Heads They Win, Tails We Lose

How Corporations Corrupt Science at the Public's Expense

Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

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The Scientific Integrity Program of the
Union of Concerned Scientists

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The Union of Concerned Scientists (UCS) is the leading science-based nonprofit working for a healthy environment and a safer world.

The UCS Scientific Integrity Program mobilizes scientists and citizens alike to defend science from political interference and restore scientific integrity in federal policy making. To learn more, visit *www.ucsusa.org/scientific_integrity*.

The Union of Concerned Scientists is the leading science-based nonprofit working for a healthy environment and a safer world.

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EXECUTIVE SUMMARY

Access to the best available science allows federal decision makers to craft policies that protect our health and safety and the environment. Unfortunately, censorship of scientists and the manipulation, distortion, and suppression of scientific information has threatened the federal scientific enterprise in recent years.

This serious problem has sparked much debate, but few have analyzed the key driver of political interference in federal science: the inappropriate influence of companies with a financial stake in the outcome. This influence affects not only the science used in decision making, but also public opinion and the decision-making process itself. By better understanding how corporations influence the use of science in federal decision making, we can both hold companies and policy makers accountable for their actions and ensure that the nation develops science-based policies that serve the public interest.

The first chapter of this report explores the numerous methods corporate interests employ to inappropriately influence how the federal government uses science to make decisions. The second chapter provides an overview of the steps the Obama administration has taken to restore scientific integrity to federal policy making. The third chapter focuses on the federal reforms still essential to ensure that authoritative and independent scientific information informs policies designed to protect public health and the environment. Recognizing that solving this problem extends far beyond what the government can accomplish alone, we also suggest broader reforms that corporations, the scientific community, academic institutions, news media, and the courts can pursue to ensure transparency and accountability in the use of science.

The twenty-first century presents the United States and the world with urgent science-based challenges. We must have the ability to use independent science to address problems such as the need for high-quality yet affordable health care, terrorism, climate change, rising demand for energy and natural resources, population growth, and the loss of biodiversity, and to anticipate and tackle challenges unknown today.

GROUND-LEVEL OZONE

The Clean Air Act requires the Environmental Protection Agency (EPA) to base standards for certain pollutants, such as ozone, solely on science. The George W. Bush administration set an ozone standard that was not supported by science, and President Obama pledged to revisit it. But as the EPA was finalizing its work, top White House officials including the White House chief of staff met with business groups including the Business Roundtable, the U.S. Chamber of Commerce, and the American Chemistry Council that were opposed to a strengthened ozone standard. Subsequently, the president ordered the EPA to stop its review.

Methods of Abuse

Corporations attempt to exert influence at every step of the scientific and policy-making processes, often to shape decisions in their favor or avoid regulation and monitoring of their products and by-products at the public's expense. In so doing, they often attempt to fundamentally alter the decision-making process and exploit executive branch agencies, Congress, and the courts.

REVOLVING DOOR

Officials who shuttle between high-level government positions and regulated industries or companies undermine the integrity of federal science and public confidence in government. While sharing expertise among different sectors can sometimes be beneficial, there is serious risk that the revolving door will allow individuals with clear financial conflicts of interest to hold key decision-making positions. Predictably, revolving-door officials develop or direct policies that benefit a former or prospective employer. The legacy of political appointees with conflicts of interest lives on even after their departure—through both the policies they helped develop and the erosion of public trust in agency integrity.

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Corrupting the Science

Corporations that stand to lose from the results of independent scientific inquiry have gone to great lengths to manipulate and control science and scientists by:

Terminating and suppressing research. Companies have controlled the dissemination of scientific information by ending or withholding results of research that they sponsor that would threaten their bottom line.

Intimidating or coercing scientists. Corporations bury scientific information by harassing scientists and their institutions into silence. Scientists have been threatened with litigation and the loss of their jobs, have had their research defunded, have been refused promotion or tenure, and have been transferred to non-research positions, leading to self-censorship and changes in research direction.

Manipulating study designs and research protocols. Corporations have employed flawed methodologies in testing and research—such as by changing the questions scientists are asking—that are biased toward predetermined results.

Ghostwriting scientific articles. Corporations corrupt the integrity of scientific journals by planting ghostwritten articles about their products. Rather than submitting articles directly, companies recruit scientists or contract with research organizations to publish articles that obscure the sponsors' involvement.

Publication bias. Corporations selectively publish positive results while underreporting negative results. While not directly corrupting science itself, these publishing and reporting biases skew the body of evidence.

Shaping Public Perception

Armed with public relations teams, private interests have launched campaigns that influence public opinion and undermine understanding of scientific consensus. Among their methods:

Downplaying evidence and playing up false uncertainty. As scientific understanding of the health effects of products and substances such as tobacco and particulate emissions emerges, companies fight regulation by attacking the science, downplaying scientific consensus, exaggerating scientific uncertainty and spreading doubt.

Vilifying scientists. Scientists analyzing the health and environmental effects of products such as asbestos and lead, and phenomena such as climate change, are publicly criticized and attacked. These attacks and allegations of misconduct discredit the scientists and deter them from continuing their research.

Promoting experts who undermine the scientific consensus. Corporations promote individuals who overemphasize research that appears to cast doubt on the scientific consensus. Often their expertise is not in a relevant field, limiting their ability to effectively evaluate the scientific findings they are criticizing.

Hiding behind front groups or "capturing" organizations. Companies use front groups, public relations firms, and other paid consultants to covertly advance corporate interests while these entities maintain the illusion of independence.

Influencing the media. Corporations inaccurately portray science by feeding the media slanted reports and news stories, or biased spokespeople.

Restricting Agency Effectiveness

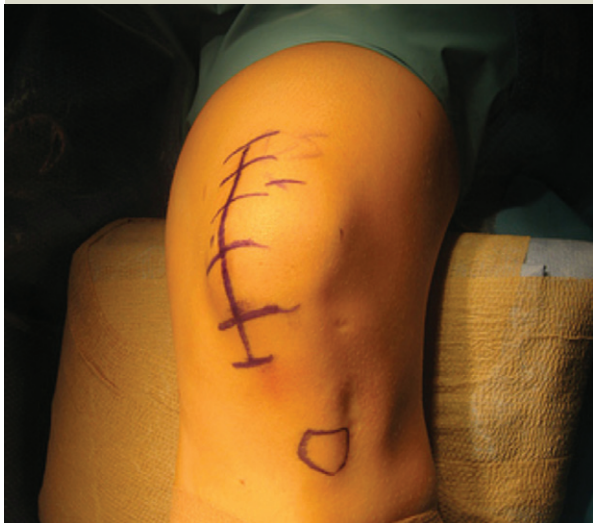
Companies engage in activities that undermine the ability of federal agencies to use independent science to regulate products. Companies also advocate for more layers of bureaucracy, and take advantage of inappropriate relationships with agency personnel, to hinder the development of policies that protect the public and the environment.

Attacking the science. Corporations have attacked the science used to inform federal policy making in an attempt to delay regulation.

Hindering the regulatory process. Corporations advocate for policies that limit the ability of agencies to use the best available science when making decisions. So-called "regulatory reforms" limit agencies' resources, curb the role of science in decision making, or put an extraordinary burden of proof on agencies before they can act.

MENAFLEX

New Jersey company ReGen Biologics attempted to gain Food and Drug Administration (FDA) approval for clinical trials of Menaflex, a device it developed to replace knee cartilage. After an FDA panel rejected the device, the company enlisted three members of Congress to influence the evaluation process. In December 2007, Sen. Frank Lautenberg, Sen. Robert Menendez, and Rep. Steve Rothman wrote to FDA Commissioner Andrew von Eschenbach asking him to personally look into Menaflex. Soon thereafter, the commissioner met with ReGen executives and heeded the company's advice to have Dr. Daniel Shultz, head of the FDA's medical devices division, oversee a new review. The FDA fast-tracked and approved the product despite serious concerns among scientists. The FDA acknowledged its error and revoked approval in 2010.



Corrupting scientific advisory panels. Government agencies rely on independent scientific advisory panels to provide objective advice. But panel members often have undisclosed financial conflicts of interest: ties to companies that stand to win or lose based on the findings of these advisory committees.

Spinning the revolving door. Officials shuttle between high-level government positions and regulated industries or corporations. This revolving door can lead to regulatory capture: federal agencies charged with protecting the public can end up as shields or advocates for the regulated industries.

Censoring scientists and their research. Federal officials with industry ties have deleted selected evidence from scientific documents, knowingly adopted flawed methodologies, put direct pressure on scientists and their supervisors to alter findings, and censored scientists to prevent them from speaking publicly or with the media.

Withholding information from the public. Besides censoring scientists, federal officials acting on behalf of corporate interests have buried scientific findings, delayed the release of information, or otherwise suppressed or withheld scientific information.

Influencing Congress

The injection of billions of dollars into congressional lobbying and election campaigns compromises the will of members of Congress to respond to the needs of the people they represent. Money and secrecy in lobbying, excessive campaign funding, and a revolving door on Capitol Hill give corporate interests unprecedented and undue access to members of Congress. This influence encourages members to challenge scientific consensus, delay action on critical science-based problems, and shape the use of science in policy making. A recent marked increase in lobbying expenditures, along with greatly relaxed rules on corporate spending on elections, has exacerbated these pressures.

Exploiting Judicial Pathways

Judges play a growing role in deciding whether to admit scientific information as evidence, and in ruling on science-based laws and regulations. Corporate interests have expanded their influence on the judicial system, used the courts to undermine science, and exploited judicial processes to bully and silence scientists. State judicial elections have become multimillion-dollar campaigns backed by political parties and special-interest groups.

Restoring Scientific Integrity: The First Three Years

President Obama is the first president to take on the challenge of creating strong federal standards for scientific integrity and improving scientific advice to the government. At the beginning, the president signaled that reforms to bolster scientific integrity would be a priority for his administration. In his inaugural address, he pledged to "restore science to its rightful place," and took several initial steps to make good on that promise.

The president appointed several top scientists to senior positions in the administration. His science advisor reports directly to him, unlike the situation during the George W. Bush administration, when the science advisor reported to the White House chief of staff, limiting the science advisor's access to many important discussions. The Obama White House also issued guidelines directing federal agencies to develop and implement scientific integrity policies. Some of the resulting policies have spurred significant, positive steps to ensure that agency decisions rest on the best available science.

A lack of transparency also facilitates political interference in how and on what basis decisions are made, and limits public access to scientists and scientific resources. Administration officials have taken several steps to make the government more transparent and accountable. The White House issued an Open Government Directive that, while not perfect, has expanded public access to large amounts of data. The White House also began releasing its visitor

logs to allow for more public understanding of who is influencing decisions, and streamlined the release of other government information through Freedom of Information Act requests and other means.

Some agencies have made transparency a priority. For example, EPA Administrator Lisa Jackson issued a "fishbowl" memorandum on her first day on the job clarifying that the agency would operate with full transparency—as if it were a fishbowl. The agency made information on the safety of chemicals used and produced by industry more publicly accessible.

Other agencies have improved the ability of their scientists to share research results and analysis with the public. For example, the National Oceanic and Atmospheric Administration's (NOAA's) scientific integrity policy explicitly gives its scientific staff the authority to speak to the media without obtaining permission from press officers, and reaffirms their right to freely express their personal opinions as private citizens.

The president reversed a Bush administration executive order that had shifted the power to commence rule making from agency heads to the White House. The administration has also fought anti-regulatory proposals from members of Congress that would undermine the ability of federal agencies to use science to protect public health and the environment.

The administration has also strengthened ethics and conflict-of-interest policies for federal employees. Federal political appointees must now submit conflict-of-interest reports and recuse themselves from policy making that affects previous employers. Appointees who are seeking jobs outside government are also prohibited from working on policies that would benefit a prospective employer.

Essential Federal Reforms

Despite these steps, further federal commitments to protect science from undue corporate influence are essential. For example, agencies and departments should strengthen and fully implement their scientific integrity policies. The federal government should also adopt the following reforms:

Protecting Government Scientists

Scientists and researchers should have the protections they need to fulfill their public service responsibilities. They should not fear intimidation or face litigation for the direction of their research, or for publishing or speaking about their results.

To support this, the administration should continue to assert that retaliation against federal employees who report political interference in science—such as by reassigning, demoting, or firing those scientists—will not be tolerated. Congress should also pass the strongest possible whistleblower protection law, and strengthen the federal entities that give employees a safe and secure

NOAA

The process of developing scientific integrity policies has contributed to positive changes in agency culture. For example, NOAA Administrator Jane Lubchenco encouraged all NOAA employees to provide input into the agency's policy. The resulting conversations raised employees' understanding of the importance of scientific integrity in government, and encouraged employees at all levels to take ownership of the final policy.

