



## TESTIMONY OF

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before the

**Committee on Small Business**  
**Subcommittee on Investigations, Oversight and Regulations**  
**U.S. House of Representatives**

**Hearing on**  
Regulating the Regulators—Reducing Burdens on Small Business

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Mr. Chairman, ranking member Clarke, and members of the subcommittee, I appreciate the opportunity to testify today on the benefits for small business of regulations that protect public health, worker and consumer safety, and the environment.

I could not agree more with the Subcommittee's overarching mission: strengthening the role of small business in repairing an economy ruined by rampant speculation and the excessive greed of financial institutions that Attorney General Eric Holder has embarrassingly implied are too big to prosecute. Rather than take an honest look at how weak regulation allowed Wall Street to engineer the 2008 crash, big business uses small business as a kind of human shield, conflating the distinctly different needs in the two sectors and pushing for deregulation that could further endanger the economy and public health.

A case in point is the Small Business Administration's (SBA) Office of Advocacy, which has consciously diverted its limited, taxpayer-funded resources away from helping truly small business understand and comply with regulatory requirement toward pursuing the complaint *du jour* of the very large companies that call the shots at the American Chemistry Council, the National Association of Manufacturers, and the U.S. Chamber of Commerce. ***These activities raise the disturbing prospect that the Office of Advocacy has broken the law.*** In fact, I hope that the evidence I put before you today will motivate you to ask the Government Accountability

Office (GAO) to investigate the SBA Office of Advocacy regarding its compliance with laws that (1) bar federally funded agencies from lobbying Congress and (2) require it to conduct its affairs in the sunshine. We hope you will also ask GAO to investigate how the Office of Advocacy ensures that its intervention in individual rulemakings genuinely advance the interests of truly small businesses. From what we can tell, it routinely intervenes in rulemakings with only tangential effects on its constituency.

I am a law professor at the University of Maryland Carey School of Law and the President of the Center for Progressive Reform (CPR) (<http://www.progressivereform.org/>). Founded in 2002, CPR is a network of sixty scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. We have a small professional staff funded by foundations. I joined academia mid-career, after working for the Federal Trade Commission for seven years and the House Energy and Commerce Committee for five years. For seven years, I served as the lawyer for small, publicly-owned electric systems that have much in common with the businesses under your jurisdiction. My work on environmental regulation includes four books, and over thirty articles (as author or co-author). My most recent book, published by the University of Chicago Press, is *The People's Agents and the Battle to Protect the American Public: Special Interests, Government, and Threats to Health, Safety, and the Environment*, co-authored with Professor Sidney Shapiro of Wake Forest University's School of Law, which comprehensively analyzes the state of the regulatory system that protects public health, worker and consumer safety, and natural resources, and concludes that these agencies are under-funded, lack adequate legal authority, and consistently are undermined by political pressure motivated by special interests in the private sector. I have served as consultant to the Environmental Protection Agency (EPA) and testified before Congress many times.

My testimony today makes four points:

***Small business deserves assistance regarding compliance with regulatory requirements and the SBA Office of Advocacy ought to provide this assistance rather than operating as an institutionalized opponent of regulations targeted by its big business cronies.***

***Two recent reports by CPR and the Center for Effective Government reveal that the Office of Advocacy systematically ignores the needs of small business and instead operates, largely in secret, as a loyal foot soldier in the big business campaign against regulation.***

***Regulation is vital to the quality of life we take for granted in America, saving lives, preserving health, and safeguarding the natural environment for our children.***

***If anything, our regulatory system is dangerously weak, and Congress should focus on reviving it rather than eroding public protections.***

### ***The Disgraceful Track Record of the SBA Office of Advocacy***

As you are no doubt aware, Congress established the SBA in 1953 to safeguard the interests of small business in an economy buffeted by World War II and the Korean War. Legitimate concerns about the competitive disadvantages that small business faced during

wartime motivated the establishment of broadly based effort to ensure small business access to federal procurement contracts and to conduct specialized outreach to women, people of color, and veterans.

The SBA Office of Advocacy was created in 1976 to represent small business before federal agencies. To the extent that the Office of Advocacy's role in the rulemaking process is to ensure that the concerns of truly small businesses are raised before agencies, this limited mission makes sense. After all, truly small businesses don't have the resources to represent their interests in Washington. And those interests are often quite distinct from the big business with which they compete.

Unfortunately, the Office of Advocacy has strayed far from this mission, as explained in two particularly shocking investigative reports I have attached to my testimony. The reports reveal that the SBA Office of Advocacy has systematically consorted with big business to pursue an agenda of undercutting health, safety and environmental agencies without considering at any point whether the way its staff spend their time confers any benefit on small business. The Office of Advocacy succeeds only in echoing the complaints voiced by well-heeled lobbyists representing the wealthiest companies and most powerful trade groups in the country. Meanwhile, the legitimate concerns of truly small businesses continue to be drowned out.

The first report, authored by the Center for Effective Government (CEG), describes how the Office of Advocacy hosts regular "Environmental Roundtables" that are attended by trade association representatives and lobbyists. The meetings are held at law firms that represent organizations like the American Chemistry Council, and feature presentations by lobbyists and lawyers who represent Fortune 100 companies. They occur behind closed doors and their agendas, attendance lists, and minutes are not published. Nevertheless, the roundtables result in positions that become the Office of Advocacy's policy positions.

Alerted by the CEG's report, environmental organization representatives attempted to participate in a roundtable, but were told that they could listen to the discussion but were not allowed to speak. (See Richard Denison, Environmental Defense Fund, "A mission corrupted: Your tax dollars pay for ACC to coach big industry on how to undercut EPA's IRIS program," <http://blogs.edf.org/nanotechnology/2013/03/05/a-mission-corrupted-your-tax-dollars-pay-for-acc-to-coach-big-industry-on-how-to-undercut-epas-iris-program/>) The roundtable consisted of presentations by Nancy Beck, a former White House Office of Information and Regulatory Affairs (OIRA) staffer who now works for the American Chemistry Council, and Robert Fensterheim, a former American Petroleum Industry staffer who now works at the RegNet/IRIS Forum, an industry group dedicated to undermining EPA's Integrated Risk Information System (IRIS).

The IRIS program compiles toxicological profiles of chemicals sold in large quantities in commerce, or otherwise threatening public health and the environment. Its profiles do not have regulatory effect, although large chemical manufacturers are very sensitive to their potential to reveal a chemical's toxicity. Given all the decisions that affect small business today, it is mystifying why the chemical industry's campaign against IRIS implicates the interests of more than a tiny handful of small businesses and, in fact, the CEG report finds no evidence that the Office of Advocacy received any request or comment from its ostensible constituency before

pursuing these issues. As the CEG report explains, these activities, especially the sponsorship of the secretive roundtables, appear to violate the Federal Advisory Committee Act (FACA).

Correspondence received in response to a CEG Freedom of Information Act (FOIA) request reveals that the SBA Office of Advocacy played a leading role in the American Chemistry Council's crusade to halt the Department of Health and Human Service's National Toxicology Program's efforts to list chemicals as "known" or "probable" carcinogens, in probable violation of the Anti-Lobbying Act and other lobbying restrictions. Once again, there is no evidence that the Office of Advocacy consulted with any small businesses in emphasizing these issues.

The Center for Progressive Reform (CPR) report, released in tandem with the CEG's investigative findings, found that the Office of Advocacy defines "small" businesses as any oil refinery that has up to 1,500 employees and any chemical plant that has up to 1,000 employees. This strange approach allows it to push for preferential regulatory treatment for relatively large firms that do not conform to any common sense understanding of what a "small business" is. This approach further obscures its efforts to win approval from big business in regulatory battles that have at best a marginal impact on small business interests. As just one example, CPR reports on the Office of Advocacy's enthusiastic participation in a rulemaking designed to reduce emissions of hazardous air pollutants such as arsenic, lead, and formaldehyde from coal-fired power plants. The Office of Advocacy argued to the EPA that the rule should be cut back to cover only mercury emissions. Its arguments closely tracked those made in a 200-page submission from the Southern Company, the fourth largest utility in the country.

CPR's report makes a crucial observation with regard to the Office of Advocacy's aggressive deregulatory efforts: by taking consistently hostile stances to health and safety rulemaking proposals, it sacrifices any opportunity to work with the agencies in an effort to mitigate the impact of the proposals on truly small businesses. We understand the reasons for this approach, and they aren't pretty. Rewriting the comments prepared by big law firms for even bigger companies is far easier than rolling up your sleeves and working with agency officials to design innovative compliance alternatives.

The report recommends that the Office of Advocacy restore its focus on helping truly small businesses—that is, those firms with 20 or fewer employees. Second, it recommends a new mission for the Office of Advocacy: promoting win-win regulatory solutions that help small businesses achieve protective regulatory standards without undermining their ability to compete with larger firms.

### ***The Benefits of Regulation***

Self-righteous crusaders against regulation have become accustomed to telling only half the story to the American people: they pretend that exaggerated regulatory costs are the only result of the system, and ignore its considerable benefits. Conversely, they suggest that if we dismantled the regulatory system, we would suffer no negative consequences and instead reap a windfall in saved money. This devious approach is like setting out to balance a family budget,

stockpiling all the available money (pay checks, investments, or social security), and ignoring whatever you are able to buy (a place to live, leisure pursuits, or a college education).

What does it mean to leave the benefits side of the ledger blank? Because the benefits of regulation are spread throughout the population, to every man, woman, and child in America—regardless of class, race, background, or ethnicity—this myopic focus on the costs to regulatory industries raises the question of which group of citizens is more important—stockholders and brokers or everyday people who need clean air and water, safe workplaces and products, and financial and health care systems free of price gouging and other forms of fraud. Should the second group risk grave harm so that the first group can maximize profits, or is there a better way?

Just ask anyone whose life was saved by a seat belt, whose children escaped brain damage because the EPA took lead out of gas, who turns on the faucet knowing the water will be clean, who takes drugs for a chronic illness confident the medicine will make them better, who avoided having their hand mangled in machinery on the job because an emergency switch was there to cut off the motor, who has taken their kids on a trip to a heritage national park to see a bald eagle that was saved from the brink of extinction—the list goes on and on.

The simple fact is that people need to be healthy enough to go to work and school. To use the example of the benefits achieved by the EPA, the agency that has served as the poster child for supposed regulatory excess: in 2010, clean air rules saved 164,300 adult lives. By 2020, they will save 237,000 lives annually. These rules save 13 million days of work loss due to pollution-related illnesses like asthma, and 3.2 million days of school loss. By 2020, they will save 17 million work loss days and 5.4 million school loss days. The economic value of Clean Air Act regulatory controls are estimated to be \$2 trillion annually by 2020, dwarfing \$65 billion in compliance costs.<sup>1</sup>

Previous Congresses did not pass the Clean Air and Water Acts, drug and food safety laws, and the Occupational Health and Safety Act simply to annoy industry. You took action so that this country does not regress to a time when our rivers caught fire, our cars exploded on rear impact, our workers contracted liver cancer from breathing in benzene, and the industrial zones of our cities and towns were smothered under a blanket of chemical haze. The legacy of regulation is not economic ruin, but the possibility that our grandchildren will be better off than their parents' generation.

### ***Revitalizing Regulation***

A series of catastrophic regulatory failures have focused attention on the troubled condition of regulatory agencies assigned to protect public health, worker and consumer safety, and the environment. The destructive convergence of funding shortfalls (many agency budgets have stagnated or declined while the size of their has grown), political attacks from Congress and even the White House, and outmoded legal authority (decades-old statutes that only allow for miniscule penalties for egregious worker safety violations, for instance) have set the stage for ineffective enforcement and unsupervised industry self-regulation. From the Deepwater Horizon

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<sup>1</sup> See ENVTL. PROTECTION AGENCY, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT FROM 1990 TO 2020 (Mar. 2011), available at <http://www.epa.gov/oar/sect812/feb11/fullreport.pdf>.

spill in the Gulf of Mexico that killed eleven and caused grave environmental and economic damage, to the worst mining disaster in 40 years at the Big Branch mine in West Virginia with a death toll of 29, the signs of regulatory dysfunction abound. Peanut paste tainted by salmonella, glasses imprinted with the Shrek logo contaminated by cadmium and sold at McDonald's, Code Red smog days when parents are warned to keep their children indoors, the Vioxx recall—at the bottom of each well-publicized event is an agency unable to do its job and a company that could not be relied upon to put the public interest first.

Consider the example of compounding pharmacies left virtually unregulated by state pharmacy boards and the Food and Drug Administration (FDA). A compounding pharmacy in Massachusetts sold drugs contaminated with meningitis to clinics and hospitals nationwide. The bad medicine has killed 48 and sickened 666, shaking public confidence to its core. In a rare display of honesty, FDA Commissioner Margaret Hamburg told the Reuters news service: “Over the years, there has been substantial debate within Congress about the appropriate amount of FDA oversight and regulation of compounding pharmacies. But unfortunately, there has been a lack of consensus and many challenges from industry.” And David Kessler, who served as FDA Commissioner during the Clinton Administration, speculated that the deeply discordant tensions of the presidential election affected the FDA's performance: “Everyone is closed down right now,” he said. “People are being very careful. No one wants to make a mistake.” Compounding pharmacies make 40 percent of the injectable drugs administered in medical facilities across the country. Yet other than excoriating Commissioner Hamburg, Congress has done nothing to improve the oversight of the industry.

As this incident illustrates, the agencies do their best to appear as if they are operating normally, when any close observer reaches the unavoidable conclusion that they are being prevented from achieving their statutory mission of protecting the public in an effective and timely manner. When industrial activities go wrong, the responsible agency's harshest critics vilify the regulators first, overlooking or making excuses for the corporate executives whose negligence caused the disaster. The result is an excruciating Catch-22: regulators are de-funded and de-fanged, but held to impossible standards when corporate negligence inevitably emerges. The real question for Congress is how to revive the agencies assigned to protect the American people, not how to demoralize their staffs, cut their budget, and squelch their rules.



# **Distorting the Interests of Small Business:**

**How the Small Business Administration Office  
of Advocacy's Politicization of Small Business  
Concerns Undermines Public Health and Safety**

**by CPR Member Scholar Sidney Shapiro  
and CPR Policy Analyst James Goodwin**

## About the Center for Progressive Reform

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

This white paper is a collaborative effort of the following individuals: **Sidney Shapiro** holds the University Distinguished Chair in Law at the Wake Forest University School of Law and is a member of the Board of Directors of the Center for Progressive Reform. **James Goodwin** is a Policy Analyst with the Center for Progressive Reform.

For more information about the authors, see page 29.

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## Executive Summary

It's likely that few outside of Washington have heard of the Small Business Administration's (SBA) Office of Advocacy, but this tiny and largely unaccountable office has quietly become a highly influential player in the federal regulatory system, wielding extraordinary authority over the workplace safety standards employers must follow, the quantity of air pollution factories can emit, and the steps that food manufacturers must take to prevent contamination of the products that end up on the nation's dinner tables.

The Office exercises this authority by superintending agency compliance with an expanding universe of analytical and procedural requirements—imposed by a steady stream of statutes and executive orders issued during the past three decades—that purportedly seek to ensure that agencies account for small business interests in their regulatory decision-making. Controversial rules can quickly become mired in this procedural muck, and an agency's failure to carry out every last required analysis with sufficient detail and documentation can spell doom for even the most important safeguards. This system provides the Office of Advocacy with a powerful lever for slowing down rules or dictating their substance.

The Office of Advocacy's role in the regulatory system bears a striking resemblance to that played by the White House Office of Information and Regulatory Affairs (OIRA). Both operate to similar effect, functioning as an anti-regulatory force from within the regulatory structure, blocking, delaying, and diluting agency efforts to protect public health and safety. Moreover, both offices have entry into the regulatory process on the strength of seemingly neutral principles and policy goals—promotion of economic efficiency and protection of small business, respectively. But in actual practice, both offices serve to politicize the process, funneling special interest pressure into agency rulemakings, even though such interests have already had ample opportunity to comment on proposed regulations. Despite these similarities, however, OIRA receives the bulk of attention from policymakers, the media, and the public.

This report shines light on the Office of Advocacy's anti-regulatory work, examining how its participation in the rulemaking process further degrades an already weakened regulatory system. As a preliminary matter, the nominal objective of the Office of Advocacy—subsidizing small businesses through preferential regulatory treatment<sup>1</sup>—is based on a needless and destructive tradeoff; the government has several policy options for promoting small businesses without sacrificing public health and safety. The Office of Advocacy nevertheless devotes much of its time and resources to blocking, delaying, or diluting regulatory safeguards or to supporting general anti-regulatory attacks from industry and its allies in Congress. In short, blocking regulations has become the Office of Advocacy's *de facto* top priority, and its commitment to this goal has led the Office to engage in matters that have little or nothing to do with advancing small business interests or with ensuring that federal policy reflects the unique needs of these firms.

**Blocking regulations has become the Office of Advocacy's *de facto* top priority, and its commitment to this goal has led the Office to engage in matters that have little or nothing to do with advancing small business interests or with ensuring that federal policy reflects the unique needs of these firms.**

More specifically, the report finds that the Office of Advocacy:

- Pursues an inherently flawed mission that needlessly sacrifices public health and safety;
- Adds several unnecessary roadblocks to the rulemaking process, preventing agencies from achieving their respective missions of helping people and the environment in an effective and timely manner;
- Sponsors anti-regulatory research designed to bolster politicized attacks against the U.S. regulatory system;
- Testifies at congressional hearings aimed at advancing politicized attacks against regulations that are inconvenient to well-connected corporate interests;
- Takes advantage of overly broad small business size standards to weaken regulations for large firms;
- Enables trade association lobbyists to subvert its small business outreach efforts;
- Interferes with agency scientific determinations despite lacking both the legal authority and relevant expertise to do so; and
- Pushes for rule changes that would benefit large firms instead of narrowly tailoring its recommendations so that they help only truly small businesses.

The report concludes by identifying several reforms that would enable the Office of Advocacy to work constructively with regulatory agencies during the rulemaking process to advance small business interests without undermining those agencies' mission of protecting public health and safety. These recommendations are summarized in Table 1.

**Table 1: Recommendations for Reforming the Office of Advocacy**

<p><b>A New Mission: Promote “Win-Win” Regulatory Solutions that Ensure Both Small Business Competitiveness and Strong Protections for People and the Environment</b></p>	<ul style="list-style-type: none"> <li>• Congress should amend the Office of Advocacy’s authorizing statutes to focus on promoting small business “competitiveness” instead of on reducing regulatory impacts or burdens.</li> <li>• Congress should provide the SBA with additional legal authorities to establish new subsidy programs that affirmatively assist small businesses meet effective regulatory standards without undermining their competitiveness.</li> <li>• Congress should establish and fully fund a network of small business regulatory compliance assistance offices.</li> <li>• Congress should significantly increase agency budgets so that they can effectively account for small business concerns in rulemakings without hindering their ability to move forward with needed safeguards.</li> <li>• The Office of Advocacy should identify and implement regulatory solutions that will enable small businesses to meet strong public health and safety standards while remaining competitive with larger firms. At a minimum, these solutions should include regulatory compliance assistance, finding opportunities to partner small businesses in mutually beneficial ways, and securing subsidized loans to cover compliance costs.</li> <li>• The Office of Advocacy should develop new guidance that helps agencies better address small business concerns in rulemakings by working toward win-win regulatory solutions.</li> <li>• The President should revoke Executive Order 13272, which empowers the Office of Advocacy to work with OIRA to interfere in agency rules.</li> </ul>
<p><b>Restored Focus: Helping Truly Small Businesses Only</b></p>	<ul style="list-style-type: none"> <li>• Congress should revise the Office of Advocacy’s small business size standards so that they (1) focus on truly small businesses (<i>i.e.</i>, those with 20 or fewer employees) and (2) prevent the Office from working on behalf of all firms, regardless of size, that work in industrial sectors that pose a high risk to public health and safety.</li> <li>• Congress should prohibit the Office of Advocacy from working with non-small businesses and should establish legal mechanisms for ensuring that this prohibition is observed.</li> <li>• Congress should conduct more frequent and thorough oversight of the Office of Advocacy.</li> </ul>

In recent years, corporate interests and their anti-regulatory allies in Congress have championed several bills that would enhance the Office of Advocacy's power to prevent agencies from carrying out their statutory missions of protecting public health and safety. Two bills—the Regulatory Flexibility Improvements Act and the Freedom from Restrictive Excessive Executive Demands and Onerous Mandates Act—would require agencies to complete several new analytical and procedural requirements purportedly aimed at reducing regulatory burdens on small businesses. The bills would empower the Office of Advocacy to monitor agency compliance with these requirements, bolstering its ability to interfere in individual rulemakings. A third bill, the Clearing Unnecessary Regulatory Burdens Act, would authorize the Office of Advocacy to second-guess agency civil enforcement actions against small businesses for certain first-time violations of regulatory reporting requirements.

These bills are part of the broader wave of anti-regulatory attacks that has dominated the political landscape ever since the Republican Party's success in the 2010 congressional elections. When launching these attacks, anti-regulatory advocates frequently invoke small-business concerns. Small business has become a highly romanticized, almost mythological concept among the public and policymakers alike, evoking images of small “mom and pop” stores lining the idyllic Main Street of some quaint village. Because no politician wants to run the risk of being painted as “anti-small business,” anti-regulatory advocates have worked tirelessly to promote their cause as essential to helping small businesses. Moreover, recent high profile catastrophes involving inadequately regulated large businesses—including the BP oil spill and the Wall Street financial collapse—have provided anti-regulatory advocates with additional impetus to adopt the frame of small business to advance their agenda. In this atmosphere, proposals to expand the powers of the reliably anti-regulatory Office of Advocacy have become especially attractive to policymakers intent on weakening the nation's already fragile regulatory system.

## Background: The Pervasive Problem of Under-Regulation

The United States faces a problem of under-regulation. The regulatory system is supposed to protect public health and safety against unacceptable risks, but the destructive convergence of inadequate resources, political interference, and outmoded legal authority often prevents regulatory agencies from fulfilling this task in a timely and effective manner. Unsupervised industry “self-regulation” has filled the resulting vacuum, yielding predictably catastrophic results.

Evidence of inadequate regulation and enforcement abounds—from the BP oil spill in the Gulf of Mexico to the Upper Big Branch Mine disaster that claimed the lives of 29 men; from the decaying natural gas pipeline networks running beneath our homes to the growing risk of imported food tainted with salmonella, botulism, or other contaminants showing up on grocery store shelves. And, of course, inadequate regulation of the financial services industry triggered the current economic recession and left millions unemployed, financially ruined, or both.

