.pbs.org/newshour/bb/environment/epa_12-21.html) (quoting DeLay as saying, “The critical promise we made to the American people was to get the government off their backs, and the EPA, the gestapo of government, pure and simply has been one of the major ‘clawhose’ that the government has maintained on the backs of our constituents.”).

95. See, e.g., SHAPIRO & GLICKSMAN, *supra* note 82, at 42 (explaining that Congress amended the Clean Air Act due to EPA's inability to regulate hazardous air pollutants under a health-based standard).

96. See JOHN S. APPLGATE & KATHERINE BAER, *CTR. FOR PROGRESSIVE REFORM, WHITE PAPER NO. 602, STRATEGIES FOR CLOSING THE CHEMICAL DATA GAP 1* (2006), available at [http://www.progressivereform.org/articles/Closing\\_Data\\_Gaps\\_602.pdf](http://www.progressivereform.org/articles/Closing_Data_Gaps_602.pdf) (pointing out a data gap between the amount of information agencies have and the amount they require in order to justify protective action).

97. See *supra* notes 50–51 and accompanying text.

Administrations. Instead, having succumbed to the temptation to make big government their scapegoat-in-chief for much of what ails the nation, these Administrations went one crucial step further, giving overpowering momentum to the idea that “big” government is “bad” government.<sup>98</sup> Paradoxically, they abandoned any real effort to repeal the elaborate regulatory mandates established by previous presidents and Congresses.<sup>99</sup> The practical effect was no change in statutory workload or expectations, but sharp decreases in agency budgets.<sup>100</sup> Unable to fulfill their responsibilities because of a lack of funds, regulatory agencies began to look like the rogues they were pictured to be in conservatives’ antigovernment rhetoric.<sup>101</sup>

One ostensible reason offered for reducing agency budgets has been to reduce federal deficits.<sup>102</sup> This budget-cutting argument is entirely specious. The total amount spent on the five agencies we have identified was 0.51% of the total U.S. budget in 1990 and 0.41% in 2005.<sup>103</sup>

It is a small wonder, then, that the single biggest cause of regulatory failure today is “hollow” government, meaning that agencies cannot possibly achieve many of the mandates for which they are held accountable with the resources provided by the White House and Congress.<sup>104</sup> Combined with the

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98. See, e.g., Governor George W. Bush, Acceptance Speech at the Republican National Convention (Aug. 3, 2000) (transcript available at <http://www.cnn.com/ELECTION/2000/conventions/republican/transcripts/bush.html>) (arguing that “[b]ig government is not the answer”); Clinton, *supra* note 3 (“The era of big government is over.”).

99. See *supra* note 52 and accompanying text.

100. See, e.g., STEINZOR, *supra* note 93, at 51 (presenting a graph indicating that EPA in 2004 had substantially less funding than it had in 1980 in constant dollars); *Product Safety Regulator Hobbled by Decades of Negligence*, OMB WATCH, Feb. 5, 2008, at graph 1, <http://www.ombwatch.org/article/articleview/4154> (indicating that CPSC currently has substantially less funding than it had in 1977 in constant dollars).

101. See, e.g., STEINZOR, *supra* note 93, at 50–54 (discussing legislation in the 1980s that greatly expanded EPA’s responsibilities, despite the Agency’s chronic underfunding).

102. For example, Stephen L. Johnson, EPA’s current Administrator, has sought to justify a 4.4% cut proposed by the Bush Administration in the Agency’s budget on the grounds that the proposed budget “meets our environmental goals while being responsible stewards of taxpayers’ dollars.” Jeff Kinney, *President Proposes 4.4 Percent Budget Cut for EPA, Targets Grants for State Projects*, [2008] Daily Env’t Rep. (BNA) 23 (Feb. 5, 2008), available at <http://ehscenter.bna.com/pic2/ehs.nsf/id/BNAP-7BJGR2?OpenDocument>.

103. OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, BUDGET AUTHORITY HISTORICAL SPREADSHEET FISCAL YEAR 2008 (2008), available at <http://www.whitehouse.gov/omb/budget/fy2008/sheets/budauth.xls> (reporting that the U.S. government allocated a total of \$6,512,188,000 for FY 1990 to the five agencies—EPA (\$5.379 billion), FDA (\$601 million), OSHA (\$267 million), CPSC (\$35 million), and NHTSA (\$229 million). In FY 2005, budgets for the agencies totaled \$10,340,000,000—EPA (\$7.959 billion), FDA (\$1.427 billion), OSHA (\$464 million), CPSC (\$62 million), and the NHTSA (\$428 million)). See *Government Spending in United States 1902–2013—Federal State Local Charts*, <http://www.usgovernmentspending.com/index.php#usgs302a> (listing the FY 1990 total federal budget as \$1,253,000,000,000 and the FY 2005 total federal budget as \$2,472,000,000,000).

104. The term “hollow government” is attributed to Edward Meyer, Army Chief of Staff, who used the phrase in the 1970s to describe the impact of insufficient funding on the nation’s armed forces. PEG MCGLINCH & PETER BARTON HUTT, *HOLLOW GOVERNMENT: RESOURCE CONSTRAINTS AND WORKLOAD EXPANSION AT FDA* (2001), <http://leda.law.harvard.edu/leda/data/>

historic factors of regulatory tools that do not fit the job, data gaps, and incompetence, budget shortfalls have crippled health and safety agencies in increasingly visible ways.

## II. Performance Accountability

The *raison d'être* of procedural accountability is to deter regulatory capture by ensuring seats at the table for the full range of affected constituencies and by requiring government in the sunshine.<sup>105</sup> The philosophical origin of performance accountability, by comparison, is associated with the practices of American public administration and the academic field of public administration.<sup>106</sup> “Simply put,” as two public-administration scholars note, “in the classic public administration ethos, well-managed governments will perform well.”<sup>107</sup> For public administration, the tool of choice to promote good management is rigorous measurement of agency and program performance. Public administrators regard GPRA as the “high-water mark” performance measurement in the federal government.<sup>108</sup>

The concept of well-managed government, however, means different things to different people. In contrast to the dogma of public administrators, who associate good government with the progressive ideal of neutral and professional management<sup>109</sup> and are primarily committed to “getting better or more effective service per dollar,”<sup>110</sup> elected officials increasingly regard well-managed government as a “war on waste.”<sup>111</sup> In this context, “the emphasis . . . is economy, or simply spending less. The war-on-waste approach to reform is associated with such popular political slogans as ‘the era of big government is over,’ ‘a government that works better and costs less,’ and ‘it is time to stamp out fraud, waste and abuse.’”<sup>112</sup>

GPRA reflects these dueling conceptions. According to GPRA’s statement of its mission:

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742/McGlinch01\_redacted.html. The term was appropriated by the editors of *Government Executive* to describe the decay of the government’s capacities during the Reagan Administration. *Id.* (citing Timothy B. Clark, *Editor’s Notebook*, GOV’T EXECUTIVE, May 1999, at 4).

105. *Cf. supra* text accompanying note 20.

106. *See* FREDERICKSON & FREDERICKSON, *supra* note 14, at 1 (asserting that both the practice and the study of public administration are “uniquely associated with questions of government performance”).

107. *Id.*

108. *Id.* (citing Government Performance and Results Act, Pub. L. No. 103-62, 107 Stat. 285 (codified in scattered sections of 5 U.S.C. and 31 U.S.C.)).

109. *Id.* (“For much of the twentieth century, most scholars thought that the key to improved government performance was a politically neutral, merit-based civil service and a well-managed government of expert public administrators. . . . Simply put, in the classic public administration ethos, well-managed governments will perform well.”).

110. *Id.* at 37.

111. *Id.*

112. *Id.*

[W]aste and inefficiency in Federal programs undermine the confidence of the American people in the Government and reduces [sic] the Federal Government's ability to address adequately vital public needs . . . . [The purpose of this Act is to] improve [that] confidence . . . by systematically holding Federal agencies accountable for achieving program results.<sup>113</sup>

GPRA has generated a mind-boggling whirlwind of reassuring statistics, cheerful narrative, and assurances that all is well at whichever regulatory agency is justifying its performance. Probe beneath the numbers, however, and these assurances lose their credibility. We provide two case studies to illustrate these phenomena. The first, involving growing paralysis in EPA's Superfund toxic-waste cleanup program, has garnered remarkably little public attention. The second, involving FDA's failure to police the safety of Vioxx after its approval as a new drug, was front-page news for weeks.

As these case studies will demonstrate, GPRA has failed as a result of its own mixed messages. The statute asks agencies to indicate the constraints under which they operate and how these constraints may affect their performance, but agencies compelled to function in an antiregulatory, even hostile, political atmosphere are predictably reluctant to tell the truth to power. Instead, their goal has become convincing congressional and White House overseers that they are performing well despite budgets that are inadequate for effective implementation of their missions. The result is a set of optimistic statistics designed to reassure the agency's overseers that they are doing fine, rather than a frank discussion of the real causes of regulatory failure.

#### A. *GPRA's Edicts*

GPRA orders all agencies to submit strategic plans covering a period of "not less" than five years to Congress and the director of OMB.<sup>114</sup> Those plans must contain a "comprehensive mission statement," as well as general "goals and objectives."<sup>115</sup> Agencies must explain how they intend to achieve their goals and then describe the "human, capital, information, and other resources" they will need to do so.<sup>116</sup> They must identify the "key factors external to the agency and beyond its control" that could affect achievement of their general goals and objectives.<sup>117</sup> The agencies are instructed to consult with Congress and also to "solicit and consider" the views of all entities that are "potentially affected by or interested in" their plans.<sup>118</sup>

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113. 31 U.S.C. § 1115 note (2000).

114. 5 U.S.C. § 306 (2000).

115. *Id.* § 306(a)(1)–(2).

116. *Id.* § 306(a)(3).

117. *Id.* § 306(a)(5).

118. *Id.* § 306(d).