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means of reporting misconduct and corruption. At the same time, the National Academy of Sciences should explore appropriate responses for scientists and institutions facing harassment or intrusive open-records requests that interfere with their ability to pursue research.

Making the Government More Transparent and Accountable

Information created by or submitted to the government should be more transparent. The science advisor should review agency policies on clearing official and nonofficial articles, presentations, and other information for publication. Agencies that have not already done so should improve their policies to allow scientists to communicate freely with the media and the public.

Agencies should also reform their criteria for designating data submitted by companies as "confidential business information," to make such data more publicly available, and continue to reform classification and declassification processes. Congress should give agencies sufficient resources to respond to open-records and Freedom of Information Act requests.

The public needs to know who is influencing federal decisions. Federal agencies should follow the lead of the White House and institute a disclosure policy for meetings with representatives of outside entities. The administration should create an online database of all federal campaign contributions, lobbying disclosures, and other expenditures that could compromise federal decision making. Congress should require entities with tax-exempt status, such as 501(c)(6), to disclose their membership and funding sources. Congress should pass a law requiring its members to disclose indirect political contributions, and strengthen post-employment rules for members and congressional staff.

To strengthen public accountability, federal agencies should establish clear procedures for addressing and publicly reporting allegations of political interference in science. The Office of Government Ethics, an independent executive branch agency, should be restructured so it can better track and enforce ethics standards at these agencies.

Reforming the Regulatory Process

The administration and Congress should improve the regulatory process. For example, Congress should consult with agencies to remove outdated or unnecessary procedures to make the regulatory process and the allocation of resources more efficient. Congress should also amend the Paperwork Reduction Act to allow agencies to better identify and resolve regulatory gaps or inefficiencies, and ensure that agencies have enough resources to expand oversight and inspection of research facilities and contractors.

The administration should restrict the White House Office of Management and Budget (OMB) from interfering in the scientific work of executive branch agencies. For its part, the OMB should work with federal agencies to make the regulatory process more transparent, expand dockets tracking regulations under development, and make the dockets more user-friendly. The OMB should issue broad guidelines on how federal regulators will use cost-benefit analysis.

The administration should terminate inappropriate interagency review of scientific documents. Agencies should disclose more information about who is involved and what scientific documents are used in regulatory decisions.

To protect the ability of agencies to carry out science-based laws as Congress intended, the president should develop and publicly release criteria for the use of signing statements, and Congress should scrutinize all signing statements and executive orders for content that oversteps the intent of legislation.

Congress and the administration should ensure that potential adverse effects of products are reported to the federal government, and should create a federal registry of scientific research submitted to agencies, similar to the FDA's clinical trials registry. Agencies should impose penalties or fines when companies submitting information to the government miss reporting deadlines.

Strengthening Scientific Advice to the Government

Congress should improve the Federal Advisory Committee Act (FACA) to ensure that FACA rules apply to all individuals who substantively influence such committees, limit conflicts of interest among the members, and improve the disclosure of such conflicts. Agencies should track the work of their scientific advisory committees more closely, and meaningfully respond to their findings and recommendations.

Congress should create a mechanism that allows members of Congress to receive timely, policy-relevant, impartial scientific and technological analysis and advice that will help them make decisions on new initiatives and laws and the allocation of taxpayer dollars.

Federal agencies should set standards for the quality of scientific information submitted by corporations, trade associations, private research companies, unions, and other institutions.

Strengthening Monitoring and Enforcement

Federal agencies should make the scientific information they gather through data collection programs public, and use it in decision making.

Congress should investigate how reduced or eliminated funding for monitoring and enforcement has undermined the integrity of science.

Beyond Government

Corporations, nonprofits, academic institutions, scientific societies, and the media also have critical roles to play in reducing abuses of science in federal decision making. As a logical extension of federal scientific integrity policies, private-sector stakeholders who contribute to or influence science used in federal policy making should develop or revisit their own policies regarding scientific integrity, ethics, and misconduct.

These institutions should promote honest scientific investigation and open discussion of the results of such research. These institutions should also refrain from actual or perceived acts of scientific misconduct, such as by suppressing or terminating research, censoring scientists, altering the scope of research, or otherwise manipulating scientific information. These institutions should embrace transparency by disclosing sources of funding, and avoid conflicts of interest.

Inappropriate corporate interference in science extends its tentacles into every aspect of federal science-based policy making. Given the unprecedented science-based challenges facing our nation and the world, federal decision makers must have access to the best available science. Addressing this interference will require overcoming high hurdles, but they are not insurmountable. With strong leadership and a sustained commitment, both the federal government and the private sector can rise to the challenge.

CRYSTALLINE SILICA

Crystalline silica, a basic component of many minerals, is a serious occupational health hazard that causes an irreversible, progressive lung disease. After 14 years of analysis, the Occupational Safety and Health Administration (OSHA) submitted a rule to the White House in February 2011 to protect workers from silica exposure. The OMB is required to review proposed rules within 90 days, yet nearly a year later, the White House had failed to do so, preventing OSHA from even seeking public input on its proposal. In the interim, industry representatives met numerous times with OMB staff about the standard.

INTRODUCTION

A strong and sustained federal investment in scientific research has given decision makers the ability to craft public policies that protect our health, safety, and environment. Unfortunately, the censorship of scientists and the manipulation, distortion, and suppression of scientific information—driven by both ideology and commercial interests—threatens the quality of federal decision making. If left unchecked, inappropriate private-sector influence on science decreases the effectiveness of the federal government, makes it less accountable to citizens, undermines the foundations of our democracy, and compromises America's role as a world leader.

Individuals acting on behalf of political, financial, and ideological interests have manipulated federal science for as long as the challenges facing our country have had strong scientific and technological components. During President Eisenhower's tenure, physicist Robert Oppenheimer was forced out of government service because of allegations that he was a security risk (Bernstein 1990). President Richard Nixon abolished the President's Scientific Advisory Committee when it became known that the council opposed missile defense and civilian supersonic transport (Branscomb 2004).

Nor has political interference in science been relegated to one side of the aisle. The Carter administration ended a Department of Energy study projecting energy consumption that undercut its policy agenda, and forced the resignation of the study's leader and the director of the U.S. Geological Survey (Branscomb 2004). President Clinton ignored the recommendations of every scientific and medical organization in the world—from the American Medical Association to the World Health Organization—that has examined the effectiveness of needle exchange in saving the lives of drug addicts, and refused to lift the federal ban on funding (Stolberg 1998).

© The White House

President Obama meets with John Holdren, federal science advisor and director of the Office of Science and Technology Policy.

The Obama administration has taken meaningful steps to address political interference in science. However, the solutions put forward thus far do not fully address the myriad levers corporations use to exert this interference.

This report explores the breadth and depth of corporate influence on the science informing federal decision making. Drawing on numerous investigations by the Union of Concerned Scientists (UCS) and other public-interest groups, the first chapter examines some of the most common methods corporate interests rely on to inappropriately influence how the federal government uses science to make decisions.

The second chapter gives an overview of steps the Obama administration has taken to address these problems. The third chapter describes the federal reforms still urgently needed to ensure that

reliable scientific information inspires policies designed to protect public health and the environment. Recognizing that solving this problem extends far beyond what the government can accomplish alone, this chapter also suggests reforms that corporations, the scientific community, academic institutions, the media, and the courts can pursue to ensure transparency and integrity in the federal use of science.

The twenty-first century presents the United States and the world with unprecedented challenges. Federal decision makers must have the ability to use accurate scientific information to address problems such as climate change, rising demand for energy and other resources, population growth, and the loss of biodiversity, and to anticipate and tackle challenges unknown today. By documenting avenues of inappropriate private-sector influence on federal science, this report enables policy makers and the public to hold corporations accountable for their actions, and to ensure that independent scientific information fully informs policies designed to protect the public good.

Independent scientific information is critical to addressing many challenges, such as reducing harmful emissions from coal-fired power plants.

History and Context

In 2003, more than a dozen senior scientists came to UCS with a troubling observation: on issues from childhood lead poisoning to air pollution, from climate change to contraception, scientists were being silenced, and science was being suppressed, rewritten, or misrepresented to support predetermined policy outcomes. UCS launched investigations and compiled case studies where politics had trumped science, and the scientists put together a statement that called on the Bush administration to restore scientific integrity to federal policy making. The statement drew an enormous amount of attention because it was signed by senior scientific advisors to both Republican and Democratic administrations dating back to President Eisenhower. Over time, nearly 15,000 scientists added their names.

From 2005 to 2011, UCS conducted surveys and received responses from more than 5,100 scientists at nine federal agencies, including the Food and Drug Administration (UCS 2010e, 2006), the Environmental Protection Agency (UCS 2008), the National Oceanic and Atmospheric Administration (UCS 2005), and the Department of Agriculture (UCS 2010e). Among other troubling trends, the results revealed that hundreds of scientists across the agencies had personally experienced political interference in their work (UCS 2010e, 2009e). Scientists attested that the interference often stemmed from inappropriate corporate influence.

Despite significant and sustained pressure from people of all political stripes, the Bush administration continued to politicize science. What was first seen as aberrant behavior was then understood to be more systemic, reinforced by centralized control of the Executive Branch under the theory of the unitary executive. The manifestation of this theory included extensive changes in procedures that limited or eliminated scientific input into policy making.

In late 2007 and early 2008, UCS convened listening sessions with science policy experts, government scientists, congressional staff, federal agencies officials, whistle-blowers, and representatives of public-interest organizations to explore long-term solutions. The resulting report, *Federal Science and the Public Good: Securing the Integrity of Science in Policy Making*, made specific recommendations for actions the administration, agencies, and Congress could take to restore scientific integrity to federal policy making (Grifo et al. 2008).

President Barack Obama initially put reforms to bolster scientific integrity at the top of his science agenda, and pledged in his inaugural address to "restore science to its rightful place" (Obama 2009a). The president immediately elevated his science advisor to be an assistant to the president, and made several high-profile appointments of individuals with excellent scientific credentials to head agencies. Two months after taking office, the president issued a memorandum on scientific integrity, stating, "It's about listening to what our scientists have to say, even when it's inconvenient—especially when it's inconvenient" (Obama 2009b).

In December 2010, the White House released guidelines on scientific integrity, and instructed federal agencies to develop specific policies that would institutionalize strong standards for scientific integrity (Holdren 2010). By the end of 2011, though, progress on the policies was uneven. While some government entities, such as the Department of the Interior and the National Oceanic and Atmospheric Administration (NOAA), had finalized and begun to implement policies on scientific integrity, many others lagged behind (Holdren 2011).

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Scientist and NOAA Administrator Jane Lubchenco helped the agency put forward a strong scientific integrity policy.

Administration officials continue to face considerable pressure to politicize science—and at times, they have. During the *Deepwater Horizon* oil disaster in 2010, NOAA public-affairs officials misrepresented scientific analysis of the amount of oil remaining in the Gulf of Mexico (Froomkin 2010). In September 2011, corporate interests factored into the president's decision to prohibit the Environmental Protection Agency (EPA) from issuing standards for ground-level ozone pollution based on the best available scientific information (Broader 2011). In December 2011, Department of Health and Human Services Secretary Kathleen Sebelius set a dangerous precedent when she overruled more than a decade of analysis by experts at the Food and Drug Administration (FDA) for the first time, and ordered the agency to refuse over-the-counter access to emergency contraception to all women of childbearing age (Harris 2011).

These pressures, both financial and ideological, are pernicious and lasting. It is time to pursue a comprehensive vision for reform that will ensure scientific integrity in federal decision making. This vision should include not only changes in the culture and operation of the federal government, but also reforms in the private and nongovernmental sectors that curb abuses of science.

CHAPTER 1

Methods of Abuse

Financial and ideological interference in science-based public policy in the United States is nearly as old as science-based public policy itself. However, the problem has become more visible and pervasive in recent years. While the Obama administration is taking steps to establish strong scientific integrity standards, financial and ideological interests continue to exert undue and often inappropriate influence over the science used in policy making. While ideological pressures are a problem, this report focuses solely on the commercial drivers behind the politicization of science.

Using their vast financial resources, corporations attempt to exert influence at every step of both the scientific and policy-making processes, often to shape decisions in their favor, or to avoid regulation and monitoring of their products. In so doing they often attempt to fundamentally alter the decision-making process.

This chapter explores this influence, outlining how the private sector corrupts the science used in policy making, shapes public perceptions, restricts agency effectiveness, exploits Congress, and influences the courts. In short, we document the many methods that companies use to tip the scales in the favor of corporate interests, with specific examples across many decades.

