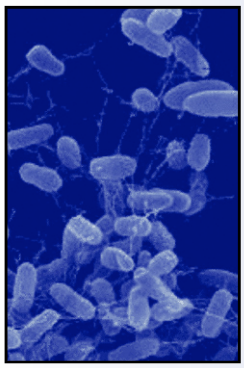


Regulatory Dysfunction:

How Insufficient Resources, Outdated Laws, and Political Interference Cripple the 'Protector Agencies'

By CPR Member Scholars
Sidney Shapiro and Rena Steinzor,
and CPR Policy Analyst Matthew Shudtz

CPR CENTER FOR PROGRESSIVE REFORM

CENTER FOR
PROGRESSIVE REFORM
WHITE PAPER #906

August 2009

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information. The Center for Progressive Reform is grateful to the Public Welfare Foundation for funding this report, as well as to the Bauman Foundation and the Deer Creek Foundation for their generous support of its work in general.

This white paper is a collaborative effort of the following Member Scholars and staff of the Center for Progressive Reform: **Sidney Shapiro** holds the University Distinguished Chair in Law at the Wake Forest University School of Law and is the Associate Dean for Research and Development. He is a member of the board of directors of the Center for Progressive Reform. **Rena Steinzor** is the Jacob A. France Research Professor at the University of Maryland School of Law and the President of the Center for Progressive Reform. **Matthew Shudtz** is a Policy Analyst at the Center for Progressive Reform.

For more information on the authors, see page 20.

www.progressivereform.org

Direct media inquiries to Matthew Freeman at mfreeman@progressivereform.org or Ben Somberg at bsomberg@progressivereform.org.

For general information, email info@progressivereform.org

Acknowledgments

The Center for Progressive Reform is grateful to the Public Welfare Foundation for its generous support of this project.

Printed in the U.S.A.

Executive Summary

In the last several years, dramatic failures of the nation's food safety system have sickened or killed tens of thousands of Americans, and caused billions of dollars of damages for producers and distributors of everything from fresh vegetables to granola bars and hamburger meat. In each case, the outbreak of food-borne illness triggered what can only be described as a frantic scramble by health officials to discover its source. Inevitably, the wrong lead is followed or a recall is too late or too narrow to prevent further illnesses, and the government has to defend itself against withering criticism. Americans expect more from the experts at the Food and Drug Administration (FDA) and their counterparts at the Department of Agriculture, but the simple truth is that they are ill-equipped to deliver.

The food safety system typifies the debilitated state of the entire regulatory system that Americans rely upon to protect their health, safety, and environment. The five "protector agencies" – FDA, the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), the National Highway Traffic Safety Administration (NHTSA), and the Environmental Protection Agency (EPA) – all grapple with hefty responsibilities to protect the American public from constantly evolving hazards. The agencies have done an adequate job of eliminating or managing the basic hazards of modern industrial society. Every new car has seatbelts and passive restraints, the use of lead in gasoline and residential paint has been eliminated, and air quality has improved in many areas. Unfortunately, this progress has been marred by a series of high-profile failures. OSHA has failed to prevent musculoskeletal injuries, the leading cause of workplace illness; billions of consumer products enter the country from foreign manufacturing sites that are never inspected by product safety specialists; and the EPA is just beginning to map out a strategy for combating climate change, a threat that could eliminate 40 percent of species and lead to the relocation of hundreds of millions of people by the turn of the century.

The "protector agencies" are in a debilitated state, in need of more resources, improved laws, and decentralized decisionmaking.

The agencies' inability to act swiftly and decisively in the last several decades is largely the result of four problems: severe shortfalls in funding, outdated authorizing statutes, political interference, and an aging, demoralized civil service. Regulatory dysfunction begins with funding gaps that defeat agency efforts to fulfill the statutory mandates assigned by Congress. These shortfalls, which push the agencies into a state of constant default on their most important missions, are compounded by congressional neglect of its oversight and reauthorization responsibilities. With two exceptions – the Consumer Product Safety Commission Improvement Act and the FDA Amendments Act of 2007 – Congress has made no effort to renew and update the statutes in at least two decades. Compounding these problems, the protector agencies operate under the watchful eye of White House political staff who frequently and freely substitute their own judgments for those of agency staff, offering a back door for special interests disappointed in decisionmaking by agency experts to exert inappropriate influence, most often behind closed doors. When this happens, agencies are blocked from providing the protective health, safety, and

environmental standards that statutes require and the public expects, and agency staff become demoralized.

The solutions to these problems – statutory amendments, an improved budget process, decentralized decisionmaking, and civil service reforms – are not simple fixes. But the alternative is a regulatory system that reverts to a purely reactionary mode, leaving public health, safety, and environmental protection to the whims of the marketplace.

Introduction

What, exactly, do we mean by "regulatory dysfunction?" We use it here to connote severe failures in performance measured by what Congress told the agencies to do. For the protector agencies, such regulatory dysfunction is manifest in:

1. Late, slow, and even nonexistent efforts to tackle the most obvious and pressing threats to public health, worker safety and the environment;

2. Failure of the most rudimentary implementation efforts – absence of routine inspections of manufacturing facilities, delays in writing or renewing permits that control industrial activities, fatal mistakes in the approval of new drugs and the monitoring of drugs already on the market, and abdication of responsibility for the safety of the growing number of imported foods and consumer products; and,

3. The collapse of enforcement of regulatory requirements against consistent violators and scofflaws.

Unfortunately, all of these cross-cutting problems cripple the effectiveness of each of the five federal agencies that Congress created to protect health, safety, and the environment. Despite significant differences in the history, statutory missions, and contemporary agendas of the five agencies, the symptoms of dysfunction are remarkably similar.

