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Body Burden Politics:
How Biomonitoring Data is Influencing Chemicals Governance in the U.S.

by

Bhavna Shamasunder

A dissertation submitted in partial satisfaction of the

requirements for the degree of

Doctor of Philosophy

in

Environmental Science, Policy, & Management

in the

Graduate Division

of the

University of California, Berkeley

Committee in charge:

Professor Rachel Morello-Frosch (Chair)

Professor Dara O'Rourke

Professor Richard Walker

Fall 2011

Abstract

Body Burden Politics: How Biomonitoring Data is Influencing Chemicals Governance in the U.S.

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Bhavna Shamasunder

Doctor of Philosophy in Environmental Science, Policy, and Management

University of California, Berkeley

Professor Rachel Morello-Frosch, Chair

This dissertation investigates how the proliferation of biomonitoring research in government, academic, industry, and advocacy arenas is influencing chemicals governance in the United States. Biomonitoring, the technology that allows for the measure of synthetic chemicals in human blood, breast milk, cord blood, and other tissues, has rapidly emerged as a valuable tool for assessing exposures to toxic chemicals. Still, it remains a contested science since many chemicals that can be measured have not been the subject of health studies and are not associated with regulatory benchmarks. Scientists from industry, advocacy organizations, and government arenas engage in heated debates about the implications of biomonitoring data for regulatory science. As biomonitoring technology has become more widely accessible, social movements have increasingly leveraged biomonitoring data to demonstrate the extent of toxic exposures.

Through interviews with a diverse array of scientists who utilize biomonitoring and case studies of the chemicals bisphenol A and chlorpyrifos, this dissertation investigates how biomonitoring data is influencing chemicals governance. It investigates the circumstances under which biomonitoring data has been successfully leveraged by social movements to compel product substitutions and chemical phase-outs. It also examines the ongoing challenges to deploying biomonitoring data towards systemic change, particularly in vulnerable communities such as workers and fence-line communities, despite extensive health evidence.

This dissertation adds to literatures in environmental justice, environmental health, chemicals governance, and science and technology studies, in order to better understand and therefore address the complex relationships among toxic chemicals, humans, and the environment.

**BODY BURDEN POLITICS:
HOW BIOMONITORING DATA IS INFLUENCING CHEMICALS GOVERNANCE IN THE U.S.**

BHAVNA SHAMASUNDER

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BODY BURDEN POLITICS: HOW BIOMONITORING DATA IS INFLUENCING CHEMICALS GOVERNANCE IN THE U.S.

Introduction

Thousands of unregulated and untested chemicals are circulated through United States commerce every day (Tickner et al, 2005). These chemicals travel from industrial sources and everyday products into unforeseen places such as remote ecosystems, wildlife, and human bodies (Cone, 2005). There is mounting evidence that exposure to many of these chemicals can lead to adverse health effects in animals and humans and toxic exposures can exacerbate already existing health problems in vulnerable individuals and communities (Morello-Frosch et al, 2011). The sheer numbers and enormous volumes of chemicals and the implications for the public health are a growing concern for consumers, environmental health and justice social movements, governments, academics, and many industries (Roberts and Langston, 2008).

In the 1980's, the Centers for Disease Control (CDC) began biomonitoring the U.S. population for accumulating synthetic chemicals as a part of the larger National Health and Nutrition Examination Survey (NHANES). Biomonitoring is the assessment of human exposure to environmental chemicals through the measurement of a chemical, its metabolite(s), or its reaction product(s) in human blood, urine, breast milk, saliva, or other human tissues (Needham, Calafat, and Barr, 2006). The CDC embarked on this national project by measuring a modest 27 chemicals in a national sample when they began publishing the *National Report on Human Exposures to Environmental Chemicals* in 2001. Now, the CDC has developed the analytical methods and laboratory capacity to measure for over 300 chemicals, with 212 of these chemicals measured in a cross-national sample of the U.S. population (CDC, 2009; www.cdc.gov/biomonitoring/index). More recently, as biomonitoring technology has become cheaper and more accessible (Namiesnik, 2000), a diverse array of scientists from advocacy organizations, industry, universities, and state and federal government have increasingly employed biomonitoring technology in research studies to better understand chemical exposures in diverse populations.

Most visibly, environmental health and justice social movements began using biomonitoring to better understand the extent of chemical exposures in the general population and in vulnerable groups and as a critique of chemical policy structures in the U.S., which allow untested chemicals on the market. Social movements began conducting small-scale biomonitoring studies that revealed hundreds of chemicals in a diversity of human bodies. Advocacy biomonitoring, as a social movement strategy, focuses particular attention on vulnerable populations such as pregnant women, newborns, and fence-line communities with the dual goals of broadening public understanding of widespread chemical contamination and to propel changes in chemical policy and regulation (Morello-Frosch, 2009). Environmental health and justice advocacy organizations across the country from Alaska to Maine, such as Commonweal (www.commonweal.org), Environmental Working Group (www.ewg.org), and Alaska

Community Action on Toxics (<http://www.akaction.org/>) have tested people living near toxic facilities and those who live far from any type of industry, demonstrating that everyone regardless of geography or social status is exposed to a mixture of untested chemicals, many of which show evidence of adverse health effects in animal studies. Advocacy groups have disseminated biomonitoring data through a host of strategies including informational websites, visually rich reports, and direct news releases through the popular media.

This dissertation investigates how the proliferation of biomonitoring research in government, academic, and advocacy arenas is influencing chemicals governance in the United States. There has been increasing academic focus in recent years on the burgeoning efforts by social movements and other actors to create new forms of regulation through multiple avenues, sometimes circumventing traditional government regulatory channels. The term “governance” and environmental governance in particular emerges from an interdisciplinary literature which investigates the strategies and resulting agreements that have cropped up in the context of significant social and environmental problems accompanied by weak or absent national regulations (Bernstein and Cashore, 2007). I use the term governance broadly to describe new forms of regulation by societal actors that include but are not limited to national or state governments, social movements, non-governmental organizations (NGOs), industry groups, and local governments who seek to influence or reform the existing chemicals economy and regulatory system. Governance could include voluntary regulation, public-private alliances in problem-solving, or new forms of multilevel policy (Biermann and Pattbert, 2008).

Biomonitoring produces new information about chemical exposures since the exposure is measured in bodies directly rather than in air, water or other media. It has led to social movement efforts to highlight the involuntary nature of “pollution in people” (EWG, 2006; Altman et al, 2008) and the harms from “toxic trespass” (Montague, 1998) with regards to human health and the environment. Industry groups have responded to these claims in numerous ways such as making changes to particular products and arguing that evidence of exposure alone does not imply harm to human health. I investigate whether and how new scientific facts about chemical exposures gathered through biomonitoring are being deployed to make changes to existing arrangements in chemicals governance in a variety of contexts, including industry practices, federal regulatory decision-making, and local and state governments with the potential to influence chemicals policy and regulation on the national stage.

Biomonitoring follows from a long history of efforts by social movements to challenge, contest, and infiltrate entrenched structures of scientific expertise in decision-making on issues such as facility siting, subsistence fishing, and illness-specific medicalized arenas such as AIDS, breast cancer, or asthma. These efforts seek to gain more power for involved communities, include local and alternative knowledge in the scientific enterprise, increase public participation, and ultimately alter scientific decision-making processes to include diverse and novel perspectives (Corburn, 2005; Epstein, 1998; McCormick, 2006). In the realm of environmental pollution, environmental health and justice social movements have created new scientific practices in order to gather their

own data in the face of government inaction or industry denial about pollution exposures. Famously, residents of Woburn, Massachusetts used environmental epidemiology to gather data and map a childhood leukemia cluster in their community that they linked to a contaminated well which had received little or no attention from regulatory officials (Brown and Mikkelsen, 1997). Their efforts brought local and federal regulatory attention to their small community and resulted in a famous lawsuit that raised national awareness of community efforts to fight toxic pollution. Social movements have also deployed new technologies to contest existing regulatory and industry science claims by collecting their own data. For example, environmental justice activists and residents of fenceline communities living adjacent to industrial facilities created the bucket brigade, an easy-to-use technology that captures local air samples. Community collected air samples through the bucket brigades provided evidence of lax regulatory air monitoring, demonstrated high levels of pollution in neighborhoods, and increased community knowledge of air quality regulatory standards while improving participation in the air monitoring process (O'Rourke and Macey, 2003).

Advocacy biomonitoring efforts follow from these traditions of contesting expert-driven scientific decision-making in the realm of toxics and pollution by seeking to spread information about pollution in human bodies. Biomonitoring originated as a technocratic tool in occupational health initially used by industry and government to test workers in factories for evidence of chemical poisoning (Sexton et al, 2004). Biomonitoring differs from other media sampling techniques because it is not a “lay” scientific technology where interested publics can be trained to capture samples; rather, it requires expertise. Biomonitoring entails collecting samples of human blood, breast milk, or tissue in ethical and medically appropriate ways and requires the use of laboratories with high-tech equipment that can analyze samples for contaminants. Unlike media sampling of air, water, soil or food, biomonitoring is incredibly powerful because it provides unequivocal evidence of human exposure and chemical uptake (Sexton et al, 2004).