Corrupting the Science

When funding their own studies, corporations may terminate or fail to report research with negative findings, tailor study designs to lead to desired outcomes, and overreport positive results. Companies may rely on the names of respected academics to publish corporate-funded research. And they may attack scientists whose research proves inconvenient.

The following examples stem from litigation or unauthorized leaks. The true extent to which corporations corrupt science is unknown.

Termination and suppression of research. Corporations have controlled the dissemination of scientific information by terminating research they have commissioned, or suppressing the results, when they would threaten corporate investments.

- GlaxoSmithKline, a pharmaceutical company that manufactures the antidepressant Paxil, commissioned five clinical trials from 1998 to 2002 to assess the drug's efficacy in addressing pediatric and adolescent depression. The company published the results of only one trial, which were mixed. The other four trials had found negative results, including that the drug raised the risk of suicide (McGauran et al. 2010). The

HOG FARM EMISSIONS

Supervisors at the U.S. Department of Agriculture prohibited James Zahn, a research microbiologist in the department, from publishing or presenting his research on no fewer than 11 occasions in 2002 (UCS 2010a). The research showed that emissions from industrial hog farms contained antibiotic-resistant bacteria. Zahn's supervisors censored him after receiving questions from a representative of pork producers (Kuehn 2004; Beeman 2002).

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company then hampered FDA efforts to investigate by blocking the agency's access to data from the clinical trials, citing confidentiality agreements GlaxoSmithKline scientists had signed (Meier 2004).

- Boots, a pharmaceutical company, commissioned Dr. Betty Dong, a scientist at the University of California–San Francisco, to test the effects of Synthroid, a replacement for thyroid hormone. Boots hoped to reveal that despite its high price, Synthroid was more effective than similar drugs. The company closely monitored the research, and when Dong found that the drug was no more effective than its competitors, instructed her not to publish the results. When she refused to comply, Boots threatened to sue. The company relented only after several years, during which consumers continued to pay for the costly product (Altman 1997; King 1996).

Intimidating or coercing scientists. Corporations bury scientific information by harassing scientists and their institutions into silence. The coercion comes in many forms. Corporations muzzle scientists by including gag orders in research or employment contracts. Scientists have been threatened with the loss of their jobs, had their research defunded, been refused promotion or tenure, and been transferred to non-research positions (Kuehn 2005; Martin 1999). Corporations have also used litigation and open-records requests to tie up their time and resources.

"When things don't 'go their way,' a company or its representatives will call and harass office directors to approve their product."

— FDA scientist (UCS 2012)

- A scientist overseeing a clinical trial of the HIV drug Remune published an article in the *Journal of the American Medical Association* concluding that the drug was ineffective. The pharmaceutical company that developed the drug sued the scientist in retaliation (McGarity and Wagner 2008; *Los Angeles Times* 2000).
- In July 2010, an FDA advisory panel recommended a recall of Avandia, used to treat Type 2 diabetes, and placed severe restrictions on its availability. Although this was the last and most stringent step in a series of FDA assessments of the drug's safety, GlaxoSmithKline, the manufacturer, had long known about its potential side effects. In 2000, Dr. John Buse at the University of North Carolina found that Avandia users had a high risk of heart disease, and published his findings. In response, Dr. Buse alleges, a representative from the company contacted his boss, accused him of lying, and threatened to sue him for a $4 billion drop in the company's stock valuation (Calabresi 2010).

Manipulating study designs and research protocols. Rather than relying on standard procedures designed to ensure unbiased research, corporations have employed flawed methodologies

NUCLEAR WASTE

In 1996, a company proposing to build a nuclear waste facility in Ward Valley, CA, threatened to sue two scientists commissioned by the U.S. Department of the Interior to investigate the facility's safety (Kuehn 2004). When the department could not guarantee that it would protect the scientists, they halted their research (Clifford 1996).

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biased toward predetermined results. Altering study designs or research methods through, for example, changes in sample sizes or control groups can obscure negative effects and promote desired outcomes.

- One analyst found that industry-funded studies were 88 times more likely to find no health effects related to secondhand smoke than non-industry-funded studies (Barnes and Bero 1998).
- To counter a study that found that formaldehyde caused cancer in rats, a formaldehyde company commissioned its own study. That study—which found no association between the chemical and cancer—exposed only one-third the number of rats to formaldehyde for half as long as the original study. A formaldehyde association quickly publicized the results and argued before the Consumer Product Safety Commission (CPSC) that they indicated "no chronic health effects from exposure to the level of formaldehyde normally encountered in the home" (McGarity and Wagner 2008).
- A marketing team at the pharmaceutical company Merck played a direct role in clinical trials of rofecoxib, an arthritis drug known by the brand name Vioxx. Internal documents, discovered through litigation, revealed that the Merck marketing team had developed a strategy called ADVANTAGE (Assessment of Differences between Vioxx and Naproxen to Ascertain Gastrointestinal Tolerability and Effectiveness) to exaggerate the drug's positive effects, to increase the likelihood of FDA approval (Hill et al. 2008). Under the ADVANTAGE strategy, scientists manipulated the trial design by comparing the drug to naproxen, a pain reliever sold under brand names such as Aleve, instead of to a placebo. The scientists wrongfully concluded that naproxen decreased the risk of heart attack by 80 percent, disregarding studies that had already found that it has no significant cardiovascular benefits (Michaels 2008; Villalba 2000). Instead Vioxx has been found to significantly increase cardiovascular risk, leading Merck to withdraw the product from the market in 2004. Patients who have taken Vioxx experience complications even years after discontinuing use of the drug (Ross et al. 2010).

"They just take you off the product review entirely if they don't like your opinion."

—FDA drug reviewer (UCS 2006)

HEXAVALENT CHROMIUM

Both ingesting and inhaling hexavalent chromium have been found to cause severe health effects, and the chemical has been linked to several types of cancer. Despite this, from 1993 through the present day, chromium industry officials have opposed regulation of the compound by the EPA and the Occupational Safety and Health Administration (OSHA). In 2003, an industry-funded report used small sample sizes and statistical maneuvering to undermine the link between hexavalent chromium and cancer. Industry trade groups such as Specialty Steel Industry of North America cited the study, which they had commissioned, to counter proposed regulations (Michaels, Monforton, and Lurie 2006). As recently as 2010, industry-funded reports concluded that further research was needed to determine whether ingesting hexavalent chromium could be linked to cancer (Sass 2010).

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Ghostwriting scientific articles. Corporations corrupt the integrity of scientific journals by planting ghostwritten articles. Rather than submitting articles directly, corporations recruit scientists or contract research organizations to publish articles that obscure the companies' involvement. Scientists have been compensated $3,000 to $5,000 to place their name and title on an article and submit it for publication (McGarity and Wagner 2008). In some cases, these scientists have had limited involvement in the study design, research, or analysis.

While the exact extent to which ghostwriting occurs is difficult to measure, confirmed instances reveal that it is abundant. One analysis found that articles on 33 of 44 industry-initiated clinical trials exhibited evidence of ghostwriting (Götzsche et al. 2007).

- Litigation revealed that Merck employees wrote 20 articles about Vioxx. Of those, 16 listed an external scientist as the primary author, despite the fact Merck personnel had drafted the articles, complete with analysis, before the outside academics became involved (Ross et al. 2008).
- From 1998 to 2007, Pfizer discreetly facilitated the publication of 15 case studies, six case reports, and nine letters to the editor to boost off-label use of Neurontin, a drug prescribed to treat seizures in people who have epilepsy and nerve pain (McGauran et al. 2010). The number of patients taking the drug rose from 430,000 to 6 million, making it one of Pfizer's most profitable products (Egilman and Druar 2011). An investigation found that Pfizer had failed to publish negative results, selectively reported outcomes, and excluded specific patients from analysis (Dickersin 2008). Pfizer failed to note that the drug increased the risk of suicide (Egilman and Druar 2011).
- The Tobacco Institute founded the faux journal *Reports on Tobacco and Health Research* in 1960 to spread uncertainty about the link between smoking and lung cancer. The journal, circulated to doctors, scientists, and the media, included articles such as "Cancer Personality Pattern Is Reported to Begin in Childhood," "Lung Specialist Cites 28 Reasons for Doubting Cigarette-Cancer Link," "Inhalation Tests Fail to Cause Lung Cancer; Virus Suggested," and "Psychological, Familial Factors May Have Roles in Lung Cancer" (Michaels 2008). In 2003, Merck replicated that strategy, setting up the *Australian Journal of Bone and Joint Medicine* to publish articles sympathetic to Merck products, and distributing it to 20,000 doctors (Krimsky 2009).

Publication bias. Corporations selectively publish positive results while underreporting negative results. They have also published duplicate articles, made negative reports harder to locate, and made positive reports more accessible. While not directly corrupting science itself, these publishing and reporting biases skew the body of evidence.

- One review found publishing and reporting bias regarding 50 drugs or medical devices used to treat 40 medical conditions. For example, of 74 trials of antidepressants, all 38 with positive

PHARMACEUTICAL GHOSTWRITING

One analysis found ghost-authorship of articles on Avandia, Fen-Phen, menopausal hormone therapy, Neurontin, Paxil, Tylenol, Vagus nerve stimulator, Vioxx, Zoloft, and Zyprexa in medical journals (Project on Government Oversight 2011).

results were published, while 22 of 36 trials with questionable or negative results were not published (McGauran et al. 2010).

- An investigation found that multiple articles on the efficacy of Risperdal, an antipsychotic medication, were based on limited research. For instance, the results of one trial appeared in six publications under different authorship (Deyo 2010).
- Pharmaceutical companies have written and published meta-analyses—overviews of results from multiple research projects—which are important in establishing scientific consensus. A study of 691 meta-analyses of anti-hypertension drugs found that those produced by individuals with ties to drug companies were significantly more likely to report results in the companies' favor. (Yank, Rennie, and Bero 2007).

Shaping Public Perceptions

Armed with public relations teams, companies have launched campaigns that influence public opinion and undermine the scientific consensus. They have done so by developing specific strategies to promote false scientific uncertainty, vilify scientists, promote sympathetic experts, and prop up industry-sponsored front groups.

Downplaying evidence and playing up false uncertainty. As scientific understanding of the negative health effects of products and substances such as tobacco, lead, and particulate emissions emerge, companies attack the science and spread doubt about the dangers, undermining regulatory will to protect the public.

- In response to evidence that cigarette smoke increased the risk of lung cancer, R.J. Reynolds argued that "statistical studies cannot prove cause-and-effect relationship between two factors," "mice are not men," and "no experimental evidence exists to show that any cigarette smoke constituent is carcinogenic to human lung tissue at the level present in cigarette smoke" (Bohme, Zorabedian, and Egilman 2005).

"No experimental evidence exists to show that any cigarette smoke constituent is carcinogenic to human lung tissue."

— R.J. Reynolds

- Other top oil companies joined ExxonMobil and the American Petroleum Institute, a trade association, to form the Global Climate Coalition and the Global Climate Science Team (Shulman, Abend, and Meyer 2007). These groups inflated the debate surrounding uncertainties of climate science leading up to the Kyoto climate negotiations in 1998. The Global Climate Science Team developed a communications plan to support efforts to prevent the United States from entering into a Kyoto agreement. The plan says that by making the "average citizen understand (recognize) uncertainties in climate science," the companies could "undercut the 'prevailing scientific wisdom'" on climate change (Shulman, Abend, and Meyer 2007).

TOBACCO HEALTH RISKS

In a now-infamous memorandum, a tobacco executive wrote in 1969 that "Doubt is our product, since it is the best means of competing with the 'body of fact' that exists in the minds of the general public" (Brown & Williamson 1969).

- The lead industry consistently underplayed scientific reports showing that exposure to lead had serious health effects, especially in children. Lead company officials denied that lead emissions posed any public health risk (Rosner and Markowitz 2002). In response to studies showing that children exposed to lead had developmental problems, a public relations firm argued that the poisoned children had been "sub-normal to begin with" (Michaels and Monforton 2008).

Vilifying scientists. Scientists researching the health and environmental effects of products such as asbestos and lead, and phenomena such as climate change, are publicly criticized and attacked. These smear campaigns and publicized attacks undermine public confidence in specific research. Libeling scientists, spreading lies, and alleging misconduct also discredit scientists and deter them from continuing research. Scientists facing the brunt of the attacks often spend much of their time defending their research rather than pursuing new research.