Strategic plans, apparently intended to be visionary and “big picture,” must be supplemented by “performance plans,” covering each “program activity” set forth in the agency’s budget.<sup>119</sup> Performance plans must establish goals, expressing them in “objective, *quantifiable*, and measurable form.”<sup>120</sup> They must identify the “indicators” agencies will use to assess “outputs, service levels, and outcomes,” and the “means” they will use to “verify and validate measured values.”<sup>121</sup> GPRA further requires the agencies to prepare annual “program performance reports” that compare their goals and indicators with their “actual program performance.”<sup>122</sup> If they fail to achieve success, they must explain why, what they intend to do about it, and whether the goals or indicators themselves are the problem and must be changed.<sup>123</sup>

### B. Toxic Waste Cleanup

The Comprehensive Environmental Response, Compensation, and Liability Act<sup>124</sup> (CERCLA or Superfund) established two sources of funding to clean up the thousands of toxic-waste sites around the country: liability and appropriations, primarily supported by industry taxes. Parties responsible for waste sites are strictly, jointly, and severally liable to either reimburse the government for cleanup costs it incurs or to carry out cleanup orders the government issues.<sup>125</sup> The statute also creates a multibillion-dollar trust fund to finance the administration of the program, enforcement actions, and federally funded cleanup.<sup>126</sup> Federal funding is especially important because it is the only resource available to remediate so-called orphan sites where the government could not find potentially responsible parties.<sup>127</sup> To support the fund, Congress levied a broad-based corporate income tax, as well as “feedstock” taxes targeted at the oil and petrochemical industries.<sup>128</sup> When the statute was last reauthorized in 1986, these taxes were projected to provide approximately \$1.7 billion annually, with additional appropriations from

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119. 31 U.S.C. § 1115 (2000).

120. *Id.* § 1115(a)(2) (emphasis added).

121. *Id.* § 1115(a)(4), (6).

122. *Id.* § 1116.

123. *Id.* § 1116(d).

124. Pub. L. No. 96-510, 94 Stat. 2767 (1980) (codified as amended at 42 U.S.C. §§ 9601–9675 (2000)).

125. 42 U.S.C. §§ 9606, 9607.

126. *Id.* § 9611.

127. RENA STEINZOR & MARGARET CLUNE, CTR. FOR AM. PROGRESS & CTR. FOR PROGRESSIVE REFORM, THE TOLL OF SUPERFUND NEGLECT: TOXIC WASTE DUMPS & COMMUNITIES AT RISK 18 (2006), available at [http://images1.americanprogress.org/il80web20037/cap/superfund\\_neglect.pdf](http://images1.americanprogress.org/il80web20037/cap/superfund_neglect.pdf).

128. See generally *id.* (explaining the funding process for Superfund).

general taxpayer revenues authorized to provide approximately \$200 million annually.<sup>129</sup>

In 1995, Congress permitted the taxes supporting the trust fund to expire, and shifted the costs of the program to general revenues.<sup>130</sup> The expired taxes raised revenues of approximately \$1.5 billion annually (or \$4 million daily), an amount that clearly is not burdensome on industry, amounting to approximately 1.8% of the 2006 profits of just six of the nation's largest oil and petrochemical companies.<sup>131</sup> The full impact of this development did not become obvious immediately because millions remained in the trust fund from previous years, EPA slowed the pace of spending, and Congress appropriated more money from general revenues. By 2001, however, the number of "construction completions" at sites on the Superfund National Priorities List (NPL) had fallen from eighty-seven in 2000 to forty-seven; in 2007, the number had fallen to twenty-one.<sup>132</sup> Figure I shows the trajectory of these reductions from 1992 to the present.

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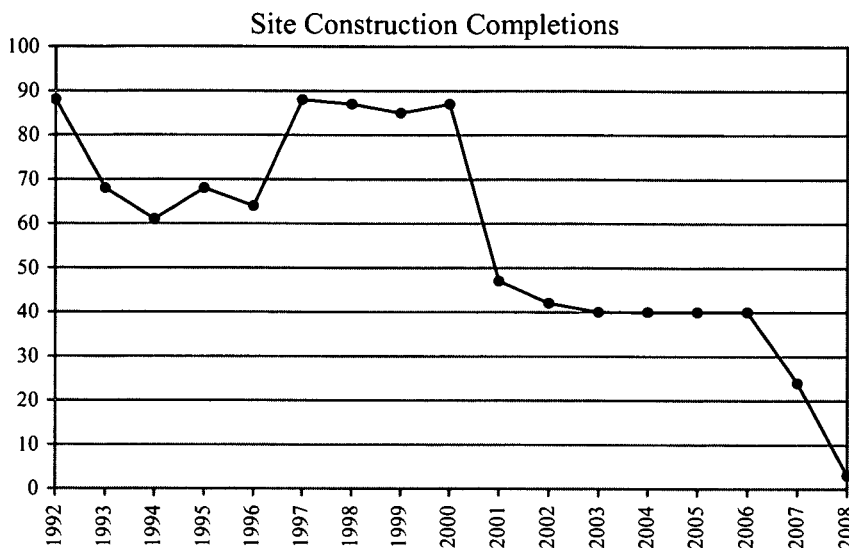
129. MARK REISCH, ENV'T'L PROT. SECTION, CONG. RESEARCH SERV., SUMMARIES OF ENVIRONMENTAL LAWS ADMINISTERED BY THE EPA: SUPERFUND (2001), <http://www.ncse.org/NLE/CRSreports/BriefingBooks/Laws/j.cfm>.

130. See generally JAMES E. MCCARTHY, RES., SCI., & INDUS. DIV., CONG. RESEARCH SERV., SUPERFUND TAXES OR GENERAL REVENUES: FUTURE FUNDING OPTIONS FOR THE SUPERFUND PROGRAM (2005) (discussing the controversy over extending Superfund taxes).

131. *Oversight Hearing on the Federal Superfund Program's Activities to Protect Public Health: Oversight Hearing Before Subcomm. on Superfund and Env'tl Health of the S. Comm. on Env't & Pub. Works*, 110th Cong. 5 (2007) (statement of Rena Steinzor, Professor, University of Maryland School of Law; Member Scholar and Board Member, Center for Progressive Reform).

132. The term "construction completion" refers to a stage in the cleanup of a site when any necessary physical construction and engineering work is complete, even if final cleanup goals have not been achieved. OFFICE OF ENVTL. & EMERGENCY RESPONSE, EPA, OSWER DIRECTIVE 9320.2-09A-P, CLOSE OUT PROCEDURES FOR NATIONAL PRIORITIES LIST SITES 3-I (2000). According to EPA, measuring success by simply looking at the ratio of deleted NPL sites to total sites on the NPL fails to "recognize the substantial construction and reduction of risk to human health and the environment that has occurred at NPL sites not yet eligible for deletion." *Id.* So, in 1990, to "communicate more clearly to the public the status of cleanup progress" among NPL sites, EPA established the new category of "construction complete" as its main indicator of program success. National Oil and Hazardous Substances Pollution Contingency Plan, 55 Fed. Reg. 8666, 8699 (Mar. 8, 1990) (codified at 40 C.F.R. pt. 300 (2008)).

Figure 1: NPL Site Construction Completions 1992 to Present



Source: EPA<sup>133</sup>

In offering these statistics, we make no claim that they are the only important quantitative measure of EPA's Superfund performance, although it is worth noting that the Agency itself highlighted construction completions as an especially important metric for judging the program's performance in 1990.<sup>134</sup> Rather, we suggest that this metric provides obvious and prominent evidence that the program underwent profound changes at the same time that it lost the primary source of funding Congress designed for it. Outside investigations confirm this conclusion. In 1999, Congress asked Resources for the Future (RFF) to conduct a study of the funding requirements of the Superfund Program.<sup>135</sup> The results of the study suggest that congressional appropriations have left a funding gap of between \$1.0 and \$3.4 billion with respect to the money necessary to clean up existing Superfund sites.<sup>136</sup> An

133. EPA, Number of NPL Site Actions and Milestones by Fiscal Year, <http://www.epa.gov/superfund/sites/query/queryhtm/nplfy.htm> (last updated May 8, 2008).

134. National Oil and Hazardous Substances Pollution Contingency Plan, 55 Fed. Reg. at 8699.

135. KATHERINE N. PROBST ET AL., SUPERFUND'S FUTURE: WHAT WILL IT COST? 2-3 (2001), available at [http://www.rff.org/rff/rff\\_press/CustomBookPages/Superfunds-Future.cfm](http://www.rff.org/rff/rff_press/CustomBookPages/Superfunds-Future.cfm).

136. RFF estimated that the total cost of the Superfund program from FY 2000 through FY 2009 would be between \$14 billion and \$16.4 billion, in constant dollars. *Id.* at 156-57, 159 fig.7-11. In 2005, Katherine Probst found that Superfund appropriations for the previous few years had been a little less than \$1.3 billion per year. Katherine N. Probst, *Superfund at 25: What Remains To Be Done*, RESOURCES, Fall 2005, at 20, 21, available at <http://www.rff.org/documents/RFF-Resources-159-Superfund.pdf>. Assuming that EPA had received \$1.3 billion in appropriations from FY 2000 to FY 2009, it would have received a total of \$13 billion in funding. As compared to



author of the RFF report recently observed, “Hundreds of sites across the country have been remediated, but there’s not enough money to finish work on the sites already designated, never mind the ones that are still being added.”<sup>137</sup>

As for the larger consequences of these failures, a report for the Center for Progressive Reform (CPR) and for the Center for American Progress (CAP) (which was co-authored by one of the authors of this Article) examined the impact of inadequate funding by studying five of the worst Superfund sites in each of the ten most populous states.<sup>138</sup> This examination revealed that the Superfund National Priorities List (NPL) includes 1,244 sites awaiting cleanup; many have languished on the NPL for more than two decades.<sup>139</sup> The sites typically contain noxious mixtures of solid and liquid wastes that infiltrate soil, surface water, and underground aquifers.<sup>140</sup> Between 205,000 and 803,000 people live within one mile of these sites, including 34,000 children and 14,000 elderly persons; a disproportionate percentage of these persons are low-income and people of color.<sup>141</sup>

EPA is one of the more ambitious agencies when it comes to compiling GPRA reports. The *2006–2011 EPA Strategic Plan*<sup>142</sup> is a beautifully illustrated, 180-page publication; the 667-page *2007 EPA Performance Plan*<sup>143</sup> is less polished in presentation but considerably more elaborate. Yet neither of these reports has anything to say about the funding challenges facing the Superfund program. Both reports fail to mention the expiration of Superfund’s taxing authorities; the number of construction completions is also omitted.