The proliferation of analytical and procedural requirements in the rulemaking process is a significant cause of this dysfunction.<sup>2</sup> Regulatory agencies must negotiate these analytical hurdles, even as their statutory responsibilities expand and their budgets remain constant or shrink. As agencies grow more “hollowed-out”—stretched thin by the demands of doing more with less—their pursuit of new safeguards becomes subject to increasing delays, while many critical tasks are never addressed at all.<sup>3</sup> Careful analysis is important, but the regulatory process has already become so ossified by needless procedures and analyses that rulemakings commonly require between four and eight years to complete.<sup>4</sup> Many of these analyses and procedures also provide powerful avenues for political interference in individual rulemakings, as the Office of Information and Regulatory Affairs’ (OIRA) centralized regulatory review process clearly illustrates.<sup>5</sup> A recent CPR study found that OIRA frequently uses this review process to delay or weaken rules following closed-door meetings with corporate lobbyists.<sup>6</sup>

**The Office of Advocacy has morphed into an institutionalized opponent of regulation, slowing the regulatory process and diluting the protection of people and the environment against unreasonable risks.**

## **The Office of Advocacy Pushes the Regulatory Process Toward Less Effective Regulation**

Since its creation, the Office of Advocacy's role in the rulemaking process has continually expanded, providing it with numerous opportunities to intervene in and potentially undermine individual rulemakings. Congress created the Office to represent small business in the regulatory system and to advocate for reduced regulation of small business. From this limited mandate to advocate on behalf of small businesses, the Office has morphed into an institutionalized opponent of regulation, slowing the regulatory process and diluting the protection of people and the environment against unreasonable risks. Yet, there is insufficient public recognition of how the Office participates in the rulemaking process and why its participation ends up making it more difficult for agencies to reduce safety, health and environmental risks. In addition, the Office engages in activities that bolster political attacks on regulation, such as publishing estimates of regulatory costs that are wildly inaccurate, and that fly in the face of estimates from other agencies of government with considerably greater expertise in the area. Such activities are frequently undertaken in conjunction with interest groups and trade associations that represent large business, not small ones. At times it is difficult to find any difference between the positions taken by the Office and those taken by such prominent regulatory opponents as the U.S. Chamber of Commerce.

Significantly, when the Office interferes in agency efforts to do the people's business—that is, implement and enforce duly enacted legislation—it does so free of virtually any public accountability mechanisms. The Office is housed within, but institutionally insulated from the Small Businesses Administration (SBA), a federal agency that supports America's small business sector through subsidized loans, preferential government contracting, and other assistance programs. As such, no chain of command connects the Office to either the head of the SBA or the President.<sup>7</sup> At the same time, Congress has shirked its responsibility to provide meaningful oversight of the Office's activities. While Office of Advocacy officials have testified at dozens of hearings in the last 16 years, only four of those hearings could be described as oversight hearings for the Office.<sup>8</sup> (In reality, two of those four hearings focused on supposed weaknesses in the Office's legal authorities and proposals for strengthening those authorities, rather than critically evaluating its performance.) By comparison, Congress has held dozens of oversight hearings for the EPA in the last year alone. Because of the lack of active oversight, Congress has no way to keep track of the Office's participation in the regulatory process or to ensure that it is not abusing its authority to intervene in rules to benefit politically powerful corporate interests at the expensive of public health and safety.

## **A Flawed Mission: Needlessly Sacrificing Public Health and Safety**

Preferential regulatory treatment for small business can include regulatory exemptions; less stringent or delayed regulatory requirements; and relaxed enforcement for regulatory violations, such as waived or reduced penalties. As with other subsidies that small businesses receive—such as subsidized loans, tax breaks, and preferential government procurement and contracting policies<sup>9</sup>—preferential regulatory treatment makes it easier for people to start and sustain small businesses. But it also enables these businesses to avoid taking responsibility for pollution, workplace risks, or any other socially harmful byproducts of their activities. In other words, preferential regulatory treatment involves an explicit policy choice to shift the costs of these social harms from small businesses to the general public.

Governments typically subsidize an activity because they want more of the benefits that the activity produces. Accordingly, policymakers typically justify small business subsidies on the grounds that these businesses generate greater job growth and innovation as compared to non-small businesses. As numerous studies have demonstrated, however, small businesses actually create very few jobs on net, and the evidence is at best mixed as to whether these firms create more innovation (however that concept is defined and measured).<sup>10</sup>

Whatever jobs or other economic benefits small businesses do create come at a certain societal price. As Professor Richard Pierce of The George Washington University Law School has pointed out, preferential regulatory treatment for small businesses can be “socially destructive,” because such firms produce greater amounts of many social harms as compared to their larger counterparts—including dangerous workplaces, instances of racial discrimination, and air and water pollution.<sup>11</sup> For example, one study found that the risk of a fatal work-related accident is 500 times greater for employees of small businesses than for employees of large businesses. In addition, small businesses are less likely than their larger counterparts to reduce their social harms in the absence of enforcement-backed regulation.<sup>12</sup> Since the cost of reducing social harms is often disproportionately greater for small businesses, they have a stronger economic incentive to avoid pursuing reductions as much as possible. Further, both reputational concerns and fear of lawsuits are less likely to motivate small businesses to reduce their social harms. Because many small businesses work in relatively anonymity, they tend not to suffer significant reputational costs when they are caught polluting or operating a dangerous workplace. Typically lacking “deep pockets,” small businesses also tend not to be attractive defendants, even when their socially harmful activities have clearly injured others.



**There is a fundamental flaw in the Office of Advocacy's core mission: Its work to weaken regulatory requirements for small businesses comes at too high a cost in terms of increased risks to public health, safety, and the environment.**

Preferential regulatory treatment doesn't just let small businesses off the hook for the social harms they create; it can also enable larger businesses to avoid taking responsibility for their social harms as well.<sup>13</sup> When small firms are exempted from regulation, larger businesses have a strong incentive to try to game the system by outsourcing their more socially harmful activities to them.

These concerns expose the fundamental flaw in the Office's core mission: Its work to weaken regulatory requirements for small businesses comes at too high a cost in terms of increased risks to public health, safety, and the environment. Preferential regulatory treatment is the worst kind of subsidy to provide for small businesses, since, as compared to larger firms, they often produce disproportionately greater amounts of the kind of social harms that regulations are meant to alleviate. To the extent that the Office succeeds at securing preferential regulatory treatment for small businesses, it is affirmatively promoting the uniquely disproportionate amount of social harms they create.

### **The Office of Advocacy Creates Roadblocks to Effective Regulation**

Passed by Congress in 1976, Pub. L. 94-305<sup>14</sup> created the Office of Advocacy and charged it with representing small businesses before federal agencies. With the passage of the Regulatory Flexibility Act<sup>15</sup> (Reg-Flex) in 1980, Congress made preferential regulatory treatment of small businesses an explicit goal of the rulemaking process and empowered the Office to push agencies to pursue this goal. The enactment of the Small Business Regulatory Enforcement Fairness Act (SBREFA) in 1996 and the issuance of Executive Order 13272 by George W. Bush in 2002 has further strengthened the Office's role as an opponent of effective regulation.

Using its authority under Pub. L. 94-305, Reg-Flex, and Executive Order 13272, the Office has employed compliance guidance, regulatory comments, and congressional communications to push agencies to delay, weaken, or abandon crucial rulemakings.

#### ***The Regulatory Flexibility Act's Analytical Requirements***

Reg-Flex requires agencies to perform several resource-intensive and time-consuming analyses of their rules to assess their potential impacts on small businesses. These analyses, layered as they are on top of the existing morass of regulatory-impact analyses, create an additional battery of procedural obstacles, further contributing to the ossification problem that already prevents agencies from developing effective new safeguards in a timely fashion.



Reg-Flex's analytical requirements apply only if, prior to proposing the rule, the agency finds that it would have a "significant economic impact" on a large number of small businesses, a concept that the Act fails to define. Otherwise, the agency can "certify" that the rule will not have such an impact, exempting it from the statute's remaining requirements. For rules found to have a significant impact, the agency must prepare two different "regulatory flexibility" analyses, an "initial" analysis for the proposed version of the rule and a "final" one for the final version.

The two regulatory flexibility analyses provide an inherently distorted picture of the regulations being assessed—one that is heavily biased against protective safeguards. Agencies must focus exclusively on the rule's potential costs on small businesses; the rule's benefits—the reason the agency is developing the rule at all—are ignored. In addition, the agency must evaluate possible alternatives that would "minimize" the rule's costs for small businesses. Among the alternatives that agencies must consider are rules that exempt small businesses, impose weaker standards, or phase in regulatory requirements over a longer timeline. Again, benefits are ignored: Such analysis automatically disregards any alternatives that would provide greater protections at equal or only slighter greater cost to small businesses.

Within 10 years of their completion, significant impact rules must go through still a third analysis—the Reg-Flex periodic look-back requirement. Reg-Flex requires that agencies review these rules to determine whether they should be eliminated or amended to "minimize" costs on small business. Again, this one-sided, anti-regulatory analytical framework ignores regulatory benefits and does not allow agencies to consider expanding rules that have proved to be successful.

#### ***Reg-Flex's Look-Back Requirement: The Real Record***

**A recent CPR study reviewed the Reg-Flex look-backs for nearly 40 Environmental Protection Agency and Occupational Safety and Health Administration regulations and found that nearly every one had concluded that the regulations were still necessary and did not adversely impact small businesses.**

*Source: Sidney Shapiro et al., Saving Lives, Preserving the Environment, Growing the Economy: The Truth About Regulation 10 (Ctr. for Progressive Reform, White Paper 1109, 2011), available at [http://www.progressivereform.org/articles/RegBenefits\\_1109.pdf](http://www.progressivereform.org/articles/RegBenefits_1109.pdf).*

In 1996, Congress amended Reg-Flex to make agency compliance with several of its provisions—including certification that a rule will not have a significant impact on small businesses—judicially reviewable. This amendment makes all agency analyses part of the record for judicial review, and it authorizes reviewing courts to reject a rule on the sole basis that the agency had failed to adequately comply with one of the Act’s procedural requirements.

### ***Guidance on Complying with the Regulatory Flexibility Act***

Responding to Executive Order 13272’s requirement that the Office of Advocacy “train” agencies on how to comply with Reg-Flex, the Office has issued a guidance document in which it spells out in great detail its excessively strict interpretation of Reg-Flex’s requirements. (The Office most recently updated and expanded the document in May of 2012.) For example, in the guidance, the Office seeks to strongly discourage agencies from certifying their rules (*i.e.*, formally concluding that the rules will not have a significant impact on small businesses, thereby exempting them from Reg-Flex’s procedural requirements) by demanding that they build a virtually bulletproof record to support the certification, including providing specific data on how many businesses the rule would affect and what economic effect the rule would have on those businesses.<sup>16</sup> In so doing, the Office sought to expand the range of rules subject to its influence (*i.e.*, by increasing the number of rules subject to Reg-Flex procedural requirements that the Office oversees). Moreover, generating such data about a rule’s potential impacts so early in a rulemaking is nearly impossible even under the best circumstances. Nevertheless, whenever agencies are unable to satisfy the Office’s strict certification record requirement, the guide advises agencies to conduct an initial regulatory flexibility analysis or even conduct a full-blown advanced notice of proposed rulemaking, procedures that add months to the process and waste scarce agency resources.

Remarkably, in the guidance, the Office also directs agencies to consider in their initial regulatory flexibility analysis regulatory alternatives that are not even within an agency’s legal authority to adopt. So, for example, the Office would encourage an agency to develop a rule that requires small businesses to test a piece of safety equipment only once a year, even though the underlying statute mandates that such equipment be tested at least twice a year. The guidance imposes this requirement even though Reg-Flex does not authorize it. Instead, the Act stipulates that any alternatives that agencies consider to minimize costs for small businesses must still meet applicable “statutory objectives.”<sup>17</sup> In clear contradiction of Reg-Flex’s plain language, the Office asserts in the guidance “that the IRFA [initial regulatory flexibility analysis] is designed to explore less burdensome alternatives and not simply those alternatives it is legally permitted to implement.”<sup>18</sup>

### **Regulatory Comments**

Pursuant to its authority under Pub. L. 94-305 to represent small businesses before federal agencies, the Office of Advocacy frequently comments on agencies' proposed rules in order to criticize agencies for not following its excessively strict interpretation of Reg-Flex's procedural requirements.<sup>19</sup> In its recent comments, the Office typically invokes the strict interpretation of these provisions that it has outlined in its Reg-Flex compliance guidance document.

Invariably, the faults that the Office of Advocacy asserts are aimed either at increasing the procedural burdens of Reg-Flex's requirements—and thus adding more delay to a rulemaking—or at weakening agency rules outright. The Office might claim that an agency has improperly certified that its rule will not have a large impact on small business (and thus is not subject to Reg-Flex's requirements). Or it might claim that the agency has not properly carried out required Reg-Flex analyses, perhaps alleging that an agency hasn't included enough detail or factual evidence, or that the agency has underestimated a rule's costs or has failed to consider adequate weaker alternatives. For example, in its recent comments on the U.S. Fish and Wildlife Services' (FWS) proposed rule that revises the agency's critical habitat designation for the Northern Spotted Owl, the Office argued that the FWS's evidentiary record in support of certification lacked the necessary specific data and detail called for in its compliance guidance document.<sup>20</sup> With such comments, the Office seeks to use procedural hurdles of its own creation as a way to hamstring federal regulators working to fulfill their statutory obligations to regulate within their areas of expertise.

Through Executive Order 13272, the President has given the Office's comments special weight, making it difficult for an agency to dismiss the comments, even when they lack merit. The Order directs agencies to “[g]ive every appropriate consideration” to these comments. The Order further requires that agencies specifically respond to any of the Office's written comments in the preamble to the final rule.

Many reviewing courts take the Office's comments as powerful evidence that an agency has failed to comply with Reg-Flex, though these courts are otherwise not obliged to defer to the Office's interpretations of Reg-Flex's provisions.<sup>21</sup> For example, a federal district court rejected a National Marine Fisheries Service (NMFS) rule setting commercial fishing quotas for Atlantic shark species after finding that the agency had failed to comply with various Reg-Flex procedures.<sup>22</sup> (As noted above, agency compliance with Reg-Flex's provisions is judicially reviewable, and courts have the authority to reject rules if they determine that an agency has failed to adequately comply with one or more of these provisions.) The court's analysis in support of this finding relied heavily on the comments that the Office submitted during the rulemaking process.<sup>23</sup>

**With its regulatory comments, the Office of Advocacy seeks to use procedural hurdles of its own creation as a way to hamstring federal regulators working to fulfill their statutory obligations to regulate within their areas of expertise.**

### ***Reports to Congress and Congressional Testimony***

Reg-Flex and Executive Order 13272 direct the Office of Advocacy to monitor and report to Congress annually on agency compliance with Reg-Flex's requirements. In these reports, the Office provides detailed critiques of each agency's purported failures to implement Reg-Flex in accordance with the Office's strict interpretation of the Act's provisions. For example, in its most recent report, the Office of Advocacy faulted the initial regulatory flexibility analysis that the Food and Drug Administration (FDA) performed for its proposed rules requiring dietary information labeling for chain restaurant menus and vending machines, arguing that the agency's analysis underestimated both the number of small businesses the rules would impact and the regulatory costs the rules would impose on those businesses.<sup>24</sup> The FDA developed these rules to implement two provisions in the Patient Protection and Affordable Care Act (PPACA)—the 2010 health care system reform law. One objective of the PPACA was to reduce overall health care costs in the United States, and these provisions were aimed at helping Americans to adopt healthier diets, which in turn would enable them to avoid potentially expensive medical problems in the future.

For agencies eager to avoid attracting unwanted attention from congressional members ideologically opposed to their statutory mission, the threat of negative reports from the Office can have a strong coercive on their activities. Many agencies take self-defeating preemptive actions, such as preparing overly elaborate or unrequired analyses or drafting inappropriately weak rules—actions that waste scarce agency resources and dilute public health and safety protections. The Office's negative report regarding the FDA's implementation of these two controversial provisions in the PPACA undoubtedly has supplied welcome ammunition to congressional Republicans who continue to wage a full-scale assault on the law.<sup>25</sup> The fear of attracting this kind of bad publicity likely pushes the FDA and others agencies engaged in implementing the health care reform law to be overly cautious with their Reg-Flex compliance, even when detrimental to the public interest.

In addition to the annual reports, Office of Advocacy officials also testify at congressional hearings to complain about what they claim are failures by agencies to properly fulfill Reg-Flex requirements. For example, in April of 2011, the Deputy Chief Counsel for the Office of Advocacy testified at a House Oversight Committee hearing dedicated to attacking the Environmental Protection Agency's (EPA) greenhouse gas regulations. In her testimony, the Deputy Chief Counsel argued that the EPA had failed to comply with several requirements, including criticizing the factual basis the agency supplied to justify certifying its first vehicle efficiency standard as not having a significant impact on small businesses.<sup>26</sup> As with the annual reports, the threat of negative publicity from Office of Advocacy testimony can push agencies to overcompensate in their Reg-Flex compliance efforts.

### ***Small Business Regulatory Enforcement Fairness Act Panels***

The 1996 Small Business Regulatory Enforcement Fairness Act (SBREFA) amended Reg-Flex to require the EPA and the Occupational Safety and Health Administration (OSHA) to give specially assembled small business panels a chance to oppose proposed rules before the rest of the public even has a chance to see them. Following the passage of the Dodd-Frank Wall Street reform bill, congressional Republicans quickly enacted a bill that subjected the Consumer Financial Protection Bureau (CFPB), an agency created by the Dodd-Frank statute to help implement many of its reform provisions, to the SBREFA panel requirement as well.

The three agencies must undertake the SBREFA panel process for all planned rules that are predicted to have a significant impact on small businesses—the same trigger for the various other Reg-Flex analytical requirements. However, as with the Reg-Flex requirements, an agency need not undertake the SBREFA panel process if it formally certifies that its planned rule will not have a significant impact on small businesses. As noted above, an agency's decision to certify is subject to judicial review. Given that the Office has set such a high bar for justifying certification, the threat of judicial review can strongly discourage agencies from certifying a rule, even when this step would be appropriate.

In some cases, the Office has pressured agencies into undertaking the functional equivalent of a SBREFA panel, even though their planned rule plainly would not have a significant impact on small businesses. For instance, OSHA buckled under Office of Advocacy pressure and conducted a pseudo-SBREFA panel process for its then-planned “300 log MSD column” rule, which would have added a column to the required injury and illness recording form so that employers can keep track of their workers' employment-related musculoskeletal injuries.<sup>27</sup> OSHA went through this process even though the rule's projected costs would amount to a mere \$4.00 per employer in its first year and \$0.67 every year thereafter.<sup>28</sup>

Much like the Office of Information and Regulatory Affairs' (OIRA) centralized review process, the SBREFA panel process focuses on weakening rules because the panels are dominated by interests opposed to strong regulatory requirements. Beside the rulemaking agency representatives, each SBREFA panel must include the Chief Counsel of the Office of Advocacy (*i.e.*, the individual who heads the Office), OIRA officials, and small business “representatives.” The Office works with these other outside participants to criticize an agency's rule with the goal of weakening it. At the end of the process, the panel prepares a report compiling all of the criticisms of the draft rule, which is then included in the official rulemaking record.

Reg-Flex requires that a rulemaking agency respond to the criticisms included in the panel's report, and a failure to do so can provide a reviewing court with a basis to reject the underlying rule. This process contributes to the ossification of the rulemaking process, mentioned earlier, and it can create a potent incentive for an agency to weaken the rule rather than mount a time-consuming defense of a stronger rule, which would require producing an elaborate analysis to respond to all the criticisms raised in the SBREFA panel report.

SBREFA panel-related delays can add up to a year to the rulemaking process if not longer. These delays come on top of the several months of delay that the other Reg-Flex requirements introduce into the rulemaking process. By law, the formal panel period is supposed to last around two months. But, eager to avoid extensive criticism during the SBREFA panel process, agencies frequently spend months revising their planned rules and any underlying economic analyses prior to convening the formal panel. For example, preparations for the SBREFA panel process appear to have delayed OSHA's work on the Injury and Illness Prevention Program (I2P2) rule by more than a year. In June of 2011, the agency had planned to convene a SBREFA panel for its rule by the end of the month. Eventually, OSHA pushed this date back to January of 2012 and then March of 2012.<sup>29</sup> According to Office of Advocacy records, OSHA still has not convened this panel,<sup>30</sup> bringing the total delay to 16 months and counting.

### ***Centralized Regulatory Review at the Office of Information and Regulatory Affairs***

Executive Order 13272 directs the Office of Advocacy to work closely with OIRA—another institution that serves to weaken regulation, as previous CPR reports have discussed—when intervening in agency rules. The Office frequently takes advantage of the Order's authorization to meet with OIRA to raise concerns about proposed agency rules. In fact, a 2012 report from CPR on OIRA meetings with outside advocates found that the Office participated in 122 of the 1,080 reported meetings (or more than 11 percent) that OIRA held over the 10-year period covered in the CPR study.<sup>31</sup> The Office was by far the most frequent non-White House participant in OIRA meetings and attended more than three times the number of meetings attended by the most active industry participant, the American Chemistry Council (39 meetings).<sup>32</sup>

This Executive Order builds off of a March 2002 Memorandum of Understanding, which establishes a formal partnership between the Office and OIRA to strictly enforce Reg-Flex's procedural requirements to "achieve a reduction" in regulatory burdens for small businesses.<sup>33</sup> The Memorandum directs the Office to seek OIRA's assistance in pushing agencies to take corrective action—including more detailed analyses, evaluating additional less costly alternatives, or even adopting a less costly alternative—when the Office determines that they have failed to satisfy its strict interpretation of Reg-Flex's requirements. Given that OIRA has the power to reject the rules it reviews, agencies are unlikely to ignore its demands for Reg-Flex-related corrective actions. As such, OIRA provides powerful reinforcement in the



unlikely event that the Office is unable to extract these corrective actions on its own. The Memorandum also deputizes OIRA to aid in monitoring agency compliance with Reg-Flex requirements as part of its normal regulatory review activities. Whenever OIRA determines that an agency has likely failed to satisfy the Office of Advocacy's strict interpretation of any Reg-Flex requirements, it must then work with the Office to push the offending agency to take corrective action.