- In the 1960s, asbestos manufacturers hired public relations firms to push back against government regulations and new research linking asbestos exposure to cancer. Public relations firms and asbestos trade organizations verbally attacked Dr. Irving Selikoff, a pioneering asbestos researcher. In a November 1965 company memorandum, one industry executive stated, "Our present concern is to find some way of preventing Dr. Selikoff from creating problems and affecting sales" (McGarity and Wagner 2008; Bohme, Zorabedian, and Egilman 2005). Publicly, asbestos officials stated that Selikoff's research was "based on limited reports relating to a relatively small group of workers who install and/or remove a variety of insulation materials" (Bohme, Zorabedian, and Egilman 2005). The Asbestos Textile Institute threatened Selikoff in a letter, stating that he should take "caution in the discussion of these activities to avoid providing the basis for possibly damaging and misleading news stories. The gravity of the subject matter and the consequences [impose]... a very high degree of responsibility [for those involved in research]" (Bohme, Zorabedian, and Egilman 2005). Even after his death, attacks on his character and work continued. In 2003, P.W.J. Bartrip wrote a letter to the *Journal of the History of Medicine and Allied Sciences* questioning Selikoff's degrees and the validity of his work. Bartrip has worked for several Britain-based asbestos companies (Egilman 2004).
- Climate scientists have become the most recent high-profile public targets. Dr. Benjamin Santer, a climate modeling specialist, was asked to draft a portion of the Intergovernmental Panel on

VILIFYING SCIENTISTS

Dr. Herbert Needleman (below, left) is well known for his tireless commitment to researching the negative effects of lead exposure on children. He has faced constant attacks from the lead industry. The Lead Industries Association and the International Lead Zinc Research Organization published a letter calling Needleman's research "flawed and irrelevant," and labeled him an overemotional, untrustworthy anti-lead fanatic (Denworth 2008). Hill and Knowlton, a public relations firm hired by a lead industry trade association, circulated a letter to science journals calling Needleman's research "worthless as a peg for government policy" (Denworth 2008). Scientists working on behalf of lead companies charged Needleman with scientific misconduct, requiring him to continually defend the integrity of his research.

"I was not prepared to defend my personal integrity. I never imagined I'd have to do that."

— Dr. Benjamin Santer

Climate Change (IPCC) report in 1995. Industry-funded groups attempted to discredit Santer by asserting that he had modified the IPCC's findings to overstate the effects of climate change. Santer was deeply affected by the attacks, stating, "I was not prepared to defend my personal integrity. I never imagined I'd have to do that" (UCS 2010f). More than 14 years later, Santer still receives hate mail from climate deniers (UCS 2010f).

- Dr. Ingacio Chapela of the University of California–Berkeley and graduate student David Quist published an article in *Nature* showing that DNA from genetically modified corn was contaminating native Mexican corn (McGarity and Wagner 2008; Quist and Chapela 2001). The research spurred immediate backlash. *Nature* received a number of letters to the editor, including several comments on the Internet from "Mary Murphy" and "Andura Smetacek" accusing the scientists of bias (Monbiot 2002). The backlash prompted *Nature* to publish an editorial agreeing that the report should not have been published (Campbell 2002). However, investigators eventually discovered that the comments from Murphy and Smetacek originated with The Bivings Group, a public relations firm that specializes in online communications and had worked for Monstanto. Mary Murphy and Andura Smetacek were found to be fictional names (Monbiot 2002).

Promoting experts who undermine the scientific consensus. Corporations promote individuals who overemphasize research that appears to cast doubt on the scientific consensus. These individuals may or may not have expertise in a relevant field.

- Tobacco companies long used industry-created "scientific advisory boards" to confuse and conflate research results. These advisory boards were supposed to appear impartial when, in fact, the industry monitored and controlled them (Bohme, Zorabedian, and Egilman 2005).
- ExxonMobil selected five scientists to relay information to the media, and "20 respected climate scientists to serve on the scientific advisory board," to bring credibility to the Global Climate Science Team, which promoted uncertainties in climate science during negotiations on the Kyoto Protocol. The George C. Marshall Institute, a free-market think-tank funded almost exclusively by oil and gas companies and other corporations, commissioned two scientists on the Global Climate Science Team, Willie Soon and Sallie Baliunas, to write a paper on the effect of sunspots on global warming, a theory that has been repeatedly refuted. The two also published an article in a peer-reviewed journal arguing that the twentieth century was not the warmest in the past thousand years, and that no warming has occurred during that time (Soon and Baliunas 2003). ExxonMobil, business-supported front groups, and even elected officials touted the articles when opposing the Kyoto Protocol and other climate change policies (Shulman, Abend, and Meyer 2007).

Hiding behind front groups or "capturing" organizations. Corporations use front groups, public relations firms, and other paid consultants to influence public opinion, undermine science, and gain access to policy makers while maintaining the illusion of independence. Corporate involvement in these groups is often obscured, as the groups do not have to disclose their funding sources. They employ innocuous names such as the American Council on Science and Health (funded by the chemical, oil, food, energy, and automotive industries), the International Life Sciences Institute (funded by food and chemical companies), the Foundation for Clean Air Progress (funded by oil, trucking, and chemical companies), and the Coalition for Animal Health (funded by industrial cattle and hog companies) (Center for Science in the Public Interest 2003).

- The Center for Consumer Freedom is a nonprofit that targets dietary guidelines recommended by the FDA, other government agencies, medical associations, and consumer advocacy organizations. The center has run ads and owns a website that accuses government agencies of overregulation, and has published articles claiming to refute evidence that high salt intake and other dietary guidelines are based on inadequate science (Center for Consumer Freedom 2011). The center was founded with a $600,000 grant from Philip Morris, but has also received funding from Cargill, National Steak and Poultry, Monsanto, Coca-Cola, and Sutter Home Winery (Center for Science in the Public Interest 2003).

SODA AND ORAL HEALTH

In 2003, the American Academy of Pediatric Dentistry accepted a $1 million donation from Coca-Cola. That year, the group claimed that "scientific evidence is certainly not clear on the exact role that soft drinks play in terms of children's oral disease." The statement directly contradicted the group's previous stance that "consumption of sugars in any beverage can be a significant factor... that contributes to the initiation and progression of dental caries." (Center for Science in the Public Interest 2003).

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- In response to proposed tobacco regulations and indoor air-quality standards, R.J. Reynolds and other tobacco companies founded the Get Government Off Our Back campaign. In order to block tobacco-related regulations, the self-described "grassroots coalition" asserted that individual freedom was at stake; companies and individuals should be able to make their own decisions on all sorts of issues. The front group was established to obscure R.J. Reynolds's involvement, as tobacco companies carried a stigma (Apollonio and Bero 2007).
- ExxonMobil has continually funded groups, think tanks, and associations that promote disinformation about uncertainties in climate science. As noted, ExxonMobil helped establish the Global Climate Coalition and the Global Climate Science Team to spread uncertainty about climate science. A UCS report also revealed that Exxon donated more than $15 million from 1998 to 2005 to organizations promoting disinformation on climate change, including the American Enterprise Institute ($1.6 million), the American Legislative Exchange Council ($1.1 million), the Competitive Enterprise Institute ($2 million), the Frontiers of Freedom Institute ($1 million), and the Heritage Foundation ($460,000) (Shulman, Abend, and Meyer 2007).

Influencing the media. To inaccurately portray science and sow doubt and uncertainty, corporations feed the media slanted reports and news stories, and biased spokespeople.

- In 2009, emails stolen from Britain's University of East Anglia surfaced just two weeks before critical international climate change negotiations in Copenhagen. Those who fail to accept the scientific consensus behind climate change mischaracterized the correspondence when talking to the media. Although six separate investigations have cleared the scientists of any wrongdoing (UCS 2011a), the manufactured controversy eroded public support for climate action and undermined the Copenhagen summit, which failed to produce a multilateral agreement to combat climate change.

- The coal and oil industries have spent millions of dollars on public relations to downplay the consensus on climate change. The American Petroleum Institute stated that "victory will be achieved when media understands (recognizes) uncertainties in climate science [and] media coverage reflects balance on climate science and recognition of the validity of viewpoints that challenge the current 'conventional wisdom'" (Shulman, Abend, and Meyer 2007).
- In the 1990s, Philip Morris contracted with the public relations firm Burson-Marsteller to develop articles to submit to mainstream media outlets attacking the EPA's assessment that secondhand smoke is carcinogenic. Forbes ran an article criticizing the EPA and accusing it of wasting taxpayers' money (Brimelow and Spencer 1992). Philip Morris paid Burson-Marsteller $7,731,000 for its work (McGarity and Wagner 2008; Philip Morris 1991).

Curbing the Effectiveness of Federal Agencies

Corporations attempt to undermine the science that federal agencies rely on to develop policy, advocate for policies that hinder the ability of agencies to fulfill their mission, create conflicts of interest, and use political connections to gain access to top-level agency officials..

Companies also attack the roles of regulatory agencies, accusing them of overstepping their legal authority. This reshapes public understanding of the laws Congress has passed to protect public health and safety, and misrepresents how agencies use scientific information to develop specific policies.

Attacking the science. Corporations have attacked the federal science used in forming regulatory policy. Whether questioning procedures or conclusions or calling federal science "junk science," corporations aim to cause regulatory delay. As noted, one tactic is to play up false uncertainty. Corporations have attacked the science underlying policies ranging from air-quality standards to protections for endangered species.

- In 2007, the Supreme Court ruled that the EPA was required under the Clean Air Act to submit an endangerment finding for greenhouse gases. Two years later, the EPA finalized a report concluding that heat-trapping emissions do in fact endanger public health, and then moved forward with regulatory procedures. Almost immediately, oil and coal trade associations and other business groups—including the Competitive Enterprise

ENDANGERED SPECIES

The Endangered Species Act, which requires the U.S. Fish and Wildlife Service (FWS) to use the best available science to determine whether a species is threatened or endangered, has often come under attack from corporations or been manipulated by corporate actors. Industries and industry-friendly government officials have labeled the science underlying such designations "junk science" (Buck, Corn, and Baldwin 2007), and challenged the agency over habitat protections for endangered species. Officials from the Department of the Interior manipulated data on the marbled murrelet and the northern spotted owl, birds native to the Pacific Northwest, under pressure from the timber industry (UCS 2009c, 2009g). Agency officials also knowingly inflated data on the viability of the Florida panther population to approve development within the panther's protected habitat (UCS 2009f).

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Institute, the American Petroleum Institute, the U.S. Chamber of Commerce, and many others—filed lawsuits challenging the EPA policy and attacking the science on which the endangerment finding was based (UCS 2010b).

- This tactic has been well used by tobacco companies to counter evidence of the toxicity of their products (Michaels 2008). Philip Morris aimed "to discredit the EPA report [that secondhand smoke is a Group A human carcinogen] and to get the EPA to adopt a standard for risk assessment for all products" (Ong and Glantz 2001). The strategy was "to form local coalitions to help us educate...about the dangers of 'junk science' and to caution them from taking regulatory steps before fully understanding the costs in both economic and human terms" (Ong and Glantz 2001). Philip Morris and APCO Associates formed the "Advancement for Sound Science Coalition," a front group whose stated mission was to advocate for the use of sound science in policy making, but that existed solely to fight proposed smoking regulations and attack the science used by the EPA (Oreskes and Conway 2010). In Europe, Philip Morris used the same tactic under the banner of "good epidemiology practices" to "impede adverse legislation," in the company's words, and undermine the science used in policy making (Ong and Glantz 2001).
- In 1976, Ethyl Corporation, a primary producer of lead, launched an attack against court-ordered regulation of lead. An Ethyl official criticized the EPA, stating, "The whole proceeding against an industry that has made invaluable contributions to the American economy for more than fifty years is the worst example of fanaticism since the New England witch hunts in the Seventeenth Century." "No person has ever been found having an identifiable toxic effect from the amount of lead in the atmosphere today" (Denworth 2008). Industry representatives attacked more stringent EPA regulations in 1978. Jerome Cole, a representative of the Lead Industries Association, stated that the ambient air-quality standards were "based on a faulty interpretation of the scientific facts," and that they were "totally unnecessary from a health point of view and ruinous for the industry" (Denworth 2008).

"No person has ever been found having an identifiable toxic effect from the amount of lead in the atmosphere."

—Ethyl Corporation spokesman

Hindering the regulatory process. Corporations advocate for policies that hinder the ability of agencies to use the best available science when making decisions. So-called "regulatory reforms" have been enacted or attempted that limit agency resources or place an unnecessary burden of proof on agencies before they can act.