Nevertheless, there are challenges involved in reporting biomonitoring data back to study participants since the ability to measure chemicals precedes knowledge of chemical health effects (Black, 2006). Since chemicals are allowed into commerce before they are tested, most chemicals that can be biomonitored have not been tested for their health and environmental impacts. The issue of communicating results to study participants is complex given lack of knowledge of health impacts and the lack of regulatory benchmarks for many measurable chemicals. Studies have offered guidelines for methods of ethical reporting, centering on individual and community involvement in discussions of biomonitoring results (Brody et al, 2007). The CDC national data set has also been utilized as a baseline against which to report smaller-scale or single chemical studies, so population-specific studies can be compared to a national average (Brody et al, 2007; Commonweal, 2007). Biomonitoring data is an accurate and valuable assessment of exposures that provides compelling information for scientists and the general public, but the complexities involved in collecting, interpreting and reporting study results to participants and the broader public means that biomonitoring is still an expert-driven and experimental science.

Biomonitoring data, while widely collected, debated, and discussed in environmental health and public arenas has yet to be incorporated into the regulatory science that provides the basis for policy-making (Jasanoff, 1995). In 2009, the Government Office of Accountability (GAO, 2009) released a report titled, *EPA Needs to Coordinate Its Research Strategy and Clarify its Authority to Obtain Biomonitoring Data* (GAO, 2009). This report found that the Environmental Protection Agency (EPA), the primary government agency responsible for national environmental decision-making had made only very limited use of biomonitoring data in risk decisions. The use of biomonitoring data was constrained by its limited availability (only 148 of the 6,000 chemicals the EPA considers the most likely sources of human and environmental exposure had available biomonitoring data), the challenge of linking exposures to a source, and limited understanding of whether exposures will lead to adverse health effects. Despite these limitations, the GAO chastised the EPA for not collecting and utilizing available biomonitoring data, for a general lack of coordination of federal biomonitoring research across government departments, and for failure to understand the extent of its own legal authority under the Toxic Substances Control Act, the main legislation guiding chemicals regulation in the United States. The GAO also suggested the EPA ask Congress for more authority to request biomonitoring data from companies if needed. To date, there is little public evidence the EPA has implemented GAO's suggestions and is utilizing biomonitoring in decision-making. The lack of incorporation into regulatory science to date undergirds many of the debates and conflicts about biomonitoring among scientists from different sectors—whether and how it should be incorporated into existing regulatory structures remains at issue.

Research Questions

Though U.S. government agencies have been slow to incorporate biomonitoring data in their decision-making processes, it has nonetheless become an important scientific tool utilized across sectors. This dissertation seeks to examine and understand the broader implications of the uptake of biomonitoring and the data produced through biomonitoring research by a diversity of sectors and actors, including chemical manufacturers, product retailers, advocacy organizations, academic scientists, government scientists, regulatory officials, and policy-makers, and examines how biomonitoring data is being deployed to influence chemicals governance broadly. My research is guided by three main questions:

How do scientists from diverse backgrounds and sectors frame and attempt to conscribe biomonitoring evidence? What is at stake in these debates?

Biomonitoring data has proliferated across sectors and though it is widely recognized as a valuable measure of chemical exposure, the meaning, significance, and interpretations of biomonitoring data remain contested. Public awareness of personal exposures has grown through media coverage of biomonitoring studies, particularly advocacy biomonitoring studies, and has led to rising public concern about possible actions to protect individual, household, and community health (MacKendrick, 2010; Altman, 2008). However, as biomonitoring data has proliferated, it has led to

negotiations and contestations among scientists from industry, social movements, and government about how biomonitoring data should be understood and ultimately utilized for regulation and policy-making. These scientific biomonitoring debates occur in narrow, expert-oriented arenas such as academic conferences, industry and government workshops, and the pages of peer-reviewed publications; but these debates are heated and the stakes are high, given that regulatory agencies are in the midst of figuring out how to incorporate biomonitoring into regulatory decision-making.

Studies of regulatory science have described how science can be strategically deployed as “apolitical,” hiding larger social, political, and economic goals (Jasanoff, 1996; Rosner and Markowitz, 1985). Second, scholars who have studied scientific contestation over issues such as tobacco and climate change have shown that despite overwhelming scientific evidence and agreement, industry is able to subvert science and engender public doubt about existing scientific data by sponsoring new studies and supporting media claims that the science is “inconclusive” (Oreskes, 2010). Third, environmental health social movements have become key players in scientific debates over biomonitoring alongside industry groups and regulatory scientists. The environmental sociology literature has described these types of organizations as “boundary movements” that straddle the divide between “expert” and “lay” and include many highly trained scientists in the quest to address environmental health concerns and push for interpretations of science that better incorporate lay experiences and interpretations (Brown, 2004).

Using data from semi-structured interviews with scientists from industrial, academic, advocacy, and governmental arenas and literatures from science and technology studies, environmental sociology, and social movement theory, I trace the context and content of scientific biomonitoring debates in order to examine how scientific evidence is framed for different audiences and with different social and political goals (Benford and Snow, 2000). I further examine how these discourses feed into larger efforts to influence the use of biomonitoring evidence in regulation and policy-making. Science and technology studies have described debates among scientists as “boundary debates”, which take place when “two or more rival epistemic authorities square off for jurisdictional control over a contested ontological domain” (Gieryn, 1999). In regulatory science debates over biomonitoring, scientists from different and sometimes opposite camps are “squaring off” for jurisdictional control over how biomonitoring data will be interpreted, understood and applied for regulatory purposes and in the policy arena.

How have social movements utilized biomonitoring data to push for changes to chemicals governance? Has advocacy pressure utilizing biomonitoring data had traction and, if so, in what ways and in which sectors?

Chemical manufacturers, product manufacturers, and retailers have been the consistent targets of advocacy biomonitoring studies and have seen the chemicals they make or the products they sell profiled in academic and advocacy biomonitoring studies. Consumers and the general public have responded to biomonitoring research with a range

of emotions and reactions, from anger to disbelief that they are not protected through government policies, and many people want to take personal actions to protect themselves, their families, and their communities (MacKendrick, 2010, Altman, 2008). Advocacy campaigns that directly target corporations or consumers through the market to directly push for changes to corporate behavior have proliferated in recent years. Called non-state market driven systems (NSMD) or civil regulation, they are defined as, “deliberative and adaptive governance institutions designed to embed social and environmental norms in the marketplace that derive authority directly from interested audiences, including those they seek to regulate, not from sovereign states”(Bernstein and Cashore, 2007). Environmental health advocacy groups have increasingly utilized market and consumer-driven strategies, with biomonitoring as an important form of evidence of chemical trespass, to push for corporate change. I examine how social movements structure their efforts to directly target the marketplace and corporate image by profiling particular chemicals, products, and companies and the role biomonitoring data may play in these efforts as a new form of scientific evidence about chemical exposure. I examine how industry, government, and academic scientists respond to advocacy biomonitoring, and whether and how these efforts have had traction towards changes in corporate behavior or other changes to chemicals regulation.

While efforts to reform chemical policy at the national level have stalled, environmental health and justice movements have pushed for regional, local and state solutions. These efforts have created a patchwork of chemical policy solutions but have also created space for changes to otherwise stagnant chemicals policies (Geiser, Tickner, and Torrie, 2009). Through interviews with legislative staffers and an examination of changes to chemical policies at local and state levels, I explore how biomonitoring evidence has been deployed towards regulatory and policy changes.

The effort to improve biomonitoring data itself has also been the target of statewide policies. In 2006, California became the first state in the country to establish a statewide biomonitoring program through Senate Bill No. 1379, now “Biomonitoring California”, largely through the efforts of environmental health advocacy organizations who had been conducting small scale studies and were able to argue for the public health benefits of statewide exposure data for more effective public health policymaking (oehha.ca.gov/multimedia/biomon/index.html). Government staffers have been working to implement Biomonitoring California over the last several years, despite California’s ongoing budget woes. The program was established in recognition of the valuable, state-level exposure data biomonitoring could provide and the benefits of community and geographic specific data (i.e. urban/rural). The Centers for Disease Control is also working to build capacity for state-based laboratory biomonitoring programs and in 2009 they awarded \$5 million to California, Washington, and New York to improve these states’ biomonitoring capabilities.

In addition, there has been a range of efforts by advocacy groups across the country to target specific chemicals in order to ban them in consumer products. For example, many states have banned phthalates and bisphenol A in children’s products and certain flame retardants have been banned in clothing as evidence of the build up in

bodies and information on the possibility of adverse health effects grow. Advocacy successes such as Biomonitoring California and various state bans on certain chemicals point to the possibility of governance efforts to circumvent lax national policies by pushing for changes at local and state levels.

What are the limitations and possibilities of biomonitoring for elucidating chemical exposures in diverse constituencies? In particular, how does biomonitoring data measured in vulnerable populations who are disproportionately exposed to environmental pollution compare to and illuminate exposures in the general population? What are the implications of biomonitoring measurements across diverse constituencies for regulation, policy, and social movement organizing around chemical exposures and contamination?

Biomonitoring studies by academic, advocacy, and government scientists have been conducted in a diversity of constituencies, such as fenceline communities, pregnant women living in low-income housing, farmworker families, children, and consumers. The Centers for Disease Control provides a national average for chemical exposures but constituency-specific measurements can elucidate the ways that chemical exposures can differentially impact various social, economic, and geographic spaces. Environmental health research on multiple, synergistic, and cumulative exposures shows that adverse health effects from disproportionate chemical exposures can be triggered or compounded by challenges of social stress, poverty, and racism (Morello-Frosch et al, 2011). While studies have focused on how vulnerable communities have fought and organized in the context of disproportionate chemical exposures and associated environmental injustices (Pulido, 1996), we know little about how chemical contamination varies across populations, in particular, how it maps onto processes of production, distribution, and consumption, thereby providing a more complete picture of how chemicals exposures influence social, economic, and health conditions across society (Casper, 2003). Biomonitoring evidence provides an opportunity to map chemical exposures across populations. And in doing so reveals the possibilities and challenges of biomonitoring data as a form of population exposure data and as an opportunity for improved cross-sector and cross-movement organizing on toxics.

