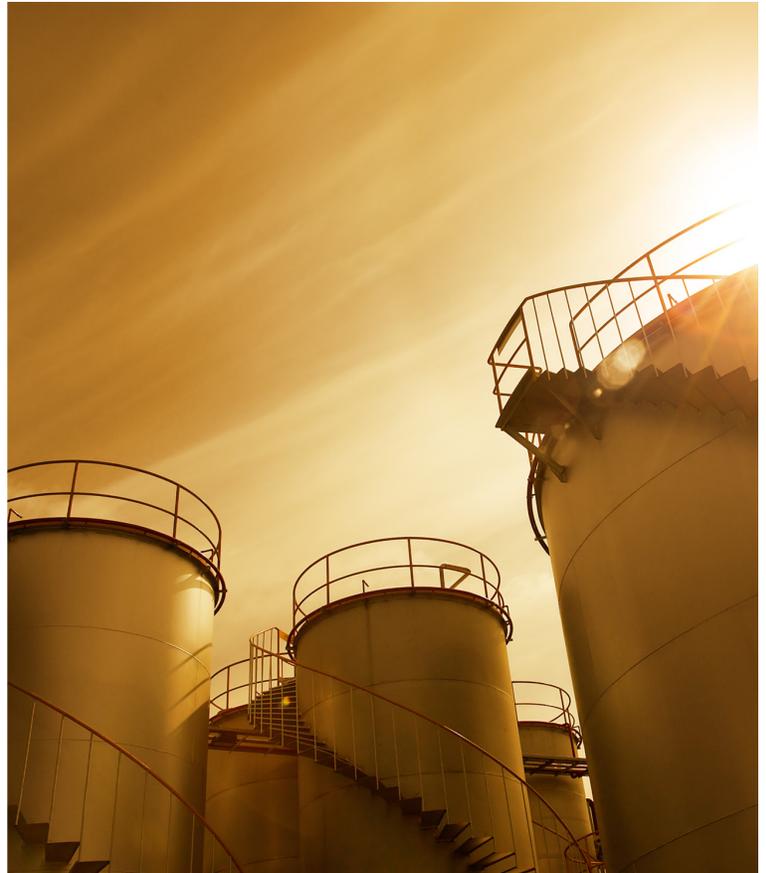


# Small Businesses, Public Health, and Scientific Integrity:

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



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

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## 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:

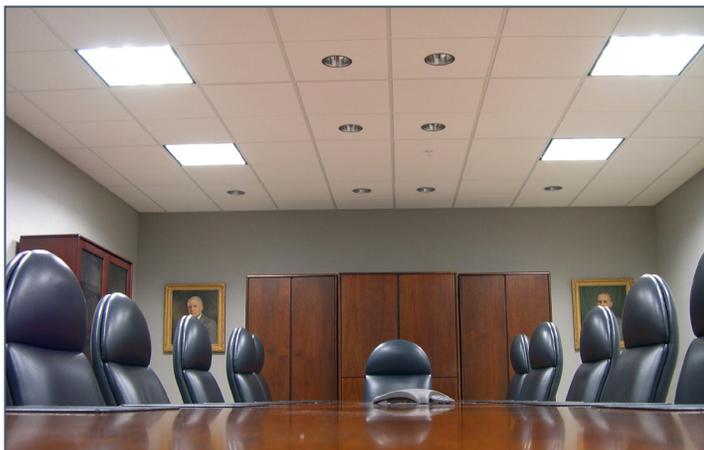
- Who asked the Office of Advocacy to intervene in these chemical assessments?
- What efforts did Office of Advocacy staff make to educate themselves on the science underlying the debates about the health risks of these chemicals?
- What efforts did the Office of Advocacy make to determine the interests 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 Burlison 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 Burlison Smith to Charles A. Maresca (Sept. 14, 2010) (sending over the list of attendees for the meeting); E-mail from Burlison 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 Bureson 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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