- The Data Quality Act consists of one paragraph that was inserted discreetly into a 2001 appropriations bill at the behest of Jim Tozzi, a consultant for companies such as Philip Morris (Baba et al. 2005). The law gives special interests the ability to challenge, deconstruct, and block scientific information used in federal policy making (Wagner 2005; U.S. Congress 2001). Corporate interests have used the act to support their criticisms of agency policies by cherry-picking data. In response to requests under the Data Quality Act, federal agencies must also conduct a regulatory appeal process, which causes further delays.
- Corporate interests have made concerted efforts through the 112th Congress to roll back regulations and restrict the ability of agencies to use the best science when developing policies. Corporate interests bolstered support for bills such as the Regulations from the Executive in Need of Scrutiny (REINS) Act, the Transparency in Regulatory Analysis of Impacts on the Nation (TRAIN) Act, and the Regulatory Accountability Act—three particularly negative bills that would require agencies to prolong the regulatory approval process and, in many cases, seek approval from Congress before enacting policies. This would

further remove science from the policy-making process and undermine the work of agencies such as the EPA and the FDA (Coalition for Sensible Safeguards 2011). Of the 48 organizations that lobbied in support of the REINS Act, 26 were energy trade groups or corporations. Supporters of REINS included the U.S. Chamber of Commerce (Josten 2011), General Electric, the National Mining Association, ExxonMobil, Koch Industries, the National Association of Manufacturers, and Marathon Oil (Narang and Lincoln 2011).

- Crystalline silica, a basic component of many minerals, can become particles small enough for workers to inhale when they chip, cut, drill, or grind objects. The substance has long been recognized as a serious occupational health hazard. Overexposure to respirable crystalline silica causes an irreversible, progressive lung disease, and is also associated with lung cancer, chronic renal disease, and autoimmune disorders (NIOSH 2002). In February 2011, OSHA finally submitted a rule to protect workers from silica exposure that it has been developing for 14 years. However, nearly a year later, the Office of Management and Budget (OMB) has failed to review the proposal, preventing OSHA from even seeking public input. The OMB is required to review proposed rules within 90 days, with the possibility of a 45-day extension. Silica industry representatives met numerous times with OMB staff about the standard (OMB 2011a, 2011b, 2011c).

Corrupting scientific advisory panels. Government agencies rely on independent advisory panels to provide advice on scientific issues. Members of scientific advisory panels must be able to make informed recommendations without conflicts of interest.

- In 1971, when the EPA was determining the dangers of airborne lead to human health, a panel convened by the National Academy of Sciences included industry representatives but no independent scientists who specialized in airborne lead. Several of the panel members, including its chair, had ties to the lead industry. A scientist who worked for DuPont and was not even on the committee wrote the section of the panel's report that focused on adult epidemiology and the role of lead from gasoline exhaust in air pollution (Denworth 2008).

CHILDHOOD LEAD POISONING

In 2002, the Advisory Committee on Childhood Lead Poisoning Prevention was preparing to recommend whether the Centers for Disease Control and Prevention (CDC) should revise the federal standard for defining lead poisoning. Just a few weeks before the committee's scheduled meeting, two scientists with clear ties to the lead industry were appointed to the committee by Department of Health and Human Services Secretary Tommy Thompson. In doing so, Secretary Thompson had for the first time rejected advice on committee membership from the CDC. The Lead Industries Association had retained one of the scientists, Dr. William Banner, a toxicologist, as an expert witness in an ongoing legal case between the State of Rhode Island and the lead paint industry. The second scientist, Dr. Kimberly Thompson, an assistant professor of risk analysis and decision science at Harvard School of Public Health, had received funding from at least 22 groups with financial interests in the panel's deliberations. In 2004, while admitting that "lead in the body at any level is not good," the committee recommended that the CDC not lower the lead standard (UCS 2009a).

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GULF OIL DISASTER

In 2010, facing substantial public pressure, the Department of the Interior abolished the Minerals Management Service (MMS), the office in charge of assigning permits and regulating offshore drilling, and transferred its tasks to other agencies. The MMS had developed close ties with the industry it was tasked with regulating, and had rubber-stamped permitting and waived environmental impact assessments for the Deepwater Horizon *oil rig off the coast of Louisiana. The rig exploded on April 20, 2010, killing 11 workers and creating the largest oil spill in history. The MMS routinely granted 250 to 400 waivers for drilling projects in the Gulf of Mexico annually (UCS 2010d). The Project on Government Oversight has compiled a list of MMS officials who took high-ranking industry positions after leaving the agency (Project on Government Oversight 2008). A 2010 report from the inspector general (IG) of the Department of the Interior found that MMS officials had engaged in sexual relationships with industry representatives, accepted gifts such as hunting and fishing trips, and found employment in the industry. According to the IG report, "Some MMS inspectors had allowed oil and gas production company personnel located on the platform to fill out inspection forms. The forms would then be completed or signed by the inspector and turned in for review" (Kendall 2010).*

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- In 1998, the EPA charged its scientific advisory committee with determining risks posed by 1,3-butadiene, a compound used to make synthetic rubber and plastics and a by-product of cigarette smoke and gasoline combustion. The chemical's carcinogenicity has been known for some time. An investigation by the Government Accountability Office found that the EPA had failed to investigate potential conflicts of interest (GAO 2001). Many panelists worked for, consulted for, or otherwise owned stock in companies affected by the policy (Infante 2005). The committee failed to classify the compound as a human carcinogen under EPA standards (Sass 2005).
- In 2004, an EPA report assessing the safety of hydraulic fracturing, the controversial process used to mine natural gas, concluded that it posed no inherent threat to drinking water supplies and did not warrant federal regulation. However, a whistle-blower came forward revealing that five of the report's seven peer reviewers would financially benefit from the decision (Grifo et al. 2008).

Spinning the revolving door. Officials who shuttle between high-level government positions and regulated industries or companies undermine the integrity of federal science and public confidence in government. While sharing expertise among different sectors can sometimes be beneficial, there is serious risk that the revolving door will allow individuals with clear financial conflicts of interest to hold key decision-making positions. Predictably, revolving-door officials develop or direct policies that benefit a former or prospective employer. Notably, the legacy of political appointees with conflicts of interest lives on even after their departure—through both the policies they helped develop and the erosion of public trust in agency integrity.

- J. Steven Griles, a Department of the Interior official who had previously been a lobbyist for Arch Coal and the National Mining Association (Center for Media and Democracy 2008), directed the

weakening of regulations on mountaintop-removal mining. Upon leaving federal service, he joined Bluewater Strategies, a lobbying firm whose clients include the American Petroleum Institute and various mining and utility companies (Center for Responsive Politics 2011h).

- Bracewell & Giuliani, formerly known as Bracewell & Patterson, has lobbied on behalf of Arch Coal, Duke Energy, Enron, the American Chemistry Council, and other corporate entities (Center for Responsive Politics 2011a). In 2011, the firm employed at least 12 lobbyists who had come from government positions. Five of these worked for the EPA under the Bush administration (Center for Responsive Politics 2011c).
- In 2004, the general counsel at the CPSC pressured agency employees to manipulate statistics to show that risks from riding all-terrain vehicles (ATV) were declining, despite indications to the contrary. Before working for the CPSC, the general counsel had represented the ATV industry. When CPSC statisticians refused to modify their conclusions, the general counsel delayed the release of their report for three months (Grifo et al. 2008).

Censoring scientists and rewriting or withholding their research. The revolving door has additional consequences. Former corporate representatives and political appointees in high-level positions during the Bush administration used their power to censor scientists and suppress their research. These officials deleted selected evidence from scientific documents, knowingly adopted flawed methodologies, colluded with industry to place pressure on scientists and their supervisors to alter scientific findings, censored scientists to prevent them from speaking publicly, suppressed or delayed the release of scientific findings, and disregarded legally mandated science.

- Julie MacDonald, a deputy assistant secretary at the Department of the Interior, "systematically distorted, manipulated, and misused the scientific process prescribed by the Endangered Species Act" (UCS 2007). She resigned after the department's IG criticized her unethical practices. The IG's report found that MacDonald "disclosed nonpublic information to private sector sources, including the California Farm Bureau Federation and the Pacific Legal Foundation" (Department of the Interior 2006). The problems at the department were not limited to MacDonald. In a 2005 UCS survey, scientists at the FWS reported that their work was subject to pervasive political interference. "Two-thirds of those who responded to the survey—303 scientists—were aware of cases in which Interior Department political appointeesi-

COHO SALMON

In 2001, a few months after the inauguration, Vice President Dick Cheney put significant pressure on Sue Ellen Woodbridge, deputy chief of staff at the FWS, to reverse efforts required under the Endangered Species Act to maintain water levels in Oregon's Klamath Basin to preserve the spawning zones of three endangered fish: the coho salmon and two species of suckerfish. Cheney recognized that preventing use of the water for irrigation had "political ramifications" for farmers and ranchers, who had heavily supported President Bush. Administration officials modified scientific documents to downplay threats to the species, and several FWS officials quit in protest. Weeks later an estimated 77,000 salmon washed up on shore, owing at least in part to a lack of water (Becker and Gellman 2007).

nterfered with scientific findings. Eighty-four scientists reported that they were directed to inappropriately exclude or alter technical information from agency scientific documents" (UCS 2007).

- In a 2010 UCS survey of food safety scientists and inspectors at the FDA, 330 said they had personally experienced instances when public health had been harmed when businesses withheld information on food safety from agency investigators (UCS 2010e).
- Bush administration officials heavily edited and censored federal reports on climate change to create the false impression of uncertainty in the science. For example, the administration removed references to an interagency national assessment of the potential impact of climate change in a number of documents, including the 2003 strategic plan of the Climate Change Science Program (CCSP). A whistle-blower within the CCSP exposed that Philip Cooney, chief of staff for the White House Council on Environmental Quality, had edited the strategic plan and other documents to convey uncertainty and downplay predicted effects of climate change (UCS 2009d). Two days after the interference was exposed, Cooney resigned, and he was soon hired by ExxonMobil. Before working at the White House, Cooney had worked for the American Petroleum Institute and led the oil industry's drive to prevent restrictions on global warming emissions (Revkin 2005).

OIL AND GAS LOBBYING

At the height of congressional debate over climate change legislation in 2009 and 2010, the oil and gas industry expended hundreds of millions of dollars to curb attempts to limit carbon emissions. In 2009 and 2010, the industry employed 800 registered lobbyists and spent $175 million and $145 million on lobbying expenses, respectively (Center for Responsive Politics 2011d). ExxonMobil, a primary opponent of climate change legislation, spent $27 million in 2009 alone—trumping the $22 million spent by all environmental organizations to advocate for the legislation that year (Center for Responsive Politics 2011d). Total lobbying expenses of the oil and gas industry were eightfold those of environmental organizations (Mackinder 2010). The oil industry's investment contributed to the defeat of climate change legislation in July 2010.

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Influencing Congress

On Capitol Hill, money and secrecy in lobbying, excessive campaign funding, and revolving doors give corporate interests unprecedented and undue access to members of Congress. These interests encourage members to challenge scientific consensus, shape how science is used in policy making, and delay action on critical science-based issues.

Money and secrecy in lobbying. Corporations fund a multibillion-dollar lobbying industry based in Washington. Corporate lobbyists have extensive influence on and private access to elected officials and their staff, opening the opportunity for corruption. Since 1998, lobbying has ballooned from a $1.44 billion industry to more than $3.51 billion in 2010 (Center for Responsive Politics 2011b).

- In the weeks leading up to the Obama administration's decision to delay standards on ozone

emissions, recommended by federal scientists and proposed by the EPA, top officials at the White House and the OMB, including White House chief of staff William Daley, met with business groups such as the Business Roundtable, the U.S. Chamber of Commerce, and the American Chemistry Council (Broader 2011; Eilperin 2011). The Clean Air Act requires regulators to base standards for certain pollutants, such as ozone, on science. Federal scientists recommended that the maximum standards be close to 60 to 70 parts per billion (ppb). However, the administration announced that it would reject the new standards proposed by the EPA and allow the limit to remain at 84 ppb.

Revolving door on the Hill. As with the revolving door between federal agencies and industry, members of Congress and congressional staff come from or leave for corporate lobbying firms or industry. In the "reverse revolving door," special-interest lobbyists go to work for congressional offices or committees. These practices give corporations and their lobbyists outsized access to elected officials and the power to craft legislation. Staff coming from or returning to corporations have insider information about congressional relationships, potential legislation, and loopholes in policies. Staff who were instrumental in creating specific legislation sometimes leave Congress for corporations affected by the legislation.

- In the last 10 years, some 5,400 former congressional staffers have left to become lobbyists, while 605 lobbyists have left their positions to work for Congress (Farnam 2011). Former lobbyists often accept positions with committees or agencies that they had previously lobbied. Nearly 400 former members of Congress are now employed by lobbying firms (Center for Responsive Politics 2011; Farnam 2011).
- After passage of the Medicare prescription drug bill in 2003, dozens of lawmakers and congressional staff directly involved in negotiating it accepted positions at lobbying firms representing pharmaceutical companies—or at trade organizations and corporations that directly benefitted from the new law. For example, Representative W.J. "Billy" Tauzin, a primary negotiator among the administration, the Pharmaceutical Research and Manufacturers of America (PhARMA), and members of Congress, retired from Congress two months after the bill passed and became president of PhARMA, with an estimated $2 million salary (Revolving Door Working Group 2005).

