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The (Non) Regulation of Endocrine Disrupting Chemicals

By

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## **Abstract**

### **The (Non) Regulation of Endocrine-Disrupting Chemicals**

**By**

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This dissertation investigates efforts in the United States to regulate endocrine-disrupting chemicals. In 1996, Congress mandated the U.S. Environmental Protection Agency to establish a screening program for chemicals that appeared to interfere with the actions of estrogens, androgens and thyroid hormones; no chemicals have yet proceeded through the full complement of assays, and many details of the program remain unresolved. Moreover, much is still unknown about endocrine-disrupting chemicals, complicating the tasks of assessing and regulating them; for example, there is significant scientific support for the notion that they can exert effects at very low-doses, but industry disputes such findings. Without an effective Endocrine Disruptor Screening Program (EDSP), human and wildlife population continue to be exposed to possible endocrine-disruptors, with long-term consequences that remain unclear.

This dissertation examines how industry stakeholders, non-governmental organizations and others have framed the scientific issues and sought to influence regulators, consumers and other audiences, through public comment, ex parte meetings and media coverage. It examines: 1) public comments from stakeholders in response to the first draft list of chemicals for the EDSP; 2) private meetings between industry representatives and the EPA about key aspects of the EDSP; and 3) news coverage of phthalates, and in particular advocacy efforts to raise awareness about their presence in brand-name consumer goods.

The results of this investigation suggest that while industry stakeholders might not appear to have significant impact on the content of rules, the regulatory process has nonetheless provided them with multiple opportunities to delay the process of EDSP development. The results also suggest that environmental and public health advocates can find different strategies for effecting policy change, with the news media playing a key

role. In particular, offering new forms of evidence and altering public perceptions about the potential hazards of everyday consumer products can exert pressure on corporations to change behaviors and reformulate products, and on politicians to take legislative action against particularly worrisome chemicals. The trade-off is that the benefits might be far narrower in scope—as in this particular case, limited to phthalates in toys and personal care products--than the protections envisioned as part of an overarching structure like the EDSP.

# The (Non) Regulation of Endocrine Disrupting Chemicals

## Chapter 1: History and Background

In the early 1990s, emerging evidence from multiple lines of research suggested that some common industrial chemicals were capable of disrupting the actions of various hormones. These chemicals appeared to mimic, block or otherwise interfere with the functioning of estrogens and androgens and were increasingly suspected of causing major reproductive and developmental abnormalities in wildlife populations, laboratory animals, and humans through environmental exposures. Studies reporting that human sperm counts had fallen significantly in industrialized countries during the previous half-century seemed to dovetail with the toxicological findings. A peer-reviewed report outlining the hypothesis appeared in *Environmental Health Perspectives* in 1993 (Colborn, vom Saal, & Soto, 1993).

Three years later, when zoologist Theo Colborn and two co-authors published their best-selling book, *Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival? A Scientific Detective Story*, the so-called “endocrine disruptor hypothesis” entered the public debate within the media, regulatory, and policy realms (Colborn et al, 1996; Krimsky, 2000). Synthesizing the science up to that date, the 1996 book proposed that vast numbers of chemicals in everyday use were interfering with the human and animal endocrine systems in subtle and ominous ways. The hormones released by the endocrine glands play a key role in numerous bodily reactions and processes, including those involved in fetal sexual differentiation and in later reproductive development and functioning; given the ubiquity of endocrine-disrupting chemicals, the arguments leveled by Colborn and her co-authors, if true, would have enormous implications for public and environmental health.

Later that year, Congress mandated the U.S. Environmental Protection Agency (EPA) to develop a comprehensive screening program for endocrine-disrupting chemicals (EDCs) in two pieces of landmark legislation. When Congress passed the Food Quality Protection Act of 1996, the bill included language that directed the EPA to design a screening program to find out “whether certain substances may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, or such endocrine effect as the Administrator may designate” (FQPA, 1996; Krimsky, 2000). Similar language was inserted in a package of 1996 amendments to the Safe Drinking Water Act (SDWA, 1996). Only three years had elapsed between the publication of the peer-reviewed report in *Environmental Health Perspectives* and the passage of this legislative mandate, which demonstrates just how rapidly health and environmental concerns about endocrine disrupting compounds had advanced onto both the public and government agendas.

In response to the mandates in the FQPA and the SDWA Amendments, EPA developed the Endocrine Disruptor Screening Program (EDSP), which is designed to assess chemicals suspected of affecting the functioning of the body's estrogens, androgens and thyroid hormones. Under the program, chemicals will be assessed through a two-tiered process. Tier 1, a battery of in vitro and animal assays, is designed to screen chemicals for potential endocrine-disrupting capabilities. Those found to have such potential progress to Tier 2, a second battery of in vitro and animal assays to test the specific endocrine-disrupting effects of each substance, as well as the doses at which the effects occur. After passing through Tier 2, substances found to have endocrine-disrupting effects will undergo risk assessment, which will guide the EPA in determining what action, if any, to take against particular chemicals.

Despite high expectations among environmental health advocates, seventeen years after passage of the 1996 legislation, the EPA's Endocrine Disruptor Screening Program (EDSP) remains a work in progress. To date, not one chemical has passed through the tiered screening process, and the program is unlikely to produce any conclusive results before 2016, the 20<sup>th</sup> anniversary of the legislation. In 2009, the agency finally issued test orders for the first group of chemicals selected to undergo Tier 1 screening. Yet the agency continues to review the results and has not announced which chemicals, if any, will proceed to the Tier 2 battery of assays; moreover, the Tier 2 battery itself is not complete. In June, 2013, almost three years after publication of a draft second list of chemicals to receive orders for Tier 1, the EPA published a final second list and plans to issue test orders.

The slowness of the federal regulatory process for addressing endocrine disrupting chemicals has led environmental and public health advocates to seek out other venues for policy-making, including raising public awareness about the presence of chemicals in many household products and the risk of exposure from everyday use. By narrowing the focus to specific EDCs, such as phthalates, and targeting specific product categories, such as brand-name toys and cosmetics, environmental health advocates adopted the kind of market-based strategies used increasingly in battles against perceived corporate misbehavior (O'Rourke, 2005). For example, several environmental organizations created and exploited new forms of scientific evidence that attracted media attention by calculating the phthalate content of popular toys and cosmetics (Winston, 2002).

Advocates achieved some success with these market-based strategies when major toy companies and cosmetics brands announced plans to remove phthalates from their products (Singer, 2006; Kay, 2005a). Politicians also responded to changing perceptions and mounting public concern about the health effects of EDCs. A law restricting phthalates in children's toys passed in San Francisco in 2006 (Kay, 2006b), followed by a cascade of activity across multiple policy and regulatory venues. In 2007, similar legislation targeting children's toys passed in California (California, 2007). In 2008, Washington passed a phthalates ban (Stiffler, 2008), and

the issue was contested in other state legislatures. The same year, Congress folded federal restrictions on phthalates in children's toys into popular legislation overhauling the Consumer Products Safety Commission (Consumer Product Safety Improvement Act, 2008).

As a result of this legislative activity, there are some protections in place against certain endocrine disruptors--such as phthalates--but the protections remain limited and fragmentary. In the absence of a functioning effort by the EPA to assess and regulate potential endocrine disrupting chemicals through the EDCSP, humans and wildlife species continue to experience widespread exposures to known and unknown EDCs, with an extensive range of possible negative health impacts. Moreover, the lethargic pace of the federal regulatory process raises questions about whether current legislative and regulatory structures are capable of responding to potential health threats and about the overall ineffectiveness of the U.S. toxic chemicals regime.

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I first became aware of the term "endocrine-disrupting chemical" as a graduate student at the UC Berkeley School of Public Health, during Professor Ann Keller's course on environmental health policy in Fall, 2000. In researching a paper on the issue, I learned that two significant studies related to EDCs had been published just that year: one linking reproductive abnormalities in male infants to in utero phthalate exposures, the first study reporting such a link (Swan et al, 2005); and a rat experiment reporting self-replicating, multi-generational epigenetic changes in male offspring arising from a single fetal exposure to EDCs (Anway et al., 2005). Taken together, the potential implications of EDC exposures for population health seemed ominous.

There is little question that such substances can, at high doses, damage reproductive functioning in human offspring. A classic example is DES, the medication that was widely prescribed for preventing miscarriages in the middle decades of the last century. Daughters of mothers who took DES while pregnant were shown to be at significantly higher risk of developing vaginal cancer than those whose mothers had not taken the drug (Holmes, 1971). But DES was an unusual case—a large-scale, unintended natural experiment on humans, with maternal ingestion and medical outcomes well-documented through medical records.

Environmental exposure to EDCs, whether occurring primarily through drinking water, personal care products, plastics, the food chain or other routes, is almost universal in modern industrialized societies. In an analysis of urine from 2,540 participants in the National Health and Nutrition Examination Survey from 1999 and 2000, researchers found metabolites of three of seven common phthalates in more than 97 percent of the samples and of a fourth in more than 75 percent of samples (Silva et al., 2004). But demonstrating exposures in biomonitoring studies



is not the same as establishing that current levels of environmental exposure can cause reproductive and other harms in humans.

Investigation into the health effects of endocrine-disruptors confronts a number of obstacles. In the real world, most people are exposed to multiple EDCs through use of everyday consumer products, and the combinations might have different outcomes than each single chemical would on its own, as animal studies have shown (Hotchkiss et al. 2008). Moreover, some adverse effects might arise only if exposure occurs during narrow windows of vulnerability in utero or early childhood, and might not appear until decades later. The effect might also depend upon the existence of additional environmental or lifestyle factors, such as smoking or other toxic exposures. And some skeptical researchers have argued that ingestion of estrogens from natural sources such as plant foods make it hard to determine the sources of animal and human phthalate exposures (Safe, 1995; Safe, 2004).

Another daunting challenge for researchers is that an unknown number of these chemicals appear to generate non-monotonic dose-response effects—for example, a measurable impact at miniscule levels and no effect or a different effect at higher levels (Vandenberg, 2012). Because the fetus is growing rapidly timeframe with an extremely complex pattern of cell maturation, division and differentiation, scientists have hypothesized that even minute concentrations of EDCs at specific developmental windows in the gestation process might cause changes that will remain undetected until offspring reach sexual maturity. The notion that adverse effects occur at environmentally relevant levels of exposure has faced considerable opposition, in particular from industry interests, although a major review of the low-dose and non-monotonic effects of EDCs last year found that evidence for both phenomena was convincing.

These scientific issues have all presented challenges to the process of developing an effective and accurate screening program for endocrine-disruptors. In learning more about the slow pace of implementation of this program, I also noticed that environmental, public health and consumer advocates were pursuing an alternate strategy, with some success. They were creating campaigns based on identifying phthalates—and often other chemicals as well--in popular product categories, especially toys and cosmetics. Their efforts were producing some results in the marketplace, with well-known companies announcing the removal of phthalates from their products. These campaigns also appeared to spark legislative efforts to regulate the uses of specific chemicals—and phthalates in particular--in a variety of jurisdictions.

The news media aggressively report high-profile legislative battles, but the conflicts that occur afterwards--during the development and drafting of rules and regulations to implement these statutes--receive far less popular attention. The academic literature on rulemaking at environmental and natural resource agencies, as well as other federal administrative agencies, has examined the role of industry interests in influencing the contents of proposed and final rules. In particular,

researchers have found that business interests tend to submit more comments in response to proposals and have more contact with regulators during the process of policy and rule development, although research on the effects of such intensive input remains ambiguous.

This dissertation adds to the environmental health, environmental policy, political science and health communications literatures through an examination of: 1) the impact of stakeholder input on EDSP-related policies and rules through ex-parte meetings and communication as well as through the public comment process; and 2) another policy-making strategy focused on altering public perceptions of brand-name products and changing consumer behavior to force industry to reformulate its products.

To date, most of the research on public comments and rulemaking has examined multiple rule development processes across a variety of agencies. They have also relied on the public record of comments and stakeholder contacts with government agencies to assess the influence of diverse interest groups on the process. This research is taking a different approach.

In Chapter 2, I examine a single cycle of public comment in response to a 2007 proposal published in the Federal Register—the draft list of the first set of chemicals slated to undergo Tier 1 screening through EPA’s Endocrine Disruptor Screening Program. This case study approach adds nuance and detail to the patterns of responses described in the earlier research; EPA’s changes to the list also provide insight into the limits of public comment as a vehicle for influencing the content of rules.

In Chapter 3, I examine a phase of rule development that other researchers have described as occurring “in the shade” or “in the black box”—i.e. when a rule is being researched and drafted—through a unique data source: Documents that detail meetings between the EPA and industry trade organizations to discuss policies and procedures related to the EDSP, both before and after the agency published relevant notices in the Federal Register. These documents are part of a larger set I obtained from the EPA in response to several requests I made under the Freedom of Information Act (FOIA). The documents provide a window onto industry efforts to lobby the agency outside the purview of the public interactions that characterize much rule development.

Finally, in Chapter 4, I step away from the regulatory processes of administrative agencies and to examine how environmental and public health advocates helped transform the debate over the uses and potential harms of phthalates by generating new forms of science and positioning phthalate-laden toys as threats to children. In exploring this issue through a content analysis of news coverage of phthalates, I also track the key role played by major news organizations in disseminating the emerging perceptions and understandings about phthalates.

## Chapter 2:

### **Public Comment in Environmental Rule Development: A Case Study from the U.S. EPA's Endocrine Disruptor Screening Program**

#### INTRODUCTION

In the American political system, Congress enacts laws but delegates much of the authority to interpret and implement them to regulators and scientists at executive-branch agencies (Jasanoff, 1990). These agencies, such as the U.S. Environmental Protection Agency (EPA), develop policies and rules that will determine the impact of the underlying legislation on regulated parties and the public at large (Kerwin, 2003). To gather information and assess stakeholder reaction, an agency often publishes a draft proposal and solicits comments from members of the public. A variety of interest groups have significant incentive to try to influence this process of administrative policy development and rulemaking (Furlong and Kerwin, 2005). In recent years, a growing literature has explored how industry and other stakeholder groups participate in and impact these activities, in the environmental as well as other domains (Golden, 1998; Kamieniecki, 2006; West, 2004; West, 2005; Yackee, 2006; Yackee and Yackee, 2006).

The current research presents a case study of a single public comment cycle at a key moment in the development of the EPA's Endocrine Disruptor Screening Program (EDSP). Congress mandated this ambitious effort to identify endocrine-disrupting chemicals in two pieces of 1996 legislation, the Food Quality Protection Act and a package of amendments to the Safe Water Drinking Act. After years spent researching and developing appropriate assays, the EPA in 2007 published a draft list of the first 73 chemicals selected for screening under the new program (EPA, 2007). The agency solicited public comments on the draft list; in 2009, it published the final list of 67 chemicals, along with a response to the comments and an explanation of the changes (EPA, 2009a; EPA, 2009).

In this paper, I first describe the process of policy and rule development at federal administrative agencies and provide background on the EDSP. I then review the public comments submitted by industry interests, private individuals, NGOs and others in response to the draft list of chemicals published in 2007. In analyzing the EPA's response to those comments, I note that the only changes to the final list were the removal of a handful of chemicals based solely on updated information about their approved uses and registration status; the agency rejected all other requests to remove chemicals from the list or to alter the overall chemical selection approach.

In the discussion section, I argue that the public comment process, at least in this case, does not appear to have democratized rule development; while the EPA

did not make significant changes in response to industry comments, the time involved in soliciting and responding to the comments served corporate interests by delaying implementation of the legislation that established the EDSP in the first place. I also suggest that stakeholder influence on the actual content of rules—and industry influence in particular—might be more apparent at an earlier stage of the process, when an agency is researching and drafting an initial proposal for publication in the Federal Register.

### Policy Development at Administrative Agencies

Federal administrative agencies have a variety of mechanisms at their disposal for developing policies and rules in order to implement Congressional mandates (Kerwin, 2003; Strauss, 2001). In the case of policies that will become part of the formal Code of Federal Regulations, agencies are required under the Administrative Procedures Act (APA) to pursue in most instances a process known as notice-and-comment rulemaking. They must publish a Notice of Proposed Rulemaking in the Federal Register, the government's daily journal for agency announcements and notices, and provide interested parties with an opportunity to comment and offer new information. An agency does not have to make changes to a proposed rule in response to these comments, but it is required to consider any relevant information submitted in establishing the final rule and to explain its actions, especially since the agency might find itself defending its response in the courts (Melnick, 1984)

In many other cases, agencies will determine that a new policy does not meet the APA criteria requiring notice-and-comment rulemaking. However, if an agency believes that a policy will have a significant impact, it often will decide, at its discretion, to pursue a similar strategy by publishing a proposed rule, soliciting public comment, and revising—or not revising—the policy in response to the comments. Although the final rule in these cases is not incorporated into the Code of Federal Regulations, it is nonetheless effectively binding on regulated parties unless they decide to mount a legal challenge (Strauss, 2001).

Public comment has been theorized as fulfilling a number of important goals, including: democratizing agency decision-making through encouraging input from outside voices; increasing agency transparency, consistency and accountability; allowing interested parties to bring additional or overlooked information to the attention of the federal bureaucracy; bolstering the acceptability of the policy among regulated parties and other interest groups, and minimizing the risk of legal challenges to final rules (Golden, 1998; Kerwin, 2003; West, 2005). But investing the time to solicit public comments, evaluate them, and frame an appropriate response can also significantly delay the actual development and implementation of rules, which might often benefit the immediate interests of regulated parties. Thus, a strategy devised as a means of broadening public participation can instead serve to impede the adoption of appropriate and necessary action, since public comment cycles can take several years.

Research on public comment, in the environmental domain as well as others, has found that business interests are more likely to participate than other stakeholders, such as environmental NGOs and private citizens, most likely because of greater access to resources and technical expertise. Yet, interestingly, scholars have also generally agreed that the impact of this participation appears limited. In a study of ten rules promulgated by three agencies--the EPA, the National Highway Traffic Safety Administration, and the Department of Housing and Urban Development--Golden reported that the only significant change occurred when the highway administration dropped a requirement that electric vehicles include a gauge and symbol to alert drivers when batteries need to be recharged (Golden, 1998). Seven other final rules included only modest revisions, such as changes in deadlines and record-keeping requirements, with two rules entirely unchanged.

More recently, Kamieniecki examined five rulemaking procedures conducted by the EPA and one each by the U.S. Forest Service and the U.S. Fish and Wildlife Service (Kamieniecki, 2006). The EPA efforts involved revisions to arsenic standards in drinking water; revisions to existing criteria for solid waste disposal facilities and practices; revisions of the Superfund program's extremely hazardous substance list; establishment of a voluntary national low-emission vehicle program; and control of mobile-source hazardous air pollutants. The two other rulemaking procedures involved efforts to prohibit road construction in undeveloped areas of national forests and to amend the classification of the gray wolf under the Endangered Species Act. Four of the five environmental rules did not undergo any changes between the proposed rule and the final version; in the final version of the controversial arsenic rule, the agency increased the allowable level. The two natural resources regulations were both weakened in ways that favored industry; the study characterized the changes as minimal but did not describe them in much detail.

These and other studies have generally reviewed multiple cases across agencies rather than focusing in-depth on the public comments submitted in response to a single Federal Register notice. This research has yielded valuable insights into aggregate patterns of comments—including who tends to submit them--and agency responses. However, it has provided little substantive information about the content of the comments that interest groups file to support their requests for changes to proposed rules. In-depth examination of a single public comment cycle could help to elucidate the types of arguments advanced by interest groups. And since agencies are required to publish explanations for why they did or did not make changes requested by the commenters, it should be possible to assess the effectiveness or influence of arguments proffered by various interest groups in achieving their requested changes.