### ***Participation in Lawsuits Challenging Rules***

Reg-Flex authorizes the Office of Advocacy to join in lawsuits brought by industry to challenge agency rules, enabling it to push the reviewing court to reject rules for failing to satisfy applicable Reg-Flex procedural requirements.<sup>34</sup> These lawsuits create the highly unusual scenario in which one office within the Executive Branch is actively engaged in a legally binding effort to undermine an action taken by another office within the Executive Branch.

The Office of Advocacy has already participated in several lawsuits in which the reviewing court returned the rule to the agency to bring the underlying analyses into compliance with one or more of Reg-Flex's provisions.<sup>35</sup> In response to these adverse rulings, agencies must undertake new and more detailed analyses, delaying the implementation of their rules and using up scarce agency resources.

## **The Office of Advocacy Bolsters Political Attacks on Regulations**

In addition to the previous rulemaking-related activities, the Office of Advocacy has taken actions to buttress the attacks that industry and its allies in Congress have waged against the U.S. regulatory system as a whole.

### ***Sponsoring Anti-Regulatory Research***

Over the years, the Office of Advocacy has doled out taxpayer money to sponsor several research projects brazenly designed to advance the cause of further weakening the U.S. regulatory system. Non-governmental researchers carry out these projects under contracts awarded by the Office with little in the way of oversight or peer review.

The most egregious Office of Advocacy-sponsored research project was the 2010 study by economists Nicole Crain and Mark Crain, which purported to find that the annual cost of federal regulations in 2008 was about \$1.75 trillion.<sup>36</sup> As a CPR white paper first found,<sup>37</sup> and a separate evaluation by the non-partisan Congressional Research Service later confirmed,<sup>38</sup> Crain and Crain were only able to achieve this outlandish cost figure by employing faulty models, biased assumptions, and erroneous data. The report's myriad methodological defects all have a distinctly anti-regulatory bias, each leading inevitably to overstated cost calculations. Beyond these methodological defects, the Crain and Crain

**The Crain and Crain report's biased frame and risibly overstated findings are tailor-made to support the false conservative narrative that eliminating regulatory safeguards will translate into economic growth and job creation.**

report is noteworthy for what it omits: any attempt to account for regulatory benefits. The report's exclusive focus on regulatory costs—absurdly high cost estimates, in fact—while ignoring benefits provides an inherently distorted picture of the regulatory system that is skewed against all safeguards, no matter how critical they are for protecting public health and safety

The Office's flawed management of the Crain and Crain report contract was equally disturbing. The contract failed to require the report's authors to disclose all of the report's underlying data, models, assumptions, and calculations, making it impossible to independently verify the integrity of the report's findings. In addition, the Office of Advocacy's peer review process for the report was woefully inadequate: One reviewer raised significant concerns with the report's underlying methodology which were never addressed while the other's review consisted of only the following 11-word comment: "I looked it over and it's terrific, nothing to add. Congrats[.]"<sup>39</sup>

Despite the Crain and Crain report's dubious provenance, regulatory opponents routinely cite its findings when attacking the U.S. regulatory system or pushing for legislation that would undermine agencies' ability to carry out their mission of protecting public health and safety. The report's biased frame and risibly overstated findings are tailor-made to support the false conservative narrative that eliminating regulatory safeguards will translate into economic growth and job creation. For example, the House Committee on Oversight and Government Reform, which has held dozens of anti-regulatory hearings since the committee returned to Republican control, cited the Crain and Crain report and its findings extensively in a February 2011 study, which attempts to make the specious argument that pending regulations are stifling job creation.<sup>40</sup> Similarly, Sen. Rand Paul (R-KY) invoked the Crain and Crain report when arguing for the Regulations from the Executive in Need of Scrutiny Act, a bill he sponsored that would effectively shut the regulatory system down by blocking all major regulations unless a majority in both Houses of Congress voted within 90 days to approve them.<sup>41</sup>

### ***Participating in Anti-Regulatory Congressional Hearings***

Office of Advocacy officials have long served as loyal allies in Congress's anti-regulatory hearings, consistently delivering testimony that reinforces the political case for weakening regulations and further hobbling the regulatory system. As noted, these officials frequently testify to criticize agency compliance with Reg-Flex procedural requirements, but the same testimony is also broadly critical of the regulatory system as a whole, echoing the talking points typically found in the testimony of industry representatives or in the opening statements of anti-regulatory Members of Congress. For example, the head of the Office of Advocacy during the George W. Bush Administration testified at a 2005 House Committee on Government Reform hearing focused on attacking various EPA regulations. His testimony helped advance the transparently political agenda of the hearing by strongly



criticizing EPA regulations as unduly burdensome—while conspicuously ignoring their benefits—and by advocating for rolling them back.<sup>42</sup>

Office of Advocacy officials have also testified at hearings to support passage of several pending anti-regulatory bills. In his testimony at a 2006 hearing, for example, the then head of the Office of Advocacy asserted that the Office “supports the goals of” a proposed bill that would amend Reg-Flex’s procedural and analytical requirements to make them more burdensome for agencies to complete.<sup>43</sup>

### **The Office of Advocacy Engages in Anti-Regulatory Activities Unrelated to Helping Small Businesses**

The focal point of the Office of Advocacy’s institutional mission has evolved from seeking preferential regulatory treatment for small businesses to opposing all regulations. Aided and abetted by industry groups and their political allies, the Office pursues this mission by working to block regulations opposed by large corporate interests and attempting to interfere in the scientific underpinning of agency regulations.

#### ***The Office of Advocacy’s Small Business Size Standards Are Overly Broad***

For the purposes of implementing Reg-Flex, the Office of Advocacy employs a definition of “small business” that is a far cry from the common understanding of that term’s meaning. Instead of being based on a single number (for example, any firm with 20 or fewer employees), the definition is actually a complex scheme that sets varying size standards for each industrial sector within the economy.<sup>44</sup> Critically, these standards are based on the relative size of different firms within each given industry, and, as a result, the “small businesses” in industries that comprise mostly large-sized firms can be huge. In some sectors, the definition of small business includes firms that employ more than 1,000 workers. For example, the Office considers a petroleum refinery to be a “small business” as long as it employs fewer than 1,500 workers. Similarly, chemical plants that employ fewer than 1,000 workers are a “small business” in the Office’s eyes.

Because of these overly broad small business size standards, the Office is able to push for preferential regulatory treatment for relatively large firms, firms far bigger than the term “small business” suggests. For example, in August of 2011, the Office submitted comments on the EPA’s proposed rule to reduce hazardous air pollution for fossil fuel-based power plants criticizing the agency’s efforts to comply with several Reg-Flex procedural requirements, including the SBREFA panel process. Among other things, the Office argued that the EPA had not adequately considered potentially less burdensome regulatory alternatives for “small business” power plants in its initial regulatory flexibility analysis.<sup>45</sup>

### ***Trade Association Lobbyists Subvert the Office of Advocacy's Small Business Outreach Efforts***

In addition, large corporate interests have supplied representatives for SBREFA panels. For example, a lobbyist from the American Farm Bureau—a politically powerful trade group that typically works to advance the interests of industrial-scale farms—recently served as a “small business” representative on the SBREFA panel for the EPA’s 2010 update to its renewable fuel standard program.<sup>46</sup> By permitting organizations such as the American Farm Bureau to participate in SBREFA panels, the Office of Advocacy has stretched the concept of small business representative beyond all recognition. The American Farm Bureau’s membership includes several industrial-scale agriculture operations that would not meet even the Office’s generous definition of small business. And, the interests of these industrial-scale operations often dictate the organization’s political agenda, even when those interests are antithetical to those of genuinely small farms.<sup>47</sup> For example, the catastrophic droughts that affected much of the United States this past summer provided a glimpse of the harsh impacts that climate change will have on America’s small farmers. Nevertheless, the American Farm Bureau worked tirelessly to help defeat the 2009 climate change bill that would have curbed greenhouse gas emissions through a comprehensive cap-and-trade system.<sup>48</sup>

In some cases, the small business representatives who participate in SBREFA panels come at the suggestion of lobbyists for large trade associations, such as the National Association of Home Builders, whose members include large corporations that do not meet the Office’s small business size standards.<sup>49</sup> This practice raises the concern that lobbyists operating to advance the interests of large corporations improperly use small businesses representatives as surrogates to attack rules they oppose, enabling these corporate interests to avoid incurring any potential political costs for opposing safeguards that are otherwise popular with the general public.

The participation of large corporate interests defeats the objective of SBREFA panels—namely, to gather the perspective of small business on pending regulations that would otherwise not be available in the absence of these panels. These panels offer small businesses a critical opportunity to offer their unique concerns regarding a planned rule—an opportunity that is all the more important because large corporate interests have come to dominate every other step in the rulemaking process, including notice-and-comment and OIRA’s centralized review.<sup>50</sup> By permitting lobbyists for trade associations and other large corporate groups take part in SBREFA panels, the Office risks allowing the voice of truly small businesses to be drowned out at this stage of the rulemaking process as well.

### ***The Office of Advocacy Interferes with Agency Scientific Determinations***

The Office of Advocacy frequently operates outside its legal authority and scientific expertise by weighing in on agencies' purely scientific determinations. For example, in October of 2011, the Office submitted regulatory comments criticizing the EPA's Integrated Risk Information System (IRIS) program.<sup>51</sup> A frequent target of industry attacks, IRIS is a centralized database that gathers human health risk assessments for various environmental contaminants, which the EPA can use to set regulatory standards.<sup>52</sup> Specifically, the Office criticized the data and models that the EPA had used in its IRIS risk assessment for the harmful chemical hexavalent chromium, and it urged the agency to revise its assessment, a process that would waste scarce resources and delay the final assessment by several months. The Office also recommended that the EPA reform the entire IRIS program, arguing that it lacked "objectivity" and adequate "scientific rigor."<sup>53</sup> Such recommendations are far beyond the expertise of the Office and have unique interests of small business. They do, however, bear a striking resemblance to the arguments that industry lobbyists make about IRIS assessments.

The Office intervenes in these kinds of scientific determinations despite the fact that they do not independently impose any regulatory requirements, and thus have no real impact on small businesses. In June of 2009, the Office intervened in the EPA's proposed greenhouse gas endangerment finding, which did nothing more than certify the federal government's official finding that greenhouse gases "endanger public health and welfare" by contributing to global climate change. Nevertheless, the Office argued in its comments that the EPA should abandon the effort completely.<sup>54</sup> The comments added nothing constructive to the EPA's endangerment finding efforts, failing to address any of the scientific questions at issue. Instead, the Office devoted its comments to arguing that the Clean Air Act's regulatory programs were not well suited to regulating greenhouse gases and might disproportionately harm small businesses—all hypothetical and unrelated matters that would be better addressed in comments on any actual Clean Air Act rules aimed at regulating greenhouse gases. Again, such arguments were not grounded in any expertise the Office might have, or in any unique small business interest, but they did comport with big-business criticisms of the EPA's finding.

The Office's decision to move into regulatory science is far removed from its statutory mission to argue for preferential regulatory treatment for small business. This interest in attacking regulatory science can only be understood as the Office assuming the role of arguing against more stringent regulation in all forums that may relate to regulatory protections, even ones where the agency has no expertise.

### ***The Office of Advocacy Pushes for Weaker Regulatory Requirements for Large Businesses***

The Office of Advocacy commonly seeks to weaken the requirements of proposed rules for all affected entities, rather than seeking rule changes that are tailored to reducing adverse impacts on small firms only. For example, in its comments on the EPA's proposed rule to limit hazardous air pollutants from oil- and coal-fueled power plants, the Office criticized the agency for not considering as a regulatory alternative a rule that would merely limit plants' mercury emissions. Remarkably, the Office recommended that this drastically scaled-back rule apply to all power plants, regardless of their size.<sup>55</sup> Such an alternative would provide no unique preferential regulatory treatment for "small" power plants. It would also leave unregulated all of the other toxic air pollutants that power plants release—including arsenic, lead, and formaldehyde—in clear violation of the Clean Air Act.<sup>56</sup> While this alternative would certainly reduce regulatory costs for small power plants, its primary effect would be to provide a huge regulatory subsidy to the large power plants that dominate the electricity generating industry. Here again, the Office offered commentary that could just have easily been written by big-business or special interest lobbyists, rather than focusing on an small-business interest in the proposed regulations.

The Office also frequently joins representatives of the largest corporations and trade groups in meetings with OIRA officials to push for rule changes that would benefit large businesses. For example, in July of 2010 an Office of Advocacy official attended a meeting with the U.S. Chamber of Commerce, the National Association of Manufacturers, and the National Association of Home Builders to try to push OIRA to block OSHA's 300 log MSD column rule.<sup>57</sup> In October of 2006 an Office of Advocacy official attended a meeting with ExxonMobil, the American Chemistry Council, and Bayer Corporation to push for changes to the EPA's pending rule to revise its definition of solid waste under the Resource Conservation and Recovery Act.<sup>58</sup>

In many cases, weaker regulatory requirements for large firms can actually have the perverse effect of harming small businesses—rather than helping them—and thus directly conflicts with the Office's mission. Regulatory subsidies for large firms can make it even more difficult for small businesses to remain competitive, inhibiting people's ability to start these firms and sustain them over the long run.

## Helping Small Businesses While Promoting Public Health and Safety: It's Time to Reform the Office of Advocacy

### A New Mission: Promoting Win-Win Regulatory Solutions

The role of the Office of Advocacy should be to develop “win-win” regulatory solutions that help small businesses meet the high regulatory standards needed to protect public health and safety, instead of lowering those standards for them. In other words, the Office should seek to protect small businesses “competitiveness” without undermining public health and safety. In many cases, the costs of complying with regulations can put small businesses at a competitive disadvantage with larger businesses, which are better equipped to pass many of these costs along to their consumers. Larger businesses are also able to afford attorneys, engineers, accountants, and other compliance consultants, who can help them devise cheaper ways to fulfill regulatory requirements.

Providing small businesses with preferential regulatory treatment helps them remain competitive with larger firms, but it comes at the expense of public health and safety. In effect, preferential regulatory treatment subsidizes small businesses by passing on to the public the socially harmful impacts of their activities, such as air and water pollution, hazardous working conditions, and unreasonably dangerous consumer products. In contrast, the Office’s current approach of working to reduce regulatory burdens across the board for all firms reduces regulatory impacts on small businesses, but does nothing to promote small business competitiveness. This approach also likely undermines regulatory safeguards more severely than would an approach that merely focuses on providing preferential regulatory treatment to small businesses alone.

**The role of the Office of Advocacy should be to develop “win-win” regulatory solutions that help small businesses meet the high regulatory standards needed to protect public health and safety, instead of lowering those standards for them.**

Fortunately, if the public agrees that small businesses need to be subsidized, policymakers have an alternative strategy: They can promote small business competitiveness by affirmatively helping them to meet effective public health and safety standards. The Office should use its role in the regulatory process to explore and promote creative solutions for achieving this goal. Such creative solutions could include:

- **Providing monetary assistance to truly small businesses so that they can meet higher regulatory standards.** Monetary assistance could include direct subsidies to cover part or all of the costs of equipment upgrades required for regulatory compliance. Alternatively, the Office could work to obtain subsidized loans to help small businesses defray regulatory compliance costs.
- **Expanding regulatory compliance assistance programs.** SBREFA established several compliance assistance programs, including requiring agencies to produce “compliance guides” for each of their rules that have a significant impact on small businesses.<sup>59</sup> These compliance guides describe the rule and explain what actions small businesses need to take to comply. Congress can help improve the effectiveness of compliance guides by providing agencies with full funding to produce and distribute them. In addition, Congress can establish local offices throughout the country staffed with compliance consultants that can help small businesses understand their obligations under different regulations. To be effective, Congress must ensure that the network of compliance consultant offices is fully funded.
- **Partnering small businesses to promote beneficial synergies on regulatory compliance.** The Office could explore different ways of partnering small businesses that will help them meet regulatory obligations in mutually beneficial ways. For example, the Office could help establish a cooperative of small businesses within a given location, which could share the cost of compliance assistance services, such as those provided by accountants or engineering consultants. Alternatively, the Office could establish partnerships that build off the Small Business Administration’s (SBA) preferential government procurement and contracting policies for helping small businesses. For example, if a small business requires special services, such as accounting, to comply with a regulation, then the Office could explore ways to partner that business with another small firm that provides those special services. In this way, the Office can assure that one small business’s compliance with regulations help to create a profitable market for another small business.

To achieve these reforms, Congress will need to:

- Amend the primary statutory authorities under which the Office operates (P. Law. 94-305 and Reg-Flex) to replace their focus on reducing small businesses' regulatory costs with a new focus on promoting win-win regulatory solutions that ensure small business competitiveness without undermining public health and safety;
- Expand the Office's legal authority as necessary to enable it to explore and promote win-win regulatory alternatives that help small businesses meet high regulatory standards while maintaining competitiveness;
- Provide the SBA with additional legal authorities to establish and implement new win-win regulatory subsidy programs that affirmatively assist small businesses remain competitive while meeting high regulatory standards;
- Establish and fully fund a network of small business regulatory compliance assistance offices; and
- Increase agency budgets so that they are able to carry out Reg-Flex analyses and compliance assistance guides without displacing critical resources needed to advance their statutory mission of protecting public health, safety, and the environment.

In addition, the Office will need to:

- Significantly overhaul its Reg-Flex compliance guide for agencies, so that it helps them to work toward creative win-win regulatory solutions that enable small businesses to remain competitive while meeting high regulatory standards and
- Work with small businesses to develop and promote win-win regulatory solutions in comments on proposed regulations, SBREFA panels, lawsuits, and sponsored research. SBREFA panels in particular will be critical for gathering the unique views of small businesses for identifying how pending regulations might inhibit their ability to compete and for developing innovative solutions for helping these firms to meet high regulatory standards while remaining competitive.

Finally, the President should revoke Executive Order 13272. Given its strong anti-regulatory culture, OIRA is unlikely to provide the Office with much assistance in identifying ways to help small businesses meet regulatory standards needed to protect public health, safety, and the environment. Instead, OIRA will likely continue to push the Office to weaken agency rules, even where potential win-win regulatory solutions are appropriate and available.



**The Office of Advocacy should employ new small business size standards, applicable to all industrial sectors, that define a “small business” as only those firms with 20 or fewer employees.**

### **Restored Focus: Helping Truly Small Businesses Only**

The Office of Advocacy has become a potent anti-regulatory force, working to block, delay, and dilute all regulations, even those that do not have a clear impact on small businesses. Whatever the policy goals are that might justify shielding small businesses from fulfilling their regulatory obligations, they certainly do not extend to larger businesses. Accordingly, the Office should restrict its actions to helping truly small businesses only.

To accomplish this goal, Congress will need to do the following:

- **Enact legislation that revises the SBA’s small business size standards.** The new size standards should define a small business as any firm with 20 or fewer employees—regardless of which industry the firm is in—rather than basing the definition on the relative size of different firms within each given industry, as the current size standards do. This revision would not only better align the regulatory definition for small business with the popular understanding of that term, it would better effectuate the policy goals that the government seeks to achieve by providing truly small businesses with preferential regulatory treatment. In addition, the small size standards should exclude certain industrial categories that pose an inherently high risk to public health and safety, such as the dry cleaning industry. Businesses in these exempted industrial categories should not qualify for win-win regulatory subsidy programs, even if they have 20 or fewer employees, because their activities are too harmful to public health and safety.
- **Enact legislation that prohibits large corporate interests from participating in or using small business surrogates to participate in SBREFA panels.** To participate in SBREFA panels, a business must first qualify as a small business under the revised small business size standard. To make this mandate enforceable, the law should further require all businesses that participate in SBREFA panels to certify that they both meet the revised small business standard and are not acting as agents for any business or trade group that does not meet the revised small business standard. Congress should declare that making a false statement in this certification is a crime under 18 U.S.C. §1001. Furthermore, Congress should bar for at least three years any business that makes a false statement in the certification from participating in any future SBREFA panels and from qualifying for any win-win regulatory subsidy programs established and implemented either by the Office or by the SBA.
- **Conduct more frequent and thorough oversight.** The House and Senate committees with primary jurisdiction over the Office—presently, the House Small Business Committee and the Senate Small Business and Entrepreneurship Committee—should endeavor to conduct at least one oversight hearing for the Office every year. One of the goals of these oversight committee hearings should be to ensure that the Office is limiting its activities to helping only businesses that meet the revised small business size standard.



Again, the President can reinforce these reforms by revoking Executive Order 13272. Because OIRA has such a strong anti-regulatory culture, any continued collaboration with OIRA will likely encourage the Office to continue working to block, delay, and dilute regulations for businesses not meeting the revised small business size standard.