More than 300 scientists and inspectors reported that they personally experienced instances when public health had been harmed when businesses withheld information on food safety from agency investigators.

—2010 UCS survey of FDA food safety scientists and USDA inspectors

Influencing Congress through financial contributions. The first laws limiting the influence of corporations on federal elections date to the early 1900s, put in place to prevent banks, railroad companies, and other companies from buying elected officials (Hossain 2010). However, the 2009 Supreme Court ruling in *Citizens United v. the Federal Election Commission* opened the door for expanded private-sector influence, as corporations can now funnel unlimited amounts of money into congressional and federal elections through political action committees (PACs).

- In the 2010 federal elections, political organizations not directly coordinating with a candidate, such as PACs, spent $304 million, a record for a nonpresidential year (Center for Responsive Politics 2011g).
- In 2010, the oil and gas sector donated more than $10 million to PACs. The largest donors were Koch Industries ($1.2 million) and ExxonMobil ($1 million).

- ReGen Biologics attempted to gain FDA approval for clinical trials of Menaflex, a device it developed to replace knee cartilage. After an FDA panel rejected the device, the company enlisted four members of Congress from its home state of New Jersey to influence the evaluation process. In December 2007, Senator Frank Lautenberg, Senator Robert Menendez, and Representative Steve Rothman wrote to FDA Commissioner Andrew von Eschenbach asking him to personally look into Menaflex. Soon thereafter, the commissioner met with ReGen executives and heeded the company's advice to have Dr. Daniel Shultz, head of the FDA's medical devices division, oversee a new review. The FDA fast-tracked and approved the product despite serious concerns from the scientific community (UCS 2009b).

Exploiting Judicial Pathways

State and federal courts are increasingly used to interfere with the science tapped to protect public health and the environment. In recent years, the courts have become a battleground for partisanship and a means to deconstruct science or delay science-based regulation. Corporate interests have expanded the influence of politics on the judicial system, used the system to undermine science, and exploited judicial processes to bully and silence scientists.

Expanding the influence of politics on the judicial system. As with congressional elections, state judicial elections have been transformed into multimillion-dollar campaigns backed by political parties and special-interest groups.

- Judicial campaign fundraising surged from $6 million in 1989–90 to more than $45 million in 2007–08 (Sample et al. 2010). A 2001 poll found that more than 90 percent of elected judges said they were under pressure to fundraise for their election (Sample et al. 2010; Lenzner and Miller 2003). Pro-business groups such as the U.S. Chamber of Commerce and the National Association of Manufacturers contributed heavily to these campaigns. The U.S. Chamber of Commerce has pumped tens of millions into judicial campaigns, and won 21 of 24 races that it participated in from 2000 to 2003 (Lenzner and Miller 2003).
- Massey Coal CEO Don Blankenship donated $3 million to thwart a challenger to Brent Benjamin, a justice on the Supreme Court of Appeals of West Virginia. The donation happened to coincide with an appeal of a $50 million fine levied against Massey that Justice Benjamin was overseeing (Sample et al. 2010).

Judicial review of scientific literature. Judges are playing a growing role in determining whether specific scientific information is admissible in court and ruling on science-based laws and regulations. In so doing, judges often end up functioning as de facto peer reviewers for scientific information, a task for which they are not adequately trained. As courts settle disputes between regulated companies and the government or the public, corporations have a lot to gain or lose from judicial decisions.

- In 2010, Oliver Wagner, a federal district judge overseeing objections to endangered-species protections for the delta smelt, an endangered fish native to northern California, threw out a report by the FWS. Wagner called the research "sloppy science," and the scientists in charge of the report "zealots" (Sullivan 2010). While the judge affirmed that the fish was worthy of endangered status, he rejected FWS proposals to protect the amount of water flowing through the Sacramento–San Joaquin River Delta. This was a victory for the Metropolitan Water District of Southern California, which had contested the protections. Shortly after his decision, Wagner retired and went into private practice. Two months later, he agreed to represent the Westlands Water District, a litigant in many of the water cases that he had ruled on. An independent FWS investigation cleared the scientists of any wrongdoing in early 2012 (Boxall 2012).

The endangered delta smelt

- In 1993, Citizens for a Sound Economy, a corporate-funded free-market think tank, sponsored a forum titled the Foundation for Research on Economics and the Environment (FREE) at a ranch in Bozeman, MT. The forum featured seminars for federal judges by corporate executives, interspersed with horseback rides and hikes. Two weeks before attending the FREE forum, one federal judge had rejected a petition from the timber industry to roll back endangered-species protections. Shortly after attending the forum the judge changed his mind. He held a rehearing and switched his vote in favor of the timber industry (Moore 2002).

- In 1985, the FDA investigated Parlodel, a drug used to stop postpartum lactation. Based on animal studies and case reports, the agency found that the drug caused a rapid rise in blood pressure. Novartis, the manufacturer, agreed to list warnings of hypertension, seizure, and stroke on the drug's label. Several women who used Parlodel sued Novartis for their seizures, strokes, and other health effects, but several judges dismissed their cases. The judges rejected the testimony of scientists and other experts who agreed with the FDA's findings because they were based on animal studies and case reports. The judges held that there was not enough epidemiological evidence of the correlation between Parlodel use and seizures and strokes (Michaels 2008).

CHAPTER 2

Restoring Scientific Integrity: The First Three Years

In the 2008 report *Federal Science and the Public Good*, UCS provided clear and immediate steps the administration and Congress could take to defend science from political and private-sector interference and promote a culture of scientific integrity within the federal government. Taking a five-pronged approach, we sought to protect government scientists, make government more transparent, reform the regulatory process, ensure robust scientific input to federal decision making, and strengthen scientific monitoring and enforcement of current laws.

Restoring scientific integrity to federal policy making is a multistep process that requires cultural change within both government and the private sector. The president and agency leaders have taken important initial steps to foster this change, but their performance has been uneven, while Congress has made little progress. This chapter examines what the government has accomplished so far. Chapter 3 then lays out solutions that both the federal government and the private sector should advance during the next presidential term.

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FDA Commissioner Margaret Hamburg speaks at the United Nations World Health Assembly.

Early Presidential Leadership

President Obama is the first president to take on the challenge of creating strong standards for scientific integrity and improving scientific advice to the federal government. From the beginning, the president signaled that scientific integrity reform would be a priority for his administration. In his inaugural address, he pledged to "restore science to its rightful place," and took several initial steps to make good on that promise:

- The president appointed a widely respected scientist, Dr. John Holdren, to lead the White House Office of Science and Technology Policy (OSTP), and placed the President's Council of Advisors on Science and Technology (PCAST) under the leadership of Dr. Holdren. The president also appointed several other top scientists to high-level positions, including Nobel laureate and Energy Secretary Stephen Chu, and NOAA Administrator Jane Lubchenco.
- President Obama's first memorandum, "Transparency and Open Government," stated that "openness will strengthen our democracy and promote efficiency and effectiveness in government." The resulting ambitious Open Government Directive provides for more public access to the work of the federal government, including scientific information.
- In March 2009, the president issued a memorandum on scientific integrity that set a goal of "ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes" (Obama 2009c). While announcing the memorandum, the president said, "It is about letting scientists like those here today do their jobs, free

from manipulation or coercion, and listening to what they tell us, even when it's inconvenient—especially when it's inconvenient."

- At the end of 2010, the OSTP formally issued guidelines requiring federal agencies to develop and implement scientific integrity policies. The policies had to encompass five key areas: foundations of scientific integrity in government, public communication, the use of federal advisory committees, professional development of government scientists and engineers, and implementation (Holdren 2010). Nineteen agencies have submitted draft policies to the OSTP, and six have publicly released draft or final policies (UCS 2011b).
- The process of developing scientific integrity policies has contributed to positive changes in agency culture. For example, NOAA Administrator Jane Lubchenco encouraged all NOAA employees to provide input into the agency's policy. The resulting conversations raised employees' understanding of the importance of scientific integrity in government, and encouraged employees at all levels to take ownership of the final policy.
- On January 30, 2009, President Obama released an executive order on regulatory review reversing three major tenets of the Bush administration's executive order 13422. The new order restored "regulatory policy officers" to a policy coordination role, and returned the power to commence regulatory rule making to agency heads. The reversal also partially insulates scientific documents from inappropriate political review by the OMB, and removes "market failure" as the primary justification for agency regulations.

"It is about letting scientists…do their jobs, free from manipulation or coercion, and listening to what they tell us, even when it's inconvenient—especially when it's inconvenient."

—President Obama

Protecting Government Scientists

Federal scientists and researchers need certain rights and protections to fulfill their responsibility to the public. Unfortunately, hundreds of government scientists have reported fearing retribution for speaking openly about their research results (UCS 2005, 2009e). Current whistle-blower law does not protect government employees who expose efforts to alter or suppress research or technical data.

Congress has come very close in recent years to passing laws that would protect federal whistle-blowers seeking to preserve scientific integrity. Good whistle-blower legislation is now making its way through both the Senate and the House of Representatives, but faces several legislative hurdles before it can be sent to the president for signature.

Making the Government More Transparent and Accountable

Decisions made behind closed doors threaten both the integrity of federal science and the foundations of democracy. Opening up federal science and decision making to scrutiny from Congress and the public is an important—and often inexpensive—means of preventing political interference in science. Such transparency should include more disclosure of the inputs to regulatory decision making and the influences on it; wider use of information technology to allow public access; and the reform of agency communication policies to allow scientists and researchers to freely share their expertise.

From the beginning, the president has provided strong and consistent leadership in this arena, issuing multiple executive orders and memoranda directing federal agencies to develop policies that would make the government more transparent and accountable. While not perfect, the administration's Open Government Directive has made public large amounts of information. Among the administration's specific accomplishments:

- Attorney General Eric Holder instructed agencies to presume that government information should be made publicly available under the Freedom of Information Act (FOIA), apart from well-defined exceptions (Holder 2009). This reversed a default position under the Bush administration that presumed the opposite.
- The administration revamped *data.gov*, a repository of data collected by the federal government, making many datasets more widely available.
- After initially claiming that its visitor logs were presidential records exempt from disclosure, the White House began periodically releasing a record of all individuals who meet with White House officials at the White House (The White House 2011).
- Some agencies have made transparency a priority. For example, EPA Administrator Lisa Jackson issued a "fishbowl" memorandum on her first day on the job clarifying that the agency would operate with full transparency—as if it were a fishbowl (Jackson 2009). The agency later made information on chemical safety more publicly accessible by putting the inventory of chemicals established under the Toxic Substances Control Act online free of charge (EPA 2010).
- Some agencies have loosened restrictions on the ability of their scientists to share their research results and analysis with the public. For example, NOAA's scientific integrity policy explicitly gives its scientists the authority to speak to the media without obtaining permission from press officers, and reaffirms their right to freely express their personal opinions as private citizens (NOAA 2011).
- Some agencies have improved their policies on providing clearance for official and non-official publications, presentations, and other information. For example, the FWS developed a publications policy that better ensures the free flow of scientific information from the agency (FWS 2008).
- The White House scientific integrity guidelines, and resulting agency policies, have affirmed that scientific peer review is the appropriate standard for ensuring the quality of federal scientific information (Holdren 2010).
- The president has begun reducing overclassification, and the use of designations such as "controlled unclassified information," by issuing an executive order instructing agencies to reform the classification process, promoting the release of more information, and eliminating outdated classification requirements (Obama 2010). The administration has set strong deadlines for revised policies to ensure that agencies follow the directive.
- While Congress has not passed the Historical Records Act, which would facilitate routine declassification of historically significant government information after a set period of time, the administration has issued an executive order creating a process to expedite the declassification of such information (Obama 2009d).
- The administration has readily embraced the use of technology to make government information publicly usable and shareable, such as by updating agency websites, expanding access to federal databases, and making online information more searchable and user-friendly.

© EPA

EPA Administrator Lisa Jackson speaks at a company that manufacturers batteries for electric vehicles.

Reforming the Regulatory Process

Our democracy is based on a clear separation of powers between the legislative, executive, and judicial branches of government. Federal agencies were created to implement and enforce U.S. laws. Each agency has developed the expertise, experience, processes, and policies it needs to pursue its mission and fulfill its particular duties. While the White House is responsible for overseeing these agencies, it should strike an appropriate balance between administration priorities and agency independence. The regulatory process should rely heavily on the reservoir of scientific and technical knowledge within the agencies. Congress, too, should recognize that the executive branch has the expertise to implement the laws that Congress has enacted.