## Background: The Endocrine Disruptor Screening Program

In 1996, with emerging public concern that many industrial chemicals were causing reproductive abnormalities in both wildlife and human populations (Colborn, Dumanouski, & Myers, 1996), Congress mandated the EPA to “develop a

screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effect as the Administrator [of the EPA] may designate” (Food Quality Protection Act, 1996). The new law—a provision tucked into the Food Quality Protection Act—specifically required testing of all pesticide chemicals; it also allowed for discretionary testing of “any other substance that may have an effect that is cumulative to an effect of a pesticide chemical” (Food Quality Protection Act, 1996). The same year, Congress also approved amendments to the Safe Drinking Water Act that mandated the agency pursue similar testing for “any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance” (Safe Water Drinking Act Amendments, 1996).

In designing the program, the EPA decided to include substances believed to interact with not only the estrogen pathways but also the androgen and thyroid hormone pathways and outlined a two-tiered framework known as the EDSP (EPA, 1998). Under this framework, chemical companies would be required to conduct two full batteries of *in vitro* and *in vivo* assays. The Tier 1 screening battery would establish whether a compound has the potential to interact with the endocrine system. The Tier 2 testing battery would determine whether a substance with positive results in Tier 1 screening actually causes endocrine-mediated adverse effects; if so, the Tier 2 battery would assess dose-response relationships. Chemicals with negative results in Tier 1 screening would be deemed not to be endocrine disruptors and would not be required to undergo Tier 2 testing. Following chemical producers’ submission of testing results, the EPA would conduct risk assessments and establish standards for each chemical.

Despite its promise, the EDSP has suffered serious delays in implementation. In August 1999, the National Resources Defense Council (NRDC) and several other groups sued the agency for failing to meet statutory deadlines. In 2001, the parties reached a settlement in which the EPA agreed to issue a draft list of the first chemicals to go through Tier 1 screening by the end of 2002, to issue the first set of orders for the screening by the end of 2003, and to validate all assays by 2005; if the deadlines were not met, the agency agreed to alert the NRDC through semi-annual reports of updates on EDSP-related activities. In fact, the agency has consistently fallen years behind these deadlines, according to a 2011 report issued by the EPA’s Inspector General, and did not publish a final list of the first chemicals or issue orders for Tier 1 screening until 2009 (EPA/Office of the Inspector General, 2011).

In December 2002, EPA published a Federal Register notice outlining its proposed approach for prioritizing and selecting the first 50 to 100 chemicals for the initial round of Tier 1 screening; the agency asked for public comment (EPA, 2002). Contrary to its settlement agreement with the NRDC, the agency did not release the actual draft list of chemicals at the same time. After reviewing public comments on this proposed approach, the EPA published a final version of the prioritization and selection process in 2005 (EPA, 2005).

The process included several planks. First, the EPA planned to start with pesticides, since pesticide testing was explicitly required under the Food Quality Protection Act; it also planned to include both pesticide active ingredients as well as pesticide inerts (compounds added to pesticide formulations to facilitate or potentiate their action by, for example, increasing product absorption). Second, it would focus for this initial list on single chemicals rather than chemical mixtures and would not accept public nominations for candidate chemicals. Third, because of uncertainties about how to interpret existing data and determine whether it does or does not demonstrate endocrine-disruption, the agency would generally select chemicals based on the extent of possible human exposures rather than existing laboratory or epidemiologic findings suggesting that a compound might or might not be an endocrine disruptor.

To assess those possible human exposures, the agency outlined a methodology based on an extensive set of databases for both pesticide active ingredients and pesticide inerts. For pesticide active ingredients, the EPA would examine several databases for evidence of possible human exposures in each of four different pathways: food, drinking water, occupational use, or residential use. Chemicals that appeared in the food and occupational pathways, and at least one of the remaining two pathways, would be considered priorities for inclusion on the draft list. For pesticide inerts, the databases for possible exposures incorporated results from human biomonitoring studies, ecological studies (specifically, studies of tissue from fish commonly eaten by people), studies of drinking water, and studies of indoor air. For the inerts, the EPA required that they appear in the human biomonitoring database and at least two of the other three pathways.

In 2007, after applying this approach to the available universe of pesticide chemicals, the agency published a draft list of 73 compounds, including 64 pesticide active ingredients and nine pesticide inerts. This paper focuses on the draft list, the public comments about the draft list, the EPA's response to the public comments, and the final list published in 2009.

## METHODS

Since 2002, the website [www.regulations.gov](http://www.regulations.gov) has facilitated the government's rule development process. Each proposed rule and related documents, including public comments and the agency's responses to them, are collected together in an e-docket housed on the site. For the current research, the EPA's June 18, 2007, draft list of initial chemicals for Tier 1 screening, the public comments about the draft list, and the final list of chemicals published on April 15, 2009, along with EPA's response to the public comments, were retrieved from the e-docket and reviewed.

This public comment cycle was chosen for three reasons. First, the selection of the initial list of chemicals represented a pivotal moment in the long-delayed development of the EDSP. Second, the 73 chemicals on the draft list numerous possibilities for requests for changes, maximizing the opportunity to assess

arguments advanced by a potentially substantial set of stakeholders as well as the EPA's responses to those arguments. Third, the most likely possible changes—removal of a chemical from the list, or the addition of a chemical to the list—would have actual impacts on stakeholders, rather than being the kinds of cosmetic or minor linguistic changes frequently made in proposed rules in response to public comments.

The public comments were reviewed and then coded by affiliation (industry, non-governmental organization, private individual, academic researcher, or other), length, type of request (request for delay, request to remove a chemical from the list, request to add a chemical to the list, request for changes in prioritization and selection procedures), and reasons for the request. The comments were also coded for the likely outcome if EPA accepted the arguments articulated. For comments from industry, the three possible outcomes were: a change in the status of an individual chemical, a delay in implementation of the EDSP, or the effective derailment of the EDSP. For comments from non-industry stakeholders, a possible fourth outcome—acceleration in implementation of the EDSP—was added.

For example, comments that provided purportedly new or updated information about the uses or registration details of a particular chemical would likely result only in a change in that substance's status—i.e. its removal from the list. Comments that challenged the accuracy of the EPA's methodology of using multiple databases for selecting chemicals for the draft list or that argued for further procedural steps, such as extensions in the comment period--would result in further delays to the program. Comments arguing that the tests required for pesticide registration already demonstrated that chemicals did not exhibit endocrine-disrupting effects would likely render the entire EDSP redundant and unnecessary, at least for pesticides.

## RESULTS

Fifty public comments were recorded as having been received at [www.regulations.gov](http://www.regulations.gov) in the appropriate e-docket. Upon review, one was found to be a duplicate and another was incomplete, with no comment attached. However, two additional comments responding to the draft list were found inadvertently in a different e-docket related to the EDSP; with these two apparently misfiled comments added, the total number of comments about the draft list was 50. Of those, 30 were from chemical industry stakeholders, 14 were from private individuals, four were from public interest advocacy groups, one was from a water utilities association, and one was from a software company offering consulting services to the EPA (Table 1).

The industry comments all challenged either the selection of one or more chemicals for the draft list, the overall process for selecting the draft list, or in some cases both. Of these 30 comments, 17 were from individual pesticide companies, and 13 were from trade groups. Of the 13 from trade groups, six and four,



respectively, were from the American Chemistry Council and CropLife America; one each was from the Chemical Producers and Distributors Association and the Consumer Specialty Products Association; and one was from a coalition of companies focused on a single chemical.

TABLE 1; Commenters by Category

<b>Stakeholder Category</b>	<b>Number/Percentage of Comments (Total Comments: N= 50)</b>
Industry Total	30/60%
Trade associations	13/26%
Chemical Companies	17/34%
Private Individuals	14/28%
Non-Governmental Organizations	4/8%
Other	2/4%

Of the six American Chemistry Council comments, two were requests for extensions of the comment period and one was a lengthy challenge to the overall approach to chemical selection. Three were from American Chemistry Council committees advocating for the removal of specific chemicals on the list. Of the four CropLife America submissions, two were requests for extensions of the comment period and two challenged the overall approach. The 17 comments from individual companies included three from Amvac Chemical Corporation, two of which were requests for an extension of the comment period. All the rest were appeals to remove one or more specific chemicals from the list.

### Industry Comments

Overall, the industry commenters requested that 35 of the 73 chemicals, or 48%, be removed from the draft list, for a variety of reasons. In addition to these requests about individual chemicals, some commenters challenged the EPA’s process for compiling the draft list and its plans for moving forward. Most of these broader expressions of concern were made in comments from trade associations, but some individual companies also included more general criticisms alongside their requests to remove specific chemicals from the list. In many cases, industry commenters included more than one argument in their efforts to have chemicals removed from the draft list or to challenge the overall EDSP process.

In addition to arguments for removing chemicals from the draft list or for changing the entire process of chemical selection, many industry commenters raised concerns about the economic and business impact of the EDSP’s listing and testing process. Some specifically mentioned the risk of “product deselection”—the process of losing market share to similarly positioned goods. They demanded that the EPA state clearly in all its communications that the presence of a chemical on the draft or

the final list should not be interpreted to mean that it was in fact an endocrine-disruptor. For example, according to comments submitted by the pesticide manufacturer Syngenta: “Recent experience with other chemicals has shown that designation as a possible endocrine disruptor, even when based on weak, unsubstantiated, or no scientific evidence at all, will result in unnecessary public concern and an ultra-conservative precautionary approach to regulation of chemicals without the appropriate consideration of societal benefits” (Syngenta, 2008).

TABLE 2: Major Industry Arguments in Public Comments Regarding EDSP Draft List

Industry Argument	Number of Times Cited	Effect on EDSP if Accepted
Changes in Usage/Registration	27 comments	Only Impacts Specific Chemical
“Functionally Equivalent” Data Already Exist	17 comments	Renders EDSP Superfluous for Pesticides
Database Methodology Flawed	10 comments	Delays EDSP Implementation
Request for More Time	6 comments	Delays EDSP Implementation

Industry comments advocating for removing chemicals from the list, revisiting the entire chemical selection process, or other changes in the process cited the following arguments, in order of frequency (Table 2):

**1. Changes in chemical registration details and/or patterns of use have reduced or eliminated possible human exposures in one or more of the targeted pathways scrutinized by the EPA, or such changes would be occurring in the near future**

This argument, cited in 27 comments, was based on the provision of updated information and would have only resulted in the removal of the cited chemical from the list. Ferro, for example, argued that butyl benzyl phthalate was “no longer contained in active Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide registrations” (Ferro, 2008). Monsanto similarly argued that propochlor was “no longer sold in the U.S. and only occasionally produced for export markets...no end-use product with propochlor is registered for sale in any state since 2004” (Monsanto, 2008a). Dupont Crop Protection argued, on behalf of methomyl and oxamyl, that “changes in use patterns...have been instituted through label changes intended to reduce exposure” (Dupont Crop Protection, 2008).

Makhteshim Agan protested on behalf of four chemicals—azinphos-methyl, diazinon, folpet, and endosulfan. The first, the company noted, had a “phase-out plan” in place, and “EPA’s records will substantiate that exposure mitigation plans for diazinon, folpet, and endosulfan have included reductions in use, (reduced rates

and numbers of applications), reductions in the crops for which the uses were labeled, and the overall reduction in the amount of product used” (Makhteshim Agan, 2008).

**2. Pesticide registration already requires a host of assays that are “functionally equivalent” to tests to be conducted under the EDSP, or other toxicological or regulatory tests have fulfilled a similar role.**

According to this argument, which was cited in 17 comments, pesticide requirements already included assays that provided sufficient information to ensure that endocrine-related effects would be detected, meaning that additional EDSP testing was superfluous and a waste of EPA and corporate resources. Therefore, these comments, if accepted by the EPA, would have undermined the argument for implementing the EDSP in the first place, at least for pesticide compounds.

For example, in seeking to remove glyphosate from the draft list, Monsanto argued that “statutory mandates already require that pesticides undergo a comprehensive battery of toxicology testing covering a broad spectrum of endocrine endpoints that are sufficient to detect the potential for endocrine disruption” (Monsanto, 2008b). Similarly, seeking to have cyfluthrin taken off the draft list, Bayer CropScience wrote that “the large number of acute, sub-chronic, and chronic studies performed for the safety evaluation and registration of pesticides include endpoints highly relevant in the assessment of endocrine disruption, such as developmental, fertility, and reproductive effects” (Bayer CropScience, 2008).

The commenters also stated that the two-generation tests required for pesticide registration, designed to measure the effects of fetal exposures, were more advanced than some of the assays included in the Tier 1 battery. Industry representatives argued that because the pesticides in question had passed the two-generation tests required for registration, they should not have to undergo the lower-level Tier 1 screens. For example, appealing on behalf of malathion, dimethoate and methyl parathion, Cheminova wrote that “higher-tiered studies have been submitted to the Agency that provide functionally equivalent information demonstrating no evidence of endocrine-related effects,” rendering the screening “redundant and unnecessary” (Cheminova, 2008).

In addition to the reliance on data mandated under for pesticide registration, commenters cited additional findings to support claims that the screening was “redundant and unnecessary” and that the chemicals in question did not exhibit endocrine-disrupting properties. These findings included EPA statements and reviews from assessments of the chemicals for other programs, such as Voluntary Children’s Chemical Evaluation Program and the High Production Volume Chemical Challenge Program, as well as statements or studies from the European Union, the Organization for Economic Co-operation and Development, the World Health Organization, and other scientific and regulatory bodies.

**3. One or more of the databases cited by the EPA for determining possible human exposures are flawed, out-of-date, and/or do not conform to federal requirements on the quality of data used by federal administrative agencies.**

This argument was cited in 10 comments and, if accepted, would have significantly delayed implementation of the EDSP. Trade groups in particular challenged the overall use of the databases. The American Chemistry Council argued that “EPA should more critically consider the informational value of the exposure data sources it relies on” (American Chemistry Council, 2008). Many of the databases, wrote the group, “are statistically limited and lack relevance,” rendering the prioritization process unscientific; others “used biased sampling designs,” lacked “information regarding the sampling, storage and analytical methodologies used,” or were not publicly available for review. To support its argument, the American Chemistry Council attached to its comments a lengthy review of all the proposed data sources.

Moreover, commenters stated that some of the databases did not adhere to the agency’s own standards for the use of data sources and to the Data Quality Act of 2000, which mandated that the federal government implement guidelines “for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.” Although the Data Quality Act’s purported purpose was to increase the accuracy and reliability of information used in government decision-making, it has in fact been deployed by industry groups in efforts to block or delay the implementation of important regulatory actions and activities (Mooney, 2005; Weiss, 2004).

Individual companies also challenged the database methodology, arguing not that their chemical’s usage or registration had changed, but that the only reason a compound appeared to be present in a pathway of possible exposure was because one or more of the databases were inaccurate, out-of-date, or flawed for some other reason. The EPA’s acceptance of such arguments in the case of an individual chemical would likely have significantly delayed EDSP implementation by opening the door to similar challenges from other companies and calling into question the reliability of the entire approach. In defending dichlobenil, for example, Chemtura acknowledged that it is approved for use with two of the country’s top 20 crops but argued that residues were not found in food (Chemtura, 2008). The company also noted that concentrations found in water “would be considered low and therefore not representative of a substantial pathway of exposure.”

**4. More time needed to prepare comments**

Six comments requested that the comment period be extended. The American Chemistry Council, CropLife America, and Amvac Chemical Corporation each requested two extensions. The EPA acceded to these requests, which obviously resulted in delay of EDSP implementation; in total, the deadline for commenting on the first draft list was extended three times, for a total of five months.

## 5. Other industry arguments

Industry commenters cited each of the following arguments three or fewer times:

**Phytoestrogens and other natural compounds in the environment and food chain are a major source of human exposure to possible endocrine-disruptors, so to focus solely on pesticides is misguided.**

This argument, if accepted, would have undermined the entire rationale for the EDSP. In its comments, Syngenta expressed concern that the program was focused “on anthropogenic chemicals with no consideration of naturally occurring endocrine disruptors, such as phytoestrogens, natural hormones or birth control hormones that can find their way into water supplies upon excretion by humans. Identifying and labeling a few synthetic chemicals as endocrine disruptors without considering the potential cumulative effects of widespread exposure to naturally occurring endocrine disruptors will do little to reduce the overall exposure of the public to endocrine disrupting substances” (Syngenta, 2008).

**The EPA did not follow the exact procedures it outlined in its 2005 publication on how it would prioritize pesticides.** Commenters noted minor shifts in how EPA implemented the 2005 selection approach and argued that these rendered the process invalid and unscientific. This argument would have resulted in significant delays in EDSP implementation.

**The testing program represented the unnecessary death of many thousands of laboratory animals, violating U.S. commitments to seek to reduce the need for their use.** Although primarily wielded by animal rights activists, this argument was also mentioned by some industry commenters. Restructuring the EDSP to incorporate these concerns would also have caused significant delays in implementation.

**The EPA should not issue a final list until it has completed other key procedural steps, such as publishing weight-of-evidence guidelines for how it intends to interpret Tier 1 results.** These procedural suggestions would inevitably have led to further delays in the generation of the final list of chemicals slated to undergo EDSP screening.

### Comments From Private Citizens

Fourteen comments were submitted from private individuals. Twelve of these comments included identical paragraphs raising methodological concerns about the EDSP, a sign that the comments were likely prompted by a particular NGO or NGO-affiliated initiative. Although the commenters did not mention any such affiliations, two identified themselves as “breast cancer survivors.” In all the comments, the writers described themselves as “deeply concerned” that the EDSP as structured was biased toward the chemical industry. None were from self-identified academics or academic researchers.

In particular, the commenters raised four methodological issues, including: whether rodent strains less sensitive to endocrine effects would be used in the EDSP; whether assays would study prenatal exposures; whether low-dose and non-monotonic effects would be studied; and whether there would be “independent checks” on the study designs to prevent industry bias. In general, responding to these concerns would have delayed implementation of the EDSP, although they would arguably have increased the program’s long-term accuracy and effectiveness.

Two additional comments were from individuals espousing conspiracy theories about purported industry and government plots to poison the American public.

### Comments from Non-Governmental Organizations

Only four comments were submitted by public interest and advocacy groups, two national and two regional: People for the Ethical Treatment of Animals (PETA), the NRDC, the Minnesota Center for Environmental Advocacy, and the Great Neck Breast Cancer Coalition. The first two groups presented systemic and general complaints about the EDSP. In contrast, the two regional groups requested that the EPA add, respectively, the herbicide acetochlor and the insecticide sumithrin to the draft list (PETA, 2008; NRDC, 2008; Minnesota Center for Environmental Advocacy, 2007; Great Neck Breast Cancer Coalition, 2008).

Although PETA’s objective was to minimize harm to animals in laboratory testing, the organization’s primary argument coincided with one offered by industry commenters: the tests are redundant because pesticides are already required to undergo extensive testing. “It is not at all clear how mechanistic screening data will influence the regulation of substances that have already been subject to extensive apical testing and complete human health and ecotoxicological risk assessments,” wrote PETA. However, PETA reached different conclusions than industry about what this prior testing indicated. The organization requested the removal of four specific chemicals from the draft list, arguing that significant evidence already pointed to their endocrine impacts and that they should be regulated without going through the process of public comment.