- **OSHA:** The Occupational Safety and Health Administration, an agency within the U.S. Department of Labor, is responsible for ensuring a safe and healthy workplace for almost every private-sector worker. (OSHA does not regulate the self-employed, family farms, and certain other occupations covered by other federal agencies.) The agency has the power to promulgate regulations that fall into two categories: safety regulations, which protect workers from such hazards as collapsing cranes or dangerous moving parts; and health regulations, which protect workers from chemical hazards like benzene or chromium. Many of the existing standards are based on science from the 1940s and 1950s and new standards are few and far between. Today, OSHA staff spend most of their time on enforcement or "compliance assistance." Even so, the agency is so bereft of resources that it would take more than 200 years to inspect every workplace in the United States. About half of the states in the United States have their own worker protection programs, which operate with financial assistance from the federal government so long as they can show that their programs are at least as protective as the federal program. OSHA is supposed to ensure the adequacy of these programs, but this too has become a neglected function.

- **FDA:** The Food and Drug Administration is the oldest of the five protector agencies, and its work may have the most immediate impact on public health, since it regulates the safety of 80 percent of the food supply (everything but meat,

poultry, and some farmed fish), as well as all over-the-counter and prescription drugs, vaccines, medical devices, the national blood supply, veterinary medicines, and even cosmetics. All told, the products regulated by FDA account for a full 25 percent of U.S. consumer spending. The agency has a variety of regulatory tools at its disposal, each tied to a particular statutory goal. For instance, to regulate drugs and devices, FDA uses an "approval" system. For food safety, the agency has labeling and contamination standards. Unfortunately, these tools are not always effective: When the agency approved Vioxx, it failed to take adequate steps to monitor the drug's use after it hit the market. As a result, between 88,000 and 139,000 Americans suffered Vioxx-related heart attacks or strokes. Various resource constraints also hamper the agency's ability to fulfill its mission of ensuring food safety.

- **NHTSA:** Following the publication Ralph Nader's groundbreaking exposé of the auto industry, *Unsafe at Any Speed*, Congress created the National Highway Traffic Safety Administration with the broad responsibility for promoting traffic safety on the millions of miles of roads that criss-cross the country. The agency addresses two of the three fundamental causes of automobile crashes – driver behavior and vehicle safety. (The other cause is the road itself, which falls under the purview of other officials in the U.S. Department of Transportation.) NHTSA's efforts to curb injury rates focus heavily on changing driver behavior ($599 million in grants to states for behavioral safety programs plus $107 million on behavioral safety research, versus $121 million on vehicle safety programs). Yet injury rates have stopped declining in recent years and traffic fatalities remain the number one cause of death for Americans between the ages of four and 34.

- **EPA:** The Environmental Protection Agency is responsible for administering perhaps the broadest set of congressional mandates, covering everything from the pesticides and fertilizers used on U.S. crops, to the engineering controls used to minimize the release of toxics into the air and water, to the quality of the drinking water that flows out of our faucets. The rules and regulations flow from EPA headquarters, but once those regulations are in place, much of EPA's work is administered and enforced in partnership with officials at state and local environmental protection agencies. Having long ago addressed those environmental problems that could be considered "low-hanging fruit" (lead in gasoline and uncontrolled releases of air toxics), EPA is now faced with second-generation environmental concerns that are harder to resolve. For example, tackling climate change will be a herculean task.

- **CPSC:** Congress established the Consumer Product Safety Commission in 1972 to be the nation's premier consumer protection agency. It is an independent agency designed to be led by a bipartisan group of five commissioners appointed by the President and confirmed by the Senate, but ideological battles over business-friendly

nominees during the Bush Administration resulted in that number dwindling to two, crippling the agency's effectiveness. The statute that created the CPSC, the Consumer Product Safety Act (CPSA), granted the agency a broad array of powerful regulatory tools – from mandatory safety standards to product recalls. Its jurisdiction covers tens of thousands of products in the U.S. marketplace. A growing number of those products are imported from foreign countries, making CPSC's job of ensuring proper adherence to its safety standards that much more complex. Eighty percent of toys found in U.S. stores come from China, but CPSC employs only 15 inspectors nationwide to ensure their safety. In 2007, the "year of the recall," literally millions of toys were recalled by their American importers because they were slathered with lead paint or contained toxic substances that posed acute threats to children's health.

To be sure, the five protector agencies have patched together a safety net that has greatly improved the quality of life in the United States. The rate of injury and death in the workplace and on U.S. roads has declined with the implementation of OSHA and NHTSA standards, the quality of food on our tables is generally very good, our medicines are generally safe, and our water and air is far less polluted than it was in the 1970s – a time when the Cuyahoga River was so polluted that it caught fire and cities were covered by dense clouds of pollution. But the safety net has gaping holes. For every statistic that shows improvements in quality of life resulting from the protector agencies' work, there is a grim tale of a dangerous product that should not be in the marketplace or an avoidable death that leaves us wondering why the government has not done a better job.

This paper will answer that question; at least, to a point. The protector agencies each have their own problems, but there are some overarching reasons why FDA, OSHA, EPA, CPSC, and NHTSA are in a dysfunctional state. These problems start with hollow government. We continually ask agencies to do more and more with less and less, forcing them to make trade-offs that undermine statutory goals. Then there is the problem of outmoded laws – laws that did not properly delegate to the agencies sufficient power to achieve statutory goals of safe workplaces, a safe marketplace, or a clean environment, particularly as these challenges evolved over the years and as new hazards emerged. But insufficient resources, weak statutory authority and poor enforcement regimes are just the beginning. Centralized power in the White House over even the most minute details of regulatory decisionmaking hinders the expert staff at the protector agencies from pushing bold initiatives to carry out their statutory obligation to manage health, safety, and environmental hazards. All of these factors delegitimize, de-emphasize, and demoralize agency staff, ultimately leading to a vicious cycle of dysfunctional agencies. The problems are serious but redressable, and now is the time for cross-cutting reforms to reinvigorate the protector agencies.

For every statistic that shows improvements in quality of life resulting from the protector agencies' work, there is a grim tale of a dangerous product that should not be on the marketplace or an avoidable death that leaves us wondering why the government has not done a better job.