- Many find the regulatory process confusing and cumbersome. In response, the White House has improved *regulations.gov*, a portal for information on proposed, pending, and final regulations, and has made the information more accessible.
- The Obama administration initially committed to developing an executive order to replace Executive Order 12866, issued under President Clinton, which outlines principles and planning processes that agencies must follow in developing regulations. That executive order also gives the OMB's Office of Information and Regulatory Affairs (OIRA) the authority to coordinate agency rule making, effectively making OIRA a gatekeeper for new regulations that are considered to be significant. In February 2009, the OMB solicited public comments on what a new executive order should include—an unprecedented approach to the process. However, the White House has not yet issued a new order.

Members of Congress have put forward many proposals that would undermine the ability of agencies to use science in carrying out laws such as the Clean Air Act and the Endangered Species Act. These include, for example, the Regulations from the Executive in Need of Scrutiny (REINS) Act, the Transparency in Regulatory Analysis of Impacts on the Nation (TRAIN) Act, and the Regulatory Accountability Act. All these bills would require agencies to prolong the regulatory approval process, and, in many cases, to seek approval from Congress before enacting policies. The Obama administration has so far opposed these proposals.

Ensuring Robust Scientific Input to Federal Decision Making

Both the administration and Congress have recorded some achievements in ensuring that federal policy decisions are fully informed by the best available science.

- The president elevated the science advisor position to report directly to the president. Under the Bush administration, the science advisor reported to the White House chief of staff, limiting his access to many important discussions.
- The administration placed PCAST under the direction of the OSTP, improving the council's ability to provide the president with timely scientific advice. PCAST has met regularly and made its bimonthly meetings accessible to the public through webcasts and public comment periods during the meetings. The latter have allowed PCAST to hear from scientists outside the government on a wide range of topics.
- The Office of Government Ethics, an independent executive branch agency, now requires new federal employees to submit conflict-of-interest statements, and to recuse themselves from policy making that affects previous employers. Federal employees who are seeking jobs outside government are also prohibited from working on policies that would benefit a prospective employer (Office of Government Ethics 2012).
- Bipartisan legislation has advanced in Congress that would reform the Federal Advisory Committee Act (FACA). In 2010, more than

The President's Council of Advisors on Science and Technology

1,000 advisory panels provided federal agencies with guidance on critical policy issues ranging from the BP oil spill in the Gulf of Mexico to FDA approval of drugs and devices (GSA 2011). The legislation would eliminate political litmus tests for potential members, such as which candidate they supported in the presidential election—a question asked during the Bush administration. The legislation would also provide a mechanism for the public to nominate or comment on potential committee members, increase disclosure of committee operations, and potentially reduce conflicts of interest. The bill also better distinguishes between "special government employees" (SGEs), who are chosen for advisory committees because of their expertise, and "representatives," who serve on behalf of a specific constituency. SGEs are required to report financial conflicts of interest, while representatives are not. Better clarity will prevent agencies from designating committee members who should be SGEs as representatives to avoid federal ethics rules. The legislation also requires agency officials and the Office of Government Ethics to assume greater oversight of such designations. Finally, the legislation closes loopholes created by court decisions that allowed corporate interests to advise the government without any disclosure or opportunity for public comment.

Restoring scientific integrity to federal policy making is a complex challenge that requires cultural change within the government and the cooperation of Congress and the executive branch. The next chapter addresses the reforms that are in progress or have yet to be realized.

CHAPTER 3

The Next Four Years

Despite the administration's achievements and reforms thus far, more action is needed to address threats to the integrity of science in federal policy making. In 2008, in *Federal Science and the Public Good*, UCS proposed a number of reforms to tackle this problem.

Some of the proposed reforms are in progress but not yet complete, such as those promoted by the White House guidelines on scientific integrity. To ensure long-term cultural change within federal agencies, they must institutionalize the needed reforms quickly and comprehensively.

Curbing inappropriate corporate influence—the main driver of political interference—will require going beyond government to institute reforms in the private sector. This section therefore lays out essential changes not only within the White House, federal agencies, and Congress, but also suggests areas of reform among corporations, academia, scientific societies, and the media.

In proposing these reforms, we have drawn on ideas from a number of organizations and individuals who track government and corporate integrity—notably OMB Watch (OMB Watch 2011), the Center for Progressive Reform (Steinzor and Wagner 2008), and the Project on Government Oversight (Revolving Door Working Group 2005). Reports by Thomas McGarity and Wendy Wagner (McGarity and Wagner 2008) and David Michaels (Michaels 2008) were also instrumental in advancing our thinking.

We will continue to develop and refine these proposals, as well as the mechanisms needed to achieve them. The reforms we propose here are not comprehensive. For example, the Supreme Court's *Citizens United* decision to allow unlimited corporate spending in federal elections has broad implications for the use of science in federal decision making, but is beyond the scope of this report.

Essential Federal Reforms

The administration, federal agencies, and Congress should continue to put in place policies that protect government scientists, make the government more transparent and accountable, reform the regulatory process, improve scientific advice to policy makers, and strengthen monitoring and enforcement of regulations. We call on Congress and the executive branch to enact these reforms to restore integrity to the science that protects our health, safety, and environment.

Protecting Government Scientists

Congress should pass the strongest possible whistle-blower protection law, and the president should sign it. Court decisions have greatly weakened the Whistleblower Protection Act of 1989 over the past two decades. The law should:

- Make clear that whistle-blower protections against retaliation apply to federal employees who report efforts to alter or suppress scientific research and technical information.
- Give federal whistle-blowers the same access to jury trials that Congress has given to millions of private-sector workers.

Congress should strengthen the Merit Systems Protection Board and Office of Special Counsel, to give federal employees a secure means of reporting misconduct and corruption and protect them from unlawful retaliation.

The administration should continue to make clear that it will not tolerate retaliations against whistleblowers through reassignments, demotions, or terminations. Agency heads who have not already done so should also issue a memorandum encouraging staff to speak out internally about concerns—especially those involving abuses of science—and assert that the agency values their input.

The National Academy of Sciences should explore appropriate responses for scientists and institutions who face harassment or intrusive open-records requests that interfere with their ability to pursue research.

Making Government More Transparent and Accountable

Agency policies on scientific integrity should incorporate the following principles regarding media:

- Scientists and researchers may freely express their personal views (outside a few narrow restrictions) if they provide an explicit disclaimer that they are speaking as private citizens and not representing official policy. Scientists should not have to obtain approval from an agency's public information officer before responding to a media request.

"Staff should be encouraged and supported to do and publish research. Currently we are discouraged from that because managers find it too burdensome."

—FDA Scientist (UCS 2012)

- Scientists and researchers have the right to review, amend, and comment publicly on the final version of any document or publication that relies significantly on their research, identifies them as an author or contributor, or purports to represent their scientific opinion.
- Agencies should develop "differing professional opinion" procedures to resolve professional disagreements over scientific information.

Agencies should strengthen their scientific integrity policies by specifying the monetary amounts, time periods, and relationships that constitute conflicts of interest for federal scientists, and enforce those policies. These policies should enhance the more general guidelines put forth by the Office of Government Ethics.

Agencies' policies on scientific integrity should establish procedures for addressing allegations of political interference in science. To ensure accountability, agencies should publicly report aggregate numbers of these allegations and detail specific instances of confirmed misconduct on an annual basis.

The science advisor should review agency policies on clearance for official and nonofficial publications, presentations, and other information, to ensure the free flow of scientific information.

- Agencies should set reasonable time limits (such as 30 days) for reviewing and clearing scientific publications and presentations. Under such a policy, a supervisor or other reviewing official would provide written clearance, specifying any needed changes, within the time period. If the reviewer did not meet this deadline, the employee could submit the material for publication or presentation with a disclaimer stating that it does not represent official agency views or policies.
- Agencies should periodically make draft versions of official documents and scientific reports available to the public. A document that has been completed by agency staff yet held up

in policy or interagency review for longer than six months should be released as drafts.

- An agency employee should not have to submit scientific work performed during personal time for internal review, even if the employee identifies his or her employer, provided that the work includes an appropriate disclaimer stating that it does not represent agency policy.

The administration should review legal barriers to the public release of scientific information held by the government, such as standards for "confidential business information" (CBI), and work with Congress to close loopholes that keep this information out of the public record. Companies that submit scientific information to the government often request CBI designation, which exempts the information from public review. Standards should shift the burden of proving that information qualifies for this exemption to those requesting it. For instance, any entity asking for CBI protection for certain information should submit a thorough explanation of why it is warranted. This is particularly important for information on drugs, chemicals, medical devices, and other products that may affect public health and safety and the environment.

The administration should continue to reform the classification process and implement existing executive orders within federal agencies. The administration should also commit to restoring independent oversight of the classification process.

- The White House should ensure that agencies are rigorously implementing executive orders 12958 and 13526, which reduce overclassification and make declassification more efficient.
- The president should work with Congress to pass the Historical Records Act, to facilitate routine declassification of historically significant information after a set period of time.

The president and Congress should continue work on FOIA reforms. Memoranda from the attorney general's office and executive orders to federal agencies have helped create a default of disclosure rather

than secrecy. However, leadership to continue the release of government information is needed.

- Congress should ask the Government Accountability Office to report on the funding that various federal agencies need to handle FOIA requests. Agencies should have adequate resources to process FOIA requests in a timely manner.
- The president should instruct the OMB's Office of E-Government and Information Technology to create a centralized digital database for FOIA requests—one that interacts with agency FOIA offices. Such a system could make the FOIA process more efficient by reducing duplication of requests and providing comprehensive public access to information released under FOIA.

While the administration has readily adopted new information technology, it should continue to improve its use to share information with the public. For example, the administration should:

- Expand and improve metadata standards, which govern how government datasets are categorized and organized, to make government data more usable, searchable, and accessible.
- Digitize older materials and make them available online.

The president should further encourage agency heads to operate under principles of openness. Basic information on how the government runs

should be freely and easily available to the public. The administration should create a searchable database of information on who receives federal grants, contracts, and other funding, how that money is spent, and who is lobbying the executive branch.

Federal agencies should follow the example of the White House and institute a transparency policy for meetings with representatives of outside entities. This policy should require that an agency post on its website a complete record of all meetings with outside entities, including for-profit and not-for-profit organizations, other agencies, and individuals (except for meetings related to national security). While the White House has committed to releasing visitor logs in a timely manner, agencies have been slow to adopt the same standards. The visitor logs should apply to political appointees, employees in the senior executive service, and GS-14–level and GS-15–level employees.

Top agency and administration officials should also publish their professional calendars online. Such a policy need not be burdensome, as officials could enter the information directly into a database before the start of any meeting. The database should include the names and affiliations of meeting attendees as well as the date, time, location, and subject of the meetings. Federal agencies should also publish aggregate statistics on when and how many times an official met with an individual or a representative of an organization. These steps would allow the public to better understand who is influencing science-based policy decisions.

The White House should restructure the Office of Government Ethics to give it more power to enforce ethics standards. Ethics officers now serve only in an advisory role. The office should have the mandate and resources to pursue ethics violations within federal agencies, monitor the revolving door, review conflict-of-interest reports of political appointees, and suggest whether a financial conflict of interest would compromise an appointee's ability to fulfill the requirements of a position. Ethics officers for each agency should report directly to the Office of Government Ethics rather than to agency officials.

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The administration should create a centralized Internet database of lobbying reports, ethics records, and campaign finance filings in a searchable, sortable, and downloadable format.

Congress should strengthen post-employment rules for members and staff.

- Congressional restrictions on lobbying should expand from a one-year limitation to a full two-year cycle. Senators are now subject to a two-year "cooling off" period before they can lobby. This provision should apply to members of the House and senior congressional staff.
- Former members of Congress who become lobbyists should be stripped of congressional privileges such as access to restricted areas.
- Loopholes in the disclosure of lobbying activity and registration requirements for lobbyists should be closed. The definition of *lobbyist* should be expanded to include those who work for lobbying firms and give "strategic advice" on legislative advocacy.

Congress should pass legislation that would expand disclosure of indirect contributions to political campaigns (such as those to super-PACs), and limit contributions that could compromise the independence of members of Congress.

- Individuals or entities who have begun negotiating a contract or lease with the federal government should refrain from making financial contributions to any political party, committee, or candidate.
- Entities that have received a federal contract or funding should be prohibited from spending funds and making contributions for election-related communication.
- Congress should improve the reporting and disclosure of political donations from individuals, corporations, nonprofits, and other organizations.

Congress should strengthen standards for certain tax-exempt statuses such as 501(c)(6) to require entities to disclose membership and funding sources. This would allow citizens to hold companies accountable for the activities of the nonprofit organizations that they fund.