The NRDC, writing with the support of 22 other environmental organizations, noted that under its legal agreement with the EPA, the agency was supposed to publish the draft list by the end of 2002 and issue test orders by the end of 2003. The comment asserted the need to quickly expand the chemical selection process to include non-pesticides and common chemical mixtures, as well as chemicals suggested by members of the public. The NRDC also criticized the EPA for lack of clarity on how chemicals with some existing evidence of endocrine-disrupting properties would be treated in the EDSP. Wrote the NRDC: “EPA is sending mixed messages--some saying that the available endocrine data are insufficient for consideration until the chemicals have gone through the EDSP, and others saying that chemicals may not need to go through the EDSP if there are existing data.”

The Minnesota Center for Environmental Advocacy mounted a case that acetochlor, an herbicide, should be added to the list. The organization cited the

chemical's presence in food, water and occupational pathways and noted that European Union scientists had designated it as having evidence of endocrine-disrupting effects. The Great Neck Breast Cancer Coalition requested that the EPA add the insecticide sumithrin to the list, on the basis of evidence of endocrine-disrupting properties. (Several related pyrethroids were already on the list.)

Responding to the systemic concerns of PETA and the NRDC would likely have increased the pace of EDSP implementation; responding to the arguments of the Minnesota and Great Neck organizations based on the information provided about the two chemicals would have solely impacted those compounds.

### Other Comments

A water utilities organization, the American Water Works Association, expressed concern that any potential action to protect drinking water sources from EDCs “is still several years away.” It urged the EPA to take steps to prevent water contamination in the first place. Finally, a software firm, Terrabase, offered to provide EPA access to computer programs that purportedly can generate estimates of chemicals’ estrogen receptor binding affinity.

### The EPA’s Response to Public Comments:

The final list of chemicals published in 2009 in the Federal Register included an explanation of the changes made—in this case, the removal of six pesticide active ingredients from the draft list of 73 and the rejection of requests to remove 29 other chemicals. The chemicals removed from the list were: aldicarb, allethrin, azinphos-methyl, dichlorvos, fenvalerate and methiocarb. The EPA posted a longer response to the comments in the e-docket at [www.regulations.gov](http://www.regulations.gov). All six chemicals were removed based on arguments in the first category noted above: new information provided about usage and/or registration details (Table 3). Azinphos-methyl and fenvalerate were removed because all uses had been or would soon be discontinued. Of the four remaining pesticides, aldicarb and dichlorvos were no longer present in the occupational pathway, allethrin was no longer present in the food pathway, and methiocarb was no longer present in either the food or occupational pathways. Since all six chemicals were no longer present in at least three exposure pathways, they fell below the agency’s threshold for inclusion.

TABLE 3: Chemicals that were removed after public comment period from EDSP draft Tier 1 chemical list.

<b>Chemical</b>	<b>Original Exposure Pathways</b>	<b>Reasons for Removal</b>
Aldicarb	Food, water, occupational	No longer in occupational pathway

Allethrin	Food, residential, occupational	No food uses registered
Azinthros-Methyl	Food, water, occupational	All uses ending by 2012
Dichlorvos	Food, residential, occupational	No current occupational exposure
Fenvalerate	Food, residential, occupational	Production of chemical ceased
Methiocarb	Food, water, residential, occupational	No longer in food and occupational pathways

The agency rejected all other appeals from industry to remove chemicals from the list, and flatly contradicted many industry claims in its response to the public comments. While many industry commenters stated that their products had experienced registration and usage changes that reduced or eliminated exposures in the pathways of concern, the EPA noted that it reviewed these claims and found them to be inaccurate.

EPA also defended the importance of specific screening and testing for endocrine-disrupting effects, despite the existence of other data from pesticide testing and registration programs. When industry commenters stated that advanced toxicology testing on particular pesticides indicated no evidence of endocrine-disrupting effects, for example, the EPA noted that “contrary to some of the comments submitted, the chemicals...have been shown to be endocrine active in one or more assays.” In response to industry claims that toxicity data “functionally equivalent” to what would be produced by Tier 1 assays already existed for registered pesticide chemicals, EPA stated: “Although a relatively broad range of toxicity data are available... in most cases EPA has not yet established how the available data might be confidently used to predict the endocrine disruption potentials of these chemicals at this time.” The agency therefore rejected efforts to remove chemicals from the draft list based on industry citations of existing toxicological data, although it promised to consider such data if submitted in response to actual test orders issued.

EPA defended its database methodology even as it acknowledged that some of the databases were dated or suffered from other limitations. To counter industry claims, the agency argued that older databases included more information about more pesticides across a broader geographic range. Since all pesticides would eventually have to undergo endocrine-disruptor testing under the terms of the statute that established the EDSP program, the database methodology was an appropriate approach for the stated purpose of selecting the initial list. “The limitations of an individual data set can be wholly or partially overcome by consideration of multiple sets of data and multiple databases,” wrote the agency. “Furthermore, EPA has not used these sources to create a definitive, scientifically rigorous list of chemicals with the potential for exposure, nor to develop quantitative exposure assessments.”



The EPA did not consider any recommendations to add chemicals to the list. As a procedural matter, the agency had stated in the Federal Register notice containing the draft list that it would not accept any recommendations for chemicals until later rounds of chemical selection, and it restated that position in its response. The agency also deflected comments about how to select chemicals for future draft lists, stating that it would address those issues at another point. Finally, the EPA rejected appeals to overhaul the chemical selection process itself or to submit the database methodology for peer-review. In response to these comments, the agency noted that it had published a draft proposal for the selection process in 2002 and had already received and considered public comments before publishing its final chemical selection approach in 2005.

## DISCUSSION

In recent decades, Congress has gradually yielded authority for fleshing out the details of increasingly complex legislation to the federal bureaucracy at administrative agencies, including the EPA. The public comment process has been presumed to exert a democratizing effect on policy development, among other benefits (Furlong and Kerwin, 2005; Kerwin, 2003). Prior research has tried to assess the extent to which industry interests dominate this process. These studies have found that, while industry tends to submit more comments than other groups, the impact of this situation on final versions of rules varies across studies; although rule changes have tended to favor industry, they have generally been quite limited in scope (Golden, 1998; Kamieniecki, 2006; Magat, Krupnick and Harrington, 1986; Yackee, 2006; West, 2004.)

As expected from earlier research, business interests dominated the public comment in this case study of the EDSP. This is not surprising; given that the companies and trade associations were responding to the EPA's request that specific chemicals undergo extensive testing, the removal of a compound from the list would represent significant savings in corporate resources. The study also demonstrates the range of arguments available to industry to challenge rules that they perceive to be unfavorable to their interests. These arguments, if adopted, would have had a number of possible effects on the EDSP, from rendering it superfluous for pesticides, delaying it significantly, or allowing the program to proceed while solely impacting the fate of specific chemicals.

In response to public comment, EPA removed six chemicals from its original draft list, while rejecting requests to remove another 29 chemicals. Of the 35 requests to remove chemicals, 27 included the argument that changes in the chemical's approved registration and/or usage had altered whether the chemicals met the exposure pathways criteria; all of the successful requests were granted on that basis alone. The second most-common argument, made in 17 of the 35 requests, was that existing data indicated a lack of endocrine effects; the EPA did not find any of these arguments persuasive enough to justify removal of chemicals from

the draft list. These two arguments were the most frequently cited by chemical industry stakeholders, and in many instances both were mentioned.

The deletion of six chemicals from the list favored business interests by removing a regulatory burden. However, the changes represented only eight percent of the total chemicals on the draft list, and 17% of the total actually requested. In all other cases, the agency rejected industry arguments. The six chemicals were removed from the list solely on the basis of updated information provided by the companies. This additional data enabled the agency to more accurately apply the chemical selection criteria published in 2005.

Although most of the other requests to remove chemicals involved similar claims of registration and/or usage changes, the EPA appeared to be able--or at least considered itself to be able--to distinguish between accurate and inaccurate information provided by stakeholders. The agency rejected all requests to remove chemicals for other reasons; in particular, it rejected all requests to remove chemicals based on claims that "functionally equivalent" data or comparable studies indicated no endocrine-disrupting effects. Thus, its decisions adhered to its previously published selection criteria while using updated and more accurate information to trim the list.

Scholars have reported that few substantive changes occur as a result of public comment and that business interests appear to have limited influence on effecting changes to proposed rules through public comment (Golden, 1998; Kameniecki, 2006). The findings here lend support to this perspective. One interpretation might be that the EPA appears to successfully resist most demands from industry stakeholders to alter rules they do not like. However, some scholars have noted that the public comment process itself promotes inertia in rendering decisions and constrains an agency's flexibility in making changes between proposed and final rules and promotes inertia (Melnick, 1984; West, 2004).

Courts, for example, have required agencies that have made major revisions between proposed and final rules to pursue a second round of public comment to subject the revisions to external scrutiny (Melnick, 1984). Moreover, agencies have already spent significant resources by the time they publish a proposed rule and might therefore have an organizational or psychological disincentive to alter it substantially (West, 2009). As a result, most of the key decisions have already been made by the time a proposed rule is published, and any changes made often involve the deletion of contentious items, as in this case, rather than the inclusion of additional elements that impose further restrictions and could be more easily challenged in court (West, 2004).

Scholars have recently explored how industry might promote its interests during policy development, even in the absence of significant changes between proposed and final rules. One possibility is that corporate stakeholders are more likely than other groups to exert greater influence at the earlier, pre-publication stage of policy development, before an agency offers the public an opportunity to comment (Rinfret, 2011; West, 2009; Wagner, 2010; Naughton, Schmid, Yackee, and

Zhan, 2009). Moreover, the process of publishing a proposed policy, soliciting public input, and responding to the comments can generate extended delays even as it bestows a democratic aura on the proceedings. Indeed, a former EPA general counsel has observed that notice-and-comment rulemaking “is to public participation as Japanese Kabuki theatre is to human passions—a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues” (Elliott, 1992).

The public comment cycle examined in this paper occupied almost two years—a period of time during which no actual testing or regulation of endocrine-disrupting chemicals could proceed. When viewed within a larger context, the production of the final list actually took seven years rather than two. According to the court settlement agreement signed by the EPA with the NRDC, the draft list was supposed to be published by the end of 2002. Yet at the end of 2002, the EPA published only the proposed approach for the selection criteria for the draft list, not the draft list itself; the agency considered the public comments and published the final version of the selection criteria in 2005. After that, the agency spent two years applying those criteria to the universe of pesticide chemicals to create the 2007 draft list.

Many of the public comments submitted in response to the selection criteria proposal from 2002 included arguments very similar to those advanced against the 2007 draft list. These comments focused largely on the purported existence of data that were “functionally equivalent” to those likely to be produced through EDSP assays the perceived inadequacies of the proposed databases used in selecting chemicals for the list. Thus, the process of seeking comment on both the 2002 and 2007 Federal Register publications essentially required in many cases that the agency invest the time and resources to respond twice to such concerns.

Given the urgency of the issue and the Congressional mandate to act, it seems reasonable to question whether this lengthy process served the public interest. Since only a few chemicals were removed solely for non-ambiguous reasons related to new information about use and registration changes, perhaps a simpler and shorter administrative process could have reached the same determinations. One such approach might have involved publishing a definitive rather than a proposed list of chemicals and considering appeals solely in response to the issuance of Tier 1 screening orders. Another might have been simultaneous publication in 2002 of both the draft proposal for chemical selection and the draft list of chemicals derived through that proposed selection strategy. The EPA could then have solicited comments on both proposals concurrently while still meeting the deadline it had established in its settlement agreement with the NRDC.

The evidence of this case supports the argument that assessing the impact of business and other stakeholder comments on proposed rules is more complex than simply measuring whether changes were made in response to public comment. If publishing a proposed rule and seeking public comment ends up delaying actual implementation, as it almost always does, then a shortage of substantive changes made to the final rule could reinforce a false narrative about a lack of industry influence on the policy development process—not to mention any influence exerted

at an earlier but less transparent stage of the process, such as during the drafting of proposed rules prior to public comment.

Given that the literature on public comment focuses largely on multiple public comment cycles across agencies, the current findings add nuance and texture to our understanding of the kinds of arguments interest groups, and industry in particular, deploy in seeking to influence federal regulators. However, this study is based on a single public comment cycle involving a single program at one agency, so the findings cannot be generalized to other programs and agencies. Moreover, in this case the EPA chose to solicit public comment on a discretionary rather than mandatory basis; it is possible that a different pattern would emerge for policies developed through the more structured process of notice-and-comment rulemaking governed by provisions of the Administrative Procedure Act.

## Chapter 3

### Meetings in the Shade: Assessing Industry Influence in Rule Development for U.S. EPA's Endocrine Disruptor Screening Program

#### INTRODUCTION

Most details of federal environmental policy are determined not through statutes enacted by Congress but through the guidelines and rules developed by the U.S. Environmental Protection Agency (EPA) and other administrative agencies charged with interpreting and implementing these legislative mandates (Kerwin, 2003). To date, most research on the influence of industry interests and others on administrative policy-making has focused on the formal interactions between agencies and stakeholders conducted through procedures enshrined in the Administrative Procedure Act, which Congress passed in 1946 to bring greater transparency to the rulemaking process (West, 2004). However, scholars have recognized that these formal interactions generally occur after a proposed policy has been published and most key policy questions have already been resolved within the agency (West, 2009). Recent research has sought to investigate whether less structured contacts between agencies and stakeholders exert greater influence during earlier phases of policy development and rulemaking (Rinfret, 2011; Wagner, Barnes, & Peters, 2011).

This research, however, has confronted some key methodological challenges. The EPA and other federal administrative agencies maintain extensive public records of their interactions with industry and other stakeholders after a draft proposal appears in the Federal Register, the government's official daily journal of notices and announcements. The accessibility of this information facilitates study of the influence of business interests and other commenters on environmental policy between publication of proposed and final versions of rules. Yet potentially influential interactions that occur *before* this stage remain largely hidden from scholars as well as the public. Nevertheless, research on the early stages of administrative rule development has tentatively concluded that industry seeks to use these less public interactions to influence the content of proposed draft rules in two ways: to *a priori* promote regulatory provisions and items they like and to block those they do not (Naughton, Schmid, Yackee, and Zhan, 2009; Yackee, 2012).

This paper explores the role of these less visible interactions and their potential influence on policies and rules through a review of a unique data source: documents about meetings between stakeholders and EPA officials obtained through requests under the Freedom of Information Act (FOIA). The documents involve the Endocrine Disruptor Screening Program (EDSP), an initiative mandated by Congress in two pieces of 1996 legislation. In this paper, I first discuss existing research on agency rulemaking and policy development, including the challenges of assessing industry influence on rule-

making during early phases that fall outside the purview of the Administrative Procedure Act; then I provide some background on the EDSP and explain the approach used to analyze the FOIA documents.

After analyzing the interactions between EPA officials and commenters--in this case primarily from industry groups--I argue that documents obtained through FOIA requests can provide insights into the relationship between EPA and industry interests at early, less visible stages of rule development that are difficult to monitor through other strategies. Current literature suggests that such ex-parte contacts help industry to exert influence on the content of rules. I argue that these unstructured and less public interactions also might benefit industry because they can lead to delays in the implementation of environmental legislation through two mechanisms. First, such ex-parte contacts can compel the EPA to expend resources--including personnel time--to discuss and debate similar issues meeting after meeting, year after year, in itself a cause of delay. Second, these contacts provide industry representatives with repeated opportunities to lobby for additional administrative and procedural steps that, if accepted by the EPA, would also delay promulgation of a final policy or rule.

### Policy and Rule Development at Federal Administrative Agencies

The EPA and other federal agencies have a range of options available to them for generating and adopting, policies and rules (Strauss, 1992). In many instances, the process includes an invitation to the public to submit comments on a proposal published in the Federal Register. When official regulations are being promulgated, agencies usually pursue a process outlined in the Administrative Procedure Act of 1946 (APA) called "notice-and-comment rulemaking." This procedure involves publishing a document called a Notice of Proposed Rulemaking, soliciting and considering comments from the public, responding to the comments, and issuing a final version of the rule. Since passage of the APA, Congress and the courts have added requirements that agencies build a public record of evidence to justify decisions they make during rulemaking (Melnick, 1984). After agencies publish a Notice of Proposed Rulemaking, they are generally required to report all subsequent contact with stakeholders about the issue (Kerwin, 2003). When agencies publish the final version of a rule, it is incorporated into the Code of Federal Regulations and enjoys the same legal weight as the underlying statute.

In many cases, agencies determine that they are not required under the APA to pursue notice-and-comment rulemaking but decide, on a discretionary basis, to publish a proposed policy and seek input from the public. Agencies might take this step to build public support for a contentious or significant policy and to create a public record of evidence, especially if their decisions are likely to be challenged in court. Unlike rules generated through notice-and-comment, these policies are not incorporated into the Code of Federal Regulations. However, they are still generally binding on regulated parties unless successfully challenged in court (Strauss, 1992).

The policies and rules developed by agencies play a critical role in the arenas of environmental protection, public health, occupational safety, and many other domains. Although these administrative activities attract less attention than the high-stakes legislative battles that precede them, it is after the legislation is enacted that the regulatory skirmishes begin—and usually far from the public eye. In fact, people might assume that the passage of legislation itself ensures that they are already protected, or soon will be, from the risks that a new statute is designed to address. Fewer might understand that the contentious process of hammering out the details of implementing the laws simply moves to the administrative domain.

Soliciting public comment has been presumed to promote transparency and exert a democratizing effect on policy by allowing individuals, NGOs, corporate interests and any other concerned parties to provide new information, offer advice, and submit recommendations to agencies implementing federal legislation (Bignami, 1999; West, 2004). Research on public comments in response to proposed rules published in the Federal Register by the EPA and other agencies has found that businesses and business groups predominate, with less participation by private citizens, NGOs, or public interest advocates (Golden, 1998; Magat, Krupnick and Harrington, 1986; Yackee, 2006; Yackee and Yackee, 2006). However, this research also shows that, while agency revisions to proposed rules tend to favor industry by weakening rules, changes generally appear to be minor (Kerwin, 2003; West, 2004).

One possible explanation of the finding that changes tend to be minor is that the EPA and other agencies are largely able to hold the line against industry influence and pressure. Another interpretation is that the process itself largely constrains agencies from making significant changes between the proposed and final versions of a policy or rule. By the time agencies publish a draft proposal, they have already expended significant time and resources, and most substantive decision-making has already occurred (West, 2004). When final versions of rules have differed significantly from notices of proposed rulemaking, courts have required agencies to pursue a second round of time-consuming public comment (Melnick, 1984). While research on public comment therefore is useful for assessing who participates at that stage of the process and how much (or how little) effect their comments produce, these studies do not reveal what happens at the earlier and less visible stages of policy development.

Indeed, E. Donald Elliott, a former EPA general counsel, has asserted that notice-and-comment rulemaking “is to public participation as Japanese Kabuki theatre is to human passions—a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues” (Elliott, 1992). Instead, Elliott noted, “real public participation—the kind of back and forth dialogue in which minds (and rules) are really changed—primarily takes place in various fora well in advance of a notice of proposed rulemaking appearing in the Federal Register.” Other scholars have referred to these less formal contacts and exchanges of information between regulators and interested parties as occurring “inside the black box” (West, 2009) or “in the shade” of the more transparent process of public comment (Wagner et al., 2011).