Methods

To examine these questions, I utilized a qualitative mixed-methods approach using a combination of data from semi-structured interviews, document analysis, participant observation, and two chemical specific case studies, bisphenol A and chlorpyrifos.

Between January 2009 to August 2010, I conducted semi-structured interviews with scientists and other technical staff working in industry, government, advocacy organizations, and academia that utilize or conduct biomonitoring research in their work (n=42). Interviews were also conducted with industry trade associations, chemical manufacturers, consumer product manufactures, retailers, advocacy organizations, consultant scientists, regulatory scientists, and academics in order to provide a breadth of

understanding on the use and relevance of biomonitoring across sectors. Scientists were contacted through a purposive sample found through their published work such as peer-reviewed research, on-line reports such as white papers or advocacy reports, their visible involvement in state or national biomonitoring efforts, or coverage of their work in the lay or trade press. Industry scientists were contacted through government and industry sponsored national workshops that included biomonitoring as a topic in exposure assessment, risk communication, or biomonitoring interpretation. Industry contacts also included product manufacturers and product retailers, some of which had made public (through issuing a press release, for example) of substitutions of chemicals in their products or on their store shelves. Additional scientists were contacted using a snowball sample. Interviews were recorded, transcribed, and analyzed for relevant themes and key debates.

I analyzed semi-structured interview data by organizing interviews segments into codes. A coding structure was developed to reflect the format of the interview questionnaire using both top level and sub codes. Top level codes included characteristics of the interviewee with sub codes such as type of training (e.g. toxicologist, epidemiologist, etc.) and sector, details of how biomonitoring differs by sector (e.g. academia, advocacy, government, or industry), biomonitoring methods (e.g. sampling strategy, cost, etc.), how study results were interpreted, report back formats, case study by chemical (bisphenol A and chlorpyrifos), the practice of biomonitoring (e.g. dissemination of results to participants or to key stakeholders), and governance implications (e.g. regulatory, industry, or policy driven governance) (See attached coding themes page, Appendix 1).

In addition to interviews, I conducted document analysis for scientific and sector-specific conversations about biomonitoring and its meaning, significance, and interpretation. I examined biomonitoring debates and news stories in trade journals such as *Chemical Week*, in scientific publications where peer-reviewed biomonitoring research is published such as *Environmental Health Perspectives*, in the lay press such as the *Washington Post*, and in advocacy biomonitoring reports such as *Is It In Us?: Chemical Contamination in Our Bodies* (www.isitinus.org). Document analysis also included public records including public comments on regulatory decisions and whether and how biomonitoring data was used in making regulatory decisions, in particular for the case study on chlorpyrifos where extensive public comments were submitted by thousands of organizations in response to the chemical's re-registration by the Environmental Protection Agency in 2000. This analysis was conducted at the Environmental Protection Agency Public Information and Records Integrity Branch in Washington, DC in April 2010.

Between 2007 and 2011, I conducted extensive participant observation at meetings of the Scientific Guidance Panel of Biomonitoring California, a quarterly public meeting held alternately in Sacramento and Oakland (www.oehha.org/multimedia/biomon/index). I also attended Biomonitoring California convened workshops on public involvement, communicating biomonitoring data, and interpreting biomonitoring data.

Finally, to investigate questions 2 and 3 in more depth, a case study approach was utilized. An analysis of how biomonitoring data is being collected, deployed, and acted upon in the context of specific chemicals provided a nuanced analysis of the complexities involved in each chemical in a chemicals economy that examines one chemical at a time. Bisphenol A (BPA) was chosen as an important case for examining the role of biomonitoring in consumer and market-driven advocacy efforts. BPA has become an incredibly high profile chemical because it is ubiquitous in consumer products and it is known to leach from water bottles, baby bottles, canned food and other high profile consumer products. It has been measured in the bodies of over 93% of the U.S. population by the Centers for Disease Control, has been the subject of hundreds of academic and government studies revealing its adverse health impacts at very low levels of exposure, but as yet has not been regulated by the federal government (vom Saal and Myers, 2007; CDC, 2009). There has been a proliferation of advocacy and academic biomonitoring studies on BPA, and industry has been forced to respond in a variety of ways to health and exposure data.

The case of BPA was examined through semi-structured interviews with trade industry scientists, retailers, advocacy scientists, and academic scientists who work directly on the issue of BPA. In addition, I conducted document analysis and a media analysis of BPA news stories in the lay press between 2005-2009, when BPA stories reached their highest coverage in the lay press (source: Google News). Bisphenol A has also been one of the chemicals widely targeted by environmental health social movements in state-by-state campaigns to ban the chemical in consumer products, particular children's products. To examine this trend, I conducted an analysis of advocacy organizations' strategies to target chemical policies at the state level by examining advocacy campaigns that resulted in state-level policies curbing the sale of products with BPA. I analyzed trends in market, state, and federal action by examining changes that have been enacted for the chemical BPA, either through government policies or through corporate actions, in order to better understand how consumer/market regulations and government policies intersect.

Chlorpyrifos, an organophosphate insecticide, was chosen as a second chemical case study because it is *not* a consumer product that can be targeted through market efforts but is still measured as present in the bodies of 96% of the U.S. population through Centers for Disease Control data. Chlorpyrifos biomonitoring studies provide important data across diverse constituencies, illuminating the benefits and pitfalls of biomonitoring. I track chlorpyrifos biomonitoring studies through three constituencies—farmworkers, agricultural fenceline communities, and consumers—in order to better understand the implications of biomonitoring studies and data for each of these. Chlorpyrifos was discontinued as a consumer product under the names Dursban and Lorsban in 2000 but allowed for continued use in agriculture. Currently, 8-10 million pounds are applied to agricultural crops every year. Farmworkers and agricultural fenceline communities continue to be exposed to chlorpyrifos at levels far above the general population, illuminating the environmental injustice of chemical exposure distribution and chemical policies in the U.S.

Chlorpyrifos biomonitoring began in farmworkers in the 1970's through cholinesterase testing, one of the earliest forms of biomonitoring, which tests workers for neurotoxic responses to the chemical in order to remove them from the field. California was the first state in the country to adopt cholinesterase monitoring and has been followed by other states such as Washington in recent years. Cholinesterase monitoring is a voluntary state program to protect farmworker health, since the toxicity impacts of chlorpyrifos and other pesticides addressed through cholinesterase monitoring are well known. Advocacy and academic studies have conducted biomonitoring exposure studies in farmworker families and other communities living on the fenceline of intensive agricultural production. Academic studies have shown farmworker children to be exposed at high levels and vulnerable to neurological development problems. Advocacy organizations have used biomonitoring data as a powerful advocacy tool to profile and target pesticide drift, which exposes fenceline communities at levels far above the national average with little or no regulatory protections.

Finally, consumer biomonitoring studies have been conducted in children, college students, and pregnant inner-city women and their children, demonstrating the ongoing exposure to consumers as well as the disproportionate impacts in already marginalized communities. Peer-reviewed, advocacy, and government studies were examined across studied populations. A subset of the forty-two interviews included scientists who work on the issue of chlorpyrifos. Finally, public comments from the 2000 regulatory decision were examined at the EPA federal library to better understand what forms of science were used in the regulatory decision and whether or not biomonitoring data played a role in this decision.

The case study of chlorpyrifos biomonitoring also provides an important perspective on social movement challenges to pesticide organizing, even with respect to a chemical that is a well-recognized neurotoxin. Many social movements for workers rights, food justice, environmental health, and environmental justice have tried to take on pesticide contamination, focusing on issues ranging from worker poisoning to pesticide drift to pesticide residues on food, but there has been little systemic change in the extensive use of such toxic pesticides. Farmworkers and agricultural fenceline communities continue to be disproportionately exposed to a range of toxic pesticides, but biomonitoring data has demonstrated that consumers too, are chronically exposed to pesticide contamination through food.

I examine the history of social movement strategies, which have often resulted in fragmented and divergent strategies for addressing pesticide contamination, since pesticides impact a diverse range of constituencies. The regulatory apparatus is complex and fragmented, with government offices and regulations addressing pesticide exposure separated from structures that address pesticide exposures in consumers. The possibility of joint social movement strategies across constituency groups (e.g, environmental, health, labor and community-based groups) have been hampered by ideological differences and strategic decisions as to the best avenues to pursue changes to pesticide regulation. By tracking the movement of the chlorpyrifos molecule through human bodies

from workers and points of agricultural production in rural communities to consumers, biomonitoring data reveals potential opportunities for cross-movement organizing since it becomes clear that exposures of workers and rural residents continue to be linked to chronic pesticide levels in consumers.