Hollow Government: Asking Dysfunctional Agencies to Do More With Less

The protector agencies are chronically underfunded. For decades, the U.S. population and workforce have grown, the consumer products industry has ballooned, and threats to the environment have become increasingly intractable. Yet all the while, the protector agencies' budgets, staff, and resources have failed to keep pace.

The CPSC is the poster child for agencies that strive to achieve broad statutory mandates with woefully insufficient resources. It is responsible for ensuring the safety of almost every durable good that U.S. consumers buy, from lamps to computers. Its jurisdiction covers more than 15,000 categories of products; or, put another way, it covers everything but food and drugs; automobiles, boats, and airplanes; alcohol, tobacco, and firearms. The consumer goods that CPSC regulates are designed, manufactured, and sold through a complex, multi-billion dollar international supply chain, yet the agency operates with a staff of just over 400 employees working on a what is, comparatively speaking, a shoestring budget of about $107 million.

CPSC was not always in such dire straits. When the agency was formed, much of the design, manufacture, and distribution of consumer goods occurred within U.S. borders. In its heyday during the first ten years of its existence, the agency had about twice as many employees as it does now (nearly 900 in 1981), and its budget, when adjusted for inflation, was much higher ($145 million in 1976). But, tragically, as the consumer products industry grew and spread around the globe, CPSC shrunk. President Reagan and his anti-regulatory allies in Congress slashed the agency's budget in the early 1980s, and no Congress or President since has had the will to reinvigorate the agency. The results are clear in CPSC's data: After a 25 percent drop in injury rates during the first five years of the agency's existence, the rate leveled off over the next 20 years.[1]

In recent years, a deluge of high-profile product-safety disasters spurred Congress to reconsider CPSC's authority and resources. In the 2008 Consumer Product Safety Improvement Act, Congress mandated specific new requirements for lead and phthalate content in children's toys, required mandatory safety testing and certification, expanded whistleblower protections, and increased penalties for violations of the Act. But the statute took no meaningful action on the import problem, directing the agency to report back to Congress on how to deal with this massive problem in 2011.

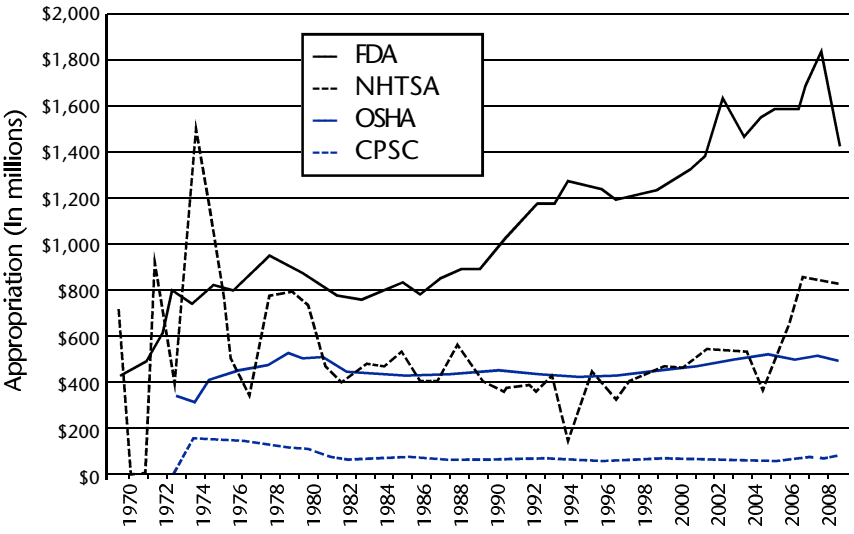
CPSC's fate exemplifies many of the hollow-government problems common to all five protector agencies. Like CPSC, all of the protector agencies have seen their jurisdiction expand greatly since they were first established. Yet, over the last three decades, CPSC, OSHA, NHTSA, and EPA have all had to manage their increasing workload with a stagnant budget. Only FDA has seen meaningful increases in its annual appropriations, but even those increases are woefully inadequate with respect to food safety.

Congress is the main culprit behind agencies' dwindling resources and growing responsibilities, the root of problem being the legislature's flawed budget process. The problem begins with the disconnect between authorizers and appropriators. House and Senate authorizing committees are responsible for writing the statutes that define the agencies' missions and mandates, but they have no formal means for consulting or establishing accountability with the appropriations committees. This structural flaw concentrates power over the budget away from the legislators and congressional staff who have the greatest understanding of the agencies' inner workings into the hands of legislators whose viewpoint tends to overlook the protector agencies. Case in point: In 2005, the House Appropriations subcommittee with power over EPA's budget had just six staff (whose attention was split between EPA and a number of other agencies). In contrast, the House Energy and Commerce Committee (in charge of much of EPA's authorizing legislation) had 61 staff.

To make matters worse, the protector agencies are recipients of the discretionary spending that is getting increasingly squeezed out of the budget. As the population ages and healthcare costs rise, Medicaid, Medicare, and Social Security costs take up an increasing proportion of federal revenues. For good reason, Congress is loath to cut these programs, which provide daily necessities to millions of Americans. National defense spending and debt-reduction often get higher priority than the protector agencies, too. In the end, the protector agencies are left fighting over table scraps. The *combined* budgets of all five protector agencies in 2008 was just over $10 billion, or *less than one-half of one percent* of the $3.5 trillion budget that Congress approved on April 2, 2009.

Congress is not solely to blame for the protector agencies' resource shortages. The White House, too, deserves some censure. Regardless of the particular spin any recent President has put on his annual budget, the numbers never change much and the protector agencies continue to get short shrift. The problem is that OMB is focused on the wrong questions when it collects budget requests from the agencies. Rather than asking the agencies to "true-up" their budgets by developing a list of statutory mandates, the tasks it needs to accomplish to achieve those mandates, and the resources needed to complete those tasks (in money, employees, and time), OMB asks them to compose a budget request based on incremental changes from previous years' appropriations.[2]

Protector Agency Budgets (adjusted for inflation)



GPRA has prompted agency budget requests that are designed to avoid cuts, rather than secure the full appropriations they need to accomplish their statutory missions.