It is not unusual for agencies to spend significant time and effort gathering information from stakeholders during the process of policy and rule development; regulated parties, in particular, frequently possess data that administrative officials need in order to develop their proposals. As policies are researched and drafted, interest groups also lobby regulators through a variety of mechanisms, including face-to-face meetings, e-mail communications, and attendance at presentations by regulators (Furlong and Kerwin, 2005). Information about these less formalized lobbying efforts and contacts is not readily available for scrutiny, yet researchers have begun to explore the extent of this early participation by industry and other stakeholders, using different methodologies.

Some studies have analyzed public comments responding to Federal Register publication of an “Advance Notice of Proposed Rulemaking” (Naughton et al, 2009; Yackee, 2012). Indeed, agencies occasionally pursue this initial procedural step to seek guidance on a variety of rule options before they draft and publish a Notice of Proposed Rulemaking. Other research has examined Federal Register dockets to identify stakeholder contacts that occur while proposals are being researched and drafted but have not yet published; agencies sometimes record such contacts even though they are not compelled to do so by law (Wagner et al., 2011). Researchers have also interviewed participants in rulemaking activities to assess their beliefs about the impact of contact between stakeholders and agency officials during this the earlier phase (Naughton et al, 2009; Rinfret, 2011).

All three approaches pose methodological challenges. Studies of comments in response to advance notices tell us little about what happens in the great majority of cases when such advance notices are not published. Relying on agencies to document contacts with interested parties even when they are not legally required to do so is only effective if such contacts are in fact documented consistently. Interviews with key informants are effective in assessing the opinions of these participants but are subject to significant recall bias and do not necessarily reflect actual outcomes. Despite such limitations, these studies have generally reported that, as with public comments, industry representatives appear to participate to a much greater extent than other stakeholders at the pre-publication stage of policy development. The research has also suggested that early involvement in policy development appears to have two goals--to promote the inclusion of provisions favorable to industry, and to block unfavorable provisions—and that industry interests enjoy some success in both (Naughton et al, 2009; Yackee, 2012).

This study takes another approach to examining these less visible contacts by analyzing stakeholder influence in the development of the EPA’s Endocrine Disruptor Screening Program (EDSP), an effort mandated by Congress in 1996 in both the Food Quality Protection Act and amendments to the Safe Drinking Water Act. Documents were obtained through two FOIA requests to the EPA. One FOIA request sought communications between industry trade associations and the agency about the EDSP, and a second FOIA request covered communications between several non-governmental organizations (NGOs) and the agency about the same program.



## Background: The Endocrine Disruptor Screening Program

In the early 1990s, a series of studies revealed significant reproductive disorders among wildlife populations exposed to chemical pollution; during the same period, studies also suggested that human male sperm counts had declined across the globe in the previous decades (Colborn, Dumanoski, and Myers, 1996; Krimsky, 2000). In 1996, Congress addressed these growing concerns about human and wildlife reproductive health and asked the EPA to establish a program for screening chemicals for endocrine-disrupting effects. Congress included the mandate in two major pieces of legislation: the Food Quality Protection Act, which amended both the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, as well as a package of amendments to the Safe Water Drinking Act.

The Food Quality Protection Act required the EPA to “develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effect as the Administrator [of the EPA] may designate.” (FQPA, 1996). The new law authorized the agency to test all pesticide chemicals as well as “any other substance that may have an effect that is cumulative to an effect of a pesticide chemical” (FQPA, 1996). The Safe Drinking Water Act amendments asked the agency to pursue similar endocrine disruptor testing for “substances that may be found in sources of drinking water in which a substantial population may be exposed” (SDWAA, 1996).

In designing the EDSP, the agency decided to include chemicals that mimic, block the action of, or otherwise interfere with the functions of estrogens, androgens and thyroid hormones. The framework included two tiers of assays, with each battery including both *in vitro* and *in vivo* studies. The Tier 1 screening battery would “identify chemicals that have the potential to interact with the endocrine system” (EPA/website, 2013). A chemical with positive Tier 1 findings would pass to the Tier 2 testing battery, which would “determine the endocrine-related effects caused by each chemical and obtain information about effects at various doses” (EPA/website, 2013). Chemicals with negative results in Tier 1 screening would be deemed not to be EDCs and would not be required to go through Tier 2 testing. Following chemical companies’ submission of testing results, the EPA would conduct risk assessments for endocrine disruptors and establish standards for each chemical.

Early delays in implementation—in particular, in developing a fully validated battery of Tier 1 screening assays--plagued the program. A coalition of public interest groups led by the National Resources Defense Council (NRDC) sued the agency in 1999 because it had not met statutory deadlines. In the 2001 settlement signed by the parties, the agency committed itself to several deadlines, including publication of the first draft list of chemicals for Tier 1 screening by the end of 2002 (EPA/settlement agreement, 2001). Later, the agency postponed that deadline to the end of 2003, and then beyond; the draft list was eventually published in 2007. Under the agreement with the NRDC-led coalition, the sanction for not meeting the agreed-upon deadlines was a requirement to send the

NGOs an update on EDSP activities every six months. In fact, the agency fell years behind all of the deadlines, according to a 2011 report issued by the EPA's Inspector General (EPA/Office of the Inspector General, 2011).

In 2002, the federal government launched an online system, currently at [www.regulations.gov](http://www.regulations.gov), to enable and encourage the public to track the progress of rule development, access relevant documents and submit comments. From 2002 through 2009—the last year of the documents received through the FOIA requests--the EPA published 31 items in the Federal Register involving the EDSP. Four of these publications were notices describing proposed EDSP policies and procedures and seeking public comment. The first notice was published in 2002, the other three in 2007 (EPA, 2002; EPA, 2007a; EPA, 2007b; EPA, 2007c). None of them were official Notices of Proposed Rulemaking; therefore, the agency was pursuing public comment prior to publishing final versions as a discretionary strategy for rules that would not be included in the Code of Federal Regulations.

These four Federal Notices concerned: 1) the proposed strategy for selecting the first draft list of 50-100 pesticides to be sent orders for Tier 1 screening; 2) the actual draft list of the first 73 chemicals selected through that strategy; 3) the proposed procedures and policies the agency intended to follow in issuing and enforcing test orders and receiving responses for those 73 chemicals, including provisions for cost-sharing of expenses related to fulfilling EDSP test orders and for protection of confidential business information; and 4) the proposed information collection request to be sent to the Office of Management and Budget for approval, outlining the costs and resources required to comply with EDSP test orders

In the 2002 Federal Register notice, the EPA described its plan to prioritize pesticides based on possible human exposures; it decided against using hazard data for this first round, citing the ambiguity of the research on specific chemicals. The agency proposed a one-time approach that would use dozens of databases to assess eight separate possible pathways of possible—four each for pesticide active and pesticide inert ingredients. For pesticide active ingredients, the databases were designed to assess exposures through pathways related to food, drinking water, occupational use, or residential use. Pesticide actives that appeared in the food and occupational pathways, and at least one of the remaining two pathways, would be considered priorities for inclusion on the draft list. For pesticide inerts, the proposed databases were also designed to cover four categories: human biomonitoring studies, ecological studies (specifically, studies of tissue from fish commonly eaten by people), studies of drinking water, and studies of indoor air. Inerts that appeared in the human biomonitoring pathway and at least two of the other three pathways could be included on the list.

After reviewing public comment and making minor revisions, the EPA published the final version of its priority-setting approach in 2005 (EPA, 2005). In June, 2007, the agency published the first draft list of 73 chemicals slated for Tier 1 screening, which was produced by applying that priority-setting approach to the universe of registered pesticides (EPA, 2007a). In December that year it published the other two Federal Register notices seeking public comment—one about EDSP policies and procedures, the other about the Information Collection Request to the Office of Management and Budget

(EPA, 2007b; EPA, 2007c). Final versions of all three 2007 notices were published in 2009 (EPA, 2009a; EPA, 2009b; EPA, 2009c).

The meetings examined in this study all included discussions of issues addressed in one or more of these four Federal Register proposals seeking public comment. This study seeks to answer the following question: What do documents accessible through FOIA reveal about industry and other interest group meetings with EPA officials during the development of key EDSP policies and rules, beyond what is captured in government records accessible to the public?

## METHODS

As part of a larger project, a FOIA request for EDSP-related documents involving communications between the EPA and several industry trade associations was filed in 2010; a parallel FOIA request was filed for communications between the EPA and several non-governmental organizations.<sup>1</sup> The requests covered letters and e-mails, including any reports and other documents sent as e-mail attachments, from 2000 through the end of 2009. For the current paper, the FOIA documents from 2002 through 2009 were reviewed for records of face-to-face meetings at which there were discussions of issues addressed in the four EDSP-related Federal Register notices seeking public comment. The year 2002 was chosen because that year: 1) the EPA published the first of the four Federal Register proposals seeking public comment, launching a major phase of EDSP implementation; and 2) the agency began using the online portal at [www.regulations.gov](http://www.regulations.gov), facilitating access to key documents, including public comments, related to the four Federal Register publications discussed in this research.

The trade associations named in the FOIA request were the American Chemistry Council, the Chemical Producers and Distributors Association, and CropLife America. These three groups were selected after a review of both public comments and records of participation on EDSP-related committees, panels, public meetings, and other official activities found that these associations were more likely than other associations to be engaged in development of the program.

Some EPA meetings with industry representatives were excluded from the analysis. Specifically, scientists from the EPA and industry held many meetings in connection with the development of specific assays for the EDSP, such as an adult male rat assay favored by industry. The design of such assays would likely influence the findings eventual determinations about whether specific chemicals were or were not endocrine disruptors,

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<sup>1</sup> After submission of initial FOIA requests identifying a larger number of groups than those mentioned above, EPA officials requested through e-mail correspondence to schedule telephone conversations to clarify details; in these conversations, they noted that requests for information about a larger number of groups would significantly delay the process of locating and identifying responsive documents, so the requests were narrowed in scope.

and were therefore a possible pathway for industry influence on EDSP outcomes. However, these scientific meetings focused on the complexities and intricacies of assay design and did not include significant discussions of the regulatory policies and procedures addressed in the four Federal Register publications soliciting public comments. In addition, the FOIA documents indicated that EPA officials gave multiple public presentations about the EDSP to audiences at industry trade association gatherings; these documents were also excluded from the analysis because they consisted of EPA talking points but did not generally include information about exchanges with industry representatives or details about industry reactions to the EPA presentations and proposals.

Documents received through a parallel FOIA request for similar EDSP-related communications between the agency and NGOs were also reviewed for records of meetings. The four NGOs included in the FOIA request were: the NRDC, the World Wildlife Fund, the Environmental Working Group and the Breast Cancer Fund. These four organizations were selected after a review of both public comments and records of participation on EDSP-related committees, panels, public meetings, and other official activities found that all of them—and especially the NRDC--were more likely than other NGOs to be engaged in the development of the program.

The two FOIA requests yielded thousands of pages of documents. The FOIA documents related to industry meetings with EPA included: brief or detailed meeting notes describing what was discussed; meeting agendas; lists of meeting attendees; e-mail exchanges between industry and EPA officials seeking to arrange meetings; e-mail exchanges among EPA personnel themselves about the meetings (although these intra-EPA e-mail exchanges were technically outside the scope of the FOIA request); attachments to e-mails, such as lists of questions, white papers and letters sent by industry groups; and brief news items in internal EPA newsletters about meetings that had taken place.

The FOIA documents of NGO communications with EPA included no information about any meetings. (These documents primarily consisted of the twice-yearly reports on EDSP progress that the EPA was required to send NRDC pursuant to the terms of the 2001 settlement agreement.)

Documents that included information about trade association meetings with the EPA were coded for date of document, date of the meeting referred to in the document, and type of document (e-mail message, meeting notes, agenda, list of participants, EPA internal newsletter, or other). Next, documents were coded for whether they contained detailed information about the discussions at the meetings, in contrast to documents that simply indicated that a meeting on EDSP topics had been held or was about to be held. In particular, documents that contained such information were coded for whether the discussions included topics addressed in the four EDSP-related Federal Register notices. These Federal Register notices were about: 1) the priority-setting approach for selecting the first list of chemicals; 2) the first draft list of chemicals itself; 3) the policies and procedures to be followed by the EPA and by those issued orders for Tier 1 screening

data; and 4) the Information Collection Request sent to the Office of Management and Budget outlining the details of the orders.

The documents were also coded for whether discussions of these topics occurred before or after publication of the relevant Federal Register notices and whether similar issues and concerns were raised in multiple meetings across the time period. In addition, they were coded for industry efforts to introduce or promote procedural or administrative steps that would have lengthened the EDSP implementation process. Details and quotes from the discussions described in the documents were extracted to help illustrate the findings.

In addition, the electronic dockets at [www.regulations.gov](http://www.regulations.gov) related to the four Federal Register publications were reviewed to determine whether the meetings identified in the FOIA documents were also documented in the government's public record.

## RESULTS

In this section, I first provide overall details about the identified meetings between stakeholders and EPA staff. Next, I describe how industry stakeholders raised the same or similar arguments and issues across multiple meetings. Finally, I examine industry requests for the EPA to introduce additional procedural steps or elements at various stages of the process; the agency's agreement to any of these requests would itself have delayed implementation.

### Meeting Details:

The FOIA documents indicated that between 2002 and 2009 the industry associations held at least 13 meetings with EPA officials to discuss aspects of the EDSP that were the subject of one or more of the four Federal Register publications (Table 1). These discussions took place both before and after publication of the relevant Federal Register Publications. Two other meetings about EDSP-related matters involving some of the same participants from the EPA and industry were also identified, although the documents did not include information about the specific topics of discussion. Of the 13 meetings documented, four were held in 2002, two in 2003, two in 2004, two in 2007, and two in 2008; the two meetings about which little is known were held in 2005 and 2006.

Detailed notes exist for nine of the 13 meetings. In three cases, the notes were prepared by an outside contractor. In four other cases, the notes were produced by EPA officials who participated in the meetings. In two cases, the notes were prepared by EPA officials in advance of the meeting, based on what they anticipated would be discussed. Less is known about the other meetings. In one case, the documents included a one-page list of topics discussed, with no additional details. In two cases, meetings were described briefly in internal EPA newsletters. In other cases, meetings were mentioned in e-mail exchanges among EPA officials or between EPA officials and industry representatives with little exchange of information about topics under discussion.

For 10 of the meetings, it was possible to determine who initiated them; in nine cases, industry representatives requested the meetings to discuss aspects of the EDSP, and in one case the EPA suggested it. In some cases, two or more trade groups met jointly with officials; at other times, individual trade groups secured meetings to discuss issues of particular interest to their members. In addition to trade organization representatives of specific chemical companies, including Proctor & Gamble, Dupont, Dow, Syngenta and Monsanto, attended meetings. Most of the meetings covered a broad range of topics and touched on issues addressed in more than one of the Federal Register notices.

TABLE 1: INDUSTRY MEETINGS WITH EPA REGARDING EDSP RULEMAKING

Date	Documents	Industry Groups	EPA Offices	Federal Register Notices	Initiator of Meeting
4/12/2002	Notes-EPA, Agenda, Attendees, Issue paper (ACC)	ACC, CPDA, CSPA, companies	OSCP, OPPT, OGC	1, 2, 3	Requested by ACC
8/6/2002	Notes-EPA ACC Letter	ACC		1, 2	
10/2002 (date N/A)	Newsletter	ACC		1, 2	
12/13/2002	Newsletter	CPDA, CLA		1, 2	
2/10/2003	Notes-Con	ACC, CPDA, CLA		1, 2, 3	Requested by CPDA
4/3/2003	Pre-meeting notes-EPA	CLA		1, 2, 3, 4	Requested by CLA
1/29/2004	Notes-Con, Agenda, Attendees, ACC letter	ACC, CPDA, CLA, companies	OSCP, OPP, OPPT, OCG	1, 2, 3, 4	Requested by ACC, CLA, CPDA
4/14/2004	Notes-Con, Issue paper (CPDA/CLA)	CLA, CPDA, companies	OSCP, OCG	3	Requested by CPDA, CLA
6/28/2005	EPA e-mail	ACC	OSCP		
11/14/2006	EPA e-mail	ACC	OCSP		
5/29/2007	Pre-meeting notes-EPA, EPA e-mail	ACC, CSPA, CLA	OCSP, OPPTS, OPP	1, 2, 3, 4	Requested by CLA, association coalition
9/12/2007	EPA e-mail	ACC, CPDA, CLA, CSPA, companies	OSCP	1, 2, 3, 4	Requested by "industry"
1/10/2008	EPA-CPDA e-mail	CPDA		3	Requested by CPDA
3/18/2008	Notes-EPA, EPA e-mail	ACC	OPPTS	3, 4	Requested by ACC
6/26/2008	Notes-EPA, Agenda, EPA-CLA letters	ACC, CLA	OPPTS	2, 3	Requested by EPA

KEY TO TABLE 1 (Empty cells indicate that information was not available):

**Documents:** "Notes-Con" were prepared by an outside contractor; "Notes-EPA" were prepared by the EPA

**Industry Groups:** ACC - American Chemistry Council; CPDA - Chemical Producers and Distributors Association; CLA - CropLife America; CSPA - Consumer Specialty Products Association

**EPA Offices:** OSCP - Office of Science Coordination and Policy; OPPT - Office of Pollution Prevention and Toxics; OPPTS - Office of Prevention, Pesticides and Toxic Substances; OPP - Office of Pesticide Programs; OCG -Office of General Counsel

**Federal Register Notices:** 1, 2, 3, and 4 are the four notices published from 2002 to 2007: 1) the method for selecting chemicals for the first draft list; 2) the first draft list; 3) the policies and procedures for

implementing test orders; 4) the ICR request submitted to the OMB, including information about the assays and costs of testing.

In contrast to the number of industry meetings, only one meeting with any of the four NGOs was referenced in the documents—a meeting between the EPA and NRDC in August, 2002, to discuss the priority-setting approach for selecting the first draft list of chemicals. Ironically, this meeting was not referenced in the documents received through the FOIA requests for communications between the NGOs and the EPA. Instead, it was mentioned in the meeting notes from one of the meetings between EPA and industry representatives. However, no further information about this meeting between EPA and NRDC was provided.

The relevant e-dockets at [www.regulations.gov](http://www.regulations.gov) included documents related to only one of the 15 trade group meetings: a meeting on January 10, 2003, between the EPA and the American Chemistry Council, CropLife America and the Chemical Producers and Distributors Association. The e-dockets also did not include a record of the one meeting with NRDC mentioned in the documents.

## DISCUSSIONS RELATED TO FEDERAL REGISTER NOTICES

The FOIA documents contained extensive discussions of topics that were the subject of the four Federal Register publications. Meeting notes, e-mails, issue papers and related documents provided a detailed look at industry interactions with the EPA as the EDSP moved forward. The documents suggest that industry groups, in addition to seeking to affect the content of policies and rules, might have been pursuing two strategies to foster delays in implementation. First, raising the same or similar objections in multiple meetings across the time period in question required the agency to expend valuable resources, including significant personnel time, to rebut them; second, taking advantage of repeated opportunities to lobby for further procedural delays increased the possibilities that the EPA might acquiesce.