## Endnotes

- <sup>1</sup> We borrow term the “preferential regulatory treatment” with slight modification from a 1998 law review article by administrative law professor Richard Pierce. See Richard J. Pierce Jr., *Small is Not Beautiful: The Case Against Special Regulatory Treatment of Small Firms*, 50 ADMIN. L. REV. 537 (1998). The term includes regulatory exemptions; less stringent or delayed regulatory requirements; and relaxed enforcement for regulatory violations, such as waived or reduced penalties. See *id.* at 542-43.
- <sup>2</sup> PUBLIC CITIZEN, THE FEDERAL RULEMAKING PROCESS, available at <http://www.citizen.org/documents/Regulations-Flowchart.pdf>.
- <sup>3</sup> Sidney Shapiro et al, *Regulatory Dysfunction: How Insufficient Resources, Outdated Laws, and Political Interference Cripple the “Protector Agencies”* 6-8 (Ctr. for Progressive Reform, White Paper 906, 2009), available at [http://www.progressivereform.org/articles/RegDysfunction\\_906.pdf](http://www.progressivereform.org/articles/RegDysfunction_906.pdf) [hereinafter Shapiro et al, *Regulatory Dysfunction*].
- <sup>4</sup> *The “Regulatory Accountability Act of 2011”: Hearing on H.R. 3010 Before the H. Comm. on the Judiciary*, 112th Cong. 6 (2011) (statement of Sidney A. Shapiro, University Distinguished Chair in Law, Wake Forest University School of Law, and Member Scholar and Vice President, Center for Progressive Reform), available at [http://www.progressivereform.org/articles/Shapiro\\_RAA\\_Tesimony\\_102511.pdf](http://www.progressivereform.org/articles/Shapiro_RAA_Tesimony_102511.pdf).
- <sup>5</sup> Shapiro et al, *Regulatory Dysfunction*, *supra* note 3, at 12-14.
- <sup>6</sup> Rena Steinzor et al., *Behind Closed Doors at the White House: How Politics Trumps Protection of Public Health, Worker Safety, and the Environment* (Ctr. for Progressive Reform, White Paper 1111, 2011), available at [http://www.progressivereform.org/articles/OIRA\\_Meetings\\_1111.pdf](http://www.progressivereform.org/articles/OIRA_Meetings_1111.pdf) [hereinafter Steinzor et al, *Behind Closed Doors*]. Specifically, the study found that OIRA routinely meets corporate interests behind closed doors during the review process and then delays or changes rules that are subject of such meetings at a disproportionately higher rate.
- <sup>7</sup> To illustrate the Office’s independence, the SBA’s organizational chart presents the Office as a “floating box” without any lines denoting a chain of command to the rest of the agency. See U.S. SMALL BUS. ADMIN., ORGANIZATION CHART, available at <http://www.sba.gov/sites/default/files/SBA%20Organization%20Chart%2003-16-2012.pdf>.
- <sup>8</sup> See *Office of Advocacy Fiscal Year 2012 Budget: Hearing Before the S. Comm. on Small Bus. & Entrepreneurship*, 112th Cong. (statement of Winslow Sargeant, Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin.), available at [http://www.sba.gov/sites/default/files/test11\\_0331.pdf](http://www.sba.gov/sites/default/files/test11_0331.pdf); *The Small Business Office of Advocacy Improvements: Hearing Before the Subcomm. on Workforce, Empowerment, & Gov’t Programs and the Subcomm. on Regulatory Reform & Oversight of the H. Comm. on Small Bus.*, 108th Cong. (statement of Thomas M. Sullivan, Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin.), available at [http://www.sba.gov/sites/default/files/files/test03\\_0401.pdf](http://www.sba.gov/sites/default/files/files/test03_0401.pdf); *Strengthening the Office of Advocacy, Hearing Before the H. Comm. on Small Bus.*, 107th Cong. (statement of Thomas M. Sullivan, Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin.), available at [http://www.sba.gov/sites/default/files/files/test02\\_0320.pdf](http://www.sba.gov/sites/default/files/files/test02_0320.pdf); *Improving the Office of Advocacy, Hearing Before the H. Comm. on Small Bus.*, 106th Cong. (statement of Jere W. Glover, Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin.), available at [http://www.sba.gov/sites/default/files/files/test00\\_0621.pdf](http://www.sba.gov/sites/default/files/files/test00_0621.pdf).
- <sup>9</sup> See Pierce, *supra* note 1, at 540-42.
- <sup>10</sup> *Id.* at 549-57. See also Ruth Marcus, Op-Ed., *The Little Engine That Can’t: The Myth About Small Businesses and Jobs*, WASH. POST, Sept. 15, 2010, available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/09/14/AR2010091405459.html>; Veronique de Rugy, *America’s Small-Business Fetish: When It Comes to Job Creation, Size Doesn’t Matter*, REASON, June 2012, available at <http://reason.com/archives/2012/05/21/americas-small-business-fetish>.
- <sup>11</sup> Pierce, *supra* note 1, at 557-60.
- <sup>12</sup> *Id.* at 562-68.
- <sup>13</sup> *Id.* at 570-74.
- <sup>14</sup> 15 U.S.C. §§634a-634g.
- <sup>15</sup> Regulatory Flexibility Act, 5 U.S.C. §§601-612.
- <sup>16</sup> OFF. OF ADVOC., U.S. SMALL BUS. ADMIN., A GUIDE FOR AGENCIES: HOW TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT; IMPLEMENTING THE PRESIDENT’S SMALL BUSINESS AGENDA AND EXECUTIVE ORDER 13272, 11-14 (2012) available at [http://www.sba.gov/sites/default/files/rfaguide\\_0512\\_0.pdf](http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf) [hereinafter OFF. OF ADVOC., RFA GUIDE].
- <sup>17</sup> See 5 U.S.C. §603(c).
- <sup>18</sup> OFF. OF ADVOC., RFA GUIDE, *supra* note 16, at 38.
- <sup>19</sup> In Fiscal Year 2011, the Office of Advocacy submitted over 50 comment letters. See OFF. OF ADVOC., U.S. SMALL BUS. ADMIN., REPORT ON THE REGULATORY FLEXIBILITY ACT, FY 2011: ANNUAL REPORT OF THE CHIEF COUNSEL FOR ADVOCACY ON IMPLEMENTATION OF THE REGULATORY FLEXIBILITY ACT AND EXECUTIVE ORDER 13272, 4 (2012), available at [http://www.sba.gov/sites/default/files/11regflex\\_0.pdf](http://www.sba.gov/sites/default/files/11regflex_0.pdf) [hereinafter OFF. OF ADVOC. FY 2011 RFA REPORT].

- <sup>20</sup> Comments on Endangered and Threatened Wildlife and Plants; Revised Critical Habitat for the Northern Spotted Owl from Winslow Sargeant, Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin., and Janis C. Reyes, Assistant Chief Counsel, Off. of Advoc., U.S. Small Bus. Admin., to Daniel Ashe, Director, U.S. Fish & Wildlife Serv., Dept. of Interior (July 5, 2012), available at [http://www.sba.gov/sites/default/files/files/Advocacy\\_Spotted\\_Owl\\_Comment\\_Letter.pdf](http://www.sba.gov/sites/default/files/files/Advocacy_Spotted_Owl_Comment_Letter.pdf).
- <sup>21</sup> *Am. Trucking Ass'n v. EPA*, 175 F.3d 1027, 1044 (D.C. Cir. 1997), modified in other respect, 195 F.3d 4 (D.C. Cir. 1999), reversed in other respect, *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457 (2001).
- <sup>22</sup> *Southern Offshore Fishing Ass'n v. Daley*, 995 F. Supp. 1411, 1436 (M.D. Fla. 1998).
- <sup>23</sup> See *id.* at 1435.
- <sup>24</sup> OFF. OF ADVOC. FY 2011 RFA REPORT, *supra* note 19, at 23.
- <sup>25</sup> For example, the nutrition information labeling rules were attacked at a recent hearing before the House Oversight and Government Reform Committee's Subcommittee on Health Care. See, e.g., *Impact of Obamacare on Job Creators and Their Decision to Offer Health Insurance: Hearing Before the Subcomm. on Health Care, District of Columbia, Census, & the Nat'l Archives of the H. Comm. on Oversight & Gov't Reform*, 112th Cong. 6 (statement of Andrew Puzder, Chief Exec. Officer, CKE Restaurants, Inc.), available at <http://oversight.house.gov/wp-content/uploads/2012/04/7-28-11-Subcommittee-on-Health-Care-District-of-Columbia-Census-and-the-National-Archives-Hearing-Transcript.pdf>.
- <sup>26</sup> *Assessing the Impact of EPA Greenhouse Gas Regulations on Small Business: Hearing Before the Subcomm. on Reg. Aff., Stimulus Oversight, & Gov't Spending of the H. Comm. on Oversight & Gov't Reform*, 112th Cong. 75-127 (statement of Claudia Rodgers, Deputy Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin.), available at <http://oversight.house.gov/wp-content/uploads/2012/04/4-6-11-Subcommittee-on-Regulatory-Affairs-Stimulus-Oversight-and-Government-Spending-Hearing-Transcript.pdf>.
- <sup>27</sup> See Press Release, Occupational Safety & Health Admin. U.S. Dept. of Labor, U.S. Labor Department's OSHA Reopens Public Record on Proposed Record-Keeping Rule to Add Work-Related Musculoskeletal Disorders Column, available at [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=NEWS\\_RELEASES&p\\_id=19824](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=19824).
- <sup>28</sup> Occupational Injury and Illness Recording and Reporting Requirements, 75 Fed. Reg. 4728, 4737-38 (proposed Jan. 29, 2010) (to be codified at 29 C.F.R. pt. 1904).
- <sup>29</sup> Rena Steinzor & James Goodwin, *Opportunity Wasted: The Obama Administration's Failure to Adopt Needed Regulatory Safeguards in a Timely Way is Costing Lives and Money* (Ctr. for Progressive Reform, Issue Alert 1204, 2012), <http://www.progressivereform.org/12RulesIssueBrief.cfm> (last visited Dec. 10, 2012).
- <sup>30</sup> See Off. of Advoc., U.S. Small Bus. Admin., *OSHA SBREFA Panels*, <http://www.sba.gov/advocacy/825/5717> (last visited Dec. 10, 2012).
- <sup>31</sup> Steinzor et al, *Behind Closed Doors*, *supra* note 6, at 26.
- <sup>32</sup> *Id.* at 18.
- <sup>33</sup> Memorandum of Understanding Between the Off. of Advoc., U.S. Small Bus. Admin., and the Off. of Info. & Reg. Aff., U.S. Off. of Mgmt. & Budget (Mar. 19, 2002), available at [http://www.sba.gov/sites/default/files/MOU\\_OIRA.pdf](http://www.sba.gov/sites/default/files/MOU_OIRA.pdf).
- <sup>34</sup> As noted above, agency compliance with many of these requirements is judicially reviewable, and violations of these requirements can result in the rejection of an otherwise lawful rule.
- <sup>35</sup> See, e.g., *Southern Offshore Fishing Ass'n v. Daley*, 995 F. Supp. 1411 (M.D. Fla. 1998); *Northwest Mining Ass'n v. Babbit*, 5 F. Supp. 2d 9 (D.D.C. 1998).
- <sup>36</sup> NICOLE V. CRAIN & W. MARK CRAIN, *THE IMPACT OF REGULATORY COSTS ON SMALL FIRMS* (2010), available at [http://www.sba.gov/sites/default/files/The%20Impact%20of%20Regulatory%20Costs%20on%20Small%20Firms%20\(Full\).pdf](http://www.sba.gov/sites/default/files/The%20Impact%20of%20Regulatory%20Costs%20on%20Small%20Firms%20(Full).pdf).
- <sup>37</sup> Sidney Shapiro et al, *Setting the Record Straight: The Crain and Crain Report on Regulatory Costs* (Ctr. for Progressive Reform, White Paper 1103, 2011) available at [http://www.progressivereform.org/articles/SBA\\_Regulatory\\_Costs\\_Analysis\\_1103.pdf](http://www.progressivereform.org/articles/SBA_Regulatory_Costs_Analysis_1103.pdf) [hereinafter Shapiro et al, *Crain and Crain Report*].
- <sup>38</sup> Curtis W. Copeland, *Analysis of an Estimate of the Total Costs of Federal Regulations 2* (Cong. Research Serv., R41763, Apr. 6, 2011), available at [http://www.progressivereform.org/articles/CRS\\_Crain\\_and\\_Crain.pdf](http://www.progressivereform.org/articles/CRS_Crain_and_Crain.pdf).
- <sup>39</sup> Shapiro et al, *Crain and Crain Report*, *supra* note 37, at 3, 4.
- <sup>40</sup> COMM. ON OVERSIGHT & GOV'T REFORM, U.S. HOUSE OF REPRESENTATIVES, *ASSESSING REGULATORY IMPACTS TO JOB CREATION* 14, 15 (Preliminary Staff Report, 2011), available at [http://oversight.house.gov/wp-content/uploads/2012/01/Preliminary\\_Staff\\_Report\\_Regulatory\\_Impediments\\_to\\_Job\\_Creation.pdf](http://oversight.house.gov/wp-content/uploads/2012/01/Preliminary_Staff_Report_Regulatory_Impediments_to_Job_Creation.pdf).
- <sup>41</sup> *Federal Regulation: A Review of Legislative Proposals, Part I: Hearing Before the S. Comm. on Homeland Security & Governmental Aff.*, 112th Cong. 1 (statement of Sen. Rand Paul), available at <http://www.hsgac.senate.gov/hearings/federal-regulation-a-review-of-legislative-proposals-part-i> (follow "Download Statement (84k)" hyperlink under "Senator Rand Paul R (KY)").
- <sup>42</sup> *The Impact of Regulation on U.S. Manufacturing: Spotlight on the Environmental Protection Agency: Hearing Before the Subcomm. on Regulatory Aff. of the H. Comm. on Gov't Reform*, 109th Cong. 2-3 (statement of Thomas M. Sullivan, Chief Counsel for Advoc., Off. of Advoc., U.S. Small Bus. Admin.), available at [http://www.sba.gov/sites/default/files/files/test05\\_0928.pdf](http://www.sba.gov/sites/default/files/files/test05_0928.pdf).

- <sup>43</sup> *Hearing on the Regulatory Flexibility Improvements Act - H.R. 682 Before the Subcomm. on Com. & Admin L. of H. Comm. on the Judiciary*, 109th Cong. 4 (statement of Thomas M. Sullivan, Chief Counsel for Advocacy., Off. of Advoc., U.S. Small Bus. Admin.), available at [http://www.sba.gov/sites/default/files/files/test06\\_0720.pdf](http://www.sba.gov/sites/default/files/files/test06_0720.pdf).
- <sup>44</sup> Section 601(3) of Reg-Flex defines a “small business” as having “the same meaning as the term ‘small business concern’ under section 3 of the Small Business Act.” 5 U.S.C. §601(3). Pursuant to Section 3 of the Small Business Act, the Small Business Administration has developed size standards for defining small businesses according to different industrial sectors of the economy, which are catalogued at 13 C.F.R. §121.201.
- <sup>45</sup> Comments on National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units from Winslow Sargeant, Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin., and David Rostker, Assistant Chief Counsel for Environment and Regulatory Reform, Off. of Advoc., U.S. Small Bus. Admin., to Lisa Jackson, Administrator, U.S. Evtl. Protection Agency (Aug. 4, 2011), available at [http://www.sba.gov/sites/default/files/files/epa11\\_0804.pdf](http://www.sba.gov/sites/default/files/files/epa11_0804.pdf).
- <sup>46</sup> FINAL REPORT OF THE SMALL BUSINESS ADVOCACY REVIEW PANEL ON EPA’S PLANNED PROPOSED RULE REGULATION OF FUELS AND FUEL ADDITIVES: RENEWABLE FUEL STANDARD PROGRAM 8-9 (2008).
- <sup>47</sup> See, e.g., Ian T. Shearn, *Whose Side Is the American Farm Bureau On?*, THE NATION, July 16, 2012, available at <http://www.thenation.com/article/168913/whose-side-american-farm-bureau#>.
- <sup>48</sup> Allison Winter, *Farm Bureau Fires Back Against Climate Bill’s “Power Grab,”* N.Y. TIMES, Jan. 11, 2010, available at <http://www.nytimes.com/cwire/2010/01/11/11climatewire-farm-bureau-fires-back-against-climate-bills-93758.html?pagewanted=all>; Donald Carr, *Drought-Stricken Farmers Pay the Price for Failed Climate Bill*, HUFFINGTON POST, Aug. 12, 2012, available at [http://www.huffingtonpost.com/donald-carr/droughtstricken-farmers-p\\_b\\_1729235.html](http://www.huffingtonpost.com/donald-carr/droughtstricken-farmers-p_b_1729235.html).
- <sup>49</sup> See FINAL REPORT OF THE SMALL BUSINESS ADVOCACY REVIEW PANEL ON EPA’S PLANNED PROPOSED RULE: LEAD-BASED PAINT; CERTIFICATION AND TRAINING; RENOVATION AND REMODELING REQUIREMENTS 30 (2000).
- <sup>50</sup> See, e.g., Wendy Wagner, Katherine Barnes & Lisa Peters, *Rulemaking in the Shade: An Empirical Study of EPA’s Air Toxic Emission Standards*, 63 ADMIN. L. REV. 99, 128-29 (2011) (reviewing public comments for EPA rules on hazardous air pollutants, and finding that industry groups submitted 81 percent of comments compared to just 4 percent submitted by public interest groups); Steinzor et al, *Behind Closed Doors*, *supra* note 6, at 20 (reviewing participation rates in OIRA lobbying meetings and finding that over 65 percent of meeting participants represented corporate interests compared to just 12 percent representing public interest groups).
- <sup>51</sup> Comments on EPA’s Integrated Risk Information System Program and the Toxicological Review of Hexavalent Chromium from Winslow Sargeant, Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin., and Sarah Bresolin Silver, Assistant Chief Counsel, Off. of Advoc., U.S. Small Bus. Admin., to Paul Anastas, Assistant Administrator, Off. of Res. & Dev., U.S. Evtl. Protection Agency (Oct. 5, 2011), available at [http://www.sba.gov/sites/default/files/files/epa11\\_1005.pdf](http://www.sba.gov/sites/default/files/files/epa11_1005.pdf).
- <sup>52</sup> Rena Steinzor, *More Anti-EPA Shenanigans? Is IRIS Next on the Hit List? We’ll Be Watching*, CPRBLOG, Sept. 8, 2011, <http://www.progressivereform.org/CPRBlog.cfm?idBlog=4A015085-B5C2-4FC8-05F55BABAECB52D0> (last visited Dec. 10, 2012).
- <sup>53</sup> *Id.* at 3-4.
- <sup>54</sup> Comments on EPA’s Proposed Endangerment and Cause or Contribute Findings for Greenhouse Gases from Shawne C. McGibbon, Acting Chief Counsel for Advocacy, Off. of Advoc., U.S. Small Bus. Admin., and Keith W. Holman, Assistant Chief Counsel for Environmental Policy, Off. of Advoc., U.S. Small Bus. Admin., to U.S. Evtl. Protection Agency 3-4 (June 23, 2009), available at <http://www.sba.gov/sites/default/files/reg%20623.pdf>.
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- <sup>56</sup> John Walke, *Industry Urges Killing Mercury & Air Toxics Standards With False Arguments to Resurrect Mercury-Only Standards*, SWITCHBOARD, June 11, 2012, [http://switchboard.nrdc.org/blogs/jwalke/as\\_we\\_approachsenator\\_inhofes.html](http://switchboard.nrdc.org/blogs/jwalke/as_we_approachsenator_inhofes.html) (last visited Dec. 10, 2012).
- <sup>57</sup> Off. of Info. & Reg. Aff., U.S. Off. of Mgmt & Budget, *Meeting Record Regarding: 300 Column (July 21, 2010)*, [http://www.whitehouse.gov/omb/1218/meeting\\_07212010](http://www.whitehouse.gov/omb/1218/meeting_07212010) (last visited Dec. 10, 2012).
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- <sup>59</sup> Small Business Regulatory Enforcement Fairness Act of 1996 §223, 5 U.S.C. §601 note.

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# Small Businesses, Public Health, and Scientific Integrity:

Whose Interests Does the Office of Advocacy  
at the Small Business Administration Serve?



January 2013

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## Small Businesses, Public Health, and Scientific Integrity:

Whose Interests Does the Office of Advocacy  
at the Small Business Administration Serve?



## Executive Summary

This report examines the activities of an independent office within the Small Business Administration: the Office of Advocacy. The Office of Advocacy has responsibility for ensuring that federal agencies evaluate the small business impacts of the rules they adopt. Scientific assessments are not “rules” and do not regulate small business, yet the Office of Advocacy decided to comment on technical, scientific assessments of the cancer risks of formaldehyde, styrene, and chromium. By its own admission, Advocacy lacks the scientific expertise to evaluate the merits of such assessments.

The report analyzes correspondence and materials received through a Freedom of Information Act request made by staff at the Center for Effective Government. Our inquiry was driven by two questions: Why did the Office of Advocacy get involved in the debate over scientific assessments that do not regulate small business? Whose interests does the Office of Advocacy of the Small Business Administration actually serve?

We found that the Office of Advocacy’s comments on these assessments raised no issues of specific concern to small business and relied almost exclusively on talking points provided by trade associations dominated by big chemical companies. Between 2005 and 2012, the American Chemistry Council (ACC) and its members spent over \$333 million lobbying Congress and federal agencies on, among other things, a protracted campaign to prevent government agencies from designating formaldehyde, styrene, and chromium as carcinogens. The Formaldehyde Council, Styrene Industry Research Council, and Chrome Coalition spent millions more. These groups asked the Office of Advocacy for assistance, and the Office became their willing partner.

We conclude that the Office of Advocacy’s decision to comment on scientific assessments of the cancer risks of certain chemicals constitutes a significant and unwarranted expansion of its role and reach beyond its statutory responsibilities. We recommend that Congress ask the Government Accountability Office (GAO) to investigate the Office of Advocacy and exert more rigorous oversight of its activities to ensure its work does not undermine the efforts of other federal agencies to fulfill the goals Congress has assigned them.

### **Key Findings:**

- The Office of Advocacy hosts regular Environmental Roundtables attended by trade association representatives and lobbyists. The discussions and minutes are kept secret, although the consensus positions that emerge appear to inform the Office of Advocacy’s policy positions. These meetings violate the spirit, and perhaps the letter, of the Federal Advisory Committee Act.

- The Office of Advocacy staff made no effort to educate themselves on the science underlying the debates about the cancer risks of formaldehyde, styrene, and chromium or to verify the accuracy of the talking points provided to them by industry lobbyists before filing comments critical of the scientific conclusions in each assessment. Instead, the Office of Advocacy simply repackaged and submitted talking points provided by trade association lobbyists as formal comments.
- Correspondence between the Office of Advocacy and trade associations dominated by large chemical companies and their lobbyists suggests the Office became entangled in a major lobbying campaign to prevent the federal government from listing certain chemicals as known or probable carcinogens. E-mails suggest the Office of Advocacy may have violated the Anti-Lobbying Act and other lobbying restrictions.
- No small businesses objected to the scientific assessments or asked the Office of Advocacy to intervene in the cancer assessments. The Office of Advocacy made no effort to determine whether the positions it took represented small business views and interests. Moreover, since small businesses may produce substitutes for toxic chemicals, a cancer finding for existing chemicals could open up new markets for substitute chemicals produced by small businesses.
- No process or procedures seem to be in place to ensure that the activities of the Office of Advocacy are consistent with, and do not work to undermine, the statutory responsibilities of other agencies.

**Recommendations:**

- The Office of Advocacy should limit its work to regulatory activities affecting small business, as authorized by the Regulatory Flexibility Act and subsequent laws.
- Congress should ask GAO to investigate whether the Office of Advocacy's Environmental Roundtables violate Federal Advisory Committee Act provisions.
- The Office of Advocacy should independently verify the factual claims it makes in comments to other federal agencies and should not comment on technical or scientific matters on which its staff have no expertise.
- Congress should ask GAO to investigate whether the activities of the Office of Advocacy represent impermissible lobbying by federal employees.
- The Office of Advocacy should develop procedures to verify that its policies represent the interests of small business. Its comments should be limited to offering a small business perspective that the regulating agency would not otherwise hear.