Although the White House might significantly improve the lot of the protector agencies by submitting budget requests to Congress that reflect the agencies' true needs (not just their desired incremental changes from the previous year), the skewed focus of the budget request is based in large part on the Government Performance and Results Act (GPRA).[3] GPRA instilled in OMB the authority to collect and review annual performance plans prepared by each federal agency. OMB then took this authority and developed a system known as PART (for "Performance Assessment Rating Tool"), which was intended to "identify a program's strengths and weaknesses to inform funding and management decisions aimed at making the program more effective."[4] But since Republicans in Congress have threatened to cut agencies' budget requests if programs receive bad PART ratings, the process has encouraged agencies to develop vague goals and the entire process devolves into a meaningless charade. In fact, the charade conceals a more dangerous problem: Since agencies' budget requests are based on their PART reports, their budget processes begin and end with goals that are designed to avoid budget cuts, rather than to secure the full appropriations they need to accomplish their statutory missions.

While PART and the congressional budget process are the roots of the protector agencies' resource problems, the growth of the problems is due in large part to anti-regulatory zealots' manipulation of PART and the appropriator/authorizer divide. A bad PART rating is as likely to be a result of insufficient resources as it is a reason to take money or personnel away from a program. But when the appropriations committee is separated from the authorizing agency that better understands the needs of the agency, members of appropriations committee who want to shrink the government have a much easier time making their case.

Holes in the Safety Net: Outmoded Laws

The protector agencies' ability to respond to all of the health and environmental threats in their domain is also constrained by laws that were conceived at a time when Congress had a fundamentally different understanding of both the threats to be regulated and the agencies' capacity to address those threats. In the intervening years, knowledge about science, public administration, and regulatory policy has evolved, but the statutes that set the boundaries on the protector agencies' powers have remained largely the same.

For example, the Toxic Substances Control Act (TSCA) requires the manufacturer of a new chemical substance to tell EPA what it knows about the risk the substance poses for people and the environment prior to distributing and selling it. (This is called a "premanufacture notice.") EPA also has the authority to issue "test rules," which are administrative orders that force manufacturers to design and conduct tests on a chemical's toxicity.

Unfortunately, both of these provisions have significant shortcomings. A manufacturer can simply submit a premanufacture notice without any toxicity data as long as it has not yet done any testing. Indeed, only 15 percent of those notices arrive at EPA with any health or test data.[5] More problematic, though, is that Congress drafted TSCA's test rule provision in a way that puts EPA in a classic Catch-22: EPA can only exercise its power to issue a test rule after establishing that it needs more information about a chemical because the chemical "may present an unreasonable risk of injury to health or the environment." Of course, establishing the potential unreasonable risk is only possible if EPA has information pertaining to risk in the first place, which it manifestly does not have, otherwise there would be no need for the test rule.

The reason that a fundamental section of a major environmental protection statute includes such a fatal flaw can be linked back to the way Congress operates in enacting protective legislation. Congress has organized itself into a complex of specialized committees and subcommittees, whose membership is largely self-selected. Legislators with a particular interest in a certain area (*e.g.,* environmental protection or worker safety) will gravitate toward the committees with jurisdiction over that area. Thus the committees, which are the true proving grounds for any piece of legislation, are populated largely by "preference outliers"[6] who are the most receptive to overtures from special interest groups with well-heeled lobbying divisions.

But more than Congress's structural attributes, the legislative process is the source of delay in reauthorizing important public health statutes. A dizzying number of steps must be taken to move a piece of legislation through committee markups, onto the floor of Congress, through the amendment process, into conference committee, and, eventually, to the President's desk. Each stage in this process provides a determined minority with the power to kill – or at least maim – a disfavored piece of legislation. And with the powerful economic and industrial forces that typically align in opposition to health, safety, and

environmental legislation, each of these "vetogates" in the legislative process is a major hurdle for the legislation's proponents to overcome.

For major legislation that is almost preordained to make it out of committee and to the Senate floor, the threat of a filibuster is the most daunting vetogate. In fact, as the current Congress considers health care reform, climate change legislation, and new labor laws, the proponents of these measures often claim that they are legislating to the preferences of the one Senator whose opposition is just malleable enough to ensure a 60th vote for cloture.

The power of special interests to shape health and safety regulation is perhaps most evident in the weak enforcement provisions written into the Occupational Safety and Health Act (OSH Act) and the consumer protection statutes. The potential criminal penalties for killing an endangered species are actually more stringent than the criminal penalties for willful violations of workplace safety and health standards that lead to a worker's death. A conviction for a knowing violation of the Endangered Species Act can bring a fine of $50,000 and a year in prison,[7] whereas penalties for a first-time conviction for a willful violation of the OSH Act that results in a worker's death are limited to $10,000 and six months in jail.[8] Perhaps most telling, "citizen suit" provisions that empower anyone in the United States to act as a private attorney general to enforce environmental laws are common, but the same is not true for worker and consumer protection laws like the OSH Act, Consumer Product Safety Act, and National Traffic and Motor Vehicle Safety Act.

Besides weak enforcement regimes, the other legal constraint on agencies that can be linked directly to congressional structure and process is ambiguous statutory commands. Too often, legislators avoid the most thorny issues in a piece of legislation, saving themselves from a bitter political dispute by punting the issue to the agencies. Though it is often done under the guise of letting the non-political, technocratic experts within the agency decide on the best policy, in reality, agency decisionmakers are subject to at least the same amount of interest group crossfire as Members of Congress; they just do not have to run for reelection. The classic example of ambiguous statutory language that Congress cannot muster the will to fix is the central jurisdictional question in the Clean Water Act. The 1972 Clean Water Act gave EPA the power to regulate the discharge of pollutants into all "navigable waters" in the United States, which were defined as "the waters of the United States, including the territorial seas."[9] Exactly what "the waters of the United States" comprise is a question that continues to confound the agency, particularly as it works with the U.S. Army Corps of Engineers to preserve the integrity of our nation's wetlands. Yet, on numerous occasions, Congress has failed to pass legislation that would provide clarification.[10]

Notwithstanding vetogates and legislative inertia, some health, safety, and environmental statutes have made it through Congress and have been signed into law by the President in a relatively strong form, only to be weakened or hampered with unwieldy analytical requirements by the courts.