The following issues were among those raised in multiple meetings across the time period in question (although these examples should not be construed as an exhaustive account of the topics addressed):

### **1. Accuracy and acceptability of the priority setting approach for selecting the first draft list of chemicals.**

In a series of meetings before and after the EPA published its priority-setting approach in December, 2002, industry groups raised a range of concerns about the overall chemical selection strategy and about some of the specific databases being used. The industry groups disliked the EPA's proposed methodology, and they repeatedly called for it to be reexamined. In a meeting on April 12, 2002, an American Chemistry Council



representative suggested that the entire process would likely have to undergo further scrutiny because any actions “must be based on sound science and other reliable bases, consistent with EPA’s published data quality guidelines” (FOIA Documents, 2002a)

A representative of the Chemical Producers and Distributors Association also suggested that database approach did not adhere to the recently passed Data Quality Act, which mandated a focus on “the quality, objectivity, utility, and integrity” of the information used for decision-making by federal agencies. According to this representative, “the purpose is to ensure maximum quality of information and provides a means for those outside the Agency to ‘correct biased information’ ... ‘Influential’ information needs the extra layer of scrutiny, provides transparency e.g. which models are used, using published information” (FOIA Documents, 2002a)

At a meeting in October, 2002, the American Chemistry Council again raised concerns about the priority selection approach. In response, according to an internal EPA newsletter, the agency “reiterated” what it had apparently told the American Chemistry Council representatives at the earlier meeting—that it planned to seek comment on the proposed selection approach before generating a draft list (FOIA Documents, 2002c). On February 10, 2003, industry groups again raised questions about the database methodology and some of the older databases in particular, according to meeting notes. EPA officials deflected the questions, noting that they had “proposed a process that would facilitate choosing chemicals with a modest investment of resources” and that the selection process for the first draft list did not require the same kind of “comprehensive exposure determinations similar to those completed for tolerance reassessments and reregistration eligibility determinations” (FOIA Documents, 2003).

Industry groups again proposed an independent review of the methodology because “this is a major scientific product for support of a regulatory action,” the notes indicated. When EPA officials responded that the proposed priority-setting approach was “very simple” and that they considered a more extensive examination of the methodology unnecessary, the industry groups again noted that they “support an independent peer review and suggested that EPA revisit whether one would be required” (FOIA Documents, 2003).

## **2. Negative economic repercussions, or “product deselection,” for chemicals appearing on the first draft list of chemicals.**

The issue of “product deselection”—the concern that identifying chemicals for the draft list would be misunderstood by market players and the public and cause reputational and financial losses--was addressed in a series of meetings before and after publication of the list in the Federal Register in 2007. At the April 12, 2002, meeting, a Chemical Producers and Distributors Association representative stated: “A preliminary or premature list of chemicals identified for testing does not offer much usefulness to the public except to scare people. The list could easily be misconstrued” (FOIA Documents, 2002a). Another representative from the organization stated that “the list will be out there (in the wind) for at least 2 years before any testing will be completed” (FOIA

Documentets, 2002a). An American Chemistry Council representative noted that the EPA bore a responsibility to offset the negative impressions by explaining the decision process and making “no reference to the compounds as being of unknown toxicity or suspected of causing endocrine disrupting effects” (FOIA Documents, 2002a).

An internal EPA newsletter report of a meeting with the American Chemistry Council in October, 2002—a follow-up to two previous meetings in April and August 2002--noted that “as at that earlier meeting, ACC representatives expressed concern about potential adverse impacts” of a first draft list of chemicals (FOIA Documents, 2002c). At a meeting held on December 13, 2002, the Chemical Producers and Distributors Association, CropLife America and several pesticide companies “reiterated concerns about possible product deselection impacts of publishing a list,” according to another short item in the internal EPA newsletter (FOIA Documents, 2002d).

These concerns arose again at a meeting held on February 10, 2003. Prior to the meeting, the American Chemistry Council submitted a list of questions, one of which was, “How does EPA intend to ‘reality check’ or ‘quality check’ the draft list candidates?” At the meeting itself, “Attendees were concerned that publication of the ‘initial list’ before the screening battery is validated and implementation procedures are defined could result in product deselection” (FOIA Documents, 2003a). At the same meeting, EPA officials indicated that because they were basing their selections for the first draft list on exposures rather than hazard data, “the proposed chemical selection approach provides minimal basis for product deselection...However, EPA cannot control the market reaction to a list, even with caveats. EPA will minimize the time between list publication and the initiation of chemical screening and testing” (FOIA Documents, 2003a).

At a meeting in early 2004, an American Chemistry Council representative stated that “there is concern about the implications of the list and EPA’s responsibility to convey the true meaning of the list.” To minimize the chances of product deselection, the American Chemistry Council representative suggested that EPA frame it as a “pilot phase” and stated that the “title [of the list] is very important and should reiterate what the list really represents...EPA should explain and state that this is a pilot program” (FOIA Documents, 2004).

Industry continued to raise concerns about product deselection. In notes prepared for an upcoming meeting with CropLife America on June 26, 2008, an EPA official wrote to colleagues that “CLA is concerned about the potential impact of the EDSP for product deselection by retailers, formulators and the general public...EPA has consistently taken care to note that the first list was selected on the basis of exposure parameters only. Hazard was not a consideration and therefore there is no basis to infer that the chemicals on the list were potential endocrine disruptors. There is nothing that could be clearer than this statement” (FOIA Documents, 2008).

### **3. The opportunity to bypass EDSP assays by submitting other data instead**

The 2007 Federal Register publication on EDSP policies and procedures included detailed information about whether and how to submit existing data from assays other than those identified in Tier 1. This topic received extensive attention in multiple meetings across the time period, both before and after publication of the Federal Register notice. Industry representatives repeatedly argued that studies required for pesticide registration or other EPA programs already included endpoints relevant to endocrine disruption and should be accepted as sufficient evidence for EDSP purposes. In particular, industry representatives argued that pesticides that had successfully passed through the mammalian, 2-generation reproductive testing required for registration had already been shown not to be EDCs and should therefore be exempt from EDSP Tier 1 screening and Tier 2 testing. The EPA routinely disagreed with this reasoning.

At the February 10, 2003, meeting, “Attendees suggested that much of the testing already conducted for pesticide actives is sufficient to evaluate endocrine disrupting potential... They noted that several existing testing endpoints for specific pesticide actives could be relevant to EDSP” (FOIA Documents, 2003a). The EPA indicated in response “that existing test methods may not be sensitive enough to detect properties relevant to endocrine disrupting potential... The 2-generation reproductive test required for pesticide chemicals may or may not be equivalent to the companion Tier 2 endocrine disruptor test.” At the same meeting, “Attendees expressed concern that EPA is not considering existing toxicity data that may be relevant to EDSP. EPA indicated that in most cases, older tests do not have endpoints sensitive enough to detect endocrine disrupting characteristics” (FOIA Documents, 2003a). In notes in preparation for a follow-up meeting with CropLife America in April, 2003, EPA officials stated that “although reproductive toxicity tests within the battery for tolerance reassessments is also the starting point for Tier 2 EDSP tests, modifications to these may be necessary to enhance ability to detect endocrine-related effects” (FOIA Documents, 2003b).

At a January, 2004, meeting, an American Chemistry Council representative noted that the mammalian 2-generation reproduction study is a “critical test for [pesticide] reassessments” and that “stakeholders are not yet convinced that the existing study is deficient” (FOIA Documents, 2004a). In a follow-up letter to EPA after the meeting, the association referred again to the mammalian 2-generation reproduction study and warned that “major modifications of the existing test guideline will likely require many years to develop the requisite data to support a validation (relevance, reliability, reproducibility) determination” (FOIA Documents, 2004a).

In notes prepared prior to a meeting with CropLife America in 2007, an EPA official discussed how one industry official had mistakenly believed that a successful mammalian, 2-generation reproductive study could exempt chemicals from all other EDSP requirements. According to the notes, the industry official “wanted to be sure registrants would have a way to prove to the agency ASAP that a pesticide upon whom EPA might throw suspicion of being an EDC was in fact ‘clean.’” But, the EPA notes continued, the industry official “seemed to forget” that Tier 2 consisted of a battery of

tests, not just a 2-generation study. “It’s not as if having a negative mammalian 2-generation would be sufficient to clear a chemical’s name,” stated the EPA notes. “I could never figure out why she [the industry official] thought her constituents would be able to clear their chemicals’ names by a simple reference to a mammalian 2-gen test” (FOIA Documents, 2007).

In a letter to EPA from CropLife America in advance of the scheduled meeting in June, 2008, the trade group stated that “in the rush to meet the deadline set by Congress, the Agency has taken action inconsistent with sound science.” Among other complaints, CropLife America expressed concern “over the fact that substantial Tier 2 equivalent data are already on file with EPA’s Office of Pesticide Programs (OPP) but EPA does not have a plan to consider these data prior to issuing Tier 1 test orders...CLA has previously stated that registrants should not be required to conduct Tier 1 screening on active ingredients for which Tier 2 data already exist that show the compound IS NOT an endocrine disruptor, and that EPA should look first to the data the Agency already has on file before issuing test orders” (FOIA Documents, 2008).

#### Additional Procedural Steps

Industry stakeholders repeatedly urged the agency to pursue additional procedural steps that would result in significant delays in EDSP implementation. These proposed steps included:

**\*Delaying Federal Register publication of the draft list until after Federal Register publication of the priority-setting approach to select the draft list.**

This was a key goal of industry representatives, who feared they would suffer losses if their chemicals were named to the list. In a meeting on April 12, 2002, a representative from American Chemistry Council stated that “it would be nice if the proposed rule or final rule came out BEFORE the priority list of chemicals...The EPA may need to delay putting its initial priority list out until after June 2002 due to reasons such as the information quality guidelines” (FOIA Documents, 2002a).

Although EPA had agreed in the settlement with NRDC to issue the list by the end of 2002, it pushed back the deadline for publishing it, first to December 2003, and ultimately until 2007—a five-year delay. At a meeting with all three trade associations on January, 2004, a Chemical Producers and Distributors Association representative “expressed that the stakeholders were pleased that EPA has decided to separate establishing the priority setting approach from the publication of an initial list” (FOIA Documents, 2004a). (Delays in the science of Tier 1 assay development, not necessarily industry lobbying, were a major factor in delaying the publication of the draft list.)

**\*Providing industry with an advance look at the draft list of chemicals.**

Because of industry groups’ concerns about product deselection, they sought to have an advance look at the draft list of chemicals for Tier 1. At a meeting on February 10,

2003, they told EPA officials that such a step “would allow for rectification of potential errors in chemical selection prior to publishing,” according to meeting notes (FOIA Documents, 2003a). In an internal EPA e-mail exchange before a follow-up meeting scheduled with CropLife America on April 14, 2003, an EPA official acknowledged that such a step could uncover mistakes but noted that it would also delay the process. He concluded overall that “the value added by pre-publication review is likely to be small... The companies should get a chance to comment on accuracy of data EPA uses at the same time as the public” (FOIA Documents, 2003b).

**\*Proceeding through more structured forms of rule development.**

Although the EPA solicited public comment through four Federal Register publications, the agency pursued a more flexible, discretionary process for engaging the public than industry would have liked. Industry groups repeatedly urged EPA officials to engage in notice-and-comment rulemaking or even a process known as “formal rulemaking,” which would require courtroom-style hearings on the issue, with cross-examination of EPA staff and other witnesses.

In recommendations issued for a meeting on April 12, 2002, the American Chemistry Council Biocides Panel stated that “to ensure that the scope...is appropriate to the level of potential risk posed by each chemical or chemical cluster being considered, the rulemaking procedure provided by the Administrative Procedures Act must be followed” (FOIA Documents, 2002a). A “white paper” submitted by CPDA and CLA before a meeting in April, 2004, noted that “while the associations understand the [sic] formal rulemaking would require a long period of time to establish, we strongly recommend that EPA use this approach” (FOIA Documents, 2004b).

The EPA understood that industry preferred more structured forms of rulemaking to the process of submitting public comments outside of the administrative framework of the APA. In planning notes for a meeting with CLA that occurred in May, 2007, an EPA official wrote: “In general, industry feels shut out of the policy development part of EDSP and will likely say so. However, the Program believes it has been as open as it can be given that industry comments have been received and the Agency is now deliberating on the best course of action” (FOIA Documents, 2007)

## DISCUSSION

In the U.S. political system, environmental, public health, and other legislation passed by Congress depends for implementation on the promulgation of policies and rules by federal agencies. Researchers have shown that business interests generally submit far more public comments in response to proposed rules than other stakeholders (Golden, 1998; Kamieniecki, 2006). Because these comments rarely appear to produce substantive changes, researchers have suggested that most major decisions have already been made by the time a proposal is published; they have also suggested that industry likely exerts greater influence at the earlier, pre-proposal stage of policy development. However, assessing contacts outside of the public comment phase, including those that

occur during the period before Federal Register notices are published, is much more difficult.

Using a unique set of EPA documents obtained through FOIA requests, the current research suggests that industry representatives appeared to enjoy significantly greater access to agency officials than other groups during key phases of development of the EDSP. Although it is impossible to ascertain whether the documents included information about all meetings concerning EDSP policies and procedures held between the EPA and stakeholders from industry groups and NGOs, the findings reported here parallel those from other studies using different methodologies to examine these less transparent stages of agency policy development (Naughton et al, 2009; Yackee, 2012; Wagner et al., 2011; West, 2009). In this case, the documents established that the trade groups most involved in monitoring the EDSP held at least 13 meetings with EPA officials at which they discussed issues pertaining to the four EDSP-related Federal Register notices seeking public comment that were published between 2002 and 2007. Moreover, the relevant e-dockets at [www.regulations.gov](http://www.regulations.gov) included information about just one of these meetings; the other 12 were not mentioned.

Thus, FOIA requests in this case yielded significantly more information about interactions during important phases of policy development than did relying solely on information contained in the government's publicly accessible e-dockets. The documents add nuance and detail to the portrait of the relationship between industry and administrative agencies during the period of rule development prior to the public comment period. Unlike previous studies that have examined contacts between agencies and stakeholders during this policy-drafting phase, this study focuses on a single program and includes details of multiple meetings with the same interest groups and individuals, which allowed for monitoring of contentious debates across the time period. In this case, the documents indicate that the EPA made significant policy decisions while holding more than a dozen meetings with industry trade groups. While the documents provided significant details about the content of nine of the meetings, nothing substantive is known about several of them because no contemporaneous notes from the meetings themselves were included.

Whether agencies pursue the kind of notice-and-comment rulemaking described in the Administrative Procedures Act or a more discretionary approach, as in the case discussed here, the process can involve a level of industry access to regulators largely hidden from public scrutiny. Such a "black box" (West, 2009) might be of minimal concern were the opportunity to meet with federal regulators equally distributed among diverse stakeholders. Yet the FOIA documents yielded information about just one meeting between the agency and an NGO—a meeting that also was not referenced in the public record. If NGOs met less often with the agency to discuss EDSP-related policies and procedures, that does not necessarily indicate indifference on the part of the EPA to the perspectives of environmental and public health advocates. The paucity of such contact might just as likely reflect a shortage of human and material resources on the part of NGOs and other public interest advocates to have such invisible contact with agency officials, compared to industry.

In the current case, industry groups sought and obtained the opportunity to participate in face-to-face meetings with EPA officials multiple times across several years of policy development. In many of these meetings, they raised the same or similar concerns, requiring the EPA to expend resources to respond repeatedly to variations of these arguments, such as concerns about the priority-setting database methodology, fears of product deselection, or questions about substituting one set of data for another. Regardless of whether such ex-parte communication results in rules that correspond to industry-preferred parameters, the multiple exchanges of messages and notes before meetings--both within the EPA and between the agency and industry representatives--suggest that government officials invested considerable time and thought in preparation. Many of these same concerns were also subsequently raised in public comments submitted by industry in response to the Federal Register notices (Tuller, unpublished research).

Tracing a direct line from industry recommendations during pre-rulemaking meetings to their appearance in proposed or final rules is challenging. The FOIA documents nonetheless indicate that the industry representatives, in addition to raising similar arguments multiple times, lobbied often for procedural steps that would have further delayed EDSP implementation. The agency's action in at least one major instance was aligned with industry demands: postponement of the publication of the first draft list of chemicals for five years, from the initial target date of December, 2002, to December, 2007. However, unforeseen delays in validation of the various Tier 1 screening assays likely also factored into that decision.

The EPA clearly rejected other efforts by industry to introduce additional procedural elements to the EDSP rulemaking process, such as submitting the priority-setting approach to peer review, providing industry with an advance look at the first draft list of chemicals, or pursuing policy development through notice-and-comment rulemaking rather than the more flexible approach of soliciting public comment on a discretionary basis. These steps would likely have added months or years to an already lengthy process.

Contact and consultation with industry is necessary and expected and should not be interpreted or construed as improper or somehow sure to result in policies that favor business. However, the disproportionate amount of contact between EPA and industry reported in this study, if accurate, indicate that corporate interests would have greater opportunity than other stakeholders to press their case "in the shade" of the critical early stages of policy and rule development (Wagner et al., 2011). Even if the proposals in this case did not appear to have been heavily influenced by this external input, regulators at other agencies might not be able or willing to deflect repeated industry demands in the absence of countervailing pressure from NGOs and other stakeholders.

Moreover, direct influence on policy is not the only mechanism through which such meetings might serve business interests. To the extent that EPA officials were preparing for and holding meetings at which similar concerns were raised over and over again, they were not spending time on other critical regulatory responsibilities. These findings

suggest that, in addition to the two industry goals elucidated by previous researchers—pushing for favorable regulatory provisions and blocking unfavorable ones—stakeholders might be pursuing two additional strategies, both of them geared toward delaying regulation: seeking additional meetings to continue to plead their case as well as requesting additional procedural steps that would extend the time-frame even more. The meetings in this case might not have led to fundamental alterations in EPA policy, but that should not be interpreted to mean that industry did not benefit from the exercise and any associated delays.

This research is based on FOIA requests that included three chemical industry trade associations and four NGOs involved with environmental causes. While these groups were identified based on reviews of EDSP-related documents as those most likely to be lobbying the government on EDSP-related issues, it is possible that other trade groups and NGOs met with the EPA about the EDSP and that documents related to those meetings were not captured through the FOIA requests. Therefore, the study cannot assert definitively that it has identified all meetings held with industry and NGO stakeholders at which EDSP policies and rules were discussed and debated.

Moreover, the four draft proposals published in the Federal Register were not Notices of Proposed Rulemaking that required the EPA to solicit and consider public response as part of the process “notice-and-comment rulemaking”; rather, the agency published draft proposals and sought public comment on a discretionary basis. The EPA was not bound by the same legal and procedural constraints, such as a requirement to report all ex parte contacts with external stakeholders after publication of a Notice of Proposed Rulemaking in the Federal Register. Therefore, the findings from this study might not reflect the pattern during more formalized and structured policy development processes conducted through compliance with the provisions of the APA. Although less studied than notice-and-comment rulemaking, the more flexible process examined here is an extremely common form of policy development at federal administrative agencies and deserves more attention in the scholarly literature.



## Chapter 4:

# Media Messaging on the Science of Phthalate Exposures and Human Health Effects

## INTRODUCTION

Phthalates are a group of synthetic chemicals widely used in consumer and commercial products since the early 1900s (Aulian, 1973; Tepper, 1973). Phthalates, also known as phthalate esters or phthalic acid esters, are most frequently found as additives to polyvinyl chloride (PVC), a group of plastics often referred to as vinyl. Phthalates act as plasticizers, rendering the material soft and pliable, and therefore greatly expand the versatility of PVC; children's toys, medical supplies, housing materials, items of clothing, and many other goods contain these plastics. Phthalates are also found in cosmetics, lotions, fragrances and other body and personal care items; they act as solvents for other ingredients, help to fix pigments, and facilitate skin absorption, among other functions (EWG, 2002). Because these chemicals are only weakly bonded to other compounds in consumer and commercial products, they tend to leach into the environment, increasing the risk of human exposures (Iles, 2007).