- Congress should exert more rigorous oversight over the Office of Advocacy to ensure its work does not delay or prevent other federal agencies from fulfilling their statutory goals, especially those scientific and regulatory agencies tasked with protecting the health of the American people.

## Introduction

Americans have long championed small businesses. According to the U.S. Census Bureau, about 5,821,277 businesses with fewer than 100 employees are operating in the U.S. today, employing about 35 percent of the workforce.<sup>1</sup> The federal government has been actively supporting small businesses since 1953, when the Small Business Administration was established to provide them with subsidized loans and assistance.



Over the years, survey after survey has shown that a majority of Americans – across the political spectrum – believes that government should continue to provide assistance and support to small businesses.<sup>2</sup>

Surveys also show broad support for federal efforts to protect public health.<sup>3</sup> The public expects the government to keep tainted food and medicines off store shelves. They want cancer-causing chemicals regulated, air pollution controlled, and the safety of our water supplies ensured. In fact, most Americans believe that existing regulations need to be better enforced.<sup>4</sup> There is no reason that these two popular functions of government should conflict.

Yet our investigation, based on correspondence and materials provided through Freedom of Information Act requests, has unearthed activities by a little-known independent office within the Small Business Administration – the Office of Advocacy – that is working to undermine efforts by federal scientists to identify public health hazards and ensure that American families are protected from cancer-causing substances. These assessments do not regulate the activities of small business and seem far outside the Office’s mission – to represent the views and interests of small businesses to other federal agencies.

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1 See *Statistics about Business Size (including Small Business)*, U.S. Census Bureau, <http://www.census.gov/econ/smallbus.html> (last visited Jan. 14, 2013).

2 See, e.g., SMALL BUSINESS MAJORITY, OPINION POLL: SMALL BUSINESS VIEWS ON TAXES AND THE ROLE OF GOVERNMENT (OCT. 25, 2012), <http://www.smallbusinessmajority.org/small-business-research/taxes/taxes-and-role-of-government.php> (finding that “the majority of small businesses believe government can play an effective role in helping small businesses thrive”).

3 See COALITION FOR SENSIBLE SAFEGUARDS, SUMMARY OF LAKE RESEARCH PARTNERS 2011 REGULATORY RESEARCH (2011), <http://www.sensible safeguards.org/assets/documents/css-lrp-summary.pdf> (summarizing the findings of a national poll conducted May 2011).

4 *Id.*

Specifically, the Office of Advocacy sought to block the publication of scientific assessments of the risks of cancer developed by the National Toxicology Program and the Environmental Protection Agency's Integrated Risk Information System. When cancer assessments are delayed or stopped, it means more Americans will be exposed to substances that can kill. Delay costs lives.

Moreover, a recent survey of a representative sample of small business owners (businesses with under 100 employees) suggests that the positions taken by the Office of Advocacy do not represent the views of the constituency on whose behalf it is supposed to advocate.<sup>5</sup> About 60 percent of small business owners reported that they believe "exposure to toxic chemicals in day-to-day life" is a very serious or somewhat serious threat today; 75 percent supported "stricter regulation of chemicals produced and used in everyday products"; 94 percent said "companies using chemicals of concern to human health should disclose their presence to customers and the public"; and 92 percent said there should be "a public, easily accessible database identifying chemicals of high concern to human and environmental health." The survey mirrored the demographics of small business owners: three quarters of the respondents were male; 82 percent were white; half identified as Republican and 23 percent as Independents.<sup>6</sup>

The activities of the Office of Advocacy described in this report represent an unwarranted expansion of its jurisdiction, extending its reach well beyond the statutory responsibilities assigned to the Office under the Regulatory Flexibility Act and subsequent legislation. The Office of Advocacy operates with little oversight by the Small Business Administration, the White House, or Congress. Its effort to expand its jurisdiction to weigh in on toxic hazards threatens important health programs designed to inform the public and federal regulatory agencies about health risks.

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5 The survey of 511 small business owners found that small business owners (SBOs) generally believe toxic chemicals pose a threat to people's health, and support stricter regulation and greater disclosure of toxic chemicals. The sample was weighted by gender, region, ethnicity, industry type, and business size to match the characteristics of small business owners nationally. The margin of error for the survey is + or - 4.4%. *Poll of Small Business Owners on Toxic Chemicals*, American Sustainable Business Council (ASBC) (Sept. 2012), <http://asbcouncil.org/node/846>.

6 *Id.*

# 1. Federal Government Support for Small Businesses and the Office of Advocacy

Congress established the Small Business Administration (SBA) as a separate, executive branch agency in 1953 to provide businesses “which are independently owned and operated and which are not dominant in their field of operation” with financial assistance, such as government-backed loans.<sup>7</sup> For the next two decades, this cabinet-level agency responded to requests for assistance by business.



In 1974, when Congress amended the Small Business Act, it created the office of Chief Counsel for Advocacy within the Small Business Administration “to represent the views and interests of small businesses before other Federal agencies whose policies and activities may affect” small businesses.<sup>8</sup> Two years later, in 1976, the Office of Advocacy became an independent office within SBA, headed by the Chief Counsel for Advocacy. The Chief Counsel is appointed by the president and confirmed by the Senate.<sup>9</sup> As head of an independent office, the Chief Counsel is not required to submit his reports and comments to the SBA Administrator or to the White House Office of Management and Budget (OMB) for review or approval.<sup>10</sup>

Since the Office was established, its statutory authority has grown. In 1980, Congress passed the Regulatory Flexibility Act (RFA), which requires every federal agency to assess and mitigate the impact of proposed and final rules on small business consistent with its statutory mission and gave the Office of Advocacy the responsibility for overseeing agency compliance with this new mandate.<sup>11</sup>

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7 Stephen L. Keleti & Joseph A. Maranto, *Planning a Full-Scale Audit of the Small Business Administration*, 10 GAO REVIEW 51 (1975), available at <http://archive.gao.gov/otherpdf/091092.pdf>.

8 Small Business Amendments Act of 1974, Pub. L. No. 93-386, sec. 10, § 5(e)(4), 88 Stat. 742, 749 (1974), amended by Small Business Act and Small Business Investment Act of 1958, amendments, Pub. L. No. 94-305, tit. 2, § 201, 90 Stat. 663, 668 (1976) (current version at 15 U.S.C. § 634c(4) (2006)).

9 Small Business Act and Small Business Investment Act of 1958, amendments, Pub. L. No. 94-305, 90 Stat. 663 (1976) (current version at 15 U.S.C. § 634a-f (2006)).

10 15 U.S.C. § 634(f).

11 OFFICE OF ADVOCACY, U.S. SMALL BUSINESS ADMINISTRATION, REPORT ON THE REGULATORY FLEXIBILITY ACT FY 2011: ANNUAL REPORT OF THE CHIEF COUNSEL FOR ADVOCACY ON IMPLEMENTATION OF THE REGULATORY FLEXIBILITY ACT AND EXECUTIVE ORDER 13272, at 1 (2012) [hereinafter OFFICE OF ADVOCACY REPORT ON THE REGULATORY FLEXIBILITY ACT FY 2011], available at [http://www.sba.gov/sites/default/files/11regflx\\_0.pdf](http://www.sba.gov/sites/default/files/11regflx_0.pdf).



Congress again expanded its statutory responsibilities in 1996 when it enacted the Small Business Regulatory Enforcement Fairness Act (SBREFA).<sup>12</sup> Among other provisions, this law required the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) to convene small business review panels for every proposed rule that will have a “significant economic impact on a substantial number of small entities.”<sup>13</sup> The head of the agency, the head of the Office of Information and Regulatory Affairs (OIRA) (an office within OMB), and Chief Counsel for Advocacy are required to attend each panel and meet with representatives of “small entities” to review new rules the agency may propose and the agency’s analysis of the impact the rule may have on small businesses. The panel then suggests ways the agency can mitigate the impact on small business. The SBREFA process delays development of workplace safety and environmental rules considerably.

In 2002, President George W. Bush further expanded the Office of Advocacy’s responsibilities through Executive Order 13272.<sup>14</sup> Under this executive order, all federal agencies were required to notify the Office of Advocacy earlier in the rulemaking process of rules that could potentially have a significant effect on small businesses. This was intended to give agencies more time to adequately consider and respond to comments submitted by the Office of Advocacy.<sup>15</sup> The Small Business Jobs Act of 2010 codified these new requirements.

The Office of Advocacy’s budget for FY 2012 was \$9.12 million. It has a staff of 46. By comparison, OIRA, a key office in OMB responsible for reviewing the rules proposed by all executive agencies, had a staff of 45 in FY 2012.<sup>16</sup>

As its budget and staff have grown, the Office of Advocacy has moved beyond commenting on how regulations impact small business to questioning the merits of scientific assessments of toxic hazards. This substantial expansion of Advocacy’s role is well beyond its statutory responsibility or substantive expertise.

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12 Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C., 15 U.S.C., and 28 U.S.C.).

13 OFFICE OF ADVOCACY REPORT ON THE REGULATORY FLEXIBILITY ACT FY 2011, *supra* note 11, at 1–3. The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 also provided that the Consumer Financial Protection Bureau must conduct Small Business Advocacy Review (SBAR) panels when proposing economically significant rules. *Id.* at 2.

14 Exec. Order No. 13272, 3 C.F.R. 247 (2003), available at <http://www.foreffectivegov.org/files/regs/library/eo13272.pdf>.

15 OFFICE OF ADVOCACY REPORT ON THE REGULATORY FLEXIBILITY ACT FY 2011, *supra* note 11, at 2–3.

16 OFFICE OF ADVOCACY, U.S. SMALL BUSINESS ADMINISTRATION, CONGRESSIONAL BUDGET JUSTIFICATION FY 2013, at 6, available at <http://www.sba.gov/sites/default/files/files/3-508%20Compliant%20FY%202013%20Office%20of%20Advocacy%20CBJ%281%29.pdf>.

## 2. Protecting the Public from Cancer-causing Chemicals: Scientific Assessments of Health Risks

A number of laws have been passed directing federal agencies to protect the public from health hazards and to reduce the cancer risks posed by toxic substances. For example, the Clean Air Act requires EPA to reduce particulates in the air based on science showing their presence increases the risk of respiratory diseases. Congress directed the Consumer Product Safety Commission (CPSC) to ban lead in toys after it was shown that ingesting lead could cause brain and organ damage in infants. Congress required the Food and Drug Administration (FDA) to ban the use of certain preservatives if they are shown to cause cancer.



However, scientific evidence about the effects of chemicals on human health is cumulative. It is rare for a single study or two to provide definitive proof of increased cancer risks. Scientists rely on controlled experiments with animals to predict a chemical's effect in humans. Epidemiological studies may indicate, but rarely prove, an association between exposure and harm for several reasons. Epidemiological studies with adequate statistical power to detect small increases in common cancers require the collection of data and analysis of effects among large groups of exposed people. They cannot be completed until enough time has passed for latent effects to be detected. And, accurate data on past exposures is rarely available; reconstructed data may not accurately reflect past exposures. Because of this, determining what amount of exposure to what chemicals causes cancer inevitably requires scientists to make informed judgments.

Rather than asking each federal agency tasked with protecting the public's health to conduct its own evaluations of the scientific evidence on carcinogens, several agencies are tasked with evaluating scientific information and disseminating their conclusions to other federal agencies and the public. Two of these programs are the National Toxicology Program in the Department of Health and Human Services (HHS) and the Integrated Risk Information System in EPA. Neither program sets emission standards for chemical discharges or enforces health or safety standards later set by other agencies. Their role is to be an "honest broker" of scientific studies. However, because labeling a substance a cancer-causing agent can have adverse consequences in the market and lead to stricter regulation down the road, chemical manufacturers watch this process carefully, challenge research findings, and develop their own research to promote alternative hypotheses about cancer causation.

## The National Toxicology Program Report on Carcinogens

The Public Health Service Act of 1978 directs the Secretary of Health and Human Services to prepare a Report on Carcinogens every other year that identifies substances with the potential to cause cancer.<sup>17</sup> The National Toxicology Program (NTP) prepares the report to be issued on behalf of the Secretary of HHS, who then communicates this information to the American people to ensure they can make informed decisions about where they live and work.

The report has two classifications: 54 substances are classified as *known to be a human carcinogen*; 186 substances are classified as *reasonably anticipated to be a human carcinogen*.<sup>18</sup> A substance is *known to be a human carcinogen* if there is “sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.”<sup>19</sup> A substance is *reasonably anticipated to be a human carcinogen* if there is some evidence of carcinogenicity from studies in humans, evidence of carcinogenicity from animal studies, or other evidence to suggest a substance causes cancer. The Report on Carcinogens only puts substances into these broad categories; it does not quantitatively estimate the risk of cancer.

Because manufacturers fear that classifying a substance as a “known carcinogen” can reduce its use, public officials have developed a thorough and scrupulous process for determining what substances should be placed on the list. The NTP permits anyone to suggest a chemical should be put on the list, removed, or reclassified. Once NTP decides to evaluate a nominated substance, it conducts a comprehensive review of the evidence of its carcinogenicity. This draft background document is submitted to an expert panel for peer review and is put online to allow the public to comment. After peer review comments are incorporated into a revised report on the substance, it is published again, and the public can again comment. The final background document is then further reviewed by two interagency scientific review groups. Taking all this feedback into account, NTP prepares a draft “substance profile” and classification listing recommendation, which is then reviewed by its own Board of Scientific Counselors (BSC). The BSC solicits comments and holds a public hearing; it then reports on whether the scientific information in the draft substance profile is technically correct, clearly stated, and supports the classification recommendation. Only after this process has been completed is the new Report on Carcinogens published.<sup>20</sup>

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17 Community Mental Health Centers Act, Amendments, Pub. L. No. 95-622, Sec. 262(b)(4), 92 Stat. 3412, 3434-35 (1978) (codified as amended at 42 U.S.C. § 241(b)(4) (2006)).

18 NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVICES, THE REPORT ON CARCINOGENS: KEY POINTS; 12<sup>TH</sup> EDITION (2011), available at [http://www.niehs.nih.gov/health/materials/report\\_on\\_carcinogens\\_12th\\_edition\\_the\\_508.pdf](http://www.niehs.nih.gov/health/materials/report_on_carcinogens_12th_edition_the_508.pdf).

19 *Report on Carcinogens: Listing Criteria*, Nat'l Toxicology Program, <http://ntp.niehs.nih.gov/?objectid=47B37760-F1F6-975E-7C15022B9C93B5A6> (last updated June 15, 2011).

20 In fact, the National Toxicology Program revised the procedures for completing the Report on Carcinogens several times since 1980 and each time, it has added opportunity for public comment and additional peer review.

These procedures mean that a great deal of time is required to complete a new edition of the Report on Carcinogens. Large chemical companies who make the chemicals being evaluated and the trade associations of which they are members commented repeatedly on the 12<sup>th</sup> Report, which was published in 2011. In fact, their comments dominated the debate at NTP over which chemicals should be listed as carcinogens.

### **The Environmental Protection Agency's Integrated Risk Information System Assessments**

Another major database of information about chemical toxicity is the Integrated Risk Information System (IRIS) at EPA, which contains information on the health effects of environmental contaminants.<sup>21</sup> IRIS assessments evaluate the scientific data on chemical hazards and calculate acceptable exposure levels – the level below which no health effects are expected (known as the reference dose or reference concentration in air). The IRIS reference dose may be used by other EPA programs in determining the dose of a chemical to which the public may be exposed.

The IRIS database contains profiles for over 550 chemicals. Like the NTP Report on Carcinogens, the assessments are the result of an extensive, multi-step review process. A new IRIS assessment involves a comprehensive literature review, multiple opportunities for public comment, rigorous peer review of draft background documents, and final review by independent experts and other agency staff. The entire process takes at least two years (and often longer). The final IRIS assessment is posted online along with the summary, toxicological review, and EPA responses to comments received.

NTP and IRIS provide citizens with important information about the cancer hazards Americans face. Neither NTP nor IRIS assessments produce rules or regulations that govern business activity. Yet the Office of Advocacy at the SBA intervened in both the NTP and the IRIS assessment processes. We investigated how and why interventions related to three specific chemicals – formaldehyde, styrene, and chromium – occurred.

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<sup>21</sup> *Integrated Risk Information System (IRIS): Basic Information*, U.S. Environmental Protection Agency, <http://www.epa.gov/iris/intro.htm> (last updated Sept. 26, 2012).

## **The Center for Effective Government's Investigation**

The Center for Effective Government (formerly OMB Watch) filed several Freedom of Information Act requests with the Office of Advocacy in the spring of 2012. One request asked for documents relating to Advocacy's comments on NTP's 12<sup>th</sup> Report on Carcinogens and the risks posed by formaldehyde and styrene. Another FOIA request asked for documents relating to the Office of Advocacy's comments on EPA's IRIS risk assessment for chromium. Advocacy staff forwarded some documents responsive to our request. After we discovered a number of missing documents, staff searched their files again and provided more relevant documents. Advocacy claims the only documents not disclosed were intra- or interagency deliberative documents withheld under FOIA exemption 5.<sup>22</sup> The Office did not provide the Center for Effective Government with a list of withheld documents.

For each of the three chemical assessments investigated, the debate over the carcinogenicity of each substance has been going on for decades and involves complex, technical evaluations of toxicological and epidemiological data. The large manufacturing companies that produce these chemicals have spent tens of millions of dollars disputing the scientific evidence showing increased cancer risks. The Office of Advocacy admits it has no scientific expertise in this area, yet it chose to intervene in these proceedings. In each of the cases we examined, we asked:

- Who asked the Office of Advocacy to intervene in these chemical assessments?
- What efforts did Office of Advocacy staff make to educate themselves on the science underlying the debates about the health risks of these chemicals?
- What efforts did the Office of Advocacy make to determine the interests of small businesses in these issues (i.e., whether small businesses felt this was a priority for them and/or the impact that a cancer designation for these chemicals would have on small businesses)?

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<sup>22</sup> FOIA exemption 5 allows the government to withhold information that concerns communications within or between agencies that are protected by legal privileges including the attorney-work product privilege and deliberative process privilege. See *Frequently Asked Questions*, FOIA.gov, <http://www.foia.gov/faq.html> (last visited Jan. 9, 2013).



### 3. The Office of Advocacy's Interventions in Scientific Debates About Public Health and Toxic Chemicals

In each of the cases discussed below, a growing body of scientific evidence documented the cancer risks of the chemical agents. But as the research evidence grew, so too did the lobbying efforts of large producers. It appears that the Office of Advocacy became inappropriately and impermissibly entangled in these lobbying campaigns. Before moving into three case studies of these activities, a word is needed about the Office of Advocacy's Roundtables because they seem to play a critical role in shaping the priorities of the Office.



#### **The Roundtables**

Our research suggests that the Office of Advocacy began holding regular roundtables on different subjects with industry groups around 1990. According to its reports, "Some roundtables have been scheduled as regularly recurring events, such as Advocacy's monthly roundtable on environmental rules and Advocacy's occupational safety roundtable, which is generally bimonthly. Other roundtables, such as those concerning transportation and homeland security, have been held quarterly, while still others have been held on an ad hoc basis."<sup>23</sup>

The Office of Advocacy issues the invitations to its roundtables, which are usually held at the law offices of a firm representing a participating trade association. From correspondence and reports we have obtained,<sup>24</sup> it seems that trade association representatives and lobbyists sometimes directly ask to give presentations at the roundtables.<sup>25</sup> In other cases, Advocacy staff have worked with trade association staff to plan presentations, asking for input on the agenda, the presenters, and the title.<sup>26</sup>

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23 OFFICE OF ADVOCACY, U.S. SMALL BUSINESS ADMINISTRATION, REPORT ON THE REGULATORY FLEXIBILITY ACT FY 2008: ANNUAL REPORT OF THE CHIEF COUNSEL FOR ADVOCACY ON IMPLEMENTATION OF THE REGULATORY FLEXIBILITY ACT AND EXECUTIVE ORDER 13272, at 2 (2009), available at <http://www.sba.gov/sites/default/files/files/08regflx.pdf>.

24 The Office of Advocacy provided the environmental roundtable e-mail list, although it is not the most current version and some e-mails may have changed in the past six months. We were given presentations for the environmental roundtable on July 29, 2011 at which representatives from the American Composite Manufacturers Association and Kitchen Cabinet Manufacturers Association made presentations. Other miscellaneous roundtable documents were provided as well.

25 E-mail from Randy Schumacher, registered lobbyist for ACC, to Kevin L. Bromberg, Office of Advocacy (Mar. 16, 2011) ("I spoke to Ann earlier this week about presenting the Cr6 research at your upcoming roundtable. Did she indicate she would like to be part of the program?").

26 E-mail from Kevin L. Bromberg, Office of Advocacy, to Charlie Grizzle, lobbyist for the Formaldehyde Council, and Jim

Most attendees at the roundtables represent trade associations that have large corporate members, as well as small business members. Advocacy does not require that attendees represent small businesses. In one e-mail, a staff member at the Office of Advocacy told a lobbyist for General Electric that he was invited to attend a Labor Safety roundtable as long as he “maintain[ed] a small business perspective! ;-)”<sup>27</sup> Several small business groups perceived to be liberal or aligned with Democrats were not on the e-mail invitation lists for roundtables held in 2010 and 2011.<sup>28</sup>

The discussions at the roundtables are closed to the press, and participants are told they cannot publicly comment on the discussions.<sup>29</sup> Any party may report to its membership what it said, but participants are asked not to report what other participants say or to repeat what representatives of the Office of Advocacy say. Our investigation suggests that Advocacy’s positions on policy issues grow out of the discussion at these roundtables.

The documents from the roundtables obtained through our Freedom of Information Act requests and interviews conducted with participants suggest that presentations on the three chemical assessments were dominated by the interests of large chemical manufacturers. The presentations strongly criticized the science showing cancer risks; no competing views were presented. Nor was there an effort to determine how cancer assessments may impact small businesses within a certain industry or whether such an assessment might open markets for substitute chemicals. The assumption seems to be that a cancer assessment that adversely affects a big chemical company will adversely affect small businesses. From the materials we were provided and from interviews, we found no evidence that “[s]mall business representatives” initiated conversation at the roundtables on “the difficulties posed by chemical risk characterizations at the Department of Health and Human Services (HHS) and at the Environmental Protection Agency”<sup>30</sup> as the Office of Advocacy later claimed.