The OSH Act is a prime example. The law gives OSHA the authority to promulgate permissible exposure limits (PELs) for toxins released into workplace air. The agency was empowered to set PELs using expedited procedures within the first two years of its existence, in order to tackle the most hazardous workplace conditions quickly. But after that first phase of rulemaking, Congress expected OSHA to update PELs to conform with emerging science using standard administrative procedures. This scheme might have worked smoothly but for the *Benzene* case,[11] where the Supreme Court saddled OSHA with the burden of quantifying a significant risk posed by each toxin before the agency regulates the chemical under the OSH Act. This requirement was not imposed by Congress in the statute but rather crafted out of whole cloth by the high court in 1980. Just over a decade after the *Benzene* decision, the Eleventh Circuit dealt OSHA a second body blow. After the *Benzene* case, OSHA's progress in setting new standards had slowed to a trickle, but it made an ambitious attempt to update hundreds of health standards in one massive rulemaking. The Eleventh Circuit invalidated this approach, holding that OSHA's recitation of scientific evidence regarding the health threats posed by each chemical was not enough – the agency also had to determine the precise, numerical risk posed by each chemical. Nearly 400 new PELs were set aside, and OSHA has since resigned itself to undertaking the arduous task of precisely quantifying individual chemical risks before suggesting new standards. The burden on agency staff is reflected in the fact that OSHA has only finalized two new standards since 1997.

None of this is to say that courts should abstain from reviewing agency actions – judicial oversight is a powerful mechanism for ensuring accountability in the regulatory process – or that the legislative process should somehow be less susceptible to compromise. Rather, the central theme here is that a functional regulatory system is fundamentally dependent on flexible statutes and a Congress that is willing to constantly reassess the adequacy of the agencies' governing statutes.

Political Interference: Backdoor Subversion of Agency Expertise

On a daily basis, agency staff are engaged in the important, if mundane, analysis of science and policy that enables them to understand and respond to the threats facing workers, consumers, and the environment. Unfortunately, over the last 30 years, this work, which Congress specifically delegated to agencies because of the specialized training and expertise of their staff, has increasingly come under strict oversight and control by the political denizens of the White House. This centralization of the regulatory decisionmaking process is not unique to Republican or Democratic administrations. It stems from the perennial and bipartisan electioneering strategy of decrying the unwieldy federal bureaucracy and promising to rein it in with new and innovative management schemes. Each successive president has invented new ways to insinuate White House staff and political appointees into the rulemaking process by establishing new procedural hurdles that agencies must negotiate before finalizing protective regulations. In addition to undermining Congress's goal of regulating health and safety based on expert analysis of the science and policy, the centralization of regulatory decisionmaking inevitably slows the regulatory process without necessarily improving regulations.

The evolution of EPA's Integrated Risk Information System (IRIS) offers a poignant example of how centralization of the regulatory process can impede beneficial regulation. In 1985, EPA staff determined that there was a need to develop a centralized database of all the various chemical risk assessments that were being developed around the agency's program and regional offices. These risk assessments were the cornerstones of regulatory decisions ranging from how to control toxins in the air and water, to how clean the soil would have to be at Superfund sites around the country. From 1985 until 2004, EPA scientists in the Office of Research and Development (ORD) coordinated the addition of new chemical assessments to the IRIS database. But in 2004, John Graham, Administrator of the Office of Information and Regulatory Affairs (OIRA, an office in the White House OMB), initiated a complete redesign of the IRIS assessment process that would eventually give OMB a powerful voice in every stage of the scientific assessment process.[12] Congressional staff have uncovered evidence that individuals at OMB went so far as to make editorial comments on specific chemical profiles, "comments that would have changed the import and meaning of the scientific findings" made by EPA scientists.[13]

Since the White House became intimately involved in the IRIS assessment process, EPA staff have struggled to cope with the added political pressures. Only a few chemical profiles are added to the database each year, ultimately hampering EPA's ability to develop second-generation air pollution regulations and cleanup standards for major Superfund sites.

The IRIS example is a powerful demonstration of how the White House has infiltrated the aspects of the regulatory system that are clearly within the realm that Congress expects should be insulated from political pressure. Chemical profiles in the IRIS database are "pre-

regulatory" documents that do not necessarily dictate the content of EPA regulations. They answer some of the scientific questions that EPA decisionmakers will ultimately consider in light of other scientific evidence and policy considerations, but they do not dictate even minimum levels of pollution control. Simply put, White House involvement in the development of IRIS profiles is a power grab that discredits EPA's scientific experts. During a congressional hearing following the Obama Administration's decision to retain centralized review of the IRIS decisions, both the the Chairman (Rep. Brad Miller (D-NC)) and the Ranking Member (Rep. Paul Broun (R-GA)) of a House science subcommittee expressed serious reservations about political interference with the IRIS process.[14]

Disturbing in its own right, the IRIS example only hints at the increasingly complex and opaque procedural requirements that presidents and Congress have imposed. Today, agencies might have to go through more than 100 discrete analytical steps before they can adopt a regulation.[15]

Executive Order 12,866 holds the dubious distinction of being the main conduit through which the White House exerts control over the federal regulatory process. Since it was first signed by President Reagan in 1981, the Order has been upheld (and slightly modified) by each successive President. It requires agencies to draft a Regulatory Impact Analysis (RIA) for each rule that it proposes to enact, and to submit the RIA to the Director of OMB prior to finalizing the rule. The main thrust of the RIA is supposed to be a cost-benefit analysis of the proposed rule (a questionable end in itself), but the White House and OMB have added more and more analytical mandates over the years.