Studies from the U.S. Centers for Disease Control and Prevention (CDC) have found measurable levels of multiple phthalate metabolites in more than 90% of the population (CDC, 2001; CDC, 2003; CDC, 2005; CDC, 2009). Different phthalate congeners are used in different products, so pathways of human exposure vary significantly; for example, women of child-bearing age show evidence of greater exposure to the phthalates most often found in cosmetics, although more recently those levels appear to have decreased as more manufacturers have removed the chemicals from their products (Zota, Calafat, & Woodruff, in press). Studies of phthalate exposures in rats first started generating concerns about liver and kidney damage by the 1970s (Tepper, 1973). However, it was not until two decades later, when further laboratory research suggested that phthalates could disrupt the development of the reproductive system, that environmental, health and public interest non-governmental organizations (NGOs) began launching attention-getting campaigns for tighter regulation.

In the late 1990s, a coalition of groups petitioned the U.S. Consumer Products Safety Commission (CPSC) to restrict or ban the use of phthalates in toys, amid growing evidence that the chemicals might pose health risks to young children. The agency declined to impose mandatory restrictions, although some brand name toymakers and retailers agreed to stop selling some children's toys and other items containing phthalates. Several years later, in 2006, San Francisco became the first U.S. jurisdiction to restrict phthalates in children's toys. The California legislature passed a similar law the following year. And in 2008, the U.S. Congress included limited phthalate restrictions in a major bill that overhauled the CPSC. The restrictions at the city, state and federal levels covered several different phthalates and a variety of children's items.

What changed from the late 1990s to the late 2000s to trigger this flurry of legislative activity? Through a content analysis of media coverage, this study examines changes in the way that phthalates and the science of chemical exposures were perceived and portrayed during that period. The news media are instrumental in setting the public agenda, framing the terms of public debate, and influencing both public opinion and public policy (Gitlin, 1980; Iyengar, 1994). In making choices about what to cover, they bring attention to some aspects of an issue while minimizing or ignoring others and impact how policy-makers are likely to respond (Wallack & Dorfman, 1996). News coverage is therefore a treasure trove of data about the process of policy development and change. Content analyses of news stories can capture how proponents and opponents understand and describe an issue. Studies can also assess how news organizations themselves shape the coverage through the selection of particular details, language, sources, quotes, and headlines, among other factors.

Through the lens of the emerging concept of civic epistemology, Iles documented how advocates challenged standard approaches to regulatory science by conducting and promoting innovative forms of research, with a particular focus on the potential health risks posed by consumer products (Iles, 2007). In this study, I first provide background on phthalates and on the theoretical construct of civic epistemology. I then examine how a sample of five major news organizations at the state and national levels covered the issue of phthalates, and in particular three important streams of science that reshaped the debate and helped trigger the flurry of political victories from 2006 to 2008. In the discussion, I argue that news organizations themselves played a key role in this shift. Their decisions to cover the new scientific evidence granted legitimacy and visibility to the efforts of public interest groups, and in at least one instance a major news organization stepped outside its traditional reporting role and adopted the advocacy strategy of testing consumer products for phthalates.

## PHTHALATES: A BRIEF HISTORY OF SCIENCE AND POLITICS

Since phthalates were first introduced in the early 1900s, more than two dozen of them have been synthesized. However, most research has focused on those with high production volume and a correspondingly large potential for human exposures, including: di-2-ethylhexyl-phthalate (DEHP), butyl benzyl phthalate (BBP), di-n-butyl phthalate (DBP), di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP), di-n-hexyl phthalate (DnHP), di-n-octyl phthalate (DnOP) (Environmental Health Perspectives, 2000; Iles, 2007). Another phthalate, di-ethyl phthalate (DEP), has been used extensively in cosmetics and body care products (EWG, 2002).

Serious concerns about the potential health risks of phthalates arose in the early 1970s, when studies found that the chemicals were leaching from medical tubing and blood storage bags (Tepper, 1973). In the 1970s and 1980s, research linked DEHP to liver cancer in rats (Peck & Albro, 1982), and some manufacturers voluntarily agreed to remove it from pacifiers and other items designed for children to mouth. Even though

some NGOs sought to raise awareness about the issue, the debates were mostly confined to scientific and regulatory venues and received minimal news coverage. More recently, however, three emerging streams of research raised new fears about phthalates; unlike earlier findings, these developments generated a great amount of news coverage and public attention, culminating in the political victories from 2006 to 2008. The new research has also undermined key premises of the standard approach to regulatory toxicology, which assesses human health risk by combining findings from animal testing with estimates of human exposure from polluted media, such as air and water (Iles, 2007).

The first stream of new evidence focused on the testing of consumer products used predominantly by children and women. For example, to counter industry and regulatory arguments about the safety of phthalates, several NGOs, including Greenpeace and the National Environmental Trust, mounted a strategy in the late 1990s that entailed testing brand-name toys for phthalates. When the groups disseminated the results, they stressed that young children were being exposed through chewing and teething the plastic goods, and appealed to the Consumer Product Safety Commission (CPSC) to ban toys containing phthalates, mostly in the form of PVCs. This strategy of focusing on the hazards created when people--in this case children--interact with popular consumer items contrasted sharply with the traditional risk-based approach pursued by regulatory agencies (Iles, 2007).

The novel NGO-sponsored approach to the science of chemical exposures from everyday products received significant media attention, including multiple articles in the *New York Times* and the *Washington Post*. While the CPSC acknowledged some concerns about potential health risks from one phthalate, DINP, the agency ruled that the evidence was not sufficient to justify mandatory restrictions. However, it requested toymakers to voluntarily remove the chemical from items designed for small children to mouth, such as pacifiers and rattles, as a precautionary measure. Some toymakers and retailers also announced their own plans to stop producing and selling some toys with phthalates, citing consumer concerns and unwanted negative public attention about the hazards of phthalates in children's products.

In the early 2000s, environmental and consumer advocates broadened the consumer products strategy but still framed it as a means of protecting children. In a 2001 report—"This Vinyl House: Hazardous Additives in Vinyl Consumer Products and House Furnishings"--Greenpeace explained that it had "expanded its investigations to include materials in the home made of vinyl, such as wallpaper and floor coverings, that children come into contact with on a daily basis." Among the study's findings: "All products tested contained detectable levels of phthalates, with a maximum of 39% by weight in a drinking straw. Indeed, some of the highest levels were found in products specifically designed for children's mouths" (Greenpeace, 2001).

Advocates also targeted cosmetics and personal care items and highlighted the risks of dermal absorption of phthalates. A coalition led by the Environmental Working Group (EWG) tested 72 brand-name cosmetic and personal care products and found that 52

contained phthalates, including all 17 fragrances tested, nine out of 14 deodorants, six out of seven hair gels and 14 out of 18 hairsprays (EWG, 2002). A market for “phthalate-free” personal care products emerged and major companies like L’Oreal and Revlon announced that they were reformulating their nail polishes to meet consumer demands (Singer, 2006; Kay, 2005a).

The second stream of phthalate research entailed human biomonitoring--also known as body burden research--which involves testing blood, serum, urine, breast milk or other human tissues for the presence of chemicals, their byproducts or metabolites. In 2001, the CDC released results of its first National Report on Human Exposure to Environmental Chemicals, a large-scale biomonitoring study of a representative sample of the U.S. population (CDC, 2001). The study showed that an enormous percentage of the American public was exposed to 27 industrial chemicals. In subsequent reports, the number of chemicals included grew to 116 in 2003, 147 in 2005, and 213 in 2009 (CDC, 2009). All of the studies included metabolites of multiple phthalates and found widespread exposures, especially among women of reproductive age. Because phthalates break down quickly in the body, finding measurable amounts of metabolites in urine suggested that the exposures were recent and ongoing. Previous biomonitoring studies had been far more limited, focusing most often on individual chemicals, such as lead, and specific vulnerable populations, such as industrial workers or young children (Morello-Frosch et al, 2009).

Documenting the presence of chemicals in toys and other consumer products demonstrated the possibilities of human exposure; documenting the unwanted presence of chemicals in the body demonstrated that exposures had actually taken place. NGOs and environmental activists framed this as “toxic trespass” and leveraged the rapidly improving analytic techniques to conduct their own “advocacy biomonitoring” (Morello-Frosch et al, 2009). Commonweal and the EWG, for example, organized and publicized their own testing results; news stories about the CDC and NGO studies helped disseminate the understanding that synthetic chemicals, including phthalates, were ubiquitous in everyday life—as well as in the human body.

To help identify the sources and pathways of these documented chemical exposures, NGOs once again pursued a creative strategy: since household dust can be inhaled and ingested, Silent Spring Institute analyzed dust and air for almost 100 chemicals, and found phthalate residues in samples from all of the homes (Rudel, Camaan, Spengler, Korn and Brody, 2003). These and other household dust studies attributed that phenomenon to the presence in the home of so many consumer and industrial products containing the chemicals, and to their ability to leach easily into the environment. The products of concern included the toys, household furnishings and body care products that advocates had previously warned consumers about.

The third stream of emerging science examined the ways in which many common industrial compounds, including phthalates, appeared to be mimicking, inhibiting or interfering in other ways with the critical functions performed by estrogens, androgens and other endogenous hormones. Through often complex pathways and mechanisms,

these chemicals were believed to be disrupting developmental processes in both animals and humans, particularly during key stages of growth. In particular, laboratory experiments and observational studies of people increasingly linked endocrine-disrupting chemicals (EDCs) to a range of reproductive abnormalities, such as declining semen quality, undescended testicles and other genital abnormalities, endometriosis, premature breast development, male and female infertility, and increased rates of breast, testicular, and ovarian cancer (Crain et al, 2008; Fisher, 2004; Fucic et al 2012; Meeker, 2010; Meeker, 2012; Sharpe and Irvine, 2004; Sharpe and Skakkabaek, 1993)

The evidence also suggested that EDCs might behave very differently from other chemicals. They appeared to induce “low-dose effects,” which the National Toxicology Program defined as “those that occur in the range of human exposures or effects observed at doses below those used for traditional toxicological studies” (Vandenberg, 2012). Some animal studies also found low-dose effects even in instances where higher doses produced no effect at all or a different kind of effect. These findings of atypical dose-response curves flatly contradicted a maxim of modern toxicology, promulgated by the 16<sup>th</sup> century physician Paracelsus: “the dose makes the poison.” The regulatory system has long relied on the monotonic presumption that higher doses cause greater adverse impacts, and the new findings threatened to undermine the prevailing toxicology paradigm (Iles, 2007).

The 1996 publication of *Our Stolen Future*, an investigation of the impact of EDCs, brought national and international attention to the issue (Colborn et al., 1996; Krimsky, 2000), one of several factors leading to Congress’ decision later that year to mandate a screening program for endocrine disrupting chemicals (EDCs). Another key moment occurred in 2005, with the publication of the first study to find an association between fetal exposure to low doses of phthalates and reproductive abnormalities in male infants (Swan et al, 2005). The study found that pregnant women with environmentally relevant levels of certain phthalate metabolites in their urine were more likely to give birth to sons with a reduced anogenital distance and related abnormalities, all considered signs of incomplete development of the male reproductive system. These new endocrine-disruption toxicity findings added to the concerns about phthalates that had already emerged from the late 1990s to mid-2000s because of the first two streams of new scientific evidence—the NGO testing of consumer products and the large-scale biomonitoring studies.

As the scientific debate over phthalates and other chemicals developed through the mid-2000s, politicians in California began to address this issue and launched efforts to protect populations thought to be at greatest risk for exposure—women and children. A 2005 California bill required that cosmetics products sold in the state must disclose ingredients linked to cancer or birth defects, including phthalates. Heavy industry lobbying contributed to the defeat of an attempt in early 2006 to pass a statewide bill restricting phthalates in children’s toys. However, Fiona Ma, a member of the San Francisco Board of Supervisors, championed the issue at the city level and won passage of citywide restrictions on the sale of toys with phthalates—the country’s first such law. Ma followed the San Francisco victory with a successful run for state assembly, and in

2007 she sponsored a statewide measure based on the San Francisco model. By this time the measure had gained enough support to override industry opposition. After Governor Schwarzenegger signed the bill into law, California Senator Diane Feinstein promised to push the issue at the federal level.

External events, not just the raft of new scientific findings, also galvanized the political debate. In 2007, the discovery of leaded paint on toys imported from China forced leading manufacturers to recall millions of products. Pet food and toothpaste from China also came under scrutiny for possible contamination with toxins. These scandals generated enormous publicity, and public interest groups like Greenpeace pressured the federal government to bolster its regulation of consumer products. In 2008, Congress voted overwhelmingly for a bill that overhauled the CPSC. The landmark legislation, signed into law by President George W. Bush that August increased the agency's budget, expanded its workforce and strengthened its mandate. Tucked into the bill was a popular amendment restricting the use of phthalates in products for children, sponsored by Senator Feinstein and backed by leading environmental and consumer health advocates (Consumer Product Safety Improvement Act, 2008).

## NEWS COVERAGE and CIVIC EPISTEMOLOGY

Despite rapid changes in the media landscape over the past decade, major news organizations retain a prominent voice in public discussions over contentious issues. Stakeholders in these societal debates have significant interest in how issues are portrayed, and they often expend significant time and resources to influence those media portrayals. Analyzing the content of news coverage can therefore yield significant data about contesting perspectives, languages and images as news organizations gather, interpret and disseminate information. This investigation can take many different forms. Some studies have focused on news stories during a narrow slice of time to understand how the issues are being framed at a particular moment. Others have documented changes in news coverage across a longer period of time and have used quantitative approaches—such as whether articles are “positive” or “negative” in tone—to track the relationship of such changes to policy and political developments (Baumgartner & Jones, 1993).

Yet assessing how news coverage of a complex scientific issue changes over time does not always lend itself to such quantitative measurement. Environmental health scholars have called for greater use of qualitative methods, including media analysis, in environmental health research (Brown, 2003; Scammell, 2010). To assess changes in the news coverage of phthalates, the evolving concept of civic epistemology provides a potentially powerful framework. Jasanoff defined civic epistemology as “the institutionalized practices by which members of a given society test and deploy knowledge claims used as a basis for making collective choices” (Jasanoff, 2005). She used the concept to explore the differing political and regulatory responses of the U.S., the U.K. and Germany to the challenges posed by biotechnology, with each country pursuing its own methods of generating, assessing and acting upon evidence.

Adopting a civic epistemology approach means asking such questions as: How are issues identified as important and how are they granted access to the public and political agendas? What kinds of knowledge or scientific evidence are deemed authoritative and actionable? Who gets to create and interpret that knowledge for the purposes of policy development? Who is allowed to participate in the decision-making process, and how is that participation structured?

Iles deployed this approach to analyze the conflicts and debates over phthalates regulation, in the U.S. and Europe (Iles, 2007). He argued that environmental advocates seeking policy change created and publicized new approaches to research, and he described how those efforts helped generate shifts in social perceptions of the risks of phthalates. In particular, he traced how the three new streams of scientific evidence—the NGO-sponsored testing of toys and personal care products, the expanded biomonitoring studies, and the research suggesting adverse human health effects from EDCs—helped broaden public awareness of the argument that phthalates could threaten human health. He also explored differences in how the U.S. and Europe responded to the new developments in the science of human exposures to chemicals.

Iles noted that political entities and interest groups each practice their own versions of civic epistemology—that is, they support and promote particular understandings of what evidence is considered trustworthy and persuasive, what evidence should spark political and regulatory action, and what form that action should take. He also noted that “[m]ethodologies to trace civic epistemologies and their changes continue to develop,” citing various sources of evidence, including “the discourses that societal actors engage in, institutional proceedings and deliberations, consumer behavior in buying products, techniques for scientific and social data collection, and manufacturer responses to calls for regulatory action.” Iles did not address the role of the media in helping to document and track shifting civic epistemologies. This paper shows that news coverage can be an important source of such data. Moreover, since news organizations themselves act to shape as well as transmit the information they gather, they are also key participants in the creation of these civic epistemologies.

## METHODS

News coverage of phthalates was examined through a content analysis of articles from four major mainstream news organizations. To provide a counterpoint to the coverage from mainstream outlets, coverage from a news organization known for its conservative perspective was also analyzed. The four mainstream news organizations were the *New York Times*, the *Washington Post*, the *San Francisco Chronicle* and *USA Today*. The first outlet was chosen because it is widely known as the country’s unofficial “newspaper of record,” not only on politics and foreign affairs but on scientific issues as well; the second because it extensively covered, more than other news organization, the push for federal action in the late 1990s and 2008; the third because it included the most

extensive coverage of the San Francisco and California efforts to regulate phthalates in 2006 and 2007, respectively; and the fourth because it is the country's highest circulation newspaper and frequently covers environmental health issues. The *Washington Times* was selected as the fifth news organization because it is known for adhering to a conservative perspective in its news coverage as well as its editorial and opinion departments.

Articles were identified in two ways: first, by searching the LexisNexis Academic database, combining the search term "phthalates" with each news organization's name; second, by searching each news organization's online archives for the term "phthalates." The San Francisco Chronicle articles were available only through the news organization's online archives dating back to 1995 and not through LexisNexis; to maintain a consistent time frame across the news organizations, therefore, the sample was divided into those from 1995 to 2008, and from before 1995. Articles that appeared between 1995 and 2008 were used to track the changing civic epistemology of phthalates, starting from the NGO campaigns of the late 1990s through the adoption of the 2008 federal legislation. Articles from 1994 and earlier were used to establish a baseline of coverage from the era before phthalates emerged as a major political and public health issue.

The articles from 1995 to 2008 were reviewed, and duplicate stories, news summaries or digests, wire stories, and blog posts were excluded. Stories in which phthalates were only cited in a list of chemicals or mentioned incidentally in a story about something else were also excluded. (Since the *Washington Times* yielded a smaller sample, all articles that mentioned phthalates were included for the analysis.) Stories that included at least a paragraph of significant information about phthalates were included. The articles were first coded for publication, date, type (news, business, home/lifestyle, editorial, opinion, letter), and length. After the initial coding, the articles were reviewed again and coded for key themes related to the civic epistemology of phthalates.

In particular, the review focused on content related to: 1) three streams of scientific evidence (NGO-sponsored testing of toys and other consumer products, biomonitoring studies by the CDC and/or NGOs, and health studies of EDCs); 2) competing standards of scientific evidence among stakeholders, including differences in regulatory policy between the U.S. and Europe; and 3) success or failure in efforts to pass legislation restricting phthalates at the local, state or federal levels. The use of images and language evoking particular framings of the scientific evidence—whether by news organizations themselves or by stakeholders quoted in articles--was also noted.

The articles from before 1995 were reviewed separately. Since most included only brief or single mentions of phthalates, none were excluded on that basis. These articles were coded for date, type of story, and context in which phthalates were mentioned. The *Washington Times* articles were also reviewed separately.



## RESULTS:

### Baseline Results:

Of the five news outlets examined, only the *New York Times* and the *Washington Post* searches yielded articles from 1994 and earlier, with 49 and 17 items, respectively. The *New York Times* sample stretched from its first article, in 1929, to 1991; the *Washington Post* sample ran from 1971 to 1985. The first mention was in a 1929 article headlined “Sweet Smells are Classified” with the following subhead: “Perfumes and Scents From the Laboratory Now Rival Those of Nature With the List of Raw Materials Continually Being Expanded.” Diethyl phthalate was cited as one of a group of chemicals said to produce smells that “rival those of nature” (New York Times, 1929).