Through these questions, interviews, document analysis, and case studies, this dissertation examines the existing and emergent role of biomonitoring exposure data for chemicals decision-making. These debates are ongoing and heated, with crucial implications for whether U.S. governance structures can keep up with emerging scientific evidence about widespread chemical exposures. Even more pressing is whether or not the U.S. will be able to protect its population from the myriad health challenges that have been associated with chemical exposures, an important question for the general public health in a time of mounting medical costs. Internationally, particularly in the EU, there is concerted effort to address widespread chemical exposures by enacting more stringent policies that are structured with attention to precautionary regulations, where the burden of proof lies on industry to prove their products are safe before they can enter the market, rather than allowing hundreds of untested chemicals on the market which can lead to unforeseen health problems. Programs such as REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) enacted by the European Union place the bulk of testing and transparency onus on product manufacturers. These types of policies have inspired environmental health activists in the U.S. (Vogel and Roberts, 2011), who recognize that the Toxic Substances Control Act is weak and outdated and are proposing new and innovative ways to transform U.S. federal chemicals policy.

CONTESTATIONS OVER TOXIC TRESPASS:
BOUNDARY MOVEMENT DEBATES ON THE HEALTH AND REGULATORY IMPLICATIONS OF
CHEMICAL BIOMONITORING

Abstract

The proliferation of biomonitoring evidence poses significant data dilemmas and policy challenges for industries that make or sell products containing chemicals that end up in human bodies. Leveraging strong moral and ethical discourses about uninvited “toxic trespass” environmental health and justice movements link biomonitoring evidence with a critique of the pervasive use of unregulated and untested chemicals. My analysis of these scientific and ethical debates regarding the meaning and significance of ubiquitous human exposures to environmental chemicals is informed by forty-two interviews with scientists and other stakeholders who produce or use biomonitoring data; participant observation in government and industry meetings; and content analysis of advocacy, peer-reviewed, and industry documents, media sources and organizational websites. I find that industry and regulatory scientists recognize that biomonitoring evidence triggers strong public and personal reactions unparalleled by other forms of human exposure evidence and are challenged to address the associated public outcry. Additionally, and with broader and longer-term implications, scientists from the advocacy, academic, government, and industry arenas are engaged in highly charged scientific debates about the meaning and interpretation of biomonitoring data with the ultimate goal of influencing how it is applied to regulatory science. In this process, moral and ethical debates regarding the failures of chemicals policy and regulation are generally subsumed into narrower questions of regulatory science. The outcomes of these regulatory debates, whether subsuming biomonitoring data into the existing risk assessment paradigm or leveraging public concern about toxic trespass to open up broader deliberations about chemical regulation and precaution, are particularly relevant to future understandings and management of toxic chemical exposures

Key words: biomonitoring, boundary debates, scientization, ethics, regulatory science

... I think the public views themselves as, you know, individually, as uncontaminated and pristine, and don't expect to have anything in their blood or their body tissues. The government—the governmental representatives in general, not the scientists, but the legislators, seem to have a general belief that most of us should have, you know, nothing in our bodies other than what “naturally belongs there.” And so we find things, and we tend to want to drive responses to them on what is largely an emotional level.....the idea that you would ban a chemical just because it is detectable, you know, is not very clear thinking.....I think that's really the core of the issue around biomonitoring is we need to find a way to interpret the results of biomonitoring studies in some sort of meaningful clinical way. And in an ideal world, you could actually tie the results to a known clinical effect.

Industry Scientist, July 27, 2009 (Personal Communication)

It's actually quite sobering to learn what chemicals you have in you and I think we've seen, somewhat universally, among individuals who get personally biomonitoring that they know to some degree of confidence that 'yeah, I know I'm going to have chemicals in my body, I'm prepared for that.' The actual numbers still kind of take them aback. ...the more information about it that gets out, the more people are concerned about it, the more they would like to see more discussion and reasonable solutions put forward to reduce the risk that chemical exposure has.

Environmental Health Advocate, May 6, 2009
(Personal Communication)

Introduction

Biomonitoring refers to the method and analytical technology that measures chemicals or their metabolites (breakdown products) in human bodies by testing blood, urine, fat, breast milk, or other human tissues. Biomonitoring has served as a government and industry tool in occupational settings for over a hundred years to assess workers' exposures to chemicals and their potential health effects (Sexton, 2004; Needham, 2008). The Centers for Disease Control has conducted chemical biomonitoring in a national sample for over three decades and currently measures the U.S. population for 212 different contaminants (CDC, 2009). Although not a new technology, access to biomonitoring has improved over the last decade through decreased cost, improved portability of the technology itself, and better detection capabilities, making biomonitoring an important and increasingly useful tool in the biological and environmental health sciences (Namiesnik, 2000). This has led to a proliferation of biomonitoring studies from academia, environmental advocacy organizations, and state and federal agencies. Advocacy organizations have also transformed biomonitoring into a social movement organizing strategy. Environmental health and justice organizations around the country have tested small subsets of high profile people such as legislative

officials or vulnerable populations such as newborns and wielded the results of biomonitoring evidence to demonstrate pervasive chemical exposures with the larger goal of improving chemicals policy and regulation. This wave of “advocacy biomonitoring” has moved biomonitoring beyond the domain of regulatory bureaucracy, surveillance, and scientific technocracy to mobilize more popular discourses about “toxic trespass” and “chemical body burden”. Environmental health and justice movements, through biomonitoring studies, have sought increased corporate accountability in production decisions, improvements to chemicals regulation and expansion of environmental and public health surveillance (Morello-Frosch et al, 2009).

California is the first state in the country to develop its own statewide biomonitoring program through legislation promoted largely by environmental health advocacy organizations (Senate Bill 1379; September 29, 2006). Some of these groups had been conducting their own small-scale biomonitoring in vulnerable populations such as fence-line residents living near pollution sources, newborns, and pregnant women. These small studies have found hundreds of chemicals in tested people and prompted arguments for the public health relevance of doing statewide biomonitoring to better understand chemical exposures in California. Biomonitoring legislation was introduced twice—the first time being vetoed by the governor in 2005 due to strong industry opposition and finally passing in 2006 to establish the California Environmental Contaminant Biomonitoring Program (CECBP), now renamed Biomonitoring California.

Industry opposition to biomonitoring in California was led by farm, chemical, and oil manufacturing industries which argued that the program might mislead people by overstating health risks to small levels of contaminant exposure. These groups also opposed proposals to fund the program through an additional sales tax on tobacco products and producer fees on industries that manufacture toxic products. Ultimately, funding for Biomonitoring California was slated to come from the state’s general fund. With the California budget in perennial crisis, however, none of this funding has materialized. Despite these resource challenges, Biomonitoring California has moved forward through the entrepreneurial efforts of staffers and successfully funded pilot biomonitoring studies with academic and independent researchers, raised federal funding from the CDC to enhance laboratory capacity to analyze samples, held regular meetings of the Scientific Guidance Panel (an expert scientific advisory group that guides decisions on chemicals selection) and sponsored several public workshops with scientific experts from throughout the country.

The contentious beginnings of Biomonitoring California have moved into debates and disagreements about the meaning, interpretation, and application of the biomonitoring data that will be collected. These debates have been carried out in multiple venues including peer-reviewed publications, trade journals, advocacy research reports, the popular press, and in an array of professional conferences and workshops sponsored by government agencies such as the Environmental Protection Agency and industry groups such as the American Chemistry Council. Whereas debates prior to the passage of California’s legislation often covered topics such as whether or not statewide biomonitoring was necessary in light of an existing federal program and the costs of the

program versus the potential benefits to public health, discussions now encompass issues such as biomonitoring and risk assessment, and how such data should be used in exposure assessment, regulatory decision-making, and chemicals policy.

In this paper, I argue that biomonitoring evidence is having a two-fold impact on chemical exposure debates. First, as a morally and ethically charged science, biomonitoring has forced industry to address public concerns about the chemicals in their products that end up in human bodies. Knowledge of bodily trespass impacts communities and consumers more personally than other forms of exposure evidence, such as media-specific monitoring of air, water or food. Scientists and decision-makers across sectors acknowledge the personal resonance of biomonitoring evidence. As knowledge of biomonitoring data becomes more widespread, industry has had to respond accordingly by addressing these concerns.

Second, industry is aware of the moral and ethical power of biomonitoring evidence but knows the real impact of biomonitoring will be determined by decisions in the regulatory arena. Regulatory science, the science used in regulatory and policy-making processes (in contrast to bench science) is a negotiated process (Jasanoff, 1993). It incorporates not only existing science, but issues such as economic feasibility and availability of chemical and product substitutes. Industry is concerned with the determination of how biomonitoring evidence will come to be incorporated into regulatory science, in order to guide standard setting for chemicals. For the chemicals that can be biomonitored, there are no longer debates among scientists, communities, or advocates about whether an exposure exists, since biomonitoring data is a clear measure of human contamination. Rather the debate has transformed to address the interpretation and use of biomonitoring data. Despite its proliferation, biomonitoring has yet to be extensively incorporated into regulatory science and policy-making, and it is still in open negotiation as to whether and how this evidence will be used.

The proliferation of biomonitoring research has triggered boundary debates, contestations, and negotiations among scientists as to how biomonitoring data should be applied and understood. This two-fold impact poses complex implications for ongoing public participation in chemical exposures discourses, with advocacy scientists continually forcing biomonitoring knowledge into the public realm through outreach and the media. Meanwhile, industry scientists push debates further into expert-driven arenas such as toxicology and risk-assessment, the frameworks that guide existing chemicals regulation. As Gieryn notes, boundary debates are ultimately about issues of power and authority, taking place when “two or more rival epistemic authorities square off for jurisdictional control over a contested ontological domain” (Gieryn, 1999). In regulatory science debates on biomonitoring, scientists from industry, advocacy organizations, academia, and government are “squaring off” for jurisdictional control over how biomonitoring data will be interpreted, understood and applied for regulatory purposes and in the policy arena.