Instead, both reports contain statistics that are puzzling at best and misleading at worst because they suggest the Agency is making progress when it is not. For example, the *2006–2011 EPA Strategic Plan* promises that by 2011, the Agency will “achieve and maintain at least 95 percent of the maximum score on readiness evaluation criteria in each region.”<sup>144</sup> The statement refers to EPA’s ability to respond to emergencies involving hazardous substances. The 95% figure is clear enough, but the report makes no effort to explain what each region’s “readiness criteria” entail. In another

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RFF’s estimate of the total cost of the program, this leaves a funding gap of between \$1.0 billion and \$3.4 billion.

137. Probst, *supra* note 136, at 20.

138. STEINZOR & CLUNE, *supra* note 127, at 2.

139. *Id.* at 1.

140. *Id.* at 3.

141. *Id.*

142. EPA, 2006–2011 EPA STRATEGIC PLAN: CHARTING OUR COURSE (2006) [hereinafter EPA 2006–2011 STRATEGIC PLAN], available at [http://www.epa.gov/ocfo/plan/2006/entire\\_report.pdf](http://www.epa.gov/ocfo/plan/2006/entire_report.pdf).

143. EPA, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL YEAR 2007: ENVIRONMENTAL AND FINANCIAL PROGRESS (2007) [hereinafter 2007 EPA PERFORMANCE PLAN], available at <http://www.epa.gov/ocfo/par/2007par/par07report.pdf>.

144. EPA 2006–2011 STRATEGIC PLAN, *supra* note 142, at 67.

section, EPA promises to “complete an additional 975 Superfund-lead hazardous substance removal actions,” noting that “[i]n FY 2005, 175 of these actions were completed.”<sup>145</sup> Not only does this promise lack any objective context (how many removals are needed?) or historical context (how many have been done in years when funding was at full strength?), but it also lacks ambition: simple math shows that EPA expects to do 162 removal actions in each of the six fiscal years between now and 2011, a 7% drop from the 175 done in fiscal year 2005.

### C. *Vioxx*

In May 1999, FDA approved Vioxx “as a prescription painkiller for use, among other things, as a treatment for the signs and symptoms of arthritis.”<sup>146</sup> On September 30, 2004, Merck, the manufacturer of Vioxx, withdrew the drug because studies indicated it significantly increased the risk of heart attacks, but not before there had been \$2.5 billion in sales of the drug.<sup>147</sup> FDA’s failure to act to remove the drug from the market at an earlier time had serious ramifications. In congressional testimony, Dr. David Graham, an associate director in FDA’s Office of Drug Safety, estimated that between 88,000 and 139,000 Americans suffered a heart attack or stroke as the result of taking Vioxx and that as many as 30% to 40% of these patients died as a result.<sup>148</sup> He added that FDA should have acted much earlier by compelling stronger warning labels, curtailing misleading advertising, and pushing for the suspension of sales.<sup>149</sup> FDA’s capacity to take these actions was compromised by funding problems and a failure of political will. Its GPRA paperwork failed to acknowledge the first problem, and it compounded the second problem by emphasizing very different priorities.<sup>150</sup>

FDA’s funding problems originated in 1992 with the Prescription Drug User Fee Amendments<sup>151</sup> (PDUFA), which adopted a user-fee program to

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145. *Id.* A “removal action” is a short-term, relatively inexpensive cleanup. See 42 U.S.C. § 9601(23) (2000) (“The term includes . . . security fencing or other measures to limit access, provision of alternative water supply, temporary evacuation . . . and any emergency assistance which may be provided . . .”).

146. RENA STEINZOR & MARGARET CLUNE, CTR. FOR PROGRESSIVE REFORM, WHITE PAPER NO. 514, THE HIDDEN LESSON OF THE VIOXX FIASCO: REVIVING A HOLLOW FDA 2 (2005), available at [http://www.progressiveregulation.org/articles/Vioxx\\_514.pdf](http://www.progressiveregulation.org/articles/Vioxx_514.pdf).

147. *Id.* at 5.

148. *FDA, Merck, and Vioxx: Putting Safety First?: Hearing Before the S. Comm. on Finance, 108th Cong.* 125 (statement of David J. Graham, Associate Director, Food and Drug Administration).

149. See *id.* at 124–25 (“I believe such a ban [on the high-dose formulation of Vioxx] should have been implemented.”).

150. See *infra* notes 164–71 and accompanying text.

151. Pub. L. No. 102-571, 106 Stat. 4491 (codified as amended at 21 U.S.C. § 379 (2000)). Congress extended PDUFA in the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 103, 111 Stat. 2296, 2299–2304 (codified as amended at 21 U.S.C. § 379), and again in the Prescription Drug User Fee Amendments of 2002, Public Health Security and

support the agency's new-drug review program. The pharmaceutical industry agreed to the user fees because it was frustrated with the pace of new-drug approvals,<sup>152</sup> but its consent came at a steep price: PDUFA imposed two limitations that set the agency up for trouble down the road. First, the legislation mandated that user fees could only be used to support FDA's review of applications to market new prescription drugs.<sup>153</sup> Second, the legislation required FDA to devote at least as much money to new-drug reviews as it spent in 1992 (later changed to 1997), adjusted for inflation.<sup>154</sup> These provisions caused FDA to reallocate money from other purposes to new-drug review in order to continue the generation of fees. A report from the General Accounting Office (GAO) found that FDA paid about \$250 million in mandatory federal employee pay increases between fiscal years 1994 and 2001, but it did not receive additional funding to support these expenditures from Congress, which further drained resources from existing-drug programs.<sup>155</sup> By 2001, FDA's efforts to rob Peter to pay Paul allocated about 1,000 more full-time equivalents (FTEs) to drug and biologic review activities and 1,000 fewer FTEs to other FDA programs that "ensure [existing] food safety, approve new medical devices such as heart valves and pacemakers, and monitor devices once on the market."<sup>156</sup>

A CPR report co-authored by one of the authors of this Article found that FDA's funding shortfalls were one of the major causes of its failure to deal effectively with the side effects of Vioxx.<sup>157</sup> In 1992, the year that PDUFA was passed, FDA's Center for Drug Evaluation and Research (CDER) spent about 53% of its total budget on new-drug reviews.<sup>158</sup> A decade later in 2002, these expenditures had risen to 74% of CDER's total budget.<sup>159</sup> That same year, the office within CDER that reviews the safety of existing drugs received just 6% of CDER's total funding.<sup>160</sup> Similarly, the office within CDER that polices deceptive drug advertising received only 1%

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Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, §§ 501–531, 116 Stat. 594, 687–97 (codified as amended at 21 U.S.C. §§ 356b, 379g–379h).

152. Barbara Ann Binzak, *How Pharmacogenomics Will Impact the Federal Regulation of Clinical Trials and the New Drug Approval Process*, 58 FOOD & DRUG L.J. 103, 112 n.58 (2003) (noting that the industry agreed to the fees "to improve the speed of the drug approval process").

153. See 21 U.S.C. § 379h(g)(1) (explicitly limiting the collection and availability of the user fees to the extent provided in the Act).

154. See *id.* § 379h(g)(2)(A)(ii) (mandating that user fees "shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of human drug applications" and that relevant calculations shall be adjusted for inflation).

155. U.S. GEN. ACCOUNTING OFFICE, GAO-02-958, FOOD AND DRUG ADMINISTRATION: EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 17 (2002), available at <http://www.gao.gov/new.items/d02958.pdf>.

156. *Id.* at 18.

157. STEINZOR & CLUNE, *supra* note 146, at 22.

158. *Id.* at 2.

159. *Id.*

160. *Id.*

of CDER's total funding.<sup>161</sup> Although FDA was actively engaged in trying to persuade Merck to feature more prominent warnings on Vioxx packaging in the months preceding the voluntary recall, it was not sufficiently forceful in these negotiations,<sup>162</sup> either because it feared it was not ready to go to court to force action or because it was under pressure from top-level political appointees.<sup>163</sup> Vioxx was a very prominent medication with clearly intolerable side effects by the time the company yielded to market pressures.

None of FDA's strategic plans or performance reports leading up to the Vioxx scandal had a hint of these funding disparities. The thirty-two-page 2003 *FDA Strategic Action Plan*<sup>164</sup> was instead preoccupied with what the agency could do to promote pharmacological and food-technology developments.<sup>165</sup> The document worried aloud about the decreasing number of new-drug applications received by FDA, speculating without much justification that its own copious new-drug approval process may have been chilling innovation.<sup>166</sup> This concern even extended onto the factory floor, with FDA pledging to update its "Current Good Manufacturing Practices" in order to "encourage" what it believed could be "large savings in production costs."<sup>167</sup> Why manufacturing efficiency should be a top priority for the only regulatory agency charged with policing the safety and efficacy of new and existing drugs in a period of budget shortfalls was never raised as an issue, much less explained.

FDA's *FY 2000 Performance Plan and Revised FY 1999 Performance Plan* notes the high level of injuries from adverse drug reactions,

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161. *Id.* at 20.

162. *See id.* at 4 (explaining that FDA eventually yielded and allowed Merck to list the risk in the "precautions" section of the label instead of the "warnings" section).