Requiring agencies to undertake the many analyses established through Executive Order is bad enough, as it forces the agencies to divert resources from assessing manageable hazards to endless regulatory review, but OMB makes things worse by using these tools for more than just oversight – they use RIA review as a way to demand substantive changes to regulations developed by expert agencies. OMB posts on its website some basic information about meetings it holds with non-government entities (trade associations, labor groups, environmentalists) on particular rules that it is reviewing, so it is not hard to connect the dots between the special interest groups' desired outcomes and OMB's requests for agencies to change their rules.

OIRA is the primary choke point for new regulations as they go through the E.O. 12,866 review process, but there are numerous other White House offices that the protector agencies must accommodate before they can finalize a new regulation. For example, one attempt to characterize White House involvement in EPA rulemaking revealed that as many as 19 White House offices were involved in reviewing EPA rules.[16] And a Pulitzer Prize-winning series in the *Washington Post* described in detail how Vice President Richard Cheney became intimately involved in many aspects of U.S. energy policy during the Bush years, wrangling from the hands of expert agencies decisions about oil and gas drilling, power plant regulation, and other questions best left to the regulatory experts.[17]

Centralized regulatory decisionmaking contributes to regulatory dysfunction mainly in terms of its opportunity costs. As explained above, the protector agencies have been tasked with congressional mandates that would be difficult to accomplish with resources many times greater than what they have. So every person-hour and every dollar spent complying with analytical requirements or resolving issues put forward in the recursive RIA reviews is a person-hour or a dollar *not* spent analyzing emerging hazards or advancing other regulatory priorities. The costs of delay are paid out continually by workers and consumers whose health and well-being would benefit from protective regulation, not to mention the environment.

Discredited and Demoralized: A Battered Federal Workforce

By this point it is clear, the public servants who work tirelessly to protect U.S. workers, consumers, and the environment are themselves in need of protection. Insufficient resources, growing responsibilities, numerous pre-rulemaking procedural requirements, overweening White House oversight, and perennial complaints about "bureaucratic red tape" all contribute to a demoralized federal workforce. Sadly, the troubles infect every level of the agencies.

> "I have never seen morale at a lower point than we currently have in EPA. Good scientists are leaving because they can no longer put up with all the micro-management that is heaped on them in lieu of effective administrative leadership."[18]
>
> — *Anonymous scientist from EPA's Office of Research and Development, in response to a survey on scientific integrity sponsored by the Union of Concerned Scientists*

> "[Y]ou really felt uneasy about being federal employees. People would look at you as if you had cancer."[19]
>
> — *Anonymous former government technical specialist, in an interview about the emotional impacts of "bureaucracy bashing" during elections*

These quotations underscore the notion that federal employees' consternation stems primarily from a feeling that their hard work, dedication, and expertise are regularly marginalized by politicians. To be sure, this problem was not unique to the Bush Administration, nor was it a function of Republican control of the White House. President Clinton famously clashed with FDA over the agency's proposal to provide federal funding for needle exchange programs, ignoring strong evidence of the programs' public health benefits due to a political concern about "looking soft" on drug abuse. Regardless of who controls the White House, federal employees usually take pride in the fact that they were hired for their knowledge and expertise, which they continue to cultivate through long careers in service of an agency mission with which they identify (the average federal civilian employee has been on the job for more than 16 years).[20]

A demoralized federal workforce threatens to add to regulatory dysfunction on two important fronts. First, it is difficult to retain workers who feel undervalued. Seventy-six percent of the Senior Executive Service (SES), a cadre of career employees who operate at the edge of the merit-based and political appointments systems, with the job stability of the former and the management power of the latter, are eligible to retire in 2012 and more than a third of them are expected to exercise the option. With the disparity between federal pay and private-sector pay increasing for many important jobs, talented younger workers are also heading for greener pastures.[21] The second issue, which exacerbates the negative consequences of growing gaps in the federal workforce, is that demoralized workers who

remain on the job are less likely to be strong ambassadors who will attract the best and brightest new employees.

The potential problems caused by a "brain drain" at the entry-level and SES ends of the workforce spectrum will only be magnified if another chronic problem is not resolved — a significant increase in the number of managers between front-line civil servants (*e.g.,* food safety inspectors or OSHA compliance safety and health officers) and the people whose decisions actually carry some legal heft (*e.g.,* the FDA Commissioner or OSHA Administrator).

Paul Light, the prominent political scientist who coined the term "thickening" to describe the increasing distance between front-line civil servants and agency heads, found that between 1960 and 1995, the number of layers of senior-level appointments at federal agencies tripled, and the number of occupants of each layer grew geometrically.[22] Extra layers of management, of course, mean extra rounds of review for everything that a front-line civil servant does, which can actually create disincentives for employees who have lost confidence that their efforts will survive the gauntlet of duplicitous reviews.

This particular form of regulatory dysfunction is more than just an incidental concern about federal employee satisfaction, it is also a matter of public health and safety. With agency budgets staying relatively stagnant, more managers results in fewer inspectors and scientists investigating potential hazards. FDA's medical device approval system is one example of a suffering program. The Government Accountability Office (GAO) has found that FDA does not review all high-risk medical devices through its most stringent premarket approval process.[23] Career staff who work in the device approval office have alleged that political interference in the device approval process is rampant and brushed under the table by managers who are more concerned with protecting political higher-ups than protecting patients with risky devices.[24]

A New Path: Leading the Dysfunctional Agencies to a More Functional Future

Americans expect their government to protect them – from unscrupulous lenders and bear markets they cannot control, from terrorist threats and natural disasters they cannot foresee, and from employers and product manufacturers whose duties to shareholders do not adequately capture their duties to their employees and customers. Americans also expect clean air, clean water, and an environment that is protected for future generations. While the protector agencies have done a decent job at making inroads toward a truly safe and healthy society, their efforts to this point have been concentrated mainly on picking the low-hanging fruit. OSHA adopted basic health and safety standards that reflected early (1940s to 1950s) science about those hazards. EPA required enough water pollution controls to prevent rivers from burning. And NHTSA has ensured that all new cars come with some sort of passive restraint system. But the regulatory system that produced these protections and delivered some immediately positive results is ill-equipped to handle the current generation of hazards. The hollowed-out agencies are still operating under laws that are not well-designed to handle these hazards, increasingly centralized decisionmaking has slowed the regulatory process to the point where it is almost non-responsive to emerging threats, and the federal workforce is being stretched to the brink of failure.