On the one hand, biomonitoring makes exposure data personal, intimate, and broadly resonant with the lay public and communities fighting toxic exposures (Brody et

al, 2007; Altman et al, 2008). It proves we are exposed to an array of toxic chemicals. The lay public, community groups, and some advocacy and public health scientists are most concerned with *hazard assessment* which centers on assessing the presence of chemical exposures that maybe of human or animal health concern. For these groups, chemical presence in the body (potential hazard) is in itself scientifically meaningful and worthy of action. Nevertheless, biomonitoring requires expertise, and use of the technology depends on trained scientists who collect samples, analyze them in a laboratory, and provide numerical results that then must be interpreted, often not simply in terms of presence but in the context of risks posed to human health. This raises contrasting arguments related to risk assessment that center on deriving dose response curves to quantitatively characterize potential health risks of chemical exposures for specific outcomes or organ systems.

This clash of scientific perspectives about the meaning and application of biomonitoring is an expert-driven exercise that threatens to restrict debates about ubiquitous chemical exposures to the purview of technocratic decision-making. These scientific and regulatory debates play out in exclusive scientific sites such as peer-reviewed journals, expert workshops, and invitation-only industry meetings. While Biomonitoring California has attempted to address the paucity of public involvement, outreach has engaged primarily government, industry, academia, and environmental advocacy groups such as Commonweal, which was one of the primary sponsors of the biomonitoring legislation.

This situation highlights an important tension. Although biomonitoring data, particularly through advocacy studies and associated outreach, has led to increased public awareness about toxic trespass (Altman et al, 2008), the communities affected by contaminant exposures and consumers who are concerned about issues such as chemicals, foods, or personal care products ending up in their bodies have been largely excluded from scientific biomonitoring debates. Rather than facilitating more community-engaged discussions about the implementation of California's Biomonitoring Program, public meetings are largely structured as a series of scientific presentations on narrowly defined topics such as chemical selection, results communication, and biomonitoring methods development—issues that exclude involvement by non-scientific audiences, because of the level of expertise required for substantive and meaningful input.

The following sections place biomonitoring data within the theoretical literature on scientization of decision-making and how these debates play out in terms of stakeholder framing strategies regarding the interpretation of biomonitoring evidence. I then discuss my research methods, the points of scientific contestation about biomonitoring posed in the scientific arena, and the public outcry over body burden studies and industry efforts to curb public concern. Finally, I discuss the implications of these ongoing contestations for environmental regulation and chemicals policy.

Contested Moral, Ethical, and Scientific Discourses of Toxic Trespass

In 2008, the Coming Clean Body Burden Work Group, a national coalition of environmental health and justice organizations, and the Commonwealth Biomonitoring Resource Center published a report entitled *Is it in Us? Toxic Trespass, Regulatory Failure, and Opportunities for Action* (Commonwealth and Body Burden Work Group, 2007). This report began with the words, “What would it feel like to learn you are contaminated with toxic chemicals that permanently damage laboratory animals? What would it feel like to learn those chemicals come from shampoo, soda cans, baby bottles, and thousands of other products that you and your family use every day?” This report published the findings of an advocacy study that tested thirty-five participants across seven states for twenty toxic chemicals. Every participant had at least seven of the twenty chemicals in their body with all participants having the chemicals bisphenol A (a chemical in plastics) and PBDE’s (flame retardants), chemicals that have become high profile due to their ubiquitous presence in the US population and globally.

Using strong emotional, moral, ethical, and scientific language, scientists affiliated with environmental health organizations have used biomonitoring evidence to critique the failed chemical regulatory structure, profile problematic chemicals, and publicize corporate profiting from products made with contaminants that end up in people. Indeed, by chronicling the chemicals found in small high profile groups of individuals, Commonwealth, Environmental Working Group, and other advocacy organizations that have conducted biomonitoring studies made four important moves: 1) They brought to light the insidious trespass of several industrial compounds in human bodies and they put a public face on the statistics of exposure assessment (Washburn, 2009); 2) they embraced biomonitoring data as a scientific exposure tool to be used by the environmental health movement and worked with physicians and researchers affiliated with academic institutions to ensure the credibility of their data (Personal Communication, July 7, 2010; New York Times Advertisement, EWG, 2000); 3) they shifted the long-term focus of human biomonitoring from occupational exposures to exposures in the general public, breaking the assumption that people are primarily exposed in workplace settings; and 4) they demonstrated the ubiquity of the embodied exposure experience by showing how “pollution comes home and gets personal” and can affect anyone, regardless of income, occupation, or geography (Altman, 2008; Brown, Zvestoski, McCormick et al, 2004) .

The majority of scientists I interviewed agree that the use of human biomonitoring technology by environmental and health social movements has undoubtedly transformed how chemical exposure knowledge is deployed, used, and perceived by broader audiences. Additionally, most scientists noted that biomonitoring exposure data is likely to affect how we assess, understand, and regulate chemical exposures. However, since the scientific and regulatory role of biomonitoring remains contested in ways that will ultimately shape the larger-scale uptake of biomonitoring. Epistemic and methodological scientific arguments are employed in debates about how regulatory benchmarks should be determined and where they should be located. These are not questions from “objective scientific investigators”, since decisions about chemicals are often not about

knowledge of the chemical itself but about economic and social demands (Rosner and Markowitz, 1985), where actors are vying to define, constrict, and cement their particular interpretation of what the multiple chemicals found in human bodies might mean in terms of harm to health and the environment. Ultimately, scientists from different sectors are debating how chemical presence will translate into production processes, community right-to-know, and chemical regulation and, perhaps more importantly, whether or not measurable chemical exposures in bodies becomes a matter of routine acceptance or an important problem to be challenged and remedied.

Frame analysis, stemming from social movement theory (Benford and Snow 2000), describes how interest groups, particularly social movement actors, develop interpretative schemes (Goffman 1974) that allow diverse publics to understand social, in this instance scientific, phenomena in a way that makes them broadly meaningful (Snow et al. 1986). Collective action frames are developed to “mobilize potential adherents and constituents, to garner bystander support, and to demobilize antagonists” (Snow and Benford 1988; Snow & Benford, 1992). Effective frames are those that are salient in potential adherents’ and constituencies’ life experiences (Kubal 1998; Snow and Benford 2000). Scientists from environmental health organizations (advocacy or public health scientists) use biomonitoring technology to employ collective action framing that highlights the failures of current chemicals policy. These frames are grounded in both scientific and moral arguments: the moral frame asserts that “toxic trespass” is involuntary and unjust and the scientific frame asserts that chemical body burden from multiple contaminant exposures is likely to affect population health adversely. Conversely, industry constructs its own frame regarding biomonitoring evidence, asserting that the mere presence of chemicals in humans and the environment does not necessarily imply harm and that interpretation of potential health effects and regulatory action to reduce exposures must be firmly based on quantitative assessments of risk that are grounded in established methods.

These debates about the meaning, interpretation and regulatory implications of biomonitoring are unfolding in an era of increasing scientization of policy-making, particularly in the realms of the environment and public health (Morello-Frosch 2006; McCormick, 2006). “Scientization” is the process by which questions are posed to science that science alone cannot answer and solutions offered are technical rather than social. These include moral and ethical dilemmas emerging from the scientific enterprise (Zavetoski et al, 2004). As science and technocratic decision-making increasingly shape social policy and environmental regulation in the United States, environmental health, environmental justice and industry stakeholders have leveraged data and contested scientific evidence each to advance their interests. Indeed, scientization reveals how scientific knowledge is produced, synthesized, translated, disseminated and framed into authoritative narratives that have resonance in the policy-making and regulatory arenas (Backstrand, 2003).

Scholars in science and technology studies generally portray scientization as a bimodal struggle between so-called experts and lay citizens, where the power and authority of expert knowledge prevails over the concerns of communities (Bimber and

Guston 1994). Indeed, Sheila Jasanoff (1996) points out that when policy decisions are made based exclusively upon scientific evidence, concerns about equity and power normally attached to decision-making are marginalized. However, contestations regarding the scientization of decision-making also occur among scientific experts themselves, who often represent diverse sectoral interests (e.g., health advocates, industry and government). This is the case regarding debates over the implications of biomonitoring evidence for environmental policy and regulation. Indeed, scientists affiliated with environmental health organizations argue that the insatiable quest for “better science” in decision-making is used to support dominant political and socioeconomic systems by slowing down policy-making, precluding precautionary action to protect public health, and ensuring regulatory paralysis through (over) analysis (Morello-Frosch, 2006). Nevertheless, in order to make regulatory decisions more credible, regulators call on science (Jasanoff, 1990). Unfortunately, emergent science can be so uncertain that regulatory decision-making and policy changes are mired in negotiations that are very slow or not forthcoming at all. Meanwhile, experts continue to debate the nuts and bolts of the issues with the goal of creating boundaries for how the science should be used and understood (Gieryn, 1999). In the process, debates regarding the costs and health risks of multiple chemical exposures become dominated by scientific experts who ensure that battles over policy remain “objective” and divorced from their socioeconomic, moral and political contexts. This phenomenon serves to slow down regulatory oversight of industrial production in ways that promote the interests of industry and the state over those of consumers, workers and the broader public (Jasanoff 1987; Beck 1992).