163. *See id.* at 5 (describing the impact of pressure from FDA senior management on the conclusions and recommendations of an FDA scientist who studied Merck).

164. FDA, STRATEGIC ACTION PLAN, FOOD AND DRUG ADMINISTRATION: PROTECTING AND ADVANCING AMERICA'S HEALTH (2003), available at <http://www.fda.gov/oc/mcclellan/FDAStrategiePlan.pdf>.

165. For example, a message from FDA's administrator, Mark B. McClellan, declared:  
[G]etting a new drug, medical device, or food technology into use with the needed confidence that it is safe and effective has grown harder, as new scientific breakthroughs seem to be adding to the time, cost, and uncertainty of developing safe and effective new products . . . .

. . . .

. . . The combination of unprecedented challenges with unprecedented opportunities is why a key element of the FDA's new strategic plan is what we call "efficient risk management." . . . We need to make the process for developing new technology less costly.

*Id.* at 4–5.

166. *See id.* at 11 ("Steps to reduce the time, cost, and uncertainty of developing new drugs and devices are thus important public health priorities. . . . Making the process of translating new discoveries into safe and effective treatments more efficient and quick is thus a high priority for the FDA.")

167. *Id.* at 12.

acknowledging that they were the “fourth leading cause of death in America, behind heart disease, cancer, and stroke.”<sup>168</sup> A similar entry notes the same problem and renews the agency’s commitment to develop a national critical-event reporting system.<sup>169</sup> Developing a nationwide reporting system for adverse reactions is certainly a worthwhile effort, but one that would not have been the most direct way to discover and prevent the Vioxx catastrophe, which involved side effects thoroughly documented in follow-up studies conducted by Merck itself.<sup>170</sup> FDA’s GPRA documents omit any mention of the relationship between PDUFA fees and the shortfalls in funding that undermined the performance of the Office of Drug Safety and the Division of Drug Marketing, Advertising, and Communications.<sup>171</sup>

PDUFA came up for reauthorization last year. Had Congress failed to extend it, user fees would have expired and an estimated 2,000 FDA employees would have lost their jobs.<sup>172</sup> Described as “the mother of all F.D.A. reauthorization bills” by the agency’s former general counsel Dan Troy, the legislation redistributed PDUFA funding to avoid future inequities.<sup>173</sup> The legislation was the first expansion of FDA powers in over a decade, and it is undoubtedly a good thing that Congress managed to break its gridlock on this occasion. But the contents of the new law were based on extreme regulatory failure that had the worst possible outcome—thousands of premature deaths.<sup>174</sup>

With the notable exception of programs to address the “worldwide terrorist threat,”<sup>175</sup> Congress has not touched the vast majority of health and safety statutes in at least a decade, and in several cases it has been more than two.<sup>176</sup> As we saw in the case of the Superfund, some programs depend on crucial statutory authorities that expired years ago. It is truly demoralizing to

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168. OFFICE OF PLANNING, FDA, FOOD AND DRUG ADMINISTRATION: FY 2000 PERFORMANCE PLAN AND REVISED FINAL FY 1999 PERFORMANCE PLAN (1999), <http://www.fda.gov/ope/fy00plan/intro00.htm> [hereinafter FDA FY 2000 PLAN].

169. See FDA, FY 2002 ANNUAL PERFORMANCE PLAN AND SUMMARY (2001), <http://www.fda.gov/ope/fy02plan/default.htm> [hereinafter FDA FY 2002 PLAN].

170. STEINZOR & CLUNE, *supra* note 146, at 3–4.

171. See, e.g., FDA FY 2002 PLAN, *supra* note 169, at § 2.2 (containing no mention of PDUFA fees in its discussion of human drugs); FDA FY 2000 PLAN, *supra* note 168 (containing only a single, passing mention of PDUFA fees).

172. Gardiner Harris, *House Passes Bill Giving More Power to the F.D.A.*, N.Y. TIMES, Sept. 20, 2007, at A18.

173. See *id.* (reporting on the increase in funding to be paid by drug makers and FDA’s expanded discretion in using the funds); Drew Armstrong, *Bill Clears After Intense Negotiation*, CQ WEEKLY, Sept. 24, 2007, at 2766 (reporting the increase in user fees to be paid by drug companies).

174. See *supra* note 148 and accompanying text.

175. See, e.g., 42 U.S.C. § 300i-2 (2000) (providing for the safeguard of public water supplies against terrorist threats).

176. Compare, e.g., Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 401, 116 Stat. 682 (codified as amended at 42 U.S.C. § 300i-2) (adding provisions to protect public drinking-water systems from “terrorist acts and other intentional acts”), with 42 U.S.C. § 300h-300h-3 (containing general provisions for the protection of underground drinking-water sources that have remained unchanged since 1986).

think that only catastrophic failure and the embarrassment of massive layoffs of government workers can prompt Congress to come to grips with the growing reality of a regulatory state on the brink of many smaller failures. Advocates of more effective government simply must think of a better way. We offer positive metrics.

### III. Positive Metrics

To review the bidding once again and briefly: procedural reforms invented by the sixties reformers are no match for the problems that plague health and safety regulatory agencies today—most prominently the crippling effect of funding gaps. Even if public interest groups had the advantages of a receptive judiciary and resources that matched those of industry, their goals would be thwarted by an underfunded bureaucracy and other problems that contribute to regulatory failure. The only solution to these dilemmas is to refocus the public's attention on the reasons why FDA, EPA, OSHA, NHTSA, and CPSC were created in the first place. GPRA had the potential to produce this shift, but it has floundered as a result of its own mixed messages.

In this Part we propose a plan for establishing positive metrics, including the eight principles that should guide the development of such a program; offer a prototype metric for the implementation of the Clean Water Act's (CWA) "safety net"—the total maximum daily load (TMDL) program; and elaborate on how the eight principles would operate.

#### A. A Plan for Positive Metrics

*Webster's Dictionary* defines "metric" as, among other things, "a standard of measurement."<sup>177</sup> "Standard" is defined as, again inter alia, "something that is established by authority, custom, or general consent as a model or example to be followed."<sup>178</sup> We embrace these broad definitions, which have the advantage of including measurements of the status quo, measurements of current and future activities and their expected results, and measurements of normative goals within the ambit of an agency's statutory mission.

As further defined by our proposal, positive metrics would focus on an agency's core statutory mission or missions. For this reason, and because positive metrics would be concise and would be made available on the World Wide Web, they should have the potential to generate publicity and oversight concerning why agencies have experienced regulatory failure. In isolation, positive metrics would not indicate why an agency has failed. Instead, they

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177. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 1424 (3d ed. 1993).

178. *Id.* at 2223.

would alert Congress, the White House, and others with oversight authority—as well as advocacy groups, the media, and the public—that those causes of regulatory failure must be found. Indeed, to make the best use of positive metrics, a system of routine oversight focused specifically on improvements in the metrics should be created.

Positive metrics could, but do not necessarily have to, supplant GPRA. Our position in this Article is that GPRA does not work for the purpose of kick-starting oversight and debate concerning why an agency is failing to achieve a statutory mission. Whether GPRA could serve as the platform for further reform is a question we cannot easily resolve. But positive metrics should remain uninfected by GPRA's perverse incentive structure, which asks agencies to grade themselves by writing their own future assignments, and then either neglects to check on whether these assignments are ever fulfilled or kicks the agencies out of school for failing to complete those tasks.

Eight principles should guide the design of a positive metrics program:

1. *Statutory Mission.* Positive metrics should be aligned with an agency's statutory mission and, if available, its more detailed statutory mandates.<sup>179</sup>
2. *Short and Concise.* Metrics should be short and concise, focusing on an agency's core statutory mission or missions.
3. *Independent Selection.* An independent body of experts familiar with the agency's work should select positive metrics.
4. *Unbounded Rationality.* Whether or not information is available to answer the question behind a metric should not have a bearing on its selection.
5. *Outcomes versus Outputs.* Positive metrics should emphasize outcome, rather than output, measurements wherever possible.
6. *Constant Change.* Metrics should be changed as often as possible to reflect progress and spur further advances.
7. *Diagnostic.* Metrics should have the potential to help diagnose the causes of regulatory failure—including funding gaps, technical complexity, lack of political will, inadequate statutory design, and agency capture.

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179. The statutory mandates for the five agencies we have discussed differ substantially. Compare Clean Air Act, 42 U.S.C. §§ 7401–7671 (2000) (spanning 270 pages), with Occupational Safety and Health Act (OSHA) of 1970, 29 U.S.C. §§ 651–678 (2000) (spanning a mere twenty-five pages).

8. *Ready Availability.* Agencies must feature positive metrics on their Internet sites and avoid what appears to be a powerful motivation to bury information about poor performance behind a wall of nonobvious links requiring multiple “clicks” to reach the desired data, thereby rendering Internet sites accessible only to the very patient or to the already well informed.

Two additional conditions would make positive metrics more effective. First, the entity that establishes the metrics initially should meet with each agency at least annually to review their status. Second, EPA, which delegates much of the work of implementing the law to its state counterparts, must be given funding adequate to pay for the information-gathering that the states would be compelled to accomplish on its behalf.

### *B. Prototype Metric*

We chose to offer a prototype metric for the Clean Water Act (CWA) provisions for cleaning up residual problems in the nation’s surface waters, because implementing these provisions has proven to be among the most intractable problem areas for EPA—largely because the Agency must depend on the states to accomplish the hard work of setting standards and requiring dischargers to reduce pollution. By taking on one of the most confounding administrative challenges faced by the agency that serves so often as a poster child for all the others, we hope to demonstrate how positive metrics would work to highlight regulatory failures and trigger a search for solutions.