Most of the *New York Times* articles were financial stories in which phthalates were mentioned in their role as commodities needed for various industrial uses. Thirteen of the articles were from the war years of 1942 to 1945, with most mentions related to phthalates’ role as plasticizers in military production. Throughout these articles, phthalates were often mentioned only as one item in a list of chemicals. These articles addressed such issues as changes in chemical prices, chemical shortages, and newly issued patents. Typical coverage included this dispatch from 1967: “Monsanto said that, effective April 1, it would reduce the price of two plasticizers used as softeners in synthetic resins, diemethyl phtalate [sic] and diethyl phthalate, by 1 cent a month. The new price will be 21 cents in bulk quantities, “to meet competitive activity,” the company said” (New York Times, 1967).

Only seven of the *New York Times* articles mentioned phthalates in a negative context, all of them dating from the 1970s and 1980s. Two of them were letters to the editor (one from 1977, one from 1982) that included phthalates on their lists of worrisome industrial pollutants . In 1979 and 1980, phthalates were briefly mentioned in two long articles about environmental pollution (Brown, 1979; xxx); a 1991 article related to the environmental devastation wrought by the Persian Gulf War mentioned that two phthalates were found among other toxic substances in smoke from burning oil wells in Kuwait (Wald, 1991).

The only articles prior to 1995 that focused specifically on phthalates were from 1982 and 1985; both addressed concerns about DEHP, the phthalate that had been used in many products meant to be teethered by infants. Both stories mentioned rat studies linking the chemical to liver cancer; the second story ran with the headline “Cancer Risk Cited in Substance Used to Make Pacifiers” (New York Times, 1985). Unlike the earlier mentions of phthalates, these articles touched on a number of themes that appeared prominently in the later articles from 1995-2008: the widespread nature of human exposures to phthalates, the range of products containing the chemicals, and the difficulties in predicting human outcomes from animal studies. A member of the CPSC was quoted in the 1982 story stating that “we are particularly concerned about the long-term effect on small children since they are literally surrounded by the stuff.”

In contrast, the *Washington Post* articles from the 1970s and 1980s all covered phthalates in the context of growing concern about industrial pollution, starting with two 1971 articles headlined “Peril of Chemicals is Growing” and “Cancer Society, Labor Plan Study of Causative Agents” (Kohn, 1971; Sullivan, 1971). The first article focused on phthalates, in 1972, was headlined “Plastics Residues Found in Bloodstreams” and reported on research from the National Institutes of Health that found phthalates in the blood of laboratory technicians and patients, as well as on wildlife studies that found measurable levels in fish, mammals and other animals. The article cited “the completely unknown long-range health effects” of the chemicals and included a prediction from Warren Muir of the White House Council on Environmental Quality: “I know this is going to be a significant future issue...It’s potentially our next bad one,” he told the news organization (Kohn, 1972).

The sample also included a second article focused specifically on phthalates, from 1985, when the CPSC was considering reports that DEHP caused liver cancer in rats. The article stressed the ubiquity of phthalates in children’s toys, medical supplies and other products but emphasized caution in interpreting the data, as the headline made clear: “Concern Over Plastics Called ‘Premature’; Experts Say Cancer Risk from DEHP is Minimal” (Squires, 1985). Yet the article also mentioned that the chemicals are easily ingested or absorbed through skin contact and that they have been associated with other problems besides cancer, including birth defects and reproductive abnormalities in animal studies.

The early *New York Times* and *Washington Post* articles suggest that from the late 1920s through the 1960s, the public image of phthalates was limited, non-problematic and stable. Like other industrial chemicals, they existed solely as useful commodities or beneficial ingredients in consumer products--significant enough to merit periodic mentions in financial and chemical news but not to be singled out for broader attention. No one raised concerns about phthalates; no one questioned the scientific consensus that they were safe and served important functions. Regulation was not part of the discussion. NGOs were not generating their own science about exposures to phthalates.

The creation of the EPA in 1970, and the passage of the 1970 Clean Air Act and the Clean Water Act of 1972, marked important milestones for the modern environmental movement—and for the civic epistemology of industrial chemicals. The establishment of new political and regulatory structures to monitor the environment was a key plank in this new civic epistemology--an acknowledgement of the need for a greater range of scientific evidence and different ways to measure hazards and assess risks. The developments also signified the public’s increased anxiety about pollution and its growing interest in submitting industry and government actions and claims about chemicals, including phthalates, to enhanced scrutiny and oversight.

Both newspapers during this period no longer mentioned phthalates solely in an industrial, non-controversial context; articles began including phthalates as industrial pollutants, but most often as one in a list of chemicals of possible concern. Only

occasionally, as in the 1971 *Washington Post* article on phthalate residues in blood, and in the three articles on DEHP from the 1980s, did specific information about phthalates break through the larger debate about industrial pollution generally to become the primary focus of concern. For the most part, however, these chemicals had yet to emerge as a major issue in their own right on the public and political agendas, as represented by the coverage from these news organizations.

#### Coverage from 1995-2008

After the mid-1990s, news coverage on phthalates increased significantly. From 1995 through 2008, the four mainstream news organizations published 135 items with significant information about phthalates and the conservative news organization published 16 items mentioning phthalates, for a total of 151 items. The mainstream coverage included 22 pieces from the *New York Times* (19 articles, two editorials, and one letter to the editor), 36 from the *Washington Post* (32 articles and four letters to the editor), 52 from the *San Francisco Chronicle* (38 articles, five editorials, four opinion pieces from unaffiliated experts, and three letters to the editor), and 25 from *USA Today* (21 articles and four letters to the editor). The *Washington Times* published 16 pieces (10 opinion pieces, four short news item, one reported article and a letter to the editor).

TABLE: Stories by year and news organization

<b>Year</b>	<b>Total # Articles: 151</b>	<b>New York Times: 22</b>	<b>Wash Post: 36</b>	<b>SF Chronicle: 52</b>	<b>USA Today: 25</b>	<b>Wash Times: 16</b>
1995						
1996						
1997	1		1			
1998	10	3	6			1
1999	16	3	5	3	1	4
2000	6	2	1		1	2
2001	8	1	4	1	1	1
2002						
2003	6			3	2	1
2004	5		2	2	1	
2005	13	2	1	8	2	
2006	10	1	1	8		
2007	35	5	2	18	9	1
2008	41	5	13	9	8	6

There was a clear trend of increasing coverage between 1997, when only two items appeared, and 2007 and 2008, when a total of 76 articles appeared, most having to do

with the political efforts to legislate phthalate restrictions on toys. In between, there were smaller clusters of stories about the emerging scientific research and related news. Thematic results related to the how the four mainstream news organizations covered the changing civic epistemology of phthalates are discussed in three sections.

The first section documents how the news organizations reported on the three emerging streams of science: NGO-sponsored studies of chemicals in toys and personal care items, expanded biomonitoring studies, and new health research on EDCs. The second section documents how news organizations reported on competing standards of scientific evidence, including the differences between the U.S. and European approaches embodied in the precautionary principle. The third section documents how news organizations covered changes in public policy involving phthalates as activity moved from the local to the national level. Because the *Washington Times* coverage diverged sharply from the others, it is discussed in a separate section.

### 1) Emerging Science on Phthalates

From the late 1990s, news coverage of phthalates documented, in succession, all three streams of scientific evidence entering the public debate--consumer product testing, human biomonitoring, and health effects of endocrine-disrupting chemicals. By highlighting the role of environmental advocates in creating and interpreting the new scientific research, the coverage implicitly granted legitimacy and credibility to their efforts to push for tighter regulation of these chemicals.

#### Chemicals in toys and personal care products

Phthalates have been used in thousands of consumer and commercial products for decades, but the public remained largely unaware of the ubiquity of these chemicals until the late 1990s, when Greenpeace, the National Environmental Trust, and other environmental and consumer groups began to test children's toys, issued public reports about the levels of phthalates found, and petitioned regulators to take action. This new approach—measuring chemicals in products from well-known consumer brands that are sensitive to negative publicity--caught the attention of the press. News organizations were more than willing to name products reported to contain surprisingly high levels of phthalates in the NGO-sponsored research.

In its first sentence, a 1998 *Washington Post* story reported that “some of the country's most popular toys” contained “high levels of a chemical compound that is toxic and may cause liver and kidney damage” (Segal, 1998). In the second paragraph, the article mentioned Teletubby toys, “Pooh Baby 1<sup>st</sup> Blocks by Mattel Inc., and Mickey Mouse bibs made by Disney Babies and Evenflo Co.” The third paragraph noted that the toys contained up to 41% of phthalates by weight. A Greenpeace spokesman emphasized--and in fact exaggerated--the high phthalate content: “If you know that about half the weight of some toys are toxic, that's pretty incredible.” A story in *USA Today* from 1999

similarly emphasized the large amounts of phthalates found through product testing, noting that “the environmental groups identified 17 toys bought from major retailers with high levels of phthalates by weight, including a Winnie-the-Pooh bath toy (47% phthalates), a Barney’s Twinken squeeze toy (57% phthalates) and a Teletubby squeeze toy (54% phthalates)” (Manning, 1999).

The stories described in graphic terms the possible pathways of children’s exposure to these chemicals; stories routinely included references to children’s habit of mouthing and chewing on anything within reach. These phrases were used by advocates and researchers quoted in the stories as well as the journalists and headline-writers themselves. A *Washington Post* piece about how Mattel promised to remove phthalates from Barbie dolls and other plastic toys bore the headline: “Toys Safe to Melt in the Mouth?” (Mayer, 1999). In a 1999 *New York Times* story, a pediatrician stated: “Children come into my office with plastic dolls and toys they have literally chewed through” (Noble, 1999). And a 1998 article in the *Washington Post* quoted a Greenpeace spokesman: “There is enough science to say let’s not put this in children’s mouths...we shouldn’t turn infants into guinea pigs” (Berselli, 1998). The same article noted that phthalates “are added to plastic toys such as teething rings and pacifiers to make them soft and spongy and give them a chewy feel.”

The articles also documented the impact of this NGO advocacy science on corporate policy. After NGOs began testing toys in Europe and the U.S. and identifying high levels of phthalates, an industry spokesman dismissed the evidence as essentially irrelevant in a *Washington Post* article, stating that “the presence of phthalates in a product does not indicate exposure.” Yet the companies also recognized the power of the NGO campaign. When one industry source referred to it as embodying “the politics of fear,” it was an implicit recognition that appealing to concerns about the use of common items by a vulnerable population such as children could be an effective strategy for gaining public attention. In taking steps to remove phthalates from some products, industry representatives made it clear that they were doing so because of public questions rather than actual health and safety concerns.

Gerber Products’ chief executive officer stated, as reported in a 1998 *Washington Post* article, that the company was removing phthalates from some products “not because they are harmful but because there are some doubts and we build our business on trust” (Mayer, 1998). Similarly, in a 1999 USA Today story, a spokeswoman for the Toy Manufacturers of America attributed removal of phthalates from children’s products to “market forces” rather than concerns about safety, stating that “retailers pulled the products off the shelves because of demonstrations being made by Greenpeace and other groups” (Manning, 1999). One chemical company executive explicitly linked the toymakers’ decisions to news coverage, noting that “you don’t want to be on the front page of this particular issue.”

In subsequent years, when NGOs investigated the presence of phthalates in personal care products, news organizations again covered the issue extensively. In 2002, a *Washington Post* story was headlined “Beauty Coverup?: A Cosmetic

Ingredient is Linked to Animal Defects. Its Human Risks Are Less Clear” (Reid, 2002). The article reported that environmental groups were seeking to alert the public about the risks of phthalates in cosmetics, lotions, soaps, fragrances and related products; their campaign had already included taking out ads in both the Washington Post and the New York Times. An article in USA Today--headlined “‘Endocrine disruptor’ won’t be on the label; But avoiding chemicals is not impossible”--warned readers that “Fragrance...is included in ingredient lists as a catch-all term for dozens of chemicals, including phthalates” (Szabo, 2007)

News organizations again reported when major brands announced plans to remove phthalates from their products, and again reported corporate executives defending their decisions on market grounds, not safety concerns. An executive from one cosmetics maker told the *New York Times*: “We are reacting here to changing consumer trends and a changing regulatory environment...There is no body of evidence that says this particular ingredient is not safe in the concentration in which it is used in nail products” (Singer, 2006). The statement was an implicit acknowledgement of changes in the civic epistemology of the issue—the new evidence brought into the public arena by advocates was having an effect on corporate policy, even if not yet on the regulatory process.

In reporting on the hazards potentially posed by the phthalates in toys and other everyday goods, news organizations implicitly endorsed the notion that non-traditional science from non-traditional sources deserved a public airing and was relevant information for regulatory action and consumer decision-making. In naming companies and products, advocates were also pursuing the kind of market campaign designed to influence corporate policy (O’Rourke, 2005). A natural corollary of this kind of strategy is that naming well-known brands increases the likelihood of coverage by news organizations seeking to attract the public’s attention.

In 2006, the *San Francisco Chronicle* took that implicit endorsement of non-traditional science one step further by commissioning its own study of the chemical content of toys (Kay, 2006b). Citing widespread confusion about the new city law restricting phthalates in products for young children, the news organization bought 16 children’s items and had them tested for phthalates. (The law at that time also included bisphenol A, another endocrine disrupting chemical suspected of causing reproductive harms, so the news organization tested the items for that chemical as well.) Several products contained high phthalate levels, including a rubber duck from Walgreen’s that had 13 times the allowable levels of one phthalate.

The article also reported that most of the companies whose products contained the chemicals were not aware of the new San Francisco ordinance until contacted by the news organization, suggesting the critical role of the media in disseminating information. “The trouble is that no one knows for sure how many baby products contain the chemicals,” wrote the news organization. “Stores, many of which are still unaware of the pending ban, will be unable to decide what to take off the shelves because manufacturers aren’t required to disclose what chemicals go into a product.” While the article mentioned

that some evidence suggests that endocrine-disruptors could cause low-dose effects, a spokesman for the CPSC quoted in the story emphasized the currently regulatory approach, telling the reporter: “We have a saying: ‘The dose makes the poison’ We are not seeing a high dose of phthalates coming out of a product and into the body of a child” (Kay, 2006b).

Since the start of their campaigns to test consumer products for the presence of phthalates, NGOs aggressively sought media attention even as they were increasingly able to disseminate the findings themselves through online postings and social media sites. The evidence suggests that this public attention spurred action among major brands, like Gerber Products and Orly International, to reformulate products, even before the success of legislative efforts to restrict uses of the chemicals. Yet awareness of the issue remained less than universal among affected parties, as became clear when the *San Francisco Chronicle* performed its own tests and informed retailers of their findings.

### Biomonitoring and household dust studies

News coverage of the presence of phthalates in toys and other products focused attention on the potential hazards posed by commonly used items. But the ubiquity of actual human exposures to phthalates—as opposed to potential exposures—gained visibility in 2001, when the Centers for Disease Control released its first large biomonitoring study of multiple chemicals in a random sample of the U.S. population (CDC, 2001). In the study, almost all of the participants were found to have measurable levels of phthalate metabolites in their bodies—a fact widely noted in the news coverage.

In reporting on these scientific findings, news organizations helped to reframe perceptions about chemical pollution as not only “out there” in the environment (and consumer products) but now found—to a previously unknown degree—in our bodies. The news articles included potent language to position these studies as significant scientific developments. A *USA Today* story about the CDC’s 2001 biomonitoring report was headlined: “Pollutants? We’re soaking in them.” The subhead was: “Tests reveal chemicals are in Americans everywhere—long-term impact unclear” (Manning, 2001). An academic scientist quoted referred to the study as “a wake-up call”—a clear suggestion that the findings could potentially alert the public and force it to recalibrate its perceptions of how people are exposed to environmental pollution.

In a *Washington Post* story, Richard Jackson, the director of the CDC’s National Center for Environmental Health, which conducted the study, called it “a milestone in biomonitoring” and “revolutionary in terms of environmental health in the United States” (Brown, 2001). A subsequent *Washington Post* opinion column suggested that the CDC findings revealed a “chemical assault on our bodies” that called for “major alarm and major action” (Mann, 2001). An advocate, noting that chemicals like phthalates accumulated in women’s breasts, was quoted in the editorial declaring that breast-feeding, therefore, involved “downloading your personal toxins into your child.”

The news organizations also covered efforts by advocacy groups to conduct their own biomonitoring research. In 2003, the *San Francisco Chronicle* profiled Michael Lerner, a well-known Bay Area activist. He was also a participant in a study conducted by the EWG, Commonweal and Mount Sinai School of Medicine, in which nine individuals who were environmental and health activists, were tested for 210 chemicals, including metabolites from several phthalates. The study was specifically conducted, noted the article, “to put a human face on the problem of environmental contamination”—a goal clearly accomplished through the *San Francisco Chronicle*’s decision to write about Lerner and his response to his results (Rosen, 2003). After learning that evidence of 101 chemicals, including phthalates, were found in his body, Lerner summed up the emerging awareness about industrial chemicals that the biomonitoring studies were likely to produce: “I thought, ‘Not so many years ago, these chemical weren’t in the body. Now, every human being in America is carrying this body burden.’”

Similarly, news organizations covered the NGO-sponsored research of household dust. A *San Francisco Chronicle* story in 2005 covered an NGO study of dust from 70 households that reported high amounts of phthalates and five other classes of industrial chemicals. The story linked the chemicals to their presence in consumer and commercial products and suggested that even the most vigilant and pollution-aware parents could not protect their children from such exposures. Among those interviewed was an environmental advocate whose household dust was tested; she reported being “taken aback” by the chemicals in the dust because “we try to be really conscious in what we do, especially as new parents trying to protect our little girl” (Kay, 2005b).

In order to explain the findings of the biomonitoring and household dust studies, news organizations frequently noted that phthalates were ubiquitous. To reinforce that point, articles from this period sometimes included long lists of industrial and consumer products known to contain phthalates. A 2005 *USA Today* story noted that phthalates are present in “vinyl flooring, detergents, automotive plastics, soap, shampoo, deodorants, fragrances, hair spray, nail polish, plastic bags, food packaging, garden hoses, inflatable toys, blood-storage bags and intravenous medical tubing” (Weise, 2005b). A *San Francisco Chronicle* story the same year reported that phthalates were “used to soften everything vinyl, including flooring, raincoats, shoes and purses, tablecloths, shower curtains, upholstery, carpet backing, garden hoses and PVC water pipes” (Kay, 2005b).

The coverage reflected the challenge that the biomonitoring studies presented to industry interests. Whereas they had earlier argued that the presence of phthalates in toys and other consumer goods did not prove actual human exposure, they appeared to move the goalpost when addressing the new human biomonitoring findings, asserting that the presence of a chemical in the body does not automatically mean it is causing harm. Federal scientists issued similarly cautious statements about the limitations in current understandings of the health implications of the biomonitoring results, but to different ends. The federal scientists were seeking to place the exposure findings in their scientific context in order to prevent the public from drawing premature conclusions. Business interests were acting to shield their phthalate-containing products from consumer



fallout—since these products were now collectively implicated in the “toxic trespass” identified through media coverage biomonitoring. Now that widespread exposures had been demonstrated through several large-scale studies, they could no longer easily discount public concern about potential health effects, particularly in vulnerable populations such as children.