The scientization of policy-making entails endless debates over what counts as science and what falls outside of the scientific realm. Scholars of science and technology studies have articulated the ways that scientists engage each other and the lay public through power struggles to demarcate the boundaries of science from non-science and “real” science from policy-relevant science (Gieryn, 1983, Jasanoff, 1987). The boundary between science and non-science is disputed, as people struggle over the resources and authority that accrue to science. Scientists continually engage in ‘boundary-work’ to maintain control over the legitimacy, authority, and resources of the scientific enterprise (Gieryn 1983; Gieryn 1999). From this boundary-work perspective, debates over scientific authority in policy-making result from efforts by scientists to legitimize their own authority and by policy-makers to use scientific authority to justify and buffer fall-out from regulatory decisions. Both of these types of boundary-work can expel alternative moral and ethical perspectives from scientific deliberations about regulatory implications of biomonitoring evidence. Moreover, when the public notices that science can be both contested and uncertain, there is an erosion of legitimacy of expertise as well as a fundamental questioning of the legitimacy of the scientific enterprise itself (Backstrand, 2004).

Although community-based and “lay” groups have not typically conducted biomonitoring research, they have collaborated with environmental health and justice organizations that have the scientific capacity to conduct their own biomonitoring studies. These groups can be considered “boundary movement organizations” because they seek

to gain power and authority by blurring the lines between scientist and advocate (Brown et al, 2004). Environmental health movements straddle the divide between expert and lay persons and push the scientific enterprise to meet the needs of their constituencies, address their movement's health concerns, democratize information, and interpret scientific findings in more socially relevant ways (Brown, 2004; Epstein, 1996; Corburn, 2005; Altman, 2008). Their biomonitoring studies entail collaborative partnerships between communities, scientists, advocates, certified and laboratories. They often follow academic review board (IRB) protocols. However, unlike groups that leverage scientific knowledge in combination with their situated perspective by being linked to a particular illness such as AIDS (Epstein, 1996) or to a particular geographic location (Brown and Mikkelsen, 1997), environmental health organizations such Commonweal and Environmental Working Group use biomonitoring to demonstrate that everyone is impacted by chemical pollution. Advocacy organizations also assert that although pollution in bodies can affect everyone, attention should be paid to the experiences of vulnerable and marginalized groups (Altman, 2008). Community-based organizations, such as Alaska Community Action on Toxics, have collected and used biomonitoring data as one tactic in a larger fight for environmental, social, and political justice to address the contamination of Native American lands and food by from military bases, former industrial sites, and the global movement of persistent chemicals.

It is not only environmental health organizations that operate on knowledge borders. Symbolic objects themselves can be enrolled in larger social and political projects. In this context, biomonitoring data can be understood as a “boundary object” that is interpreted and adapted according to the needs of those using it while maintaining a common identity across sites. Scientific boundary objects can have different meanings in different social worlds, while satisfying the information requirements of each of them. In this way, these objects are recognized, translatable, and coherent across different social worlds (Leigh Star and Griesemer, 1989). This quality as a boundary object is what gives biomonitoring data power and leads to scientific conflicts and boundary debates. For example, biomonitoring data collected by the Centers for Disease Control are considered to be the “gold standard” of human chemical exposure assessment by most scientists across sectors (i.e., industry, government, environmental health advocacy organizations) (Personal Communication). These data are made available to the scientific community and the broader public as a government report entitled the *National Report on Human Exposures to Environmental Chemicals* with tables, statistics, and chemical information (CDC, 2009). Yet, how these data are used to understand the distributions of chemical exposures among diverse populations and their potential health implications is contested among scientific experts.

For example, the organization Pesticide Action Network North America (PANNA) has translated CDC data to highlight that Mexican Americans carry some of the heaviest pesticide body burdens nationally. PANNA interpreted the CDC data for their constituency base and emphasized biomonitoring data as evidence of disproportionate environmental exposures. Their report, titled *Chemical Trespass: Pesticides in our Bodies and Corporate Responsibility* was published for community information as well as for organizing purposes to call for regulatory and corporate action

(Schafer et al, 2004). As a boundary object, advocacy groups can deploy biomonitoring data as form of “data judo”, where scientific research is used to make connections between corporate responsibility and regulatory failure while aiming to make policy change (Morello-Frosch, 2009). Conversely Dow AgroSciences, the maker of the insecticide chlorpyrifos, the chemical profiled by PANNA in their report, writes on their website, “[Biomonitoring] if appropriately conducted and interpreted, can provide important exposure information for regulators and public health officials..... It is regrettable that activists are misrepresenting data issued by the CDC and creating confusion among people and health professionals” (DowAgrosciences www.dowagro.com/chlorp/na/rpa/biomon, accessed April 22, 2011). PANNA highlights exposures as a potential health hazard because chlorpyrifos is a known neurotoxin and their constituencies are disparately exposed to the chemical. Dow, however, argues that highlighting exposure serves to confuse the general public and that there is no scientific evidence of adverse health impacts from the exposure. As a boundary object, there is widespread agreement that CDC biomonitoring evidence provides valuable human exposure data but how that data is interpreted, used and applied for regulatory and policy purposes is hotly contested.

Undergirded by scientific evidence, environmental health social movements are fundamentally arguing for new institutional arrangements that are embedded in principles of justice and human rights that will take up “the task of divorcing our economy from its current dependencies on chemical toxicants that are known to trespass inside our bodies, without our consent, thus violating, as some have argued, our security of person” (Shostak, 2004; Steingraber, 2009). Advocacy biomonitoring has propelled environmental health social movements forward by enrolling growing numbers of aware consumers, citizens, and communities concerned about the thousands of untested chemicals allowed on the market (Morello-Frosch, 2009; Montague, 1996). They can be considered a form of social protest, raising important moral issues and encouraging questions about the chemicals economy and chemicals regulatory system (Jasper, 1999).

In this study, scientists across sectors with a diversity of training and backgrounds noted that biomonitoring data triggered a range of emotional and ethically driven responses. Biomonitoring evidence elicits a cascade of follow-up questions such as: *Should chronic human exposure to contaminants be normalized unless scientific evidence shows harm? How do we ensure that vulnerable populations such as children or workers are adequately protected from exposures?; How much exposure is too much, and how do we account for chronic exposures to multiple contaminants?; How do we communicate to individuals and the broader public the meaning of biomonitoring data when the health implications and main sources of exposure remain unclear, especially for emerging contaminants?* These questions challenge how we should address toxic chemical exposures through standard setting or use restrictions and bans. They also highlight pervasive tensions between public right-to-know about bodily trespass versus the capacity to act to reduce exposures. Industry and advocacy scientists differently frame their responses to these contestations with advocacy scientists often supporting precautionary action and hazard based approaches to chemicals management which would fundamentally restructure chemicals regulatory systems while industry scientists

commonly support the existing risk based approaches to chemicals management. The following sections detail the extent and specifics of the scientific contestations about biomonitoring and whether and how it should be incorporated into regulatory science and policy-making.

Methods

I utilized a qualitative mixed methods approach to examine the public response to biomonitoring data and conflicts over the meaning and interpretation of biomonitoring data among scientists. I conducted forty-two semi-structured interviews between January 2009 and August 2010 with scientists and associated staff from academia, advocacy organizations, state and national government, industry associations, product manufactures, retailers, and chemical companies who conduct biomonitoring or use biomonitoring data in their work. I contacted scientists through a purposive sample based on peer-reviewed published research, coverage in the media about biomonitoring, or from other published data such as white papers or government reports that indicated their involvement in biomonitoring debates. I also contacted a purposive sample of scientists involved in Biomonitoring California, the first statewide biomonitoring program in the country. In addition, I made contacts with scientists nationally at government and industry sponsored meetings. Additional scientists were contacted using a snowball sample. To understand public response to the proliferation of biomonitoring, I examined the lay press for biomonitoring news stories and included interview questions about interviewee's experiences with public response to biomonitoring data, communicating biomonitoring data to the lay public, and responding to public concerns.

Interviews were recorded, transcribed, and analyzed for patterns using qualitative analysis coding to assist with data interpretation. A coding structure was developed to reflect the format of the interview questionnaire using both top level and sub codes. Top level codes included characteristics of the interviewee with sub codes such as type of training (i.e., toxicologist, epidemiologist, etc.) and sector, details of how biomonitoring differs by sector (i.e., academia, advocacy, government, or industry), biomonitoring methods (i.e., sampling strategy, cost, etc.), how study results were interpreted, report back formats, case study by chemical (bisphenol A and chlorpyrifos), the practice of biomonitoring (i.e., dissemination of results to participants or to key stakeholders), and governance implications (i.e. regulatory, industry, or policy driven governance).

Between 2007-2011, I conducted extensive participant observation in public and academic meetings. I attended industry workshops about biomonitoring and chemicals exposure assessment and meetings of the Scientific Guidance Panel of Biomonitoring California, a quarterly public meeting held alternately in Sacramento or Oakland, California (www.oehha.org/multimedia/biomon/index). I also attended Biomonitoring California convened workshops on public involvement, communicating biomonitoring data, and interpreting biomonitoring data. Finally, I conducted document analysis of the trade press, advocacy biomonitoring reports, government reports, and peer-reviewed publications.