Reforming the Regulatory Process

Congress should consult with agencies to remove outdated or unnecessary procedures to make the regulatory process and the allocation of resources more efficient.

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Congress should amend the Paperwork Reduction Act. Reforms should eliminate required yearly reductions in paperwork "burden," which have curbed the ability of agencies to conduct surveys and collect data. Reforms should return authority to federal agencies to collect the information they need to evaluate programs, identify regulatory gaps, and otherwise pursue their missions.

Federal agencies should have the resources to expand oversight and inspection of research facilities and research contractors. As more government work shifts to contractors, the government should have the ability to hold them accountable.

Congress and the president should work together to ensure that potential adverse effects of products are reported to the federal government, and in a timely manner. These products should include chemicals heavily used in manufacturing, and drugs and medical devices submitted for FDA review.

- Federal agencies should strengthen and broaden the definition of adverse effects and potential adverse effects.
- Entities that have knowledge of the potential risk of a product, such as a hazardous substance, drug, or medical device, should be required to disclose any information about the product.
- Congress should make federal contractors individually responsible for reporting potential adverse effects.
- Congress should stipulate that requirements to report adverse effects override any protections for CBI and confidentiality clauses in contracts.
- Congress should pass legislation that makes individuals—not merely the companies they work for—accountable for failure to report potential adverse effects.

A federal registry, similar to the FDA's clinical trials registry, should be created for scientific research submitted to agencies such as the EPA and OSHA. Corporations that provide information to the

government as part of a regulatory process or requirement should have to submit all research and studies that they have commissioned rather than selecting those that are most favorable.

Agencies should impose penalties or fines when companies reporting information to the government miss required deadlines. This is particularly important for information regarding toxic substances, natural resources, drugs, and medical devices. The FDA now penalizes corporations that do not provide information required for the drug approval process by moving them to the back of the queue.

The president should clarify the role of the OMB in the regulatory process, restricting it from interfering in the scientific work of executive branch agencies. While the OMB plays an important role in coordinating and overseeing the process of crafting regulations, it does not have the expertise to credibly review the scientific findings underlying policy decisions across multiple federal agencies. In many documented cases, the OMB, acting in corporate interests, has overruled or delayed proposed rules or otherwise compromised the ability of agencies to fulfill their mission.

- The president should issue an executive order outlining the process his administration will follow in developing regulations. The regulatory process should respect the scientific and technical expertise of regulatory agencies, and exclude the OMB from participating in purely scientific determinations.
- The OMB should replace its overly prescriptive, "one-size-fits-all" policies on peer review and risk assessment with broader and more flexible guidelines that leave room for individual agencies to devise their own policies.

The president should instruct the OMB to set forth broad guidelines on the use of cost-benefit analysis in the regulatory process. These guidelines should emphasize that such analysis should be used according to agency discretion, should be consistent with the intent of the relevant congressional statute, and should not determine the regulatory outcome unless specifically required by law. The cost-benefit analysis process should also be fully transparent, and the White House should never manipulate the results.

The OMB should work with federal agencies to make the regulatory process more transparent, expand rule-making dockets, which track regulations under development, and make the dockets more user-friendly. Despite some reforms making the regulatory process more transparent, it is still very difficult for the public to find comprehensive information on how regulations are crafted. Because corporate agendas have influenced OMB decisions, the rule-making docket should incorporate the following reforms:

- The OMB should encourage the use of interactive technology to engage the public in the regulatory process.
- The OMB should develop a regulatory tracking system that provides information on regulatory proposals earlier in the rule-making process. The OMB now produces reports on the president's regulatory agenda and the status of any rules in preparation only twice each year. A regularly updated tracking system would provide the public with more accurate and timely information on pending regulations.
- Agencies should disclose more information about how they developed a regulation, to prevent political appointees or interested parties from inappropriately influencing the process. The rule-making docket should contain:
  i. All scientific studies in an agency's possession related to a proposed regulation, regardless of whether a regulation cited a study or a study directly informed the final decision.
  ii. All official interagency communications regarding regulations under review, including those from the White House.
  iii. Completed and peer-reviewed drafts of agency documents prepared by scientific or technical staff before they are subjected to White House or interagency review.

The president should terminate inappropriate interagency review of scientific information. The administration should clarify which agencies have primary authority in various areas of scientific expertise, and limit other agencies' review of that information to advice and comment. In doing so, the president should consult the legislation authorizing each agency, which describes its particular duty to the people of the United States.

The president should develop and publicly release criteria for the use of signing statements, which instruct agencies how to implement or enforce laws, and Congress should scrutinize all signing statements and executive orders for content that oversteps the intent of legislation.

Agencies should publish a summary statement of the scientific basis for any regulatory decisions informed by science. The statement should be available in a timely fashion—perhaps included in a regulation's preamble—and should clarify how officials made the final decision given the evidence. The statement should include:

- The rationale for the decision, including all scientific documents and data used to make it.
- A minority report voicing any significant dissenting scientific evidence or opinions, and an explanation of how the agency resolved such differences of opinion.
- Identification by name of each official and employee who participated in the decision.

The FDA Amendments Act of 2007 incorporates such transparency requirements, and other federal agencies adapt them.

Strengthening Scientific Advice to the Government

Congress should enact legislation to close loopholes in FACA. These changes should:

- Extend FACA rules to all advisory committees, including panels, subcommittees, and contractor-convened panels.
- Extend the definition of committee membership, and FACA's "balance" requirements, to include non-voting members who regularly attend meetings and provide information.

Agencies should better track the work of advisory committees and respond to their findings and recommendations.

- Agencies should clearly state what product they require of each advisory committee, and set a timeline and work plan for creating that product.
- Agencies should clarify whether the mandates of individual advisory panels are purely scientific, a mix of scientific and policy, or purely policy.
- Agencies should establish and enforce clear policies for incorporating committee findings and recommendations into agency decision making.
- Agencies should also publicly document any decision to overrule the recommendations of a scientific advisory committee, and provide a legitimate explanation of the decision.
- Agencies should improve the disclosure of financial conflicts of interest of advisory committee members, and limit the number of waivers granted. Any recommendation from an advisory committee should include the number of waivers. The ultimate goal is to make advisory committees conflict-free.

FDA Advisory Committee meeting

Congress should create a mechanism for giving members timely, policy-relevant, and impartial scientific and technological analysis and advice that will help them make decisions on new initiatives and laws and allocate taxpayer dollars.

To create good policies, legislators must understand a wide range of highly technical subjects. Congressional staff members who can analyze technical information and distill it into a concise and useful form are an essential resource. None of Congress's research offices is equipped to provide the needed advice. The National Academy of Sciences remains the gold standard for advice on scientific topics, but it operates on a longer timeline and is not set up to respond to short-term congressional needs, such as interpreting information and comparing policy options. The Government Accountability Office and the Congressional Research Service are better able to meet the needs of legislators, but they do not have a broad base of scientific expertise.

Federal agencies should set standards that allow them to better assess the quality of scientific information submitted by corporations, trade associations, private research companies, unions, and other institutions.

- Federal agencies should require financial conflict-of-interest disclosure for any scientific information submitted to the government.
  i. Agencies should require conflict-of-interest statements for all research considered during policy making, whether publicly or privately funded. Conflict-of-interest policies should ensure that financial conflicts are publicly disclosed when scientific information is submitted. Conflict-of-interest policies should include the disclosure of "all financial affiliations, funding sources and financial relationships that could be perceived as potential sources of bias" (*Science* 2012). Scientists should also report and describe the role sponsors had "in the study design; collection, analysis and interpretation of data; writing of the report; and the decision to submit the report for publication" (International Committee of Medical Journal Editors 2009).
  ii. If a researcher is unable to obtain or provide this information to federal officials, they should provide a summary of whether they deemed the information reliable.
  iii. Knowingly failing to report financial conflicts of interest should be treated as scientific misconduct.
- The government should hold companies from which they accept information accountable to high scientific integrity standards. Companies submitting scientific information to the government should:
  i. Never enter into contracts that limit the ability of researchers to publish their data or findings. Scientists should have the right to publish research findings without the influence or consent of a sponsor.
  ii. Affirm that interested parties were not directly involved in the study design, data collection, analysis, or report write-up. The science should be protected from manipulation, reanalysis, or suppression.
  iii. Make individuals, not merely the companies they work for, subject to penalties for any manipulation or suppression of science.

Strengthening Monitoring and Enforcement

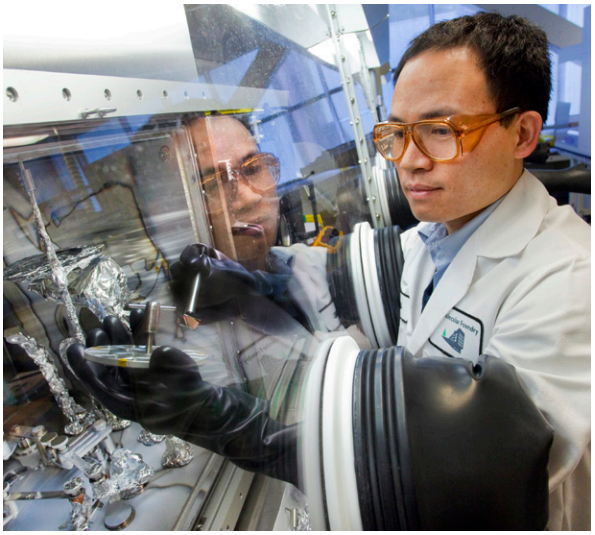
Agencies should make the scientific information they gather through monitoring (data collection) programs public and use it in decision making. A searchable, shareable database of federal monitoring programs should be available to the public through *science.gov*. Examples of such monitoring programs include air pollution monitoring networks, satellite observations of Earth systems, and the collection of statistics on workplace injuries. Agencies should work to identify data gaps, restore important monitoring systems that have been downsized, and convene advisory committees to identify new monitoring needs.

Congress should investigate the ways in which reduced or eliminated funding for monitoring and enforcement has undermined the integrity of science. Greater transparency in budget and spending decisions would help expose instances where funding levels have been manipulated for political purposes. Congress should conduct oversight of these instances either through hearings or through investigations by the Government Accountability Office.

Private-Sector Reforms

Corporations, nonprofits, academic institutions, scientific societies, and the media all have critical roles to play in reducing abuses of science. As a logical extension to federal scientific integrity policies, these institutions should develop or revisit their policies on scientific integrity, ethics, and misconduct. The following principles could provide a useful starting point:

- Organizations should foster a culture in which honest investigation, open discussion, and a firm commitment to evidence are highly valued. Continued training in and discussion of scientific integrity are key.
- Employees should refrain from actual or perceived acts of scientific misconduct. These include but are not necessarily limited to fabrication of results, falsification of data, and plagiarism in proposing, conducting, and reviewing scientific analysis.
- Scientists should never be subject to gag orders, instructed to suppress their research, or censored in any way. Scientists must not face legal repercussions for publishing information or be coerced to work in unethical ways.
- Research should not be terminated or have its scope altered because the research would potentially be negative to the financial interests of the home institution.
- Organizations should disseminate scientific proposals and findings in a transparent manner, including by fully disclosing funding sources for both research and its publication.



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- Scientists and other employees should ensure that scientific information is of the highest integrity and free from inappropriate influence.
- Organizations and scientists should publicly disclose funding sources and potential conflicts of interest for scientific information used in policy making.

Conclusion

Undue and inappropriate corporate interference in science is a large and growing threat, with tentacles in every aspect of federal science-based decision making. Addressing this interference will require overcoming difficult hurdles, but they are not insurmountable. With strong leadership and a sustained commitment, both the federal government and the private sector can rise to the challenge.

Over the next four years, change is essential. Given the complex science-based challenges facing our nation and our world, decision makers must have access to the best available science. While this report does not describe every avenue for reform, it provides a stepping-stone for further efforts to expose and curb this threat to the nation's future.

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Heads They Win, Tails We Lose

How Corporations Corrupt Science at the Public's Expense

Access to the best available science allows federal decision makers to craft policies that protect our health and safety and the environment. Unfortunately, censorship of scientists and the manipulation and suppression of research, combined with attempts to restructure how science should inform decisions, undermine the integrity of the policy-making process and our democracy. It is essential that we better understand the key driver of political interference in science: inappropriate influence by commercial interests.

This report uses case studies to illustrate how corporations exert influence at every turn, corrupting the science, shaping public perception, restricting agency effectiveness, influencing Congress, and exploiting judicial pathways. It also examines the efforts of the Obama administration to restore scientific integrity to policy making and outlines reforms that would better protect science from undue corporate influence.

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