1. *Restoring Impaired Waters.*—Three decades of technology-based controls have dramatically improved the environmental status of surface waters (rivers, lakes, streams, creeks, estuaries, etc.). But serious problems are emerging and reemerging. Two prominent examples include toxics—especially mercury—and pollution as a result of runoff from agricultural operations.<sup>180</sup> EPA’s most recent 2002 *Water Quality Inventory* of “impaired” waters—those polluted to the point at which they are unfit for a “designated use” such as drinking, swimming, or recreational boating—indicates substantial regulatory failure.<sup>181</sup> EPA estimates that 45% of assessed river and stream miles and 47% of assessed lake acres were not

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180. EPA, EPA-841-R-02-001, NATIONAL WATER QUALITY INVENTORY: 2000 REPORT (2000), available at <http://www.epa.gov/305b/2000report>.

181. EPA, EPA-841-R-07-001, NATIONAL WATER QUALITY INVENTORY: REPORT TO CONGRESS, 2002 REPORTING CYCLE (2007) [hereinafter WATER QUALITY INVENTORY 2002], available at <http://www.epa.gov/305b/2002report>. The Inventory reports are required by § 305(b) of the Clean Water Act, which is codified at 33 U.S.C. § 1315 (2000).



clean enough to support uses such as fishing and swimming.<sup>182</sup> An “assessed” water body is one that has been monitored by a state.<sup>183</sup>

The actual extent of impairment, however, is unknown for two reasons. First, according to EPA, the states have assessed only 19% of the nation’s total river and stream miles and 37% of its lake, pond, and reservoir acres.<sup>184</sup> Second, the statistics reported by the states are too unreliable to create a national picture of regulatory success or failure. According to a 2002 report by GAO,<sup>185</sup> states use sampling methodologies that are inconsistent with each other and, as a result, the information in EPA’s database of impaired waters is of “questionable reliability.”<sup>186</sup> Because states categorize and sample water quality inconsistently, “the numbers of impaired waters cannot be compared from one state to the next and EPA cannot reliably tally the number of TMDLs that must be completed nationwide.”<sup>187</sup> No one would argue that monitoring must occur every few feet along the banks or in the middle of the nation’s great lakes, rivers, and streams. However, measuring the water quality of a river segment that runs through agricultural lands and using those figures to characterize problems along a ten-mile segment that runs through a major urban area does not establish the baseline needed to tackle these important problems.

Once a “water quality segment” is listed as impaired, states must establish a schedule for issuing total maximum daily loads (TMDLs) for each segment.<sup>188</sup> TMDLs establish limits on the discharge of pollutants that are causing the segment’s impairment at the cumulative level at which water quality will improve sufficiently to allow resumption of the segment’s designated use.<sup>189</sup> After TMDLs are set, the states must rewrite the permits for the pollution sources causing the problem, reducing each source’s allowable discharges.<sup>190</sup> States were originally required to issue TMDLs by 1979, but none managed to do so until at least a decade later when a series of successful lawsuits brought by environmental groups forced their hands.<sup>191</sup> Today, most states have made only scant progress toward these goals, and it will

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182. *Id.*

183. See 33 U.S.C. § 1313(d)(1) (requiring states to identify impaired waters).

184. WATER QUALITY INVENTORY 2002, *supra* note 181, at 9 fig.1, 11 fig.2.

185. At the time, this institution was called the General Accounting Office.

186. U.S. GEN. ACCOUNTING OFFICE, GAO-02-186, WATER QUALITY: INCONSISTENT STATE APPROACHES COMPLICATE NATION’S EFFORTS TO IDENTIFY ITS MOST POLLUTED WATERS 3 (2002) [hereinafter INCONSISTENT EFFORTS].

187. *Id.*

188. TMDL requirements are set forth in 33 U.S.C. § 1313(d)(1).

189. *Id.* § 1313(d)(1)(C).

190. See *id.* § 1313(d)(2) (explaining the method by which states are to proceed once TMDLs are established).

191. See generally OLIVER A. HOUCK, THE CLEAN WATER ACT TMDL PROGRAM: LAW, POLICY, AND IMPLEMENTATION 49–108 (2d ed. 2002) (describing the states’ delays in implementing these requirements and how litigation forced them to act).

take many years before they have completed TMDLs, much less implemented them through revised permits.<sup>192</sup>

2. *EPA GPRA Reporting.*—The 2006–2011 EPA Strategic Plan does not mention that less than a third of waters have been assessed, and it further omits any acknowledgment of the GAO findings. Nevertheless, EPA pledges that by 2012 it will:

[A]ttain water quality standards for all pollutants and impairments in more than 2,250 water bodies identified in 2002 [out of 39,798 water bodies identified by states] as not attaining standards . . . .

[R]emove at least 5,600 of the [69,677] specific causes of water body impairment . . . .

[I]mprove water quality conditions in 250 [out of 4,800] impaired watersheds nationwide . . . .<sup>193</sup>

These goals are extraordinarily modest and suggest a pace that would not address current, much less future, water-quality problems for a century or more. While public interest activists can lament this lack of ambition, these numbers alone do not communicate enough information to determine why the pace is so slow and what could be done to accelerate it.

3. *Positive Metrics.*—We envision a three-year program to develop positive metrics concerning impaired waters. The first year would involve estimating how much it would cost and how long it would take to: (a) synchronize federal and state data, and (b) expand monitoring to a statistically valid sample of surface waters. The first year would also involve creating an interactive map that shows the impaired waters for all states, the reasons for impairment, and the schedule compiled by each state for setting TMDLs for impaired segments.<sup>194</sup> The schedules should show when each state will complete the TMDLs.

In its second year, the program would require an explanation of progress made on the synchronization and expansion of monitoring. The second year would yield an updated interactive map consisting of the same elements as the first-year map.

In its final year, the program would require another explanation of progress made on synchronization and would yield another updated interactive map. This time the map would include, on a state-by-state basis, a schedule for implementing TMDLs by writing the limits into individual facility permits. Beyond this three-year time horizon, we would expect the

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192. *Id.* at 104–08.

193. EPA 2006–2011 STRATEGIC PLAN, *supra* note 142, at 43.

194. EPA has made rudimentary efforts to build this kind of tool, although most examples of “enviromaps” on the Agency’s website do not work well and are missing the layers of data we suggest. *See, e.g.*, EPA, EnviroMapper Storefront, <http://www.epa.gov/enviro/html/em>.

metrics plan for each year to continue this pattern of tracking performance and constantly raising the bar.

### C. *The Eight Criteria*

The previous example illustrates how positive metrics can highlight regulatory failure, but this objective is not easily achieved. As this subpart elaborates, the eight criteria that we propose are intended to address some of the challenges and complexities of implementing a program of positive metrics.

1. *Statutory Missions.*—Positive metrics should be aligned with the agencies' statutory mandates, including the historical record of each agency in defining these missions. The goal is to measure the extent to which each agency has accomplished its statutory missions and the extent to which it has fallen short of legislatively mandated goals.

Experience with “performance-based” or “results-oriented” management demonstrates the limited utility of elaborate metrics involving hundreds of measures that necessarily are couched in vague, qualitative terms. Positive metrics should therefore number no more than thirty for each agency and should be based on quantitative data or measurements that need empirical data to be complete. We recognize the arbitrariness of this number; forty-five or twenty-seven metrics obviously would not violate the spirit of our proposal. The overriding goal must be to produce metrics that encompass the core missions of an agency.

For example, the Clean Air Act (CAA) requires EPA to identify “criteria” air pollutants, set primary and secondary standards for each,<sup>195</sup> and oversee the development of state implementation plans that will bring air quality into compliance with these standards—accomplishing each task under strict deadlines.<sup>196</sup> Geographic areas that do not meet the standards are called “non-attainment” areas.<sup>197</sup> An estimated ninety million Americans live in non-attainment areas.<sup>198</sup> The CAA mandates suggest metrics that disclose the levels of criteria pollutants in the ambient air across the country and explain how long it will take the Agency to catch up on its work.

Similarly, the purpose of OSHA is to “assure so far as possible every working man and woman in the Nation safe and healthful working conditions.”<sup>199</sup> Ideally, positive metrics for OSHA would measure the extent

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195. See 42 U.S.C. § 7408 (2000) (requiring EPA to publish a list of air pollutants); *id.* § 7409 (requiring EPA to establish primary and secondary ambient-air-quality standards). A primary standard protects human health, *id.* § 7409(b)(1), while a secondary standard is based on potential environmental and property damage, *id.* § 7409(b)(2).

196. *Id.* § 7410.

197. *Id.* § 7501(2).

198. NAT'L SAFETY COUNCIL, SECTION 1: BACKGROUND ON AIR POLLUTION (2006), <http://www.nsc.org/ehc/mobile/acback.htm>.

199. 29 U.S.C. § 651(b) (2000).

to which OSHA has accomplished its mission of ensuring healthy workplaces by identifying whether the number of workers who become ill from workplace exposure to toxic chemicals is declining. But this second step is out of reach for the foreseeable future due to the unavailability of reliable data on the incidence of workplace illnesses. A positive metric, however, could measure OSHA's progress in regulating the number of toxic chemicals in the workplace.<sup>200</sup>

2. *Short and Concise.*—As noted above, experience with performance-based or results-oriented management has shown that elaborate metrics involving hundreds of vague, qualitative measures have limited utility. To accomplish the goal of developing short and concise metrics, the metrics should be focused on the broad nature of the agency's statutory mission, rather than on the means and methods of accomplishing that mission.

This goal is achievable if a distinction is made between *metrics*, which measure an agency's success or failure in achieving a statutory mission, and *priority-setting*, which determines individual projects, rules, or programs to achieve that mission. For example, as discussed in the previous section, OSHA's progress in reducing workplace illness could be measured by the number of toxic chemicals for which it has regulations. In our scheme, it would be left to OSHA to determine which chemicals to pursue in which order. Nevertheless, more than one metric might be employed to measure OSHA's progress without impinging on OSHA's prerogative to set its own priorities. OSHA's progress might be measured by determining how many high-volume chemicals it regulates, tracking its progress in updating older regulations on chemical exposure, or determining the number of known toxins for which OSHA has modern regulations. Indeed, all of these measures might be appropriate.