Scientific Contestations about the Use of Biomonitoring in Regulatory Science

...The ultimate goal really is to enable the biomonitoring data to be used as an input into risk assessment or risk management evaluations, and perhaps as a tool for prioritization amongst the multiple chemicals and issues that people, who are in a regulatory risk management, risk environment face.....We think that the BE's [biomonitoring equivalents] provide a practical tool that really can increase the value of the chemical biomarker data, both in terms of prioritization of risk assessment and risk management efforts and to inform resource allocations for the next generation of research.

Dr. Lesa Aylward, Summit Toxicology on the use of Biomonitoring Equivalents (BE's). Presentation at public workshop of Biomonitoring California, "Understanding and Interpreting Biomonitoring Results", Oakland, CA, March 17, 2011

I don't say you shouldn't use your Biomonitoring Equivalents. I mean, I think that they offer a preliminary benchmark. And as we say, you know, if it's worth doing, it's worth doing badly. But it requires some caveats, I think, to be clear and honest with folks about what you can and can't say with reasonable confidence. And you know, and I mean measurements have the appearance of precision. And I think it's hard not to convey this single- the confidence that it does of a single point value. So, I don't know whether you want to try to convey a cloud rather than that, giving some representation of uncertainty about the reference range..... I mean it's nice to have this nice X you know but maybe that's not—maybe if reality is a cloud, maybe you can make some other representation of it.

Dr. Dale Hattis, Clark University. Presentation at public workshop of Biomonitoring California, "Understanding and Interpreting Biomonitoring Results", Oakland, CA, March 17, 2011

Biomonitoring is, in some ways, almost beyond the downstream end. It's sort of after we've failed, you know. We have contamination in people. And our interventions, our public health interventions, should be before we get to that point..... I mean, we have perhaps, what I might call, gratuitous exposure in toxicity, I think, in some of the products, where we don't really need to have the exposure. We don't need to have the toxic substance. Maybe we can think of ways to measure that and move toward that.

Dr. Amy Kyle, University of California, Berkeley. Presentation at public workshop of Biomonitoring California, "Understanding and Interpreting Biomonitoring Results", Oakland, CA, March 17, 2011

On March 17, 2011, Biomonitoring California held a public workshop titled, "Understanding and Interpreting Biomonitoring Results" (OEHHA, March 17, 2011). The goal was to bring together scientists from academic, industry, and government sectors to discuss the challenge of communicating biomonitoring results, addressing multiple chemical exposures, and interpreting biomonitoring data. The three scientists quoted above were the lineup of speakers to discuss interpreting biomonitoring results and each of their talks provided a different frame on the potential uses of biomonitoring data to benefit public health. While each scientist framed their comments differently, much of the debate pivoted around whether and how biomonitoring might fit into the existing practices of risk assessment and risk management, the guiding tools for chemical decision-making by regulatory bodies such as the US EPA and Cal-EPA which must

establish exposure standards based on the estimated risks that chemicals pose for the environment and human health.

The three speakers at Biomonitoring California reflect the multiple framings of national and international debates about the potential applications of biomonitoring for regulatory science and decision-making. As biomonitoring has proliferated, scientists across sectors agree that this data will become increasingly relevant for exposure assessment and must somehow be incorporated into chemicals regulation (Personal Communication). How this will happen and what it will look like is at issue. I demarcate the key conversations scientists are currently engaged in about biomonitoring data and its potential application, pitfalls, and benefits. I first trace the scientific debates as they have narrowed to address issues such as the role of biomonitoring in risk assessment, interpretation of health implications and the challenges of limits of detection. I then turn to public responses to biomonitoring data, detailing the ways in which industry and regulatory agencies have responded to public concern and environmental health advocates. I conclude by discussing the implications of these contrasting debates for regulatory science and policy-making.

Meanings and Interpretations of Biomonitoring Data for Regulation

Hazard-based versus risk-based applications of biomonitoring data

Scientists widely agree that biomonitoring evidence improves our understanding of chemical exposures. There is less agreement on how an improved understanding about *what* we are exposed to translates into concrete actions about *what to do* about these exposures. Chemical exposure in the U.S. is regulated through a risk-based approach. This entails assessing the probability that a person will be harmed or will experience an adverse health effect if exposed to a chemical hazard. Risk assessment was developed in the 1970s and 1980s to systematically evaluate the degree and likelihood of harmful side effects from products and technologies. In terms of chemical regulation, risk assessment uses biostatistics, toxicology and other epidemiological evidence to characterize the probability that a chemical exposure will result in harm to human health.

Risk assessment generally consists of four parts: characterizing what is known about the health effects of a chemical; quantifying the relationship between the exposure and the health effect (dose-response); assessing variations in exposures across populations; and quantifying risks by combining exposure estimates with dose response information. Risk assessment approaches for cancer assume that dose-response effects are likely to be linear (i.e., no safe dose). For non-cancer health effects, risk assessment assumes that there is a threshold exposure level below which it is likely to be “safe” (Woodruff et al., 2011). The National Academy of Science has asserted that although risk assessment may clarify relationships between individual chemicals and potential health effects, it does not adequately account for other factors that can influence risk of disease, such as age, genetics, preexisting conditions, and exposures to multiple chemicals (NAS 2009).

Because of these limitations, risk assessment has been an ongoing subject of controversy within the realm of policy and regulatory science. As quantitative risk assessment became the norm for making regulatory decisions, industry increasingly insisted that harm must be quantified and proven scientifically before regulatory action could be taken to restrict the use of chemicals (Myers and Raffensperger, 2006). Indeed, industry groups such as the American Chemistry Council argued that the risk assessment framework undergirds public health evaluations and should continue to do so (Hogue, 2008; LaKind, 2008). Industry scientists have pushed to further incorporate emerging science such as systems biology, genomics, and biomonitoring, which are currently being evaluated for regulatory purposes, into risk assessment processes (Henry C.J., 2003). For example, Dr. Lesa Aylward from Summit Toxicology, a research group funded by the American Chemistry Council and other trade groups stresses the relevance of translating biomonitoring data into “biomonitoring equivalents” (BE’s), which can be defined as, “a basic, screening level approach for putting biomonitoring data into a health risk context” (Hays, Aylward et al, 2008). She validates the use of quantitative risk assessments based on established methods and proposes a process by which determining regulatory benchmarks through risk assessment could incorporate biomonitoring through the use of biomonitoring equivalents, determining acceptable internal chemical doses. Since 2007, Summit Toxicology, with funding from both industry and government, has moved forward in developing biomonitoring equivalent values for over eighty chemicals (OEHHA Public Workshop, 2011).

Conversely, communities that are disproportionately impacted by toxic chemical exposures from multiple sources such as freeways and factories have argued that risk assessment and its numerous uncertainties mask discriminatory social, economic, and racial regulatory practices (O’Brien, 2000; Wigley and Shrader-Frechette, 1996). Environmental health advocates and some scientists argue that risk assessment places too heavy a burden on a process that is inherently inexact. This perspective has been used to counter industry’s promotion of biomonitoring equivalents in regulatory decision-making. Dr. Dale Hattis, a research professor, has criticized the systemic uncertainty embedded in risk assessment as “SWAG (Scientific Wild Ass Guess).” He argues that BEs could be a beginning point for interpreting the health implications of biomonitoring data but that the tendency of both risk assessments and BEs to focus on arriving at one number, a data point, obfuscates the many concerns and uncertainties that play into understanding potentially toxic effects. Instead, Hattis proposes the notion of a data cloud, which could incorporate multiple inputs into problems of chemical exposure, and could better represent the uncertainties inherent in regulatory decision-making.

Environmental health advocates argue that combining biomonitoring with current risk assessment approaches will only be used to further delay precautionary action by decision-makers (Myers and Montague, 2006). Dr. Amy Kyle, a public health scientist, argues that biomonitoring alone comes far too late in the process after the harm may already be done to address some of the larger systemic problems of chemical exposure. More attention should be paid towards removing exposures before we actually detect them ubiquitously in diverse populations. These diverse perspectives not only highlight scientific contestations regarding the use of biomonitoring in risk assessment, but also

unveils the apolitical façade of regulatory science more broadly as containing little “true” science since these tools also incorporate social issues such as economic and technical feasibility (Jasanoff, 1995). Nevertheless, regulatory agencies rarely acknowledge that decisions related to standard setting for chemicals are inherently value-laden rather than purely scientific (Wagner, 1995; Cranor, 1993; Weinberg, 1972).

Interpretation of biomonitoring evidence

Although biomonitoring promises to improve our understanding of exposures, it has important drawbacks. Biomonitoring cannot easily be used to identify exposure sources and quantifying chemicals in biological samples precedes scientific understanding of their health effects since exposure measurements are required in order to make the links back to health (Morello-Frosch, 2009). As biomonitoring technology has improved through advances in analytical chemistry, an increasing number of chemicals can be detected at lower levels. This creates a real challenge for policy makers and regulatory agencies that follow a paradigm where the determination of an action level is linked to a quantitative assessment of the potential for an adverse health outcome. Many chemicals that can be biomonitoring do not have toxicological or human data on health effects that could facilitate the interpretation of levels for health.