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Skillen, Dir., RISE, cc: Jane C. Luxton, Attorney, Pepper Hamilton, LLP (June 25, 2010) (Subject line: Draft Roundtable Notice\_ please review) (“Jane, Charlie – you can decide if I should list both of you or just Charlie. Also, Charlie, I would be interested in a formaldehyde update also – if you could handle it. I would list that separately. . . . *Jim – we can add an additional speaker with you if you like. Please review the time frames also.*”); E-mail from Kevin L. Bromberg to David Fischer, ACC, Ann Mason, ACC, and John Schweitzer, ACMA (June 28, 2011) (“I’m thinking of two presenters on the NTP process for styrene and formaldehyde – and to contrast this process with the IRIS risk assessment process, and the merits of the science controversies – for an hour slot on the 29<sup>th</sup>. Thoughts?”); E-mail from David Fischer to Kevin L. Bromberg, Ann Mason, and John Schweitzer (July 6, 2011) (“Kevin, I think discussing NTP process would be very worthwhile but not sure two talks would be necessary since the flaws in the formaldehyde process were also apparent in styrene’s as well. I’m wondering if we want to discuss the larger issue of rampant redundancy and inconsistency in hazard/risk assessment within the federal govt. In particular, is the RoC still relevant? Thanks.”); E-mail from John Schweitzer to Kevin L. Bromberg (July 11, 2011) (“We’ve got a toxicologist standing by for the July 29 SBA Roundtable. . . .”); E-mail from John Schweitzer to Kevin L. Bromberg (July 22, 2011) (“I will likely present the styrene issue next week, instead of Jim Bus. Since NTP is not participating, we don’t need to employ our big ‘science guns.”); E-mail from Kevin L. Bromberg to David Fischer and John Schweitzer (July 12, 2011) (asking for suggestions for the title of Advocacy’s environmental roundtable scheduled for July 29<sup>th</sup>, 2011 and offering three titles for consideration).

27 E-mail from Bruce E. Lundegren, Office of Advocacy, to Pat K. Casano, General Electric (Jan. 10, 2011).

28 After testifying at a joint hearing before the House Science Committee and Small Business Committee on April 25, 2012, American Sustainable Business Council was invited to attend the Environmental Roundtables.

29 See E-mail from Kevin L. Bromberg, Office of Advocacy, to John Schweitzer, ACMA (Aug. 1, 2011). In editing a press release for ACMA, Mr. Bromberg wrote “we prefer that we stick to what was presented at the Roundtable – and not a reference to the discussion at the Roundtable- which we try to keep confidential to aid in having an open discussion (see the bottom of all Roundtable notices). Participants are free, however, to make known their own comments.”

30 OFFICE OF ADVOCACY REPORT ON THE REGULATORY FLEXIBILITY ACT FY 2011, *supra* note 11, at 5.



When a federal agency relies on a group of outside advisors to formulate policy, the process is supposed to be governed by the Federal Advisory Committee Act (FACA).<sup>31</sup> This law is designed to “limit the influence of special interests” in the public policy decision making process. The law requires that meetings of advisory groups be open to the public and that advisory committees be balanced.

The Office of Advocacy’s roundtables may represent improperly constituted advisory committees. Advocacy invites a group of private citizens to regularly meet and solicits their input on policy positions. The Office of Advocacy appears to rely on the “consensus views” expressed during these meetings to formulate the positions it takes. Yet Advocacy conducts the roundtables behind closed doors and does not disclose records of what is said. Clearly, the roundtables are incompatible with the goals of FACA.

### **The Formaldehyde War**

Formaldehyde is a colorless, flammable, strong-smelling chemical that is used as an adhesive, disinfectant, and preservative. It is found in the home in products such as particleboard, plywood, and glues. Exposure to formaldehyde can cause sensory and skin irritation and chemical sensitivity. Workers who produce or use formaldehyde are exposed to greater levels than the general public.<sup>32</sup> In 1981, formaldehyde was listed as *reasonably anticipated to be a human carcinogen* in the NTP Report on Carcinogens.

The early evidence of the relationship between formaldehyde and cancer actually came from the Chemical Industry Institute of Toxicology (CIIT), a research group founded by 11 large chemical companies.<sup>33</sup> In 1979, it reported that rats exposed to formaldehyde contracted cancer. Shortly after this finding, and a strategy memo put out by a Georgia-Pacific health and safety official,<sup>34</sup> the CIIT shifted its focus to conducting research showing that humans metabolize formaldehyde differently than rats, so that given the same level of exposure, people absorb less formaldehyde than rats. Risk assessments based on actual cancer incidence among formaldehyde-exposed workers show risks 50 times higher than those predicted by CIIT’s models.<sup>35</sup> A lobbying effort to block the regulation of formaldehyde as a cancer-causing substance was funded by the Formaldehyde Institute.

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31 FACA rules apply when an assemblage of individuals that includes at least one non-federal employee (a) is working as a group and (b) is “established or utilized” by agency (c) to provide “advice or recommendations” to the agency. 5 U.S.C. App. 2 § 3(2) (2006).

32 See generally *Formaldehyde and Cancer Risk*, Nat’l Cancer Institute, <http://www.cancer.gov/cancertopics/factsheet/Risk/formaldehyde> (last reviewed June 10, 2011); *Formaldehyde*, Ctrs. for Disease Control and Prevention, <http://www.cdc.gov/niosh/topics/formaldehyde/> (last updated Mar. 3, 2012).

33 DAN FAGIN ET AL., *TOXIC DECEPTION: HOW THE CHEMICAL INDUSTRY MANIPULATES SCIENCE, BENDS THE LAW, AND ENDANGERS YOUR HEALTH* 47 (1996).

34 Georgia-Pacific, a subsidiary of Koch Industries, is one of the country’s top producers of formaldehyde. Other large chemical companies who have been active in the fight include Cleanese, Dupont, and other members of the now-defunct Formaldehyde Institute. See *Formaldehyde Added to “Known Carcinogens” List Despite Lobbying by Koch Brothers*, *Chemical Industry, Democracy Now* (June 14, 2011), available at [http://ec.libsyn.com/p/8/5/6/8565271316161e75/dn2011-0614-1.mp3?d13a76d516d9dec20c3d276ce028ed5089ab1ce3dae902ea1d01cd8032d8ce5c4d5e&c\\_id=3325818](http://ec.libsyn.com/p/8/5/6/8565271316161e75/dn2011-0614-1.mp3?d13a76d516d9dec20c3d276ce028ed5089ab1ce3dae902ea1d01cd8032d8ce5c4d5e&c_id=3325818); Laurie Bennett, *The Mighty Formaldehyde Lobby*, *Muckety* (Oct. 7, 2012, 7:09 AM), <http://news.muckety.com/2012/10/07/the-mighty-formaldehyde-lobby/38441>.

35 FAGIN ET AL., *supra* note 33, at 76.

Based on the NTP assessment in 1981, the Occupational Safety and Health Administration (OSHA) sought to regulate workplace exposure to formaldehyde. Industry opposition was so intense that a new exposure limit was only published in response to a court order.<sup>36</sup> OSHA's final standard, not issued until 1987, fully considered, and rejected, the industry theory; instead, OSHA concluded that formaldehyde posed a significant cancer risk to exposed workers.<sup>37</sup>

EPA also set out to evaluate formaldehyde's risks. In the 1980s, its risk assessment accepted the industry theory that formaldehyde posed little cancer risk to humans,<sup>38</sup> even though EPA's own Science Advisory Board warned the agency against this approach in 1992.<sup>39</sup>

Over the past two decades, a growing body of human epidemiology studies has consistently shown upper airway and blood cancers among workers exposed to formaldehyde. In fact, the International Agency for Research on Cancer (IARC) designated formaldehyde a "probable human carcinogen" as early as 1987 and in 2006 concluded that there is "sufficient evidence in humans" that formaldehyde causes cancer of the nasal passages and "strong but not sufficient" evidence for a causal association between leukemia and formaldehyde.<sup>40</sup>

By 2008, a paper by EPA concluded that the industry risk model showing minimal human risk was "unsupportable."<sup>41</sup> As a result, EPA revised its formaldehyde risk assessment in 2009, concluding, as had IARC, that formaldehyde is known to cause cancer of the nasal passages and leukemia.

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36 UAW v. Donovan, 756 F.2d 162 (D.C. Cir. 1985).

37 UAW v. Pendergrass, 878 F.2d 389 (D.C. Cir. 1989). Although both OSHA and the courts rejected the formaldehyde industry's self-serving interpretation of the chemical's cancer risk, economists at OMB's Office of Information and Regulatory Affairs (OIRA) accepted it. OIRA repeatedly cited OSHA's formaldehyde standard as a rule with large costs but few benefits. OIRA's analysis of the costs and benefits of formaldehyde regulation has been thoroughly discredited. See Lisa Heinzerling, *Regulatory Costs of Mythical Proportions*, 107 YALE L.J. 1981 (1998).

38 See FAGIN ET AL., *supra* note 33, at 89-91.

39 *Id.* at 73.

40 Int'l Agency for Research on Cancer (IARC), *Formaldehyde, 2-Butoxyethanol and 1-tert-Butoxypropan-2-ol*, 88 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS (2006), available at <http://monographs.iarc.fr/ENG/Monographs/vol88/mono88.pdf>.

41 Franklin Mirer, *Risky Business: Forming Your Opinion Regarding Cancer and Formaldehyde*, THE SYNERGIST, Apr. 2009, at 32 (quoting Kenny S. Crump et al., *Sensitivity Analysis of Biologically Motivated Model for Formaldehyde-Induced Respiratory Cancer in Humans*, 52:6 ANNALS OF OCCUPATIONAL HYGIENE 481 (2008)).

Producers immediately began a campaign to block the new IRIS risk assessment. Initially, the Formaldehyde Institute led the fight against designating formaldehyde as a carcinogen, but it disbanded in 1993 after documents showing the industry's research strategy of obfuscating formaldehyde's risks were produced during discovery in a lawsuit seeking damages for illnesses caused by formaldehyde exposure. The Formaldehyde Council assumed its role as the dominant industry trade association in 1995. It was dominated by big chemical companies that were manufacturing formaldehyde.<sup>42</sup> In 2010, it ceased operations at the same time that the American Chemistry Council (ACC) formed a Formaldehyde Panel funded by Georgia-Pacific (owned by Koch Industries) and Hexion Specialty Chemicals.<sup>43</sup> Beginning in 2010, efforts to block the IRIS and NTP assessments of formaldehyde, at federal agencies and in Congress, were led by lobbyists for the ACC.

Sen. David Vitter (R-LA) put a hold on an EPA nominee until the agency asked the National Academy of Sciences (NAS) to review the IRIS formaldehyde risk assessment shortly after a lobbyist for the Formaldehyde Council held a fundraiser on the senator's behalf.<sup>44</sup> Koch Industries and a Formaldehyde Council lobbyist also gave generous campaign contributions to other senators leading the effort to delay the assessment.<sup>45</sup> Responding to this political pressure, EPA requested the review, which NAS published in April 2011.<sup>46</sup> The NAS review affirmed EPA's conclusion that formaldehyde was a known human carcinogen, causing upper airway cancers, but directed EPA to restate its reasons for concluding that formaldehyde caused leukemia in humans. EPA has not released revisions to its formaldehyde IRIS assessment since the NAS review was completed.

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42 The by-laws of the Formaldehyde Council require that members of the Board of Directors represent Tier 1 members of the Council. Companies must pay \$200,000 to become Tier 1 members, so it is unlikely that many small businesses sat on the Formaldehyde Council's governing body.

43 See ACC Forms New Formaldehyde Panel, American Chemistry Council, <http://www.americanchemistry.com/11312>.

44 Joaquin Sapien, *How Senator Vitter Battled the EPA over Formaldehyde's Link to Cancer*, ProPublica (Apr. 15, 2010, 2:30 AM), <http://www.propublica.org/article/how-senator-david-vitter-battled-formaldehyde-link-to-cancer>.

45 *Id.* (linking Koch Industries and Charles Grizzle, a lobbyist for the Formaldehyde Council, to campaign contributions to Sens. Inhofe and Vitter).

46 COMMITTEE TO REVIEW EPA'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE, NAT'L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011), available at [http://books.nap.edu/openbook.php?record\\_id=13142](http://books.nap.edu/openbook.php?record_id=13142). Industry interprets the NAS report as critical of EPA's risk assessment; environmental groups such as Natural Resources Defense Council interpret the report as questioning EPA's discussion of how formaldehyde causes blood cancers, without disagreeing with its conclusion that formaldehyde is carcinogenic.

At HHS, NTP responded to the IARC listing and new research by proposing to move formaldehyde from an “anticipated” human carcinogen to a “known human carcinogen,” causing upper airway cancers and leukemia, as they prepared the 12<sup>th</sup> Report on Carcinogens. The Formaldehyde Council and the ACC strongly objected, filing multiple comments with NTP. Industry demanded that NTP incorporate the NAS analysis of the IRIS risk assessment into its evaluation, which it did. But the ACC and Dow Chemical continued to lobby Congress to delay publication of the Report on Carcinogens until another NAS review was conducted.<sup>47</sup> Republican House representatives unsuccessfully pushed an appropriations rider to delay the Report’s release.<sup>48</sup>

**“NTP Excerpt – What is the detailed industry argument that this is incorrect?”**

-e-mail subject line from Kevin L. Bromberg, Office of Advocacy, to Randy Schumacher, registered lobbyist for ACC

### **Advocacy Involvement**

The Office of Advocacy waded into the debate in November 2011 with formal comments claiming that “[s]mall businesses have taken issue with . . . formaldehyde’s listing as ‘known to be a human carcinogen’” and that they were “concerned with the quality of scientific analysis” relied upon by NTP.<sup>49</sup>

**“I guess he’s essentially wrong. It’s probably better for now that I keep the NTP contact in the dark.”**

-e-mail from Kevin L. Bromberg, to David Fischer, ACC

Our review of the materials gathered from our Freedom of Information Act request shows no documents from any small businesses asking the Office of Advocacy to intervene in the formaldehyde listing, nor did any small business file comments with NTP criticizing its analysis.<sup>50</sup> Instead, internal Advocacy documents show that Advocacy communicated regularly with registered lobbyists for the Formaldehyde Council and ACC.<sup>51</sup>

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47 See Jennifer Sass, *Health Scientists Sign on to Tell Congress Not to Strip Funding for the Report on Carcinogens*, Switchboard: Natural Resources Defense Council Staff Blog (Sept. 5, 2012), [http://switchboard.nrdc.org/blogs/jsass/health\\_scientists\\_sign\\_on\\_to\\_t.html](http://switchboard.nrdc.org/blogs/jsass/health_scientists_sign_on_to_t.html).

48 COMMITTEE ON APPROPRIATIONS, 112<sup>TH</sup> CONGRESS, WORKING BILL ON APPROPRIATIONS FOR DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES FY 2013, (Comm. Print 2012), available at <http://appropriations.house.gov/uploadedfiles/bills-112hr-sc-ap-fy13-laborhhsed.pdf>.

49 Letter from Winslow Sargeant, Chief Counsel for Advocacy, and Sarah Bresolin Silver, Assistant Chief Counsel, Office of Advocacy, to Kathleen Sebelius, Sec’y of Health & Human Services, U.S. Dept’t of Health & Human Services (Nov. 22, 2011), [http://www.sba.gov/sites/default/files/Advocacy\\_Comment\\_Letter-Report\\_On\\_Carcinogens.pdf](http://www.sba.gov/sites/default/files/Advocacy_Comment_Letter-Report_On_Carcinogens.pdf).

50 The only comments NTP received were from trade associations, large chemical companies, consulting firms, and academic and research institutions. See *Formaldehyde [CAS No. 50-00-0], Public Comments: Substances Newly Reviewed for the 12<sup>th</sup> RoC*, Nat’l Toxicology Program, <http://ntp.niehs.nih.gov/index.cfm?objectid=20A477F2-F1F6-975E-7472FC6B0DA56D9C#formaldehyde> (last updated July 19, 2012).

51 See E-mails between Kevin Bromberg, Office of Advocacy, and Randy Schumacher, registered lobbyist for ACC (May 2011); E-mails between Kevin Bromberg, Office of Advocacy, and Charles Grizzle, registered lobbyist for the Formaldehyde Council (June-Aug. 2010).

Moreover, documents show that the Office of Advocacy made no effort to evaluate the scientific evidence behind the NTP assessment. Instead, Advocacy asked lobbyists for ACC to provide a “detailed industry” rebuttal to NTP.<sup>52</sup> In May 2011, Advocacy staff followed up with ACC and its lobbyists about their meetings with agency officials regarding formaldehyde.<sup>53</sup> Advocacy also collaborated on press strategy with ACC<sup>54</sup> and discussed whether and when to share materials with agency staff.<sup>55</sup>

## **Styrene Skirmishes**

Styrene is a clear, liquid, volatile organic compound used predominantly in the manufacture of plastics and rubber.<sup>56</sup> Synthetic styrene derived from oil and natural gas is most commonly found in carpet backing, fiberglass composites (e.g., bathtubs and kitchen countertops), and even in polystyrene food containers. Styrene may be released into the environment during manufacture, use, or disposal, contaminating air and drinking water.

As far back as 1988, studies showed styrene caused cancer in laboratory mice.<sup>57</sup> Human studies in the years since have suggested that occupational exposure to styrene can lead to increased risk of lymphomas, leukemia, and pancreatic or esophageal cancers.<sup>58</sup> The IARC has listed styrene as “possibly carcinogenic to humans” since 2002.<sup>59</sup> Growing evidence from animal studies and limited evidence of cancer risks among workers caused NTP to propose listing styrene as “reasonably anticipated” to cause cancer in its 12<sup>th</sup> Report on Carcinogens.

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52 E-mail from Kevin L. Bromberg, Office of Advocacy, to Randy Schumacher, registered lobbyist for ACC, and cc: David Fischer, ACC (May 25, 2011). The e-mail contained the subject line, “NTP Excerpt – What is the detailed industry argument that this is incorrect?”

53 E-mail from Kevin L. Bromberg, Office of Advocacy, to Randy Schumacher, registered lobbyist for ACC (May 24, 2011) (“News from the meeting?”); E-mail from Kevin L. Bromberg, Office of Advocacy, to David Fischer, ACC (May 24, 2011) (“Was there an ACC meeting today with HHS? Any news?”).

54 E-mail from Kevin L. Bromberg, Office of Advocacy, to David Fischer, ACC, and Randy Schumacher, registered lobbyist for ACC (May 25, 2011) (Kevin Bromberg: “Will the news about an RoC delay get into the press? Do you want it there?”).

55 E-mail from David Fischer, ACC, to Kevin L. Bromberg, Office of Advocacy (May 25, 2011) (David Fischer: “Who at NTP were you thinking of sharing it with? John Bucher of NTP essentially told House committee staff that the NRC’s report was not relevant to the NTP RoC.”); E-mail reply from Kevin L. Bromberg to David Fischer (May 25, 2011) (Kevin Bromberg: “I guess he’s essentially wrong. It’s probably better for now that I keep the NTP contact in the dark.”).

56 AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP’T OF HEALTH & HUMAN SERVICES, TOXICOLOGICAL PROFILE FOR STYRENE 1–8 (2010), available at <http://www.atsdr.cdc.gov/toxprofiles/tp53.pdf>; NAT’L TOXICOLOGY PROGRAM, U.S. DEP’T OF HEALTH & HUMAN SERVICES, STYRENE: KEY POINTS (June 2011), available at [http://www.niehs.nih.gov/health/materials/styrene\\_508.pdf](http://www.niehs.nih.gov/health/materials/styrene_508.pdf); *Frequently Asked Questions*, Styrene Info. & Res. Center, <http://www.styrene.org/faq.html#one> (last visited Jan. 7, 2013).

57 Barbara Conti et al., *Long-Term Carcinogenicity Bioassays on Styrene Administered by Inhalation, Ingestion and Injection and Styrene Oxide Administered by Ingestion in Sprague-Dawley Rats, and Para-Methylstyrene Administered by Ingestion in Sprague-Dawley Rats and Swiss Mice*, 534 ANNALS OF THE N.Y. ACAD. OF SCI. 203–34 (1988).

58 NAT’L TOXICOLOGY PROGRAM, *supra* note 50.

59 Int’l Agency for Research on Cancer (IARC), *Some Traditional Herbal Medicines, Some Mycotoxins, Napthalene, and Styrene*, 82 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS 437–522 (2002), available at <http://monographs.iarc.fr/ENG/Monographs/vol82/mono82.pdf>.

Not surprisingly, companies producing styrene vigorously disputed its danger to humans. Like formaldehyde producers, they argued that humans metabolize the toxin differently than animals, so higher exposures are less toxic to people than to laboratory mice. The Styrene Information and Research Council (SIRC) spent over \$20 million on 47 studies examining the health and environmental effects of styrene exposure; none found clear cancer risks.<sup>60</sup> Yet other evidence tells a different story.<sup>61</sup>

In fact, OSHA has regulated styrene's "narcotic" health effects on workers since 1971.<sup>62</sup> By 1989, with evidence of cancer risks increasing, OSHA proposed to revisit its limits on permissible exposure to styrene.<sup>63</sup> But industry associations strongly objected to OSHA characterizing styrene as carcinogenic, arguing there was insufficient data to support such a classification.<sup>64</sup> OSHA backed down; its final rule reducing styrene exposure, later overturned in court, relied only on "its narcotic effects" as justification.<sup>65</sup>

In 1998, SIRC convinced EPA to allow SIRC to conduct the IRIS hazard assessment of styrene.<sup>66</sup> The industry assessment was of such poor quality that it was unusable. However, the tactic delayed EPA's IRIS assessment update of the cancer risks of styrene for some time.<sup>67</sup>

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60 *Summary of SIRC-Supported Research*, Styrene Info. & Res. Center, [http://www.styrene.org/science/research\\_summary.html](http://www.styrene.org/science/research_summary.html) (last visited Jan. 7, 2013).

61 *See supra* notes 57–59.

62 Air Contaminants, 29 C.F.R. § 1910.1000 tbl. Z-1 (1999).

63 The update was referred to by OSHA as the PEL project and OSHA sought to substitute outdated consensus standards, first adopted by the American Conference of Government Industrial Hygienists (ACGIH) in the 1960s, with consensus standards current in the late 1980s. Final Rule, Air Contaminants, 54 Fed. Reg. 2332–2983 (Jan. 19, 1989), *revoked* 58 Fed. Reg. 35338–35351 (June 30, 1993).