At an agency like EPA, which has multiple statutory mandates to implement, care should be taken not to produce dozens of metrics, which would only deflect attention away from the accountability goal. The number of positive metrics for large agencies with complex statutory missions should be limited to not more than two or three dozen, in order to avoid the distraction produced by unnecessary complexity.

3. *Independent Selection.*—The task of compiling positive metrics could be assigned to each of the health and safety agencies. Their professional staffs understand their programs better and are more familiar with their authorizing statutes than any ad hoc body of independent experts. But inevitably, the results of such reviews would be determined by an elaborate "log-rolling" exercise as each portion of the bureaucracy assembled its outside constituencies to lobby for metrics that would make that unit look

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200. The section that follows describes more fully how positive metrics could accomplish this.

good. For example, FDA staff responsible for reviewing new drugs would assemble pharmaceutical companies to ensure that fast disposition of such applications remains a top priority, while staff responsible for reviewing the safety and efficacy of existing drugs would press for metrics highlighting the need for additional funding of those efforts.

Utilizing this kind of pluralistic decision making has some advantages. For example, staff-driven efforts to define metrics are more likely to encourage rapid and willing compliance with reporting requirements than outsider-driven efforts to impose metrics. The question is whether such advantages are important enough to justify accepting the considerable downsides of an essentially self-interested selection process. For example, to the extent that agencies have already wandered far from their statutory missions, as was the case in both the Superfund and Vioxx examples we gave in our discussion of GPRA compliance,<sup>201</sup> putting an underperforming agency in charge of metrics selection could defeat or substantially undermine the goals of positive metrics. We favor the establishment of independent entities to perform the task of metric selection.

The log-rolling process that would occur if agencies were tasked with metrics selection would invariably produce an overly lengthy and complicated list of metric candidates because agencies would compromise by accepting everyone's proposed metrics. Moreover, to work properly, positive metrics must be accessible to outsiders who are not steeped in the highly technical details of an agency's work. While agency complexity and opacity could also plague an independent selection committee, lack of involvement in an agency's daily work is likely to make it far easier for those outsiders to achieve the goal of establishing accessible positive metrics.

The independent entity assigned the task of compiling positive metrics could be established within existing institutions: the National Academy of Sciences, the Government Accountability Office, or individual agency inspectors general are all possibilities.<sup>202</sup> Alternatively, Congress and the president could establish new independent metrics-selection entities, modeling them along the lines of other blue-ribbon commissions, with some members selected by Congress, some selected by the president, and some selected from among an agency's constituencies.<sup>203</sup>

Although we favor independent selection of metrics, individual agencies should have a substantial role in advising the independent entity that chooses the metrics. Their advice would give the independent entity the advantage of the agency's expertise, while still protecting against the selection of the type

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201. See *supra* subparts II(B)–(C).

202. We omit OMB because of its strong reputation as a critic of regulation, sustained across several administrations.

203. See, e.g., Defense Base Closure and Realignment Act of 1990, 10 U.S.C. § 2687 note (2000) (describing the process of appointments to the Base Realignment and Closure Commission, whose members are nominated by the president and appointed by the Senate).

of self-protective measurements that show up in the GPRA process. Indeed, it may be efficient to have an agency propose metrics as the starting point of the entity's process. The independent entity should also consult with or receive input from interested persons through written submissions or some type of hearing process.

Two additional characteristics should shape the role of independent selection entities. First, in addition to selecting the metrics, the independent entities should routinely review and revise them as information emerges and progress is made. Second, this entire scheme to ensure independence would be most effective if Congress holds oversight hearings in which agencies would answer for their performance in achieving these goals on an annual or biannual basis.

4. *Unbounded Rationality.*—As in our prototype, metrics should not depend—or be circumscribed by—the availability of information needed to determine if they are met. Instead, agencies should understand at the outset of the process that it may take years to accumulate the data needed to assess their performance. If an agency lacks the information to complete a metric, it should acknowledge this limitation and commit itself to establishing the necessary information base to complete the metric. If an agency lacks the statutory authority to obtain such information, it should acknowledge this limitation and seek the necessary authority from Congress.

Our prototype metric illustrates the importance of unbounded rationality. Because EPA is dependent on states to monitor the surface waters within their jurisdictions, and because it has never established national standards for how this work is going to be carried out, roughly 70% of surface waters remain unmonitored.<sup>204</sup> Similarly, implementation of TMDLs—the only statutory tool available to achieve progress in this arena—is dependent on state efforts, all of which are compromised by the budget shortfalls, lack of bureaucratic will, incompetence, and political interference that also challenge EPA.<sup>205</sup> The troubled state of the federal–state partnership and solutions to those intractable problems are beyond the scope of this Article, although one of the authors has discussed them in other contexts.<sup>206</sup> Suffice

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204. See *supra* section III(B)(1).

205. HOUCK, *supra* note 191, at 142–47 (describing the challenges that have confronted EPA and the states as they try to implement these provisions).

206. See generally Rena I. Steinzor, *EPA and Its Sisters at 30: Devolution, Revolution, or Reform?*, 31 *Envtl. L. Rep. (Envtl. Law Inst.)* 11,086 (2001) (explaining the causes of regulatory failure at the state level); Rena I. Steinzor, *Devolution and the Public Health*, 24 *HARV. ENVTL. L. REV.* 351 (2000) (exploring the ramifications of devolving more responsibility to the states for the protection of public health and the environment); Rena I. Steinzor, *Reinventing Environmental Regulation Through the Government Performance and Results Act: Are the States Ready for the Devolution?*, 29 *Envtl. L. Rep. (Envtl. Law Inst.)* 10,074 (1999) (describing the historical battles between EPA and the states over GPRA implementation); Rena I. Steinzor, *Unfunded Environmental Mandates and the "New (New) Federalism": Devolution, Revolution, or Reform*, 81

it to say that these problems will pose major challenges to the implementation of positive-metric systems.

5. *Outcomes Versus Outputs.*—GPRA’s inventors had one overriding claim to make about why their solution would succeed when so many other efforts to herd the bureaucracy had failed: the statute would compel civil servants to stop “counting beans” and stand accountable for “results.”<sup>207</sup> This distinction is described in the political-science literature as the difference between procedural accomplishments (i.e., rules written, permits issued, enforcement actions taken) and “outcomes” (i.e., pollution reduced, accidents avoided, dangerous drugs kept off the market). As James Q. Wilson explains in his classic book, *Bureaucracy*:

First, identify a course of action . . . call it the treatment. A “treatment” can be a police tactic, a school curriculum, or a welfare program. Second, decide what impact the treatment is intended to have; call this the outcome. The outcome can be a crime rate, an achievement score, a work effort, a housing condition, or an income level.<sup>208</sup>

Or, as President Clinton explained in his GPRA signing statement:

It may seem amazing to say, but like many big organizations, [our government] is primarily dominated by considerations of input, how much money do you spend on a program, how many people do you have on the staff, what kind of regulations and rules are going to govern it, and much less by output, does this work, is it changing people’s lives for the better, can we say after we take money and put it into a certain endeavor that it was worth actually having it away from the taxpayers, into this endeavor, and their lives are better?<sup>209</sup>

During the decade-and-a-half since GPRA was enacted, GAO has repeatedly acknowledged the difficulties agencies face in making this transition.<sup>210</sup> Not only must agencies struggle with the deeply embedded

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MINN. L. REV. 97 (1996) (tracing the states’ rebellion against unfunded mandates that caused a major erosion in the federal–state relationship).

207. Senator Roth, lead sponsor of the legislation, said in his floor statement: “The Federal Government today is primarily process-oriented. Its focus is on following detailed procedural rules within rigidly structured programs. . . . [Under GPRA, agencies will] publish annual performance reports showing the actual outcomes.” 139 CONG. REC. 17,973 (1993).

208. JAMES Q. WILSON, *BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT* 373–74 (1989).

209. Remarks on Signing GPRA, *supra* note 13, at 1310–11.

210. U.S. GEN. ACCOUNTING OFFICE, GAO-04-38, *RESULTS-ORIENTED GOVERNMENT: GPRA HAS ESTABLISHED A SOLID FOUNDATION FOR ACHIEVING GREATER RESULTS* 9 (2004), available at <http://www.gao.gov/new.items/d04594t.pdf>; U.S. GEN. ACCOUNTING OFFICE, GAO/GGD-98-44, *MANAGING FOR RESULTS: AGENCIES’ ANNUAL PERFORMANCE PLANS CAN HELP ADDRESS STRATEGIC PLANNING CHALLENGES* 7 (1998), available at <http://www.gao.gov/archive/1998/gg98044.pdf>; U.S. GEN. ACCOUNTING OFFICE, GAO/GGD-97-83, *MANAGING FOR RESULTS: REGULATORY AGENCIES IDENTIFIED SIGNIFICANT BARRIERS TO FOCUSING ON RESULTS* 1 (1997), available at <http://www.gao.gov/archive/1997/gg97083.pdf>; U.S. GEN. ACCOUNTING OFFICE,

habit of counting what they do, as opposed to what they cause to happen, health and safety agencies must find a way to actually monitor their results in the real world. When records are readily available, the problem boils down to making the effort to compile it. However, when the data does not exist it is often expensive to set up a system to generate the information, and the data may not be obtainable in some cases.