It is time that Congress, the White House, and agency political heads stop tinkering with minor adjustments to the regulatory process and start working toward fundamental changes that will revitalize the protector agencies.

A Positive Vision of Government

The first thing the agencies need is a citizenry, legislature, and Executive Branch who share a positive vision of government. To his credit, President Obama is leading the way. Instead of resorting to the hackneyed tactic of bureaucracy bashing, he used his 2008 presidential campaign to espouse an affirmative view of the role of government in our lives:

> Now, understand, I don't believe that government can or should try to solve all our problems. You don't believe that either. But I do believe that government should do that which we cannot do for ourselves—protect us from harm; provide a decent education for all children—invest in new roads and new bridges, in new science and technology.[25]

Polls indicate that President Obama's depiction of our shared vision of government is accurate: A majority of Americans support broad government intervention to help us deal with issues ranging from greenhouse gas emissions[26] to health care.[27]

But Americans have a longstanding love/hate relationship with government. That is not surprising. For years, politicians have railed against "red tape" and "bureaucracy," painting a portrait of government employees indifferent to agency missions, lazy, and incompetent. The truth, however, is that many of those politicians helped create the problem, forcing agencies to operate under severe resource constraints and under suffocating pressures from the White House, Congress, and special interest groups. A more honest portrayal of the problem would allow Americans to better understand these pressures, which would, in turn, be a first step toward crafting progressive solutions to the problems.

Adequate Resources

The protector agencies need resources sufficient to meet their long-term needs, based on a "true-up" that asks them to provide best estimates of the resources necessary to properly meet their legal mandates. The first step toward achieving this goal will be an intensive process. Each agency will have to develop an accurate and meaningful list of broad statutory mandates and all of the tasks that it must accomplish to fulfill those mandates. No doubt, the budget numbers that agencies would derive through this process would vastly exceed current appropriations. Just think of the personnel CPSC and FDA would have to hire to properly inspect the products shipped to the United States from foreign countries with weak regulatory systems. With a Congress that is inherently skeptical of agencies requesting more money and a White House that has other priorities, agencies' "true-up" budgets are unlikely to elicit immediate budget increases. But at least it will give them a baseline that has more meaning than the current baseline (previous years' budgets).

New Accountability Mechanisms

Congress and the President need to re-think the accountability mechanisms they use to judge agency performance. Agencies should be required to adopt "positive metrics," which, like "true-up" budgets, are fundamentally tied to agencies' statutory mandates. With the guidance of independent experts, agencies should develop comprehensive lists of statutory mandates and the tasks associated with those mandates. So, for instance, FDA is supposed to monitor the safety and efficacy of pharmaceuticals and medical devices that it has approved for sale to the public. A positive metric to measure the agency's progress (one that FDA has already used) would be to calculate the percentage of adverse event reports that hospitals, doctors, patients, or manufacturers have filed with the agency but have not been reviewed by the staff in a timely and systematic way.[28] Positive metrics should lay out the *who, what,* and *when* of the tasks that support agencies' achievement of their statutory missions. Those elements will help Congress and other resource managers identify the causes of regulatory shortfalls.

Decentralized Decisionmaking

Finally, we need to ensure that agency staff are treated with the respect they need to accomplish their mission, by decentralizing decisionmaking authority and creating a federal workforce where career civil servants have significant impact on the development of regulations.

The best way to accomplish these goals is to end the practice of having OMB review every agency rule. Executive Order 12,866, which is the primary basis for OMB review, embodies a basic distrust of agencies and their staff, and it should be abolished. At the same time, there need to be limits on how far political appointees can burrow into agency management structures. While it is important for the President to have oversight of agencies through high-level political appointees, congressionally mandated limits on political appointments could improve agency morale and lead to stronger resistance to improper political pressure.[29]

Conclusion

Since their creation, the five protector agencies have struggled to achieve their goals of protecting public health, welfare, and the environment in the face of Congresses and presidential administrations that have alternated between being neglectful and outright hostile to their missions. With limited resources and a platoon of political appointees second-guessing their every move, agency staff have had difficulty regulating industries that have become increasingly adept at evading existing regulations and staunching the flow of new regulations. The changing nature of the American workplace, globally distributed product design and supply chains, and emerging risks from new chemicals and technologies have made it imperative that Congress and the Executive Branch begin to design a next-generation regulatory system that truly empowers the protector agencies.

About the Authors

Sidney Shapiro holds the University Distinguished Chair in Law at the Wake Forest University School of Law and is the Associate Dean for Research and Development. He is a member of the board of directors of the Center for Progressive Reform. Professor Shapiro has taught and written in the areas of administrative law, regulatory law and policy, environmental policy, and occupational safety and health law for 25 years. Professor Shapiro has been an active participant in efforts to improve health, safety, and environmental quality in the United States. He has testified before congressional committees on administrative law and occupational safety and health issues.

Rena Steinzor is the Jacob A. France Research Professor of Law at the University of Maryland School of Law, with a secondary appointment at the University of Maryland Medical School Department of Epidemiology and Preventive Medicine. Among the courses she teaches are risk assessment, critical issues in law and science, and a survey of environmental law. Professor Steinzor received her B.A. from the University of Wisconsin and her J.D. from Columbia Law School. She joined the faculty in 1994 from the Washington, D.C. law firm of Spiegel and McDiarmid. From 1983 to 1987, Steinzor was staff counsel to the U.S. House of Representatives' Energy and Commerce Committee's subcommittee with primary jurisdiction over the nation's laws regulating hazardous substances. She is the President and a Director of the Center for Progressive Reform.