64 Letter from John B. Jenks, Chairman, Styrene Info. & Research Ctr. et al., to Joseph A. Dear, Assistant Sec'y of Occupational Safety & Health, U.S. Dep't of Labor (Jan. 30, 1996), *available at* [http://www.acmanet.org/ga/osha\\_styrene\\_agreement\\_docs\\_1996.pdf](http://www.acmanet.org/ga/osha_styrene_agreement_docs_1996.pdf).

65 OSHA's PEL update was invalidated by the 11<sup>th</sup> Circuit. *AFL-CIO v. OSHA*, 965 F.2d 962 (11th Cir. 1992); *see also* *Revocation of Final Rule*, 58 Fed. Reg. 35338–35351 (June 30, 1993).

66 *See* JENNIFER SASS & DANIEL ROSENBERG, NATURAL RESOURCES DEFENSE COUNCIL, *THE DELAY GAME: HOW THE CHEMICAL INDUSTRY DUCKS REGULATION OF THE MOST TOXIC SUBSTANCES 15* (2011), *available at* <http://www.nrdc.org/health/files/IrisDelayReport.pdf>.

67 *Id.* at 16.



Since styrene was nominated for inclusion in the 12<sup>th</sup> Report on Carcinogens in 2004, SIRC filed 22 comments arguing against listing the substance.<sup>68</sup> As the Report neared publication, the industry group doubled its lobbying expenditures, increasing its funding from \$200,000 in 2010 to over \$400,000 in 2011.<sup>69</sup> Rep. Rick Boucher (D-VA), Rep. John Shadegg (R-AZ), and 34 other members of Congress sent a letter to HHS Secretary Kathleen Sebelius criticizing the NTP assessment of styrene's risks,<sup>70</sup> and the American Composite Manufacturers Association (ACMA) campaigned "aggressively to overturn the NTP listing."<sup>71</sup> When the Report on Carcinogens was finally released on June 10, 2011, it listed styrene as "reasonably anticipated" to cause cancer. The same day, SIRC and Dart Corporation filed suit challenging this assessment of styrene's risks.<sup>72</sup>

Dow Chemical is a founding member of SIRC. Two of the association's websites are registered to the Management Information Systems Director at the American Chemistry Council. SIRC's offices, coincidentally, were in the same location in Arlington, VA, as those of the Formaldehyde Council. And one of its lobbying firms also lobbied for ACC, while another of its firms lobbied for Dow Chemical.

### **Advocacy Involvement**

The Office of Advocacy was asked by lobbyists from SIRC and ACMA to comment on the NTP assessment of styrene and did so. A consultant from a lobbying firm hired by SIRC first contacted the Office of Advocacy on June 4, 2010, regarding the styrene listing under review for the 12<sup>th</sup> Report on Carcinogens.<sup>73</sup> Following that contact, the same consultant helped ACMA representatives plan a meeting with Advocacy on Sept. 15, 2010, to discuss ACMA's concerns about the styrene assessment.<sup>74</sup>

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68 Intervenor-Defendants' Reply in Support of Defendants' & Cross Motions for Summary Judgment at 6, *Styrene Info. & Research Ctr., Inc. v. Sebelius*, No. 11-1079 (D.D.C. Aug. 10, 2012).

69 SIRC's lobbying expenditures had been minimal before 2010. *Lobbying: Styrene Information and Research Center (2011)*, Center for Responsive Pol., <http://www.opensecrets.org/lobby/clientsum.php?id=D000057259&year=2011> (last visited Jan. 7, 2012); *Lobbying: Styrene Information and Research Center (2010)*, Center for Responsive Pol., <http://www.opensecrets.org/lobby/clientsum.php?id=D000057259&year=2010> (last visited Jan. 7, 2012).

70 Letter from Rep. Rick Boucher and Rep. John Shadegg et al., to Kathleen Sebelius, Sec'y of Health & Human Services, U.S. Dep't of Health & Human Services (Apr. 21, 2010) (requesting that the listing of styrene be deferred for review until the 13<sup>th</sup> Report on Carcinogens).

71 *ACMA Continues Fight on NTP Styrene Listing*, Am. Composites Manufacturers Ass'n (ACMA), <http://www.acmanet.org/ga/styrene.cfm> (last visited Jan. 7, 2013). ACMA had lobbying expenses relating to NTP of at least \$56,000 in 2010 and \$70,000 in 2011. *Lobbying: American Composites Manufacturers Assn (2011)*, Center for Responsive Pol., <http://www.opensecrets.org/lobby/clientsum.php?id=D000023940&year=2011> (last visited Jan. 7, 2013); *Lobbying: American Composites Manufacturers Assn (2010)*, Center for Responsive Pol., <http://www.opensecrets.org/lobby/clientsum.php?id=D000023940&year=2010> (last visited Jan. 7, 2013).

72 Complaint, *Styrene Info. & Research Ctr., Inc. v. Sebelius*, No. 11-1079 (D.D.C. June 10, 2011), available at <http://www.styrene.org/news/pdfs/06-10-11-SIRCVSebeliusComplaint.pdf>.

73 E-mail from Bureson Smith to Kevin L. Bromberg (June 4, 2010) (attaching letters sent by the Styrene Information and Research Council and members of Congress to the Secretary of Health and Human Services requesting that the styrene listing be deferred and re-reviewed in the 13<sup>th</sup> Report on Carcinogens).

74 E-mail from Bureson Smith to Charles A. Maresca (Sept. 14, 2010) (sending over the list of attendees for the meeting); E-mail from Bureson Smith to Charles A. Maresca (Sept. 15, 2010) (attaching the ACMA Issue Summary in advance of the meeting outlining ACMA's "previous efforts to ask NTP to review all of the data . . .").



At the meeting, directors of ACMA or its lobbyists asked Advocacy to schedule an interagency meeting with the Office of Management and Budget and NTP to discuss the assessment and to submit a request to Sebelius asking her to drop the styrene listing.<sup>75</sup> After a second meeting on Nov. 30, 2010, ACMA directors submitted letters to the Office of Advocacy asking the Office to get involved with the styrene listing.<sup>76</sup> Staff at Advocacy quickly did as they were asked and forwarded ACMA's letter to HHS on the same day.<sup>77</sup> In its letter, ACMA claimed the NTP listing would jeopardize 500,000 jobs. That figure represents more than 75 percent of all jobs SIRC identifies as styrene-related.

When these efforts failed to block the listing, industry lobbyists asked for help in securing changes to the assessment procedures so that they could have more opportunities to influence the process, even though the industry trade associations and research groups had already commented extensively on NTP's proposed listing. The ACC launched a lobbying campaign to get Congress to change the procedures; SIRC actively lobbied in support of this effort.<sup>78</sup>

No individual small business contacted Advocacy about the styrene listing. The Office of Advocacy received correspondence about the styrene assessment only from SIRC and ACMA. Small businesses did not file comments on styrene with NTP independent of ACMA.<sup>79</sup>

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75 E-mail from Burlison Smith to Charles A. Maresca (Sept. 15, 2010). The e-mail includes an attachment describing ACMA's actions related to the styrene listing and asks the Small Business Administration to: "Elevate this issue as a priority within the Office of Advocacy and assign a member of your staff to champion this effort; Contact the Office of Management and Budget Office of Information and Regulatory Affairs (OMB-OIRA) and request an interagency meeting with NTP to evaluate these claims; Submit a request to the Secretary of Health and Human Services Sebelius to postpone making her determination regarding styrene until the 13<sup>th</sup> RoC in order to implement the improvements to the process and to review all of the data for styrene before making a determination regarding the potential for carcinogenicity in keeping with other review processes." Cf. Letter from Winslow Sargeant, Chief Counsel for Advocacy, Office of Advocacy, to Kathleen Sebelius, Sec'y of Health & Human Services, U.S. Dep't of Health & Human Services (Dec. 1, 2010), available at [http://www.sba.gov/sites/default/files/hhs10\\_1201.pdf](http://www.sba.gov/sites/default/files/hhs10_1201.pdf).

76 E-mail from Burlison Smith to David J. Rostker (Nov. 30, 2010) (sending a follow-up email from the meeting earlier that day with an attachment to an Information Quality Act Request for Corrections that SIRC submitted to HHS in October 2009); E-mail from Angie Castillo to David J. Rostker (Dec. 1, 2010) (attaching separate letters from Tom Dobbins and Monty Felix to the Chief Counsel for Advocacy).

77 E-mail from Angie Castillo to David J. Rostker (Dec. 1, 2010) (attaching separate letters from Tom Dobbins and Monty Felix to the Chief Counsel for Advocacy). Letter from Winslow Sargeant, Chief Counsel for Advocacy, Office of Advocacy, to Kathleen Sebelius, Sec'y of Health & Human Services, U.S. Dep't of Health & Human Services (Dec. 1, 2010), available at [http://www.sba.gov/sites/default/files/hhs10\\_1201.pdf](http://www.sba.gov/sites/default/files/hhs10_1201.pdf). Advocacy's comment letter "encourage[s] NTP to consider all relevant scientific data in making its recommendations, including studies that show negative or null results" and to "carefully consider these concerns as the 12<sup>th</sup> Report on Carcinogens is finalized and the preparations for the 13<sup>th</sup> report are begun." *Id.* ACMA quickly thanked Advocacy for its help. E-mail from Tom Dobbins to David J. Rostker (Dec. 2, 2010) ("Thanks to you, Dr. Sargeant and the rest of the team for the quick turnaround on this important letter.").

78 Kate Sheppard, *Republicans Attempt to Ax Program Monitoring Carcinogens*, Mother Jones (Aug. 24, 2012, 2:00 AM), <http://www.motherjones.com/blue-marble/2012/08/republicans-attempt-ax-program-monitoring-carcinogens>; Sarah Vogel, *Hands off the Report on Carcinogens*, Environmental Defense Fund (Sept. 5, 2012), <http://blogs.edf.org/nanotechnology/2012/09/05/hands-off-the-report-on-carcinogens/>; Nicholas D. Kristof, *The Cancer Lobby*, N.Y. Times (Oct. 6, 2012), [http://www.nytimes.com/2012/10/07/opinion/sunday/kristof-the-cancer-lobby.html?\\_r=0](http://www.nytimes.com/2012/10/07/opinion/sunday/kristof-the-cancer-lobby.html?_r=0); see also sources cited *supra* note 69.

79 *Scientific Reviews for Listings in the 12<sup>th</sup> Report on Carcinogens: Public Comments*, Nat'l Toxicology Program, <http://ntp.niehs.nih.gov/index.cfm?objectid=20A477F2-F1F6-975E-7472FC6B0DA56D9C#styrene> (last updated July 19, 2012).

Advocacy filed a second set of comments after the Report on Carcinogens was published and SIRC had filed its lawsuit challenging the styrene classification. In its comments in November 2011, Advocacy criticized the NTP listing of styrene again, in the same letter it sent criticizing the formaldehyde listing, expressing concern about “the quality of [the Report on Carcinogens’] scientific analysis, the robustness of the scientific process, including procedures for peer review and public comment procedures, and that [the Report on Carcinogens] is duplicative of other federal chemical risk assessment programs, particularly the IRIS.”<sup>80</sup> These comments repeated the talking points provided by ACMA and SIRC.<sup>81</sup>

The Office of Advocacy became involved in the styrene issue in response to a request by the affected trade associations, which are dominated by big businesses or their lobbyists, and its comments repeated their arguments. At a hearing on the Report on Carcinogens, held by the House Science Committee and Small Business Committee in April 2012, Advocacy staff admitted they made no effort to verify industry’s claims.<sup>82</sup> After hearing the testimony, Rep. Brad Miller (D-NC) commented that the Office of Advocacy “relied for their scientific judgment and process comments on the information provided by Styrene lobbyists, so their testimony was really just an echo of what we heard from the Dow Chemical industry scientist.”<sup>83</sup>

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80 Letter from Winslow Sargeant, Chief Counsel for Advocacy, and Sarah Bresolin Silver, Assistant Chief Counsel, Office of Advocacy, to Kathleen Sebelius, Sec’y of Health & Human Services, U.S. Dep’t of Health & Human Services (Nov. 22, 2011), [http://www.sba.gov/sites/default/files/Advocacy\\_Comment\\_Letter\\_Report\\_On\\_Carcinogens.pdf](http://www.sba.gov/sites/default/files/Advocacy_Comment_Letter_Report_On_Carcinogens.pdf); Letter from Winslow Sargeant, Chief Counsel for Advocacy, and Sarah Bresolin Silver, Assistant Chief Counsel, Office of Advocacy, to Dr. Ruth Lunn, Director, Office of the Report on Carcinogens 4 (Dec. 14, 2011), available at <http://ntp.niehs.nih.gov/NTP/RoC/Thirteenth/Process/PublicComm/SBA20111214.pdf>.

81 E-mail from Burlison Smith to Charles A. Maresca (Sept. 15, 2010). This e-mail includes an attachment of an ACMA Issue Summary to be discussed at the meeting with Advocacy on Sept. 15, 2010. The document identifies four major areas of concern: [1] The styrene listing will raise unnecessary concerns about the safety of styrene among employees and communities exposed to the chemical; [2] NTP’s position on styrene is inconsistent with a European report and a Blue Ribbon Panel report on styrene because NTP failed to adequately consider negative studies; [3] NTP’s review process causes concerns about the scientific quality and validity of its findings on styrene; and [4] Businesses that have participated in the NTP process have not been assured that their comments were considered during the review process. These talking points were reiterated in a presentation by ACMA at Advocacy’s environmental roundtable on July 29<sup>th</sup>, 2011. Advocacy’s letter on November 22, 2011 regarding styrene and formaldehyde mirror the talking points made in these two documents.

82 Webcast, *How the Report on Carcinogens Uses Science to Meet its Statutory Obligations, and its Impact on Small Business Jobs*, Hearing Before the Subcomm. on Investigations and Oversight of the H. Comm. on Science, Space, and Technology and the Subcomm. on Healthcare and Technology of the H. Comm. on Small Business, 112<sup>th</sup> Cong. (2012) [hereinafter *Hearing on Report on Carcinogens*] (statement of Charles A. Maresca, Dir., Interagency Affairs, Office of Advocacy, U.S. Small Bus. Admin.), available at <http://science.edgeboss.net/wmedia/science/sst2012/042512.vwx>.

83 Press Release, Committee on Science, Space, and Technology Minority, Subcommittee Misses Opportunity to Understand the Impact of National Toxicology Program’s Report on Carcinogens (Apr. 25, 2012), <http://democrats.science.house.gov/press-release/subcommittee-misses-opportunity-understand-impact-national-toxicology-program%E2%80%99s-report>.

## Chromium Battles

Chromium is a naturally occurring heavy metal, found in two widely used classes of compounds: trivalent chromium (chromium-3) and the more carcinogenic hexavalent chromium (chromium-6).<sup>84</sup> Hexavalent chromium is used for chrome plating, dyes and pigments, treating wood, and for producing steel and other alloys.<sup>85</sup> Hexavalent chromium exposure can come from inhaling or ingesting the substance. Inhalation of hexavalent chromium has long been recognized as a cancer risk to workers in the chromium industry. In fact, hexavalent chromium has been listed as a “known human carcinogen” in NTP’s Report on Carcinogens since 1980,<sup>86</sup> and the EPA IRIS database has calculated maximum limits for chromium inhalation since 1998.<sup>87</sup>

OSHA began regulating worker exposure to chromium in 1971, after it adopted a consensus standard as a mandatory workplace limit.<sup>88</sup> The National Institute for Occupational Safety and Health recommended OSHA improve its chromium-6 standard in 1975 to better protect workers,<sup>89</sup> but no new OSHA standard was forthcoming. In 1993, Public Citizen and the Oil, Chemical and Atomic Workers sued OSHA to compel it to set new exposure standards to reduce workers’ chromium cancer risk.<sup>90</sup>

The Chrome Coalition, a trade association of chromium manufacturers, immediately hired consultants to publicize the findings from 18 studies on the health effects of hexavalent chromium it had commissioned; all found minimal cancer risks.<sup>91</sup> Industry groups also urged OSHA to delay action until an EPA study on chromium’s cancer risk had been completed. When the study showed cancer risks, industry interests urged further delays and more analysis.

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84 See generally Int’l Agency for Research on Cancer (IARC), *Chromium, Nickel and Welding*, 49 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS (1990), available at <http://monographs.iarc.fr/ENG/Monographs/vol49/mono49.pdf>.

85 AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP’T OF HEALTH & HUMAN SERVICES, TOXICOLOGICAL PROFILE FOR CHROMIUM 1-8 (2012), available at <http://www.atsdr.cdc.gov/toxprofiles/tp7.pdf>.

86 Notice, First Annual Report on Carcinogens, 45 Fed. Reg. 61,372 (Sept. 16, 1980); see also IARC, *supra* note 84 (explaining that hexavalent chromium was identified in the IARC monographs as a known human carcinogen in 1973, and supplementing the monograph with new evidence in support of the original classification).

87 U.S. ENVIRONMENTAL PROTECTION AGENCY, IRIS TOXICOLOGICAL REVIEW OF HEXAVALENT CHROMIUM (1998), available at <http://www.epa.gov/iris/toxreviews/0144tr.pdf>.

88 Air Contaminants, 29 C.F.R. § 1910.1000 tbl. Z-1 (1999). *Public Citizen Health Research Group v. Chao*, 314 F.3d 143, 146-47, 2002 U.S. App. LEXIS 26778 (3d Cir. Dec. 24, 2002) (explaining that OSHA’s 1971 standard for hexavalent chromium was based on a recommended standard by the American National Standards Institute (ANSI) in 1943. ANSI’s standard followed from reports from the 1920’s about hexavalent chromium’s acute effects).

89 NAT’L INSTITUTE FOR OCCUPATIONAL SAFETY & HEALTH, DHHS (NIOSH) PUB. NO. 76-129, CRITERIA FOR A RECOMMENDED STANDARD: OCCUPATIONAL EXPOSURE TO CHROMIUM (VI) (1975), available at <http://www.cdc.gov/niosh/docs/1970/76-129.html>.

90 OCCUPATIONAL SAFETY AND HEALTH LAW § 13 (Randy S. Rabinowitz & Scott H. Durham eds., 2d ed. Supp. 2008). OSHA had attempted to set a new standard for chromium-6 as part of a cumulative carcinogen standard in 1977, but the Supreme Court invalidated the OSHA rulemaking, finding that the agency must perform an individual risk assessment for each chemical standard it develops. See DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY’S ASSAULT ON SCIENCE THREATENS YOUR HEALTH 97-100 (2008).

91 MICHAELS, *supra* note 90, at 100-01; David Michaels et al., Commentary, *Selected Science: An Industry Campaign to Undermine an OSHA Hexavalent Chromium Standard*, *Envtl. Health: A Global Access Sci. Source* 2 (2006), available at <http://www.ehjournal.net/content/pdf/1476-069X-5-5.pdf>.

As the debate over the cancer risks of inhaling chromium-6 progressed, another battle opened up. The movie *Erin Brockovich*, which premiered in 2000, described the struggle of residents of Hinkley, CA, to get compensation from Pacific Gas & Electric after it contaminated the town's drinking water with chromium, making many residents ill. The case settled for \$333 million in 1993, making it the largest class-action in U.S. history at the time.<sup>92</sup>

By 2010, an NTP study showed that ingestion of drinking water contaminated with hexavalent chromium caused cancer in laboratory animals,<sup>93</sup> and staff at EPA believed there was enough information to calculate a reference concentration (maximum exposure level) for chromium ingestion. If EPA was able to do this, new drinking water standards for chromium levels nationwide would likely follow.

Industry objected,<sup>94</sup> arguing that chromium is metabolized by humans into a less toxic form of the metal, thus posing minimal cancer risk from drinking water. Their "evidence" was a 1997 re-analysis (shown to be fraudulent in 2005<sup>95</sup>) of a 1987 Chinese study.<sup>96</sup> The American Chemistry Council's Hexavalent Chromium Panel, the apparent successor to the Chrome Coalition, led the objections, urging EPA to delay its IRIS assessment until an industry-funded study had been completed.<sup>97</sup> Since October 2010, the American Chemistry Council has filed 25 separate comments objecting to the IRIS assessment of hexavalent chromium – almost half of the total number of comments filed.<sup>98</sup> EPA bowed to industry pressure and agreed to indefinitely delay its IRIS assessment.<sup>99</sup>

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92 Sedina Banks, *The "Erin Brockovich Effect": How Media Shapes Toxics Policy*, 26 ENVIRONS ENVTL. L. & POL'Y J. 219, 230 (2003). In 2003, Honeywell International, Inc., was ordered to pay \$400 million for cleanup of chromium in New Jersey. REBECCA SUTTON, ENVIRONMENTAL WORKING GROUP, CHROMIUM-6 IN U.S. TAP WATER 17 (2010), available at [http://static.ewg.org/reports/2010/chrome6/chrome6\\_report\\_2.pdf](http://static.ewg.org/reports/2010/chrome6/chrome6_report_2.pdf). A similar class action suit was filed against Honeywell & PPG Industries in 2010. *Smith v. Honeywell Int'l, Inc.*, No. 2:10-cv-03345, 2011 U.S. Dist. LEXIS 51854 (D.N.J. May 13, 2011).

93 NAT'L TOXICOLOGY PROGRAM, NTP TR 546, TECHNICAL REPORT ON THE TOXICOLOGY AND CARCINOGENESIS STUDIES OF SODIUM DICHROMATE DIHYDRATE (CAS No. 7789-12-0) IN F344/N RATS AND B6C3F1 MICE (DRINKING WATER STUDIES) (July 2008), [http://ntp.niehs.nih.gov/ntp/htdocs/LT\\_rpts/tr546.pdf](http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr546.pdf); Press Release, Nat'l Institute of Health, Hexavalent Chromium in Drinking Water Causes Cancer in Lab Animals (May 16, 2007), <http://www.nih.gov/news/pr/may2007/niehs-16.htm>.

94 See U.S. ENVIRONMENTAL PROTECTION AGENCY, PUBLIC DOCKET FOLDER, DRAFT TOXICOLOGICAL REVIEW OF CHROMIUM: IN SUPPORT OF SUMMARY INFORMATION ON THE INTEGRATED RISK INFORMATION SYSTEM (IRIS), EPA-HQ-ORD-2010-0540, <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;D=EPA-HQ-ORD-2010-0540> (last visited Jan. 10, 2013).

95 *Id.* As a result of the fraudulent study, the Journal pulled it from publication and issued a letter regarding the incident. P. Brandt-Rauf, Editorial Retraction, *Cancer Mortality in a Chinese Population Exposed to Hexavalent Chromium in Water*, 48(7) J. OCCUPATIONAL & ENVTL. MEDICINE 749 (2006).