### Endocrine-disrupting chemicals

News articles also linked the issue of phthalates to the emerging science of endocrine disruption. In discussing the potential harms caused by phthalates, the articles from the late 1990s mainly referenced concerns about liver and kidney damage, and cancer in particular. By the mid-2000s, a substantial body of published research supported the EDC hypothesis and found that phthalates exhibited endocrine-disrupting properties, and news articles increasingly focused on the chemicals’ possible reproductive and developmental harms. In 2005, the first study to find an association between reproductive abnormalities in male infants and fetal exposures to phthalates—as assessed through measurements of phthalate metabolites in the urine of pregnant women—sparked interest among news organizations (Swan et al. 2005). The abnormalities included undescended testicles, a smaller penis, and a reduced anogenital distance—all considered markers of incomplete masculinization of the reproductive system.

News organizations noted that the new research found in humans the kinds of phthalate-induced reproductive changes previously found in animal studies. In a *USA Today* story about the study, one academic researcher called the findings “strong evidence in humans that this endocrine-disrupting chemical is associated with changes in boys.” Several months after the study was published, the news organization ran an extensive examination of the issue of EDCs, including phthalates, titled: “Are our products our enemy?” (Weise, 2005b) The story noted the significance of the recent study in providing evidence for human impacts. A CDC scientist explicitly cited the connection between phthalates and male reproductive problems: “The big concern of the phthalates is that they have anti-androgen activity. They get rid of things that are in the testosterone line, the things that make a man a man.”

The following year, the *Washington Post* also published a major look at EDCs, including phthalates, with the headline: “Inquiry Turns to Humans on Pollutant, Hormone Tie” (Fahrenthold, 2006). The story cited the 2005 infant boy study as “dramatic” and laid out the hypothesis in stark terms, quoting a research scientist stating that “there’s a lot of concern that a lot of chemicals to which we are exposed routinely, and without our knowledge, are interfering with the way hormones work.” The article noted the “wealth of studies in animals” but added that “the implications for human health are unclear.”

The *San Francisco Chronicle* did not cover the story as news, but the news organization published an opinion piece by the study’s senior author, Dr. Shanna Swan, then of the University of Rochester. In her opinion piece, published in January 2006, Swan linked her findings to the need for legislative action to restrict the use of

phthalates,, bolstering her argument by explicitly citing the three streams of evidence that were altering perspectives on the issue: the NGO reports of high levels of phthalates in everyday consumer products, the biomonitoring studies indicating widespread exposure to phthalates, and the emerging evidence of endocrine-disrupting effects in humans (Swan, 2006).

## 2) From Standards of Evidence to Policy: The United States vs. the European Union

A key difference in the civic epistemologies of environmental advocates and industry interests is their understanding of the appropriate standards of evidence to be used in assessing chemicals for the purposes of making policy or creating regulations. In particular, the debate revolves around whether the U.S. should move away from its traditional risk assessment approach and closer to the more precautionary approach being pursued in Europe (Schapiro, 2007). This tension between contesting paradigms played out in the news coverage. Many articles mentioned that the EU and/or individual European countries held chemical companies to a stricter standard and limited the use of phthalates in children's toys accordingly. In a 1999 *USA Today* article, a European environmental advocate noted that “the Europeans recognize a different standard for children's products... We think the standard should be that toys are proven safe, not that they should be proven unsafe” (Manning, 1999).

Some articles specifically mentioned the precautionary approach in discussing efforts to pass phthalates legislation in San Francisco, California and the U.S. Congress. When SF Supervisor Fiona Ma proposed her ordinance in 2006, she herself invoked the city's own precautionary policy, according to an article in the *San Francisco Chronicle*: “We have a precautionary principle here in San Francisco... If there's a possibility of harm or damage, then we should err on the side of caution” (Kay, 2006a). Senator Feinstein similarly told news organizations that her phthalate amendment to the CPSC overhaul legislation was the “first legislation of its kind... we are essentially able to establish precautionary standards” (Kay, 2008).

Few stories provided any details about the European approach or about its Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program, or focused specifically on developments abroad; in many of the articles, only a sentence or two touched on the differences between the U.S. and Europe. But those differences nonetheless warranted a mention, however brief, in articles from throughout the time period and about each of the new streams of evidence. Since the Europeans were far more aggressive in restricting phthalates, their example provided news outlets with a ready-made contrast, with the U.S. seeming lax by comparison--and many news outlets took advantage that opening.

A couple of pieces detailed a major consequence of such differential standards between Europe and the U.S. They posited that the U.S. would now be the repository—the “dumping ground,” as a 2008 *San Francisco Chronicle* editorial noted--for toxic products no longer sold in Europe (San Francisco Chronicle, 2008). That editorial, about

efforts by the Bush administration to weaken the impact of the recently enacted CPSC overhaul legislation, accused the government of seeking to “put toxic chemicals back in the mouths and bodies of the country’s young children...All so manufacturers can be assured that the U.S. remains a dumping ground for phthalate-ridden toys.”

These arguments in favor of shifting the civic epistemology of industrial chemicals in general, and phthalates in particular, toward the precautionary approach favored in Europe were challenged by corporate executives. In comments to news organizations, they questioned the relevance of the findings on toxicological and human health effects and they reasserted that the chemicals were safe. One argument was that any evidence of harm arose from studies in which laboratory animals were given much higher doses of phthalates than those to which humans are typically exposed, and that these studies therefore had little or no implications for human health. In a 1999 *USA Today* story, an industry researcher acknowledged that high exposures harm rats but noted that “the mechanism through which this effect occurs in rats and mice is not relevant to humans” (Manning, 1999).

Industry representatives also sought to reframe the issue. Representatives of the American Chemistry Council, for example, appeared to adopt what could be called a criminal justice paradigm for the defense of chemicals when they commented that no researchers thus far had produced evidence that constituted a “smoking gun” or “smoking guns.” In obvious contrast to the precautionary principle, such a metaphor would imply that the evidence must prove a chemical’s guilt beyond a reasonable doubt—as in a criminal prosecution—for regulation to occur. Industry interests did not themselves invoke the criminal justice paradigm, but an environmentalist made the association explicit in a letter to the editor. “That might be an appropriate defense for a criminal suspect, but not for chemicals,” he wrote.

### 3) Shopping for Political Success

After the biomonitoring studies and new findings related to endocrine disruption prompted widespread news coverage and added to the concerns already raised about phthalates in toys and personal care products, articles from the mid-2000s documented how multiple legislative venues took up the issue in quick succession and how politicians—two California politicians, in particular--capitalized on the new scientific evidence. The articles also framed the success at the city level as a boost to the growing political momentum as the debate expanded to California and then to the national level.

The California legislature failed to restrict phthalates in toys in early 2006, after heavy industry lobbying. The same year, San Francisco Supervisor Fiona Ma adopted the issue and successfully introduced a similar bill at the local level—and used that victory as a stepping-stone to higher office. According to a *San Francisco Chronicle* article about her sponsorship of the city measure, “Ma, a candidate for state Assembly, has promised to work on children’s safety issues if she is elected” (Kay, 2006a). The article noted that the current holder of the assembly seat, who was retiring, had voted against the statewide

phthalates regulation in the previous legislative session—suggesting that Ma’s leadership on the issue was one of her political selling points as a candidate.

A *San Francisco Chronicle* article about the passage of the state law in 2007 noted in its first sentence that the bill was expected to have a ripple effect: “One day after California became the first state in the nation to ban toys containing toxic plastic softeners, supporters of the measure announced plans Monday to help at least nine other states—and perhaps even Congress—enact similar laws” (Chorneau, 2007). The article quoted an environmental advocate: “We’ve been looking at this and saying, ‘If we can get this passed in California, can we get the ball rolling in these other states?’” It also noted that Senator Dianne Feinstein “wants to replicate the California prohibition nationally.”

These local and state legislative events generated significantly more media coverage in the *San Francisco Chronicle* than earlier news involving phthalates. A major reason is that a piece of legislation generates potential stories at multiple points along its path toward either victory or defeat, as opposed to the release of new research. The *San Francisco Chronicle*, for example, published 26 stories in 2006 and 2007, most of them related to the progression of city and state legislation. *The Washington Post* and the *New York Times*, along with the *San Francisco Chronicle* also published a significant number of stories about the 2008 federal legislation. All the editorials in the sample—two in the *New York Times* and five in the *San Francisco Chronicle*—were related to these legislative efforts.

A *Chronicle* editorial in support of the federal law—headlined “From the mouths of babes”—noted that in her Senate presentation about her phthalates amendment, Senator Feinstein “showed a slide of her communication director’s 8-month-old son sucking on his favorite book, which she described as ‘loaded with phthalates’” (San Francisco Chronicle, 2008). The editorial also noted that Senator Feinstein mentioned as well the *Chronicle*’s 2006 research on phthalates in toys bought in local stores. By invoking the baby and the *Chronicle* study in her presentation, Senator Feinstein was essentially endorsing the new civic epistemology of phthalates and the notion that non-traditional evidence had a role to play in the public debate over federal action—a point strongly disputed by industry and adherents of a different approach to chemicals regulation.

#### The Conservative Alternative: Coverage from the *Washington Times*

In contrast to the coverage from the mainstream news organizations, the *Washington Times* covered the issue largely through commentaries by outside authorities rather than through reported news stories. Of the 16 published articles, four from 1999 and 2000 were news round-ups that included brief items about European efforts to restrict phthalates in toys, one was a 2000 news article about advocates’ annual list of dangerous toys that mentioned phthalates in passing, and one was a letter to the editor.

The remaining 10 were opinion pieces written by outside commentators that all focused on the same theme—public concern about chemical exposures. These commentaries all adopted the industry perspective: that any such concern was due to flawed science, news hype, and over zealous politicians, and was not warranted by any of the scientific evidence. The commentaries bore headlines such as: “Setting off the toy shop alarm.” “Save plastic IV-bags so they can save you,” “Overstating the risks,” “Plastic hysteria strikes again,” and “Unfounded health scares” (Fumento, 1999; Milloy, 1999; Phillips, 2001; Ross, 2008; Whelan, 2008b). A commentary about the CDC’s first biomonitoring report, for example, noted that “unfortunately, some uninformed activists have misinterpreted this report—scaring people unnecessarily. They claim this report is sounding alarm bells and that we should all be afraid. This is simply not the case. In fact, scientists agree that minute amounts of substances—even those dubbed ‘hazardous’—can be absorbed into the body without causing harm” (Phillips, 2001).

In naming phthalates as one of the “top 10 baseless scares of the year,” a 2008 commentary argued that “there is absolutely no evidence that phthalate-containing products pose any risk to human health—but that did not stop California from banning most of these chemicals, and causing a nationwide panic... These claimed health risks are totally bogus and based on rodent data” (Whelan, 2008b). Several commentaries portrayed parents as credulous victims of manipulation. For example, another 2008 commentary noted that: “If you are a parent (or grandparent) of a young child, you are a target for manipulation by activists (some with scientific degrees) who claim we are surrounded by a sea of chemical ‘toxins’ and ‘carcinogens.’ You are easy prey—because you care so deeply about the health and welfare of your babies and children. Purveyors of unfounded health scares know that” (Whelan, 2008a).

In contrast to the coverage from the four mainstream news organizations, the *Washington Times* essentially declined to cover the scientific, regulatory or political developments as news. However, it found the issues of significant import to warrant publication of 10 commentaries articulating the business arguments. That this conservative news organization chose this particular method of covering the issue suggests that the other news organizations were also making choices of their own—albeit choices that implicitly challenged the regulatory status quo.

## DISCUSSION

Environmental advocates have long been frustrated at the haphazard nature of chemicals regulation and the difficulty in gaining enough public attention and political traction to effect policy change. News coverage has long been known to influence public and political agendas through the issues it chooses to focus on—or ignore—and how it chooses to cover them. Iles noted that methodologies for assessing changes in civic epistemologies are still being developed (Iles, 2007). This content analysis demonstrates that news coverage can be an effective and readily accessible source of data for assessing such changes. The current analysis examined decades of news coverage of phthalates, with a focus on coverage between 1995 and 2008, a period during which significant

policy and political changes took place. The analysis found that the news coverage: 1) documented new forms of scientific evidence entering the debate and contributed to increased public awareness and changes in the civic epistemology of phthalates, and 2) tracked subsequent policy developments sparked in part by those changes.

Prior to 1995, news coverage mentioned phthalates largely in passing, usually in the context of business news. As new concerns about industrial pollution entered the public debate in the 1970s and 1980s, early health concerns about phthalates received sporadic media attention. However, in the late 1990s environmental advocates generated new research on the hazards of consumer products—the first of the three new streams of evidence that sparked a wave of continuing coverage through 2008. During that period, the four mainstream news organizations examined here—but not the conservative news outlet—provided environmental and public health advocates with a public forum to air their concerns and to challenge corporate and government standards and policies. Just as advocates stepped outside their traditional advocacy roles in producing science, at least one news organization—the *San Francisco Chronicle*--adopted the NGO strategy of testing toys for the presence of phthalates and reported the results in a high-profile news story. In the new civic epistemology of chemicals regulation, even news organizations can become science producers whose impact is not only felt but cited as authoritative in the policy arena—as evidenced by Senator Feinstein’s public invocation of the news organization’s research findings.

Given the traditional U.S. regulatory focus on banning chemicals only after harms have been definitively proven, news coverage that addressed the emergence elsewhere of a competing standard—the precautionary approach, as evidenced in the E.U. adoption of its REACH regulations—also represented a significant challenge to the prevailing civic epistemology of chemicals regulation in the U.S. Articles frequently noted that the E.U. or individual European countries adhered to this more precautionary standard; a couple cited advocates’ provocative conclusion that the U.S. was becoming a “dumping ground” for products deemed unsafe in other industrialized nations. In contrast, industry representatives quoted in articles reiterated their adherence to the traditional U.S. approach, dismissing the new forms of scientific evidence as examples of “the politics of fear.” Industry interests demanded the level of evidence akin to a “smoking gun”—in other words, the proof beyond a reasonable doubt required in the criminal justice system.

Demonstrating a causal relationship between news coverage and subsequent real-world events is difficult. In rare instances, such as a *Chicago Tribune* investigative series on flame retardants last year that immediately sparked a range of policy responses, it is possible to draw such links (Cordner, Mulcahy, & Brown, 2013). In the case of phthalates, at least some shifts in corporate policy appeared to be directly linked to the public attention and news coverage that NGOs brought to the issue with their studies of phthalates in toys and personal care products. While corporate representatives referred mainly to “market forces” causing these shifts rather than concerns about safety, at least one mentioned that the prospect of “being on the front page” in the news about this issue motivated them to rethink their product formulation.

By 2006, the news coverage had largely explored the new streams of evidence and legitimized the role of non-traditional actors as producers of scientific knowledge. After that, coverage largely shifted to developments in the political arena. It is worth noting that legislative changes at the city, state and federal levels only occurred after all three new streams of evidence had emerged as important elements of the public debate, suggesting that all three were necessary to generate political movement. Moreover, it took as well the exogenous shock of the scandals over Chinese toys and other consumer products to galvanize broad-based action on the federal level. Senator Feinstein seized that moment to successfully advocate for restricting phthalates as part of the popular CPSC reform legislation, invoking non-traditional science to press her case.

Political scientists have long debated how policy change occurs in the U.S. and how advocates and other political actors can expand their bases of support, mobilize new audiences, and take advantage of political opportunities (Schattschneider, 1960; Sabatier, 1988; Baumgartner & Jones, 1993). For environmental and public health advocates, the current findings suggest that simply providing new and accurate information to the public might not be enough to effect policy change. Rather, targeting the prevailing civic epistemology—for example, through creating and promoting research that reframes perceptions about human exposures to chemicals, focusing on how the use of brand-name products might pose risks to vulnerable populations, and raising questions about standard approaches to toxicology and chemical regulation—can be an effective way to generate news coverage, capture public attention, and put pressure on corporate, regulatory and political decision-makers.

But the analysis also reveals limitations of relying on news coverage as a vehicle for carrying this message. News coverage tends to be sporadic and inconsistent, and is often restricted in scope and depth. Advocates can therefore find themselves in something of a Catch-22. Major news organizations remain central actors in shaping and reshaping the civic epistemologies of controversial issues. However, the imperative to attract a large audience can lead to gaps and distortions in their coverage, and therefore in the perceptions of the public and policy-makers. Advocates should recognize the presumptions and emphases of news coverage and find alternate channels to communicate more complex understandings of an issue.

In this case, the articles illuminated larger themes at play in shifting civic epistemologies—such as whether NGOs should be taken seriously as producers of scientific knowledge and whether governments should adopt a precautionary approach. Yet the coverage ignored many of the significant but harder-to-explain details and nuances involved in the actual policies and political decisions under discussion; they focused instead on aspects with more immediate emotional weight and attention-grabbing appeal. While the news coverage played a role in building momentum for policy changes, it did not deeply examine whether the policy changes proposed as legislation would be the most effective ones for addressing the serious issues raised.

For example, phthalates vary in their commercial applications as well as health effects, and environmental laws and regulations divide them into specific subgroups.

However, much of the news coverage lumped them into a single category without distinguishing among them. In addition, the media often did not clarify that the animal and human research causing the most concern about EDCs involved *in utero* and not post-birth exposures (Anway et al., 2005; Crain et al, 2008). In fact, the population considered most vulnerable to the effects of phthalates and other EDCs is believed to be fetuses, especially when exposed during critical but sometimes narrow windows of development during the pregnancy, not toddlers chewing on rubber-duckies. And most articles contained minimal discussion of concerns that phthalates, like other EDCs, appear to have atypical dose-response curves with dramatic low-dose effects (Vandenberg et al, 2012).

Moreover, the articles often referred to toys without identifying several key sub-categories considered separately in the various policies and legislative acts. These sub-categories included: 1) teething rings, pacifiers, and other items specifically designed for infants to put in their mouths; 2) bath and squeeze toys and other objects that infants and little children often put in their mouths but aren't specifically intended for that purpose; and 3) all toys for children under three that they were likely to put in their mouths. News articles often blurred these distinctions and rarely addressed their significance from either a scientific, public health or regulatory perspective.

The major limitation of this study is that it is based on a reading of stories from four mainstream news organizations and one conservative news organization—all with roots in the newspaper world. Social media and emerging platforms play a much greater role in the dissemination of information than they did in 1995 or even in 2008. These technologies have already influenced public opinion and policy developments in far-reaching ways not apparent from an analysis of mainstream news coverage. This study also did not consider the increasing use of new media by interest groups themselves—whether industry, NGOs, or others--to disseminate their own information unmediated by news organizations, which can also impact public opinion and policy developments.



# **The (Non) Regulation of Endocrine Disrupting Chemicals**

## **Conclusion**

This dissertation has examined efforts to confront a major environmental program in both the regulatory sphere and the larger public and consumer marketplace. The potential risks of endocrine disrupting chemicals became broadly apparent during the 1990s and emerged as a source of concern. Despite adoption of a federal mandate for the creation of an ambitious screening program, development of that program continues, but it is unlikely that any EDCs will actually proceed through the full range of testing before the 20<sup>th</sup> anniversary of the legislation in 2016. It is not surprising that the research and development of something as ambitious as the Endocrine Disruptor Screening Program takes time. But given the Congressional sense of urgency about the issue in 1996, it is likely that proponents of the underlying legislation did not expect the process to take this long.

Previous research on rule development at environmental and other federal administrative agencies has focused largely on whether stakeholders—and in particular industry—exert an undue influence on the process. For the most part, this research has not found that business voices appear to significantly influence the actual content of proposed and final rules. The research in this dissertation suggests that industry groups and representatives might also seek to benefit from procedural obstacles that delay rule development as well as from changes in the rules themselves. The findings also suggest that advocates can achieve policy change more quickly and efficiently by pursuing high-visibility, market-based strategies—but at the expense of broad-based, comprehensive protections.

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