Matthew Shudtz, J.D., is a Policy Analyst at the Center for Progressive Reform, providing research, drafting, coordination and other staff assistance to CPR's Clean Science and Corporate Accountability Issue Groups. Prior to joining CPR, Mr. Shudtz worked as a legal intern for the Natural Resources Defense Council and as a legal/legislative intern for the Chesapeake Bay Foundation.

End Notes

[1] *See* U.S. Consumer Product Safety Commission, *2003 Strategic Plan* at 1, *available at* http://www.cpsc.gov/cpscpub/pubs/reports/2003strategic.pdf (accessed August 20, 2009).

[2] *See* OMB Circular A-11, Section 51, *available at* http://www.whitehouse.gov/omb/assets/a11_current_year/s51.pdf (accessed August 20, 2009) (describing basic elements of agency budget justifications, which focus on "strategic goals" and changes in the agency's budget as compared to the previous year, and 5- and 10-year trends, without mention of statutory mandates).

[3] Pub. L. No. 103-62, 107 Stat. 285 (Aug. 3, 1993).

[4] Office of Management and Budget, *Assessing Program Performance*, at http://www.whitehouse.gov/omb/performance_default/ (accessed August 20, 2009).

[5] U.S. Gov't Accountability Office, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458, at 11 (2005).

[6] Eskridge, Frickey, and Garrett, Legislation: Statutes and the Creation of Public Policy 3d, 29 (2001).

[7] 16 U.S.C. § 1540(b).

[8] 29 U.S.C. § 666(e).

[9] 33 U.S.C. §§ 1311(a), 1362(7).

[10] *See U.S. v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 135-39 (1985) (recounting the failed attempt to redefine "navigable waters" in the 1977 amendments to the Clean Water Act); *see also, e.g.,* Clean Water Restoration Act of 2007, H.R. 2421, 110th Cong., 1st Session (introduced in House, reported to committee, one hearing held, but failed to move out of committee).

[11] *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980).

[12] *See* Nipping IRIS in the Bud: Suppression of Environmental Science by the Bush Administration's Office of Management and Budget, A staff report by the Majority Staff of the Subcommittee on Investigations and Oversight for Subcommittee Chairman Brad Miller, Committee on Science and Technology, U.S. House of Representatives (June 11, 2009).

[13] *Id.* at 1.

[14] *Fixing EPA's Broken Integrated Risk Information System*, Committee on Science and Technology, Subcommittee on Investigations and Oversight, U.S. House of Representatives (June 11, 2009); *information available at* http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=2485 (accessed August 20, 2009).

[15] *See* Mark Seidenfeld, *A Table of Requirements for Federal Administrative Rulemaking*, 27 Fl. St. Univ. L. Rev. 533 (2000).

[16] Lisa Bressman and Michael Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 Mich. L. Rev. 47 (2006).

[17] *Angler: The Cheney Vice Presidency*, *available at* http://blog.washingtonpost.com/cheney/ (accessed August 20, 2009).

[18] Union of Concerned Scientists, *Interference at the EPA: Science and Politics at the U.S. Environmental Protection Agency* 52 (April 2008).

[19] R. Sam Garrett, James A. Thurber, A. Lee Fristchler, and David H. Rosenbloom, *Assessing the Impact of Bureaucracy Bashing by Electoral Campaigns*, 66 Pub. Administration Rev. 228, 232 (March/April 2006).

[20] Congressional Budget Office, *Characteristics and Pay of Federal Civilian Employees* 3 (March 2007).

[21] *See* National Commission on Public Service, *Urgent Business For America: Revitalizing the Federal Government for the 21st Century*, *available at* http://www.brookings.edu/reports/2003/01governance.aspx (accessed August 20, 2009).

[22] Paul C. Light, Thickening Government: Federal Hierarchy and the Diffusion of Accountability (Brookings Institution Press, 1995).

[23] *See* U.S. Gov't Accountability Office, *MEDICAL DEVICES: Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishments*, GAO-09-370T (June 18, 2009).

[24] Letter from FDA physicians and scientists to Rep. John D. Dingell (Oct. 14, 2008), *available at* http://energycommerce.house.gov/images/stories/Documents/PDF/Newsroom/110-ltr-101408.CDRHscientists.pdf (accessed August 20, 2009).

[25] Barack Obama, "Closing Argument Speech" (transcript as delivered at the Canton Memorial Civic Center, Canton, OH, October 27, 2008), *available at* http://blogs.suntimes.com/sweet/2008/10/obama_closing_argument_speech_1.html (accessed August 20, 2009).

[26] Steven Mufson and Jennifer Agiesta, *Limits on Emissions Have Wide Support*, Wash. Post, June 25, 2009, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2009/06/24/AR2009062403648.html (accessed August 20, 2009).

[27] Kevin Sack and Marjorie Connelly, *In Poll, Wide Support for Government-Run Health*, N.Y. Times, June 20, 2009, *available at* http://www.nytimes.com/2009/06/21/health/policy/21poll.html (accessed August 20, 2009).

[28] *See*, Gov't Accountability Office, *MEDICAL DEVICES: Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspection of Device Manufacturing Establishments* 14, GAO-09-370T (June 18, 2009), *citing* U.S. Food and Drug Administration, *Ensuring the Safety of Marketed Medical Devices, CDRH's Medical Device Postmarket Safety Program* (January 18, 2006).

[29] Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 Tex. L. Rev. 1601, 1643-44 (2008).

To see more of CPR's work or to contribute,
visit CPR's website at www.progressivereform.org.

455 Massachusetts Avenue, NW
150-513
Washington, DC 20001

202-747-0698 (phone/fax)

RETURN UNDELIVERABLES TO:

CENTER FOR PROGRESSIVE REFORM
455 Massachusetts Avenue, NW
150-513
Washington, DC 20001