While we recognize the importance of driving agencies to develop outcome information, we also realize that output information may not be available in the short term, and that input information may be a reasonable substitute in the meantime. For example, one might seek to judge OSHA's performance on the basis of trends in workplace fatalities, injuries, and illnesses. The Bureau of Labor Statistics (BLS), a division of the Department of Labor, publishes such statistics, but the data is extraordinarily incomplete and inaccurate.<sup>211</sup> BLS faces a particularly daunting challenge in developing data about occupational disease because the BLS system relies on employers to report fatalities, injuries, and illnesses, but occupational diseases often do not appear until workers have suffered years of exposure and may have left employment at the facility where the exposure occurred. Data from a non-BLS source suggests that occupational diseases cause 50,000 to 70,000 deaths annually.<sup>212</sup>

We are unsure of how long it will take to develop an alternative system of estimating trends in occupational illnesses, or whether this even can be done. In the meantime, a regulatory metric could be focused on outputs. OSHA has permissible exposure limits (PELs) for only 500 chemicals, which is a small fraction of the thousands of substances present in the American workplace.<sup>213</sup> Moreover, OSHA has exposure limitations for fewer than 200

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GAO/HEHS/GGD-97-138, MANAGING FOR RESULTS: ANALYTIC CHALLENGES IN MEASURING PERFORMANCE 1 (1997), available at <http://www.gao.gov/archive/1997/h297138.pdf>; U.S. GEN. ACCOUNTING OFFICE, GAO/AIMD-97-46, PERFORMANCE BUDGETING: PAST INITIATIVES OFFER INSIGHTS FOR GPRA IMPLEMENTATION 2 (1997), available at <http://www.gao.gov/archive/1997/ai97046.pdf>; U.S. GEN. ACCOUNTING OFFICE, GAO/GGD-96-118, EXECUTIVE GUIDE: EFFECTIVELY IMPLEMENTING THE GOVERNMENT PERFORMANCE AND RESULTS ACT 1 (1996), available at <http://www.gao.gov/archive/1996/gg96118.pdf>; see U.S. GEN. ACCOUNTING OFFICE, GAO/GGD-97-36, GPRA: MANAGERIAL ACCOUNTABILITY AND FLEXIBILITY PILOT DID NOT WORK AS INTENDED 3 (1997), available at <http://www.gao.gov/archivc/1997/gg97036.pdf> (explaining why the GPRA managerial accountability and flexibility pilot program was unsuccessful).

211. See, e.g., J. Paul Leigh et al., *An Estimate of the U.S. Government's Undercount of Nonfatal Occupational Injuries*, 46 J. OCCUPATIONAL ENVTL. MED. 10, 10 (2004) (estimating that BLS statistics miss between 33% and 69% of all injuries); Kenneth D. Rosenman et al., *How Much Work-Related Injury and Illness Is Missed by the Current National Surveillance System?*, 48 J. OCCUPATIONAL ENVTL. MED. 357, 357 (2006) (estimating that BLS statistics account for only approximately one-third of all work-related injuries and illnesses in Michigan).

212. Phillip J. Landrigan & Dean B. Baker, *The Recognition and Control of Occupational Disease*, 266 J. AM. MED. ASS'N 676, 676 (1991).

213. *Is OSHA Working for Working People?: Hearing Before the Subcomm. on Employment and Workplace Safety, S. Comm. on Health, Educ., Labor & Pensions*, 110th Cong. 3 (2007)



of the approximately 3,000 chemicals characterized by EPA as “high volume production” chemicals (meaning more than a million pounds of the substance is produced or imported each year).<sup>214</sup> Many of OSHA’s existing emissions limitations, which were adopted at the time that the agency was founded, are out of date,<sup>215</sup> and OSHA has promulgated new occupational disease regulations for only about thirty substances since it was founded.<sup>216</sup> In the last ten years, OSHA has issued standards for a total of only two new chemicals.<sup>217</sup>

We are also aware that both output and outcome information are necessary to measure and assess agency activities, especially in the enforcement arena. Deterrence-based enforcement systems often depend on high-profile, relatively frequent prosecution of entities in all segments of an industrial sector. Focusing on only one outcome would reward an agency for prosecuting one large emitter because the agency could claim its action took many tons of pollutants out of the air. In periods of acute budget shortfalls, enforcement characterized by large one-entity prosecutions could supplant routine enforcement against smaller entities that may, in the aggregate, emit much larger amounts of pollution. Without the latter type of enforcement, however, the entire sector of smaller players could fall into noncompliance.

6. *Constant Change.*—Static metrics would come close to being worse than no metrics at all because they would rapidly degenerate into a rote effort that no one could take very seriously.<sup>218</sup> As our prototype illustrates, initial metrics would ask agencies to take stock of the problem, admitting when they do not have the information necessary to fully characterize the milestones they must reach to achieve a statutory mission. Over time, as that information is developed, metrics should shift to an evaluation of the progress

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[hereinafter *OSHA Hearing*] (statement of David Michaels, Research Professor, George Washington University).

214. *Id.*

215. All of OSHA’s other emissions limitations, called permissible exposure limits (PELs), were adopted in 1970 based on the recommendations of private standard-setting groups, primarily the American Conference of Governmental Industrial Hygienists (ACGIH). Many of these PELs are out of date because ACGIH has updated their recommendations and OSHA has not been able to update its PELs in response. OSHA’s 1992 attempt to update the PELs was blocked by a court. *Am. Fed’n of Labor & Cong. of Indus. Orgs. v. OSHA*, 965 F.2d 962, 968–69 (11th Cir. 1992). A second problem is that the PELs adopted in 1970 are not comprehensive standards—the regulations are only exposure limitations and they do not provide for other employee protections, such as requirements for employers to conduct exposure monitoring, provide medical surveillance, or provide worker training.

216. *OSHA Hearing*, *supra* note 213, at 3.

217. *See* 29 C.F.R. § 1910.1051–.1052 (2007) (setting standards for 1,3-butadiene and methylene chloride).

218. Experience suggests that a failure to review and revise the compliance status of any interim goals for programs dooms such efforts to failure. *See, e.g.*, Thomas McGarity, *Missing Milestones: A Critical Look at the Clean Air Act’s VOC Emissions Reduction Program in Nonattainment Areas*, 18 VA. ENVTL. L.J. 41, 84–85 (1999) (arguing that EPA’s failure to penalize states that did not meet interim milestones under the Clean Air Act undercut its efforts to get them to attain the Act’s standards).

agencies are actually making in achieving these milestones. Or, in other words, initial metrics would be replaced by more demanding metrics that gradually ratchet up expectations for the agency's performance.

7. *Diagnostic*.—The great advantage of metrics that constantly change and are set without regard to whether information is available to satisfy them is their potential to help overseers discover the root cause of an agency's poor performance. Our prototype metric for implementation of the TMDL program—the CWA's safety net for technology-based standards—would ask EPA to estimate the resources it needs to accomplish comprehensive monitoring while also requiring the Agency to disclose how far the states are from meeting the Act's overall water-quality goals. Lack of resources is at the heart of EPA and its sister agencies' problems in this arena. Once these shortfalls are made obvious, it would be up to Congress and the president to decide whether to remedy them. Public interest advocates would have the information they need to advocate for those results. This diagnostic capacity stands in sharp contrast to the implementation of GPRA over three presidencies. The "party line" recitations of progress that characterize GPRA reports are useless from a diagnostic perspective.

8. *Ready Availability*.—Current information about agency performance varies in its transparency. EPA, for example, offers elaborate output and outcome data on its Web site, but the information is difficult to find. From the EPA home page, the reader needs to click on *Air* in a box called *Quick Finder*,<sup>219</sup> which leads the reader to a page with the heading *Air*.<sup>220</sup> The reader then clicks on *Office of Air and Radiation*, which takes the reader to a page that contains another *Quick Finder* box.<sup>221</sup> The reader then clicks on *Air Trends* within the box, which takes the reader to the page named *Air Trends*.<sup>222</sup> This location gives the reader a number of options, including a box with the heading *Air Quality and Emissions—Progress Continues in 2006*, which moves the reader to page with a summary of some performance data.<sup>223</sup> Another option is *Reports and Data*, which moves the reader to a page listing reports EPA has prepared on its performance.<sup>224</sup> The reader can

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219. U.S. Environmental Protection Agency, <http://www.epa.gov> (last updated May 16, 2008).

220. EPA, *Air*, <http://www.epa.gov/ebtpages/air.html> (last updated May 16, 2008).

221. EPA, *Air Trends*, <http://www.epa.gov/oar/airtrends> (last updated Apr. 28, 2008).

222. EPA, *Air Quality Status and Trends Through 2006*, <http://www.epa.gov/oar/airtrends/2007/index.html> (last updated Jan. 22, 2008).

223. EPA, *Basic Information, Air Trends*, <http://www.epa.gov/oar/airtrends/sixpoll.html> (last updated May 8, 2008).

224. EPA, *Reports and Data, Air Trends*, <http://www.epa.gov/oar/airtrends/reports.html> (last updated Apr. 28, 2008). Two of these reports contain detailed information about EPA's regulatory successes and shortfalls. See generally, AIR QUALITY STRATEGIES AND STANDARDS DIV., EPA, EPA 454/R-03-005, NATIONAL AIR QUALITY AND EMISSIONS TRENDS REPORT: 2003 SPECIAL STUDIES EDITION (2003), available at <http://www.epa.gov/air/airtrends/aqtrnd03> (explaining

also click on a sidebar that leads to specific monitoring results, such as county-by-county reports for the entire country.<sup>225</sup>

At other agencies outcome information is available, but often only in raw numbers. Despite the significance of data on workplace illnesses and injuries, OSHA's Web site contains no such information,<sup>226</sup> although there is a jump-link to a page entitled *Statistics*, which contains a jump-link to *BLS Injury, Illness and Fatality Statistics*.<sup>227</sup> The BLS Web site<sup>228</sup> offers visitors the opportunity to see various combinations of data, but it is not obvious how one could use the data that is not preassembled, such as a list of workplace fatalities from 1971 (the year OSHA was founded) to the latest year for which statistics are available. It appears BLS intended the Web site to facilitate research by academics and others familiar with its statistical databases—which is a good thing—but it is not the same thing as making basic performance data easily and obviously available to the public.