96 See ENVIRONMENTAL WORKING GROUP, CHROME-PLATED FRAUD: HOW PG&E'S SCIENTISTS-FOR-HIRE REVERSED FINDINGS OF CANCER STUDY (2005), <http://www.ewg.org/book/export/html/8626>.

97 Letter from Ann Mason, Senior Director, Am. Chemistry Council, to Rebecca Clark, Acting Director, Nat'l Ctr. for Env'tl. Assessment, U.S. Environmental Protection Agency (Dec. 23, 2010), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-ORD-2010-0540-0027> (select the pdf icon by "view attachment" to download the attached file). American Chemistry Council's Hexavalent Chromium Panel funded this new, \$4 million study, which was conducted by Tox Strategies and a team of scientists with ties to industry. According to ACC's website, "The panel's primary activities include sponsoring research to fill the scientific database informing the risk levels for hexavalent chromium in drinking water and communicating the findings of this research." *Hexavalent Chromium*, AmericanChemistry.com, <http://www.americanchemistry.com/HexavalentChromium>. ACC also began a letter writing campaign from industry organizations to EPA asking the agency to delay its assessment until the new industry study is complete. See, e.g., E-mail from Randy Schumacher to Kevin L. Bromberg (Sept. 15, 2011) (attaching several letters from trade associations all asking EPA Administrator Lisa Jackson to postpone the IRIS assessment of chromium until ACC completes its ongoing research project and EPA has had an opportunity to consider the data).

98 U.S. ENVIRONMENTAL PROTECTION AGENCY, PUBLIC DOCKET FOLDER, *supra* note 94.

99 IRISTrack Detailed Report: Chromium VI Assessment Milestones and Dates, U.S. Env'tl. Protection Agency, [http://cfpub.epa.gov/ncea/iristrac/index.cfm?fuseaction=viewChemical.showChemical&sw\\_id=1114](http://cfpub.epa.gov/ncea/iristrac/index.cfm?fuseaction=viewChemical.showChemical&sw_id=1114) (last updated Jan. 8, 2013).



## Advocacy Involvement

The Office of Advocacy became involved in the debate about the cancer risks of ingesting chromium after being contacted by the same ACC lobbyist who had urged Advocacy to become involved in the debate about formaldehyde risks.<sup>100</sup> In June 2011, the lobbyist suggested Advocacy staff write a letter to EPA asking that it delay completion of the chromium assessment until after the ACC study had been completed.<sup>101</sup> The request did not mention any small business concerns.

Advocacy did not attempt to research or validate the ACC's position on chromium. Staff at the Office of Advocacy did ask if there was evidence showing a link between chromium-laced drinking water and cancer and was assured that new industry-funded research would answer these questions.<sup>102</sup> This apparently satisfied Advocacy staff.<sup>103</sup>

Staff at the Office of Advocacy also asked if any small businesses were affected by the chromium risk assessment. ACC assured Advocacy that they were, and Advocacy staff asked no more questions.<sup>104</sup> No small business contacted the Office of Advocacy to challenge the IRIS chromium assessment. A few small businesses filed comments with EPA on the IRIS chromium assessment, echoing the comments already filed by ACC asking EPA to delay the IRIS assessment until after completion of ACC's new study.

On Oct. 5, 2011, Advocacy submitted a letter to EPA expressing the concerns of "small business representatives" over EPA's IRIS evaluation that hexavalent chromium is carcinogenic.<sup>105</sup> The Office of Advocacy went on to claim that EPA did not have sufficient data to estimate the risk from ingestion of chromium and argued that EPA should not rely on a linear model to estimate the cancer risks of exposure to low doses of chromium. The Office asked EPA to delay its final assessment until a new industry study was completed and its results incorporated into the assessment.

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100 E-mail from Randy Schumacher to Bruce E. Lundegrun (Feb. 3, 2011) ("May I impose on you to help arrange a meeting with your Advocacy Office colleagues who handle environmental issues? The Senate EPW Committee held a hearing on drinking water contaminants yesterday at which Administrator Jackson testified. My interest in setting up the meeting has been raised substantially as a result of her testimony. As you may recall, I represent the American Chemistry Council's Hexavalent Chromium Panel, and Cr6 was one of the topics of the hearing").

101 E-mail from Randy Schumacher to Kevin L. Bromberg (June 28, 2011) ("I would like you to be aware EPA's Cr6 risk assessment is moving forward apparently without waiting for ACC's MOA and PK studies to be completed and accepted for publication, notwithstanding the agency's own peer reviewers strong recommendation. NFIB recently sent a letter to Administrator Jackson calling upon her to stop the Cr6 risk assessment process to do exactly as EPA's peer reviewers deemed advisable. . . . Since it appears EPA needs to hear from more constituents for it to listen to its own peer review team, would SBA be willing to send a letter to Ms. Jackson to weigh in on this matter?").

102 E-mail from Kevin L. Bromberg to Jeff Hannapel, Steve Via, and Randy Schumacher (Feb. 25, 2011) ("Birnbaum told the committee that studies, other than EWG, have found a 'statistically significant association between hexavalent chromium in drinking water and cancer.' Does anyone have these studies, or the references to these studies?"); E-mail from Randy Schumacher to Kevin L. Bromberg (Feb. 25, 2011) ("ACC's research is examining why this occurs and whether Cr6 at low doses (consistent with existing drinking water standards) has the same carcinogenic effects and mode of [*sic*] action. . . .").

103 E-mail from Kevin L. Bromberg to Randy Schumacher (Feb. 25, 2011) ("thx.") (responding to chain of e-mails on the association between hexavalent chromium in drinking water and cancer).

104 E-mail from Kevin L. Bromberg to Ann Mason and Randal Schumacher (Oct. 3, 2011) ("Since this is the oral ingestion standard, is this toxicological review even relevant to platers, like NAMF? Isn't that only inhalation risk – and a separate risk assessment, that I believe is under development? Isn't this review solely of interest to drinking water suppliers?"). Reply e-mail from Ann Mason to Kevin L. Bromberg and Randal Schumacher (Oct. 3, 2011) ("Yes the oral tox review will impact drinking water systems AND will impact all cleanup and possible effluent standards. So the industries interested in the Cr6 oral tox review include all of the Cr6 user industries, including all industries that do plating or use chromium.").

105 Letter from Winslow Sargeant, Chief Counsel for Advocacy, and Sarah Bresolin Silver, Assistant Chief Counsel, Office

The ACC lobbyist provided the Office of Advocacy with these talking points and edited its draft letter to EPA.<sup>106</sup> Advocacy's final letter to EPA precisely mirrors the text forwarded to it by the ACC and is remarkably similar to ACC's comments to EPA.<sup>107</sup>

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of Advocacy, to Paul Anastas, Assistant Adm'r, U.S. Environmental Protection Agency (Oct. 5, 2011), <http://www.sba.gov/advocacy/816/27201>.

106 See E-mail from Randy Schumacher to Kevin L. Bromberg (Sept. 15, 2011) (attaching several letters from trade associations all asking EPA Administrator Lisa Jackson to postpone the IRIS assessment of chromium until ACC completes its ongoing research project and EPA has had an opportunity to consider the data); E-mail from Kevin L. Bromberg to Ann Mason and Randy Schumacher (Oct. 3, 2011) ("Ann, Randy – a question on Cr 6: 'Initial results show that Cr(VI) is not mutagenic at low [ ] and that the human stomach has a substantial ability to reduce Cr(VI) to the benign chromium-3. Confirmation of a threshold would mean that there is no cancer risk at low doses, contrary to the current EPA model. Would you edit these sentences – or is this accurate?"); E-mail from Randy Schumacher to Ann Mason (Oct. 3, 2011) (providing his suggested edits to Kevin Bromberg's text); E-mail from Ann Mason to Randal Schumacher and Kevin L. Bromberg (Oct. 3, 2011) ("This text is ok with me as edited by Randy. Note that some of the EPA peer reviewers were particularly emphatic about this point. Kevin, did you want/need to include a quote from them?"); E-mail from Kevin L. Bromberg to Randal Schumacher and Ann Mason (Oct. 3, 2011) ("Can you get some good quotes from scientists not named in the NRDC letter? Also, is there a good argument about the gastric issue that you could offer?").

107 Letter from Winslow Sargeant, Chief Counsel for Advocacy, and Sarah Bresolin Silver, Assistant Chief Counsel, Office of Advocacy, to Paul Anastas, Assistant Adm'r, U.S. Environmental Protection Agency (Oct. 5, 2011), <http://www.sba.gov/advocacy/816/27201>; U.S. ENVIRONMENTAL PROTECTION AGENCY, PUBLIC DOCKET FOLDER, *supra* note 94.

## 4. Did the Office of Advocacy's Actions Really Serve the Interests of Small Businesses?

Like most Americans, we believe a vibrant small business sector supports a more resilient economy. The assistance the Small Business Administration provides to small business owners is an important public service, increasingly so when markets are dominated by large corporations. The mission of the Office of Advocacy is to ensure that other federal agencies consider small business concerns.



However, this investigation reveals that, rather than aligning its mission with the work of other federal agencies, the Office of Advocacy actually worked with large business interests to obstruct and delay the work of at least two agencies tasked with protecting the health and safety of the American people. One part of government should not be working to undermine the efforts of another.

The correspondence into and out of the Office of Advocacy that we have examined paints a picture of a federal agency extremely responsive to the agenda of trade associations dominated by big chemical manufacturers and their lobbyists. No small business asked the Office of Advocacy to intervene with the NTP Report on Carcinogens or the EPA IRIS assessments of cancer risks. Advocacy's comments on these assessments offered no small business perspective to NTP or IRIS. No small business filed an independent comment critical of the formaldehyde and styrene assessments; a few small businesses did comment on the chromium assessment. In each case, the Office of Advocacy made no attempt to determine whether the views of the American Chemistry Council, the American Composite Manufacturers Association, or the Formaldehyde Council actually represented the views or interests of small businesses.



The Office of Advocacy's close coordination of its efforts with lobbyists seeking legislation to obtain the same results suggests its staff engaged in impermissible lobbying. Advocacy's efforts to block the NTP and IRIS assessments were initiated by the American Chemistry Council and groups or lobbyists associated with it. ACC is made up of 140 chemical companies; it claims that 70 of its members are "small and medium sized businesses" but doesn't specify what it means by "small" or "medium." Its membership is dominated by the largest chemical companies in the country, including Dow, DuPont, Exxon Mobil, Georgia-Pacific, and more. Its federal lobbying expenditures in the fourth quarter of 2011 were the fifth highest of any group filing lobbying reports. Its Formaldehyde Panel is funded by Georgia-Pacific and Hexion, both large companies. Dow is a major player in both ACC and the Styrene Information and Research Council. ACC's Chromium Panel succeeded the Chrome Coalition. There is no evidence of any small business role in any of the ACC coalitions.

This is not surprising since small businesses do not share the anti-regulatory views of large chemical companies. A survey by the American Sustainable Business Council concluded that:

Organizations like the American Chemistry Council have made anti-regulation legislation in Congress and state legislatures a top priority, pushing the myth that all regulations are a threat to small business growth . . . . But the reality is that small business owners see the value of sound regulations to help guide the market to deliver innovation for safer chemicals and products, which consumers are demanding. This data shows that no matter what your political affiliation is, there is agreement that toxic chemicals need to be regulated to prevent risk for business and the public.<sup>108</sup>

Even the Office of Advocacy's own research shows that challenging cancer assessments is simply not a priority of actual small business owners. According to an initiative to identify the interest of small business (referred to as the r3 initiative<sup>109</sup>), the top regulatory issues of concern to small business related to their ability to compete against large businesses for government contracts; EPA rules, particularly its "Once in, Always in" policy,<sup>110</sup> were also a concern. Advocacy received no nominations related to scientific assessments.<sup>111</sup>

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108 *Toxic Chemical Reform Good for Business—New Poll*, American Sustainable Business Council (ASBC) (Nov. 13, 2012), <http://asbcouncil.org/node/845>.

109 *Small Business Regulatory Review and Reform Initiative*, SBA Office of Advocacy, <http://archive.sba.gov/advo/r3/>. The r3 Initiative began under Chief Counsel for Advocacy, Tom Sullivan, but did not continue after he resigned in 2008. The initiative was designed to allow small businesses to nominate rules for review, which Advocacy would then review and publish as a top ten list in its annual RFA report. *Post Hearing Questions and Answers for the Record Submitted to Sen. Olympia Snowe by Winslow Sargeant, Jan. 25, 2011 (Next Steps for Main Street: Reducing the Regulatory and Administrative Burdens on America's Small Businesses: Hearing Before the U.S. Senate Committee on Small Business and Entrepreneurship* (Nov. 18, 2010)), available at <http://www.sba.gov/advocacy/2675/14163>; see also *New Small Business Program Will Influence Agency Regulatory Reviews*, OMB Watch (Sept. 11, 2007), <http://www.foreffectivegov.org/node/3419>.

110 See U.S. ENVIRONMENTAL PROTECTION AGENCY, POTENTIAL TO EMIT FOR MACT STANDARDS -- GUIDANCE ON TIMING ISSUES (May 16, 1995) for an explanation of the Once in, Always in air quality policy, <http://www.epa.gov/ttn/caaa/t3/memoranda/pteguid.pdf>.

111 *Regulatory Review and Reform (r3) Top 10 Rules, 2008* in REPORT ON THE REGULATORY FLEXIBILITY ACT FY 2007: ANNUAL REPORT OF THE CHIEF COUNSEL FOR ADVOCACY ON IMPLEMENTATION OF THE REGULATORY FLEXIBILITY ACT AND EXECUTIVE ORDER 13272, at Appx. B (2008), available at <http://www.sba.gov/sites/default/files/files/07regflx.pdf>; *Regulatory Review and Reform (r3) Top 10 Rules, 2009*, SBA Office of Advocacy, [http://archive.sba.gov/advo/r3/r3\\_nominations09.html#10](http://archive.sba.gov/advo/r3/r3_nominations09.html#10). Although

Moreover, testimony at a recent joint hearing of the House Science Committee and Small Business Committee<sup>112</sup> suggests that small businesses may in fact *benefit* from stricter regulation of some toxic substances, because the prohibition of some chemicals may open up new markets for those who manufacture “green” substitutes. The Vice President of BioAmber, Ally Latourelle, stated in her testimony that “recognition that styrene is ‘reasonably anticipated’ to be carcinogenic is not detrimental to our small business. In fact, for our business, as an alternative to petrochemicals, and the developers of non-toxic styrene replacement products, reports published by government on the toxicology of chemicals and regulations of those chemicals is a driver to our business as well as our strategic partners in the area of chemical production and manufacturing.”<sup>113</sup> Apparently, the Office of Advocacy never inquired about these issues.

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Advocacy’s website indicated that it was accepting nominations until December 31, 2010 for its 2011 r3 initiative, the r3 Top Ten list has not been published in the RFA since 2009.

112 *Hearing on Report on Carcinogens, supra* note 82 (statement of Ally Latourelle, Vice President, Gov’t Affairs, BioAmber, Inc.).

113 *Id.*

## 5. Conclusions

The Regulatory Flexibility Act assigns to the Office of Advocacy responsibility for ensuring that federal agencies evaluate the impacts on small businesses of the rules they adopt. Cancer risk assessments are not covered by the Regulatory Flexibility Act. They do not regulate small business. The Office of Advocacy had no reasonable basis for becoming involved in the NTP or IRIS assessments.

The Office of Advocacy's decision to comment on technical, scientific assessments represents a significant and unwarranted expansion of its role and extends its reach well beyond the regulatory process. By its own admission, Advocacy lacks the scientific expertise to evaluate the merits of the NTP/IRIS assessments. Advocacy's comments on these assessments raised no issues of specific concern to small business but relied almost exclusively on talking points provided by trade associations engaged in major lobbying campaigns.

Between 2005 and 2012, the American Chemistry Council and its members spent more than \$333 million lobbying Congress and federal agencies.<sup>114</sup> The Formaldehyde Institute/Council, Styrene Industry Research Council, and Chrome Coalition spent millions of dollars in a protracted lobbying campaign to prevent government agencies from designating these substances as carcinogenic and tens of millions more on research carefully designed to support their claims that these substances do not cause cancer in humans. These groups asked the Office of Advocacy for assistance, and the Office became a willing partner in these lobbying efforts.

The Office of Advocacy's efforts to block the NTP and IRIS assessments came amid efforts by the ACC to win congressional approval of legislation overhauling the NTP and IRIS assessment processes. Both ACC and Dow Chemical lobbied Congress to delay publication of the Report on Carcinogens until the National Academy of Sciences conducted yet another review.<sup>115</sup> Rep. Denny Rehberg (R-MT) unsuccessfully pushed an appropriations rider to do just that.<sup>116</sup>

Besides the moral and ethical concerns raised by efforts to keep substances known to cause cancer on the market and in wide use, the activities of the Office of Advocacy are disturbing because they may be illegal. Civil and criminal laws bar federal employees from lobbying. While the Government Accountability Office admits that lobbying restrictions are "unclear and imprecise," the Comptroller General has said anti-lobbying laws prohibit providing "administrative support for teh [*sic*] lobbying activities of private organizations."<sup>117</sup>

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114 Jeremy P. Jacobs, *Industry Group Boosted Political Spending Last Year – And it Paid Off*, E&E Daily (Feb. 7, 2012), <http://www.eenews.net/public/EEDaily/2012/02/07/1>.

115 See Sass, *supra* note 47.

116 COMMITTEE ON APPROPRIATIONS, *supra* note 48.

117 U.S. GENERAL ACCOUNTING OFFICE, GAO/T-OGC-96-18, TESTIMONY BEFORE THE COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT, HOUSE OF REPRESENTATIVES: H.R. 3078, THE FEDERAL AGENCY ANTI-LOBBYING ACT; STATEMENT OF ROBERT P. MURPHY, GENERAL COUNSEL, GENERAL ACCOUNTING OFFICE (1996), available at <http://gao.justia.com/department-of-the-interior/1996/5/h-r-3078-the-federal-agency-anti-lobbying-act-t-ogc-96-18/T-OGC-96-18-full-report.pdf>; *Lobbying and Publicity or Propaganda Guidelines: Appropriations Act Riders*, Nat'l Institute Of Health Ethics Program, <http://ethics.od.nih.gov/>

Our investigation raises serious questions about the lack of oversight of the Office of Advocacy's actions. The Office's activities are not reviewed by the administrator of the Small Business Administration or the White House. Congress has conducted no oversight hearings on the Office in more than 25 years, and GAO has not investigated the Office's activities.

## Specific Findings and Recommendations

The Office of Advocacy submitted comments regarding three widely used chemicals, objecting to cancer assessments by the National Toxicology Program and the Environmental Protection Agency's Integrated Risk Information System, even though no federal regulation was at stake. These actions were not authorized by the Regulatory Flexibility Act and improperly expanded the Office of Advocacy's jurisdiction into areas in which it has no expertise.

- Recommendation: The Office of Advocacy should limit its work to regulatory activities affecting small business, as authorized by the Regulatory Flexibility Act and subsequent laws.

The Office of Advocacy hosts regular Environmental Roundtables attended by trade association representatives and lobbyists. The discussions and minutes are kept secret, although the consensus positions that emerge appear to inform the Office of Advocacy's policy positions. These meetings violate the spirit, and perhaps the letter, of the Federal Advisory Committee Act.

- Recommendation: Congress should ask GAO to investigate whether the Office of Advocacy's Environmental Roundtables violate Federal Advisory Committee Act provisions.

The Office of Advocacy staff made no effort to educate themselves on the science underlying the debates about the cancer risks of these chemicals or to verify the accuracy of the talking points provided to them by industry lobbyists before filing comments critical of the NTP/IRIS processes and the scientific conclusions in each assessment.<sup>118</sup> Instead, the Office of Advocacy simply repackaged and submitted talking points provided by trade association lobbyists as formal comments.

- Recommendation: The Office of Advocacy should independently verify the factual claims it makes in comments to other federal agencies and should not comment on technical or scientific matters on which its staff have no expertise.

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[topics/Lobby-Publicity-Guide.htm#Footnote](#) (last updated Feb. 18, 2011). A 2009 investigation condemned the activities of a small unit inside the Department of Interior where communication between government staff and external parties "created the potential for conflicts of interest or violations of law." Rep. Rob Bishop (R-Utah) who had called for the investigation responded: "The ongoing, explicit, far-reaching coordination between special interest lobbying groups and [government staff] . . . is troubling . . . . This inappropriate meddling of private and public lobbying efforts is precisely the sort of thing I warned against . . . ." Bruce Hosking, *Role of BLM Employees Questioned in Federal Investigation*, Examiner.com (Oct. 8, 2009), <http://www.examiner.com/article/role-of-blm-employees-questioned-federal-investigation>.

118 In each of these cases (formaldehyde, styrene, and chromium), other federal agencies like OSHA, NIOSH, ATSDR also extensively reviewed their cancer risks. The Office of Advocacy made no effort to even compare the NTP or IRIS assessments to the work of other federal agencies.

Correspondence between the Office of Advocacy and trade associations dominated by large chemical companies and their lobbyists suggests the Office became entangled in a major lobbying campaign to prevent the federal government from listing certain chemicals as known or probable carcinogens. E-mails suggest the Office of Advocacy may have violated the Anti-Lobbying Act and other lobbying restrictions.

- Recommendation: Congress should ask GAO to investigate whether the activities of the Office of Advocacy represent impermissible lobbying by federal employees.

No small businesses objected to the scientific assessments or asked the Office of Advocacy to intervene in the cancer assessments. The Office of Advocacy made no effort to determine whether the positions it took represented small business views and interests. Moreover, since small businesses may produce substitutes for toxic chemicals, a cancer finding for existing chemicals could open up new markets for substitute chemicals produced by small businesses.

- Recommendation: The Office of Advocacy should develop procedures to verify that its policies represent the interests of small business. Its comments should be limited to offering a small business perspective that the regulating agency would not otherwise hear.

No process or procedures seem to be in place to ensure that the activities of the Office of Advocacy are consistent with, and do not work to undermine, the statutory responsibilities of other agencies.

- Recommendation: Congress should exert more rigorous oversight over the Office of Advocacy to ensure its work does not delay or prevent other federal agencies from fulfilling their statutory goals, especially those scientific and regulatory agencies tasked with protecting the health of the American people.





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