Agencies should maintain separate and distinct Web pages for their positive metrics, and agencies should clearly indicate the existence of these pages on their home pages. Readers should be able to get to the positive-metrics page with one click from the home page. Moreover, the metric

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positive air quality trends for different criteria pollutants and regions in great detail, providing information on all nonattainment regions, and providing summaries of selected academic studies of policy relevance); AIR QUALITY STRATEGIES AND STANDARDS DIV., EPA, 454/K-03-001, LATEST FINDINGS ON NATIONAL AIR QUALITY: 2002 STATUS AND TRENDS (2003), available at [http://www.epa.gov/air/airtrends/aqtrnd02/2002\\_airtrends\\_final.pdf](http://www.epa.gov/air/airtrends/aqtrnd02/2002_airtrends_final.pdf) (detailing the trends towards higher air quality for many criteria pollutants and tying these successes to various EPA regulatory initiatives).

225. The reader must click on *Air Quality Monitoring Information*, a link that leads to a page with the same name. EPA, Air Quality Monitoring Information, Air Trends, <http://www.epa.gov/air/airtrends/factbook.html> (last updated Oct. 7, 2007). One of the choices on this page is *Air Quality Statistics by County, 2006*, which leads to the EPA report EPA, AIR QUALITY STATISTICS BY COUNTY (2006), available at <http://www.epa.gov/air/airtrends/pdfs/ctyfactbook2006.pdf>.

226. OSHA is not alone in forcing researchers to go on a treasure hunt for data. For example, NASA recently released raw performance data in a manner that did not permit independent researchers to interpret the data. NASA, National Aviation Operational Monitoring Service (NAOMS) Information Release, <http://www.nasa.gov/news/reports/NAOMS.html> (last updated May 13, 2008). The agency surveyed more than 25,000 pilots from 2001 to 2004, and the results seem to suggest that flying is less safe than other statistics indicate. Thomas Claburn, *NASA Report on Air Safety Draws Criticism*, INFO. WEEK, Jan. 2, 2008, <http://www.informationweek.com/news/security/showArticle.jhtml?articleID=205207258>. NASA originally kept the report secret on the grounds that its release would needlessly scare the public about the safety of flying. *Id.* Under pressure from Congress, it made the results available to the public on December 30, 2007, in an apparent attempt to deflect news coverage. *Id.* The released data did not enable independent assessment. See *id.* (quoting Congressman Brad Miller, who complained that NASA simply “dumped . . . unanalyzed data”). NASA has asked the National Academy of Sciences to review the data, which will eventually produce an independent assessment of the data, but apparently there will be no independent assessment of NASA's data in the meantime. See Telephone Media Briefing on the Release of Aviation Safety Data with Michael Griffin, Administrator, NASA (Dec. 31, 2007) (transcript available at [www.nasa.gov/pdf/207317main\\_NAOMS\\_Media\\_Telecon\\_Transcript.pdf](http://www.nasa.gov/pdf/207317main_NAOMS_Media_Telecon_Transcript.pdf)).

227. OSHA Home Page, <http://www.osha.gov>; OSHA, Statistics & Data, <http://www.osha.gov/oshstats/index.html>.

228. OSHA, Injury/Illness Incidence Rates, <http://www.osha.gov/oshstats/work.html>.

information should be complete and presented in an accessible manner. No assembly should be required.

#### IV. Metrics and Political Agendas

Positive metrics would offer feedback to Congress, the White House, advocacy groups, and the media, and also would offer the public better information about regulatory outcomes. This reform would not necessarily mean that agencies would be held more accountable for regulatory gaps and shortfalls. But there is reason for optimism based on what we know about the policy process.

As we have noted, positive metrics identify a problem but not its solution. Regulatory failure has numerous causes. The goal of positive metrics is therefore to kick-start a discussion of what went wrong. Put another way, the goal is to put the problem of regulatory failure on the government agenda. John Kingdon defines this agenda as “the list of subjects or problems to which government officials, and people outside of the government closely associated with those officials, are paying some serious attention at any given time.”<sup>229</sup>

In Kingdon’s model, the agenda-setting process is a function of three relatively independent streams of activities that influence the policy process with the assistance of advocacy groups, policy entrepreneurs, and the media.<sup>230</sup> There is a “problem stream,” which affects the perception and definition of a problem; a “policy stream,” which is composed of policy experts who debate and define solutions for problems; and a “politics stream,” which reflects the political climate and public mood—both of which are affected by the activities of advocacy groups and policy entrepreneurs—at any given time.<sup>231</sup> A policy entrepreneur is someone who is willing to invest time, energy, and reputation in the hope of bringing about a policy change.<sup>232</sup> In Congress, Henry Waxman is the iconic example of such a policy entrepreneur.<sup>233</sup>

Kingdon focuses on the significance of “policy windows” in agenda-setting.<sup>234</sup> A policy window exists when there is an opportunity to make a change in a public policy.<sup>235</sup> Policy windows open because of a change in the political stream, such as “a change of administration, a shift in the

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229. JOHN W. KINGDON, *AGENDAS, ALTERNATIVES AND PUBLIC POLICIES* 3 (1984).

230. See *id.* at 20–21, 61 (discussing the roles of advocacy groups, policy entrepreneurs, and the media as “agenda setters”).

231. *Id.* at 20–21.

232. *Id.* at 129–31.

233. See Karen Tumulty, *The Scariest Guy in Town*, *TIME*, Dec. 4, 2006, at 47, 47 available at <http://www.time.com/time/magazine/article/0,9171,1562974,00.html> (describing Waxman’s legislative successes).

234. KINGDON, *supra* note 229, at 174–76.

235. *Id.* at 94.

partisan or ideological distribution of seats in Congress, or a shift in the national mood,” or “because a new problem captures the attention of government officials and those close to them.”<sup>236</sup> When a policy window opens, a problem moves from the government agenda to the decision agenda.<sup>237</sup> A matter on the decision agenda is in position for a legislative enactment, a decision by the President, or action by an agency administrator.<sup>238</sup>

Positive metrics can promote agenda setting in two ways. First, positive metrics would flow into the “problem stream,” elevating the perception that regulatory failure is a significant and important national problem that deserves the attention of government officials and those around them. Second, positive metrics would assist government officials, advocacy groups, policy entrepreneurs, and others in the political stream to move the issue of regulatory failure to the decision agenda. As Kingdon warns, the position of an issue or item on the decision agenda will be fleeting if a problem cannot be found.<sup>239</sup>

Positive metrics should assist consumer and environmental advocacy groups to hold agencies accountable despite the fact that these groups have fewer resources than their business counterparts.<sup>240</sup> The communication of policy problems is an important aspect of interest group activity.<sup>241</sup> At the present time, consumer and environmental groups, for the most part, must create the metrics for themselves and also communicate them in the political stream.<sup>242</sup> Even the EPA Web site, which contains ample information about regulatory gaps and shortfalls concerning the CAA, does not create the type of accessible and obvious metrics that we seek. By reducing this burden, positive metrics will assist advocacy groups in making the case for regulatory ineffectiveness, and thereby make it more likely that such problems will be recognized in the agenda-setting process.

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236. *Id.* at 176.

237. *See id.* at 174–75 (explaining that the decision agenda is composed of a small subset of issues on the government agenda that are ripe for legislative or executive action, and noting that the opening of a policy window is a key opportunity to obtain such legislative or executive action).

238. *Id.* at 175–76.

239. *Id.* at 187.

240. *See supra* notes 62–80 and accompanying text.

241. *See* Michael E. Kraft & Diana Wuertz, *Environmental Advocacy in the Corridors of Government*, in *THE SYMBOLIC EARTH: DISCOURSE & OUR CREATION OF THE ENVIRONMENT* 95, 97 (James G. Cantrill & Christine L. Oravec eds., 1996) (observing that the “communications strategies of environmental organizations are tied intimately to the larger process of agenda setting and policy change”).

242. *See generally, e.g.*, DIANE BAILEY ET AL., *NATURAL RES. DEF. COUNCIL, HARBORING POLLUTION: THE DIRTY TRUTH ABOUT U.S. PORTS* (2004), available at <http://environmentnow.org/pdf/cca-reports-harboring-pollution-the-dirty-truth-about-US-ports.pdf> (documenting the failure to effectively reduce air and water pollution in and near U.S. ports); James Parks, *Millions of Workers Lack Even Most Basic Safety Protections*, AFL-CIO NOW BLOG: NEWS, Apr. 26, 2007, <http://blog.aflcio.org/2007/04/26/millions-of-workers-lack-even-most-basic-safety-protections> (noting the undercounting of injuries and illnesses by BLA and linking that undercounting to lack of effective regulation).

## V. Conclusion

Shortly before this Article went to press, the United States Supreme Court decided *Riegel v. Medtronic, Inc.*,<sup>243</sup> an opinion with far-reaching implications for the future of health and safety regulation. Holding that the Medical Device Amendments to the Food and Drug Act preempted state common law,<sup>244</sup> the Court raised the stakes for an effective FDA sky-high. Unless Congress reverses this misguided decision, any careless, poorly documented, or simply mistaken conclusion by the government's scientific experts will leave severely injured consumers without any recourse in the courts. Just as unfortunately, the indirect message of the opinion is that manufacturers of medical devices, and potentially thousands of other products, are wise to invest significant resources in lobbying to influence the outcome of regulatory decisions because success will also provide tort immunity. Agencies will need to be quite sturdy to withstand such newly invigorated campaigns.

Placing such an enormous burden on the shoulders of a fragile bureaucracy emphasizes as few other developments could the timeliness, and indeed the urgency, of the reforms we advocate here. Positive metrics should prepare the way for effective oversight, provide an early warning of impending regulatory failure, and prompt a diligent search for solutions that will rehabilitate the regulatory safety net. In a system of justice that narrows the remedies available to injured consumers down to effective prevention, these steps seem like the least we can do.

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243. 128 S. Ct. 999 (2008).

244. *Id.* at 1001.