Despite these limitations, scientists widely acknowledge that biomonitoring evidence has been linked to some very important policy successes through its ability to measure changes in exposure. The story that scientists repeatedly pointed to in order to highlight the utility of biomonitoring for policy-making is lead, a known neurotoxicant (personal communication). As the U.S. phased out the use of leaded gasoline between 1976 and 1980, national biomonitoring data by the Centers for Disease Control showed declines in blood lead levels that matched the declines in the usage of leaded gasoline (Jackson, 2002). Jackson notes that, “this was very powerful during the Reagan administration, when they pushed to reintroduce lead into gasoline; this was the smoking gun to prove that the whole thing wouldn’t really work” (Personal Communication, May 29, 2009). As lead could be measured in blood at increasingly low levels, these lower levels, too, were linked to adverse neurological outcomes, particularly in young children. This evidence of low dose effects on the cognitive function of children resulted in the progressive lowering of the regulatory level of health concern for lead in human blood. Needleman, 2004; CDC, 2001; See Figure 1). Lead was considered to be “of concern” at 20 parts per million/deciliter of blood and now this level is set at 10 micrograms/deciliter (the level at which the Centers for Disease Control recommends public health actions be initiated). However, even this level is now considered inadequate as studies now indicate significant declines in the cognitive functioning of children at levels below 10 micrograms/deciliter (Gilbert and Weiss, 2006; Kraft and Scheberle, 2005).

The case of lead casts a long shadow over biomonitoring debates. Some scientists have argued that even where there is significant knowledge of health impacts as in the case of lead, regulators and scientists have been wrong about where to set regulatory benchmarks. Waiting for health studies to emerge about the hundreds of chemicals that

can now be biomonitored but where there is little known about health impacts, could work to the detriment of the public's health.

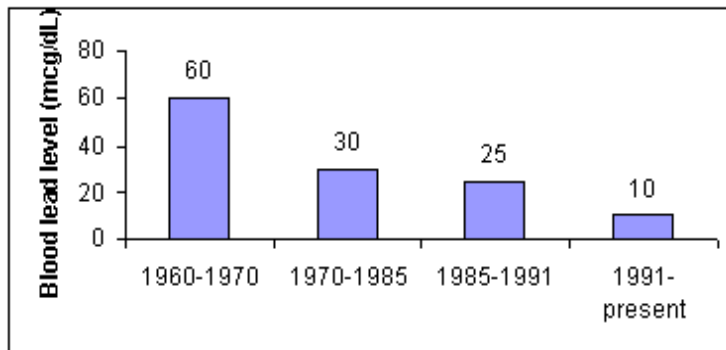


Figure 1: Lowering of CDC Recommended Action Level over time (Source ATSDR)

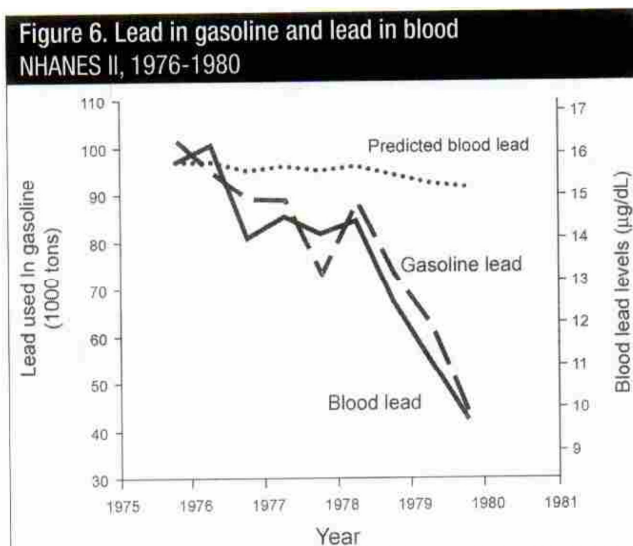


Figure 2: (Source: Jackson R, 2002)

The story of lead comes up repeatedly in interviews and discussions of the relevance of biomonitoring for public health. As detection levels through biomonitoring improve, scientists are able to detect adverse health effects at levels that were previously considered safe. While this has enabled better chemical understanding, there can be significant public health consequences of waiting to assess the health effects of a chemical such as lead that has significant and permanent neurotoxic effects. Instead, biomonitoring would be better utilized as a tool to monitor how well policies that seek to reduce chemical exposures such as bans or phase-outs are working to reduce exposures.

Biological Mechanism and Pharmacokinetics

A chemical's biological mechanism, how it's metabolized and the way a chemical interacts with other physiological processes, also called pharmacokinetics is an important issue among scientists interested in biomonitoring. Pharmacokinetics is widely used by

toxicologists and physicians. It comes from the field of pharmacology where it provides a mathematical basis for the time course of a drug, its effects, and metabolism in the body, including the processes of absorption, distribution, metabolism, and excretion (Dhillon and Gill, 2006). Unlike pharmaceuticals, which are tested before they enter the market, very few of the existing 82,000 chemicals in use today have been tested for their impacts on health (Tickner et al, 2005). For this reason, most biomonitoring chemicals have little mechanistic data and even less is known about the health outcomes of interactions of chemicals with biological processes.

For industry scientists, understanding the biological mechanism of a chemical in the body is an overriding concern. One industry scientist I interviewed asserted that, “we don’t care about exposure for exposure’s sake” and pointed out the need for understanding chemical exposures in the context of environment, genetics, and health. Another industry scientist stressed that the interpretation of biomonitoring data and the transit of chemicals through the body must be connected to an understanding of biology. He stated,

One question you didn’t raise is about a female who says they are pregnant and if this is going to affect the fetus. 1) Does it cross the placenta? (sic) And 2) What are the pharmacokinetics? Essentially what we tell someone is what you have in your blood, 20, 30, 40% might be in your fetus. Is this alarming? Yes. But that’s biology. There are a heck of a lot of things that cross the placenta. Most people don’t know that so it’s part of education. Then the question is what does this mean to a developing fetus at critical life stages? You need to know what the reproductive and developmental biology is in humans. (Industry Scientist, July 27, 2009; Personal Communication)

For most of the other industry scientists I spoke with, the dominant framing is that regardless of whether or not a chemical crosses the placenta, whether or not it is in the body, it is only suspect if it is linked to harm.

Academic and advocacy scientists are more concerned with how little is known about a chemical’s influence on vulnerable populations, such as infants or *in utero* exposures to a developing fetus when chemicals can increase the risk of disease throughout the life course (Stein et al, 2002) Specific stages of human development are now considered to be windows of vulnerability to the toxic effect of pollutants. These stages include the fetal stage, infancy, early childhood, and puberty. For example, early childhood behaviors, such as crawling and constant hand-to-mouth activity, can increase infant exposures to chemicals. Biomonitoring studies have documented higher levels of certain contaminants, such as lead and brominated flame retardants, in children compared to their parents or other adults. While industry scientists insist on knowing the mechanism of harm before asserting whether or not a chemical poses a problem, public health advocates suggest that the mechanism is not likely to be well understood or will take years to fully understand. For this reason, evidence of hazard is sufficient to take action without data on the pharmacokinetics of a chemical. Finally, advocacy and academic scientists point out that human exposures during these critical windows of development entail multiple chemicals with potentially synergistic effects that have yet to

be fully understood. In a 2005 study by the Environmental Working Group and Commonweal, 10 newborns were tested for their chemical body burden and on average each newborn had an average of 200 chemicals in their cord blood.

Of the 287 chemicals we detected in umbilical cord blood, we know that 180 cause cancer in humans or animals, 217 are toxic to the brain and nervous system, and 208 cause birth defects or abnormal development in animal tests. The dangers of pre- or post-natal exposures to this complex mixture of carcinogens, developmental toxins, and neurotoxins have never been studied. (EWG and Commonweal, *The Pollution in Newborns*, 2005)

By producing their own data and leveraging scientific evidence from other academic sources, advocacy scientists have sought to push regulatory science to avoid responding to scientific uncertainty about the health effects of chemical exposures with inaction. Currently, toxicity assessments that inform the regulation of major use or ubiquitous chemicals can take decades. Assessments for chemicals such as dioxin and trichloroethylene that the EPA started in the 1980s have still not been completed (NAS, 2009). As debates about data uncertainties rage on, the public remains chronically exposed to potentially harmful chemicals (Woodruff et al, 2011).

To address this stalemate, public health scientists propose that in the absence of full data to characterize the health risks of chemical exposures, regulatory decisions should be made based on available, albeit incomplete, evidence such as information on chemical structure and other indicators of potential toxicity. This approach to interpreting and acting on emerging scientific evidence requires overhauling U.S. chemicals policy. Under the Toxic Substances Control Act of 1976, chemicals are essentially assumed to be safe until shown by regulatory agencies to be harmful, with few requirements placed on manufacturers to supply data on population exposures or potential health effects (Wilson, 2008; Cranor, 2011). This makes it impossible for EPA to regulate chemicals before they are put into widespread use.

By making possible the measurement of hundreds of chemicals in human populations, biomonitoring has revealed the failures of regulatory science and chemicals policy. Industry scientists emphasize that these measurements alone mean little without better human studies, animal evidence, and pharmacokinetic information. Public health scientists point out that no data does not mean no problem, and that biomonitoring provides an expedited approach to hazard identification that could help prioritize and expedite the regulation of chemicals without falling into the rabbit hole of protracted risk assessments. This circular conversation is politically charged. Even government scientists note they feel continually pushed to prove there is a problem and that for this reason biomonitoring “is a very powerful tool and it’s of great interest to scientists and policymakers. If you step back and look at the big picture, if we change the way that we brought chemicals to market, you wouldn’t need biomonitoring. I think that a lot of people that (sic) work on biomonitoring programs would like to see chemical policies be different and this is the corner we’ve been pushed into... very scientifically rigorous, legitimate way of demonstrating there’s a problem” (Government Scientist, January 22, 2009).

What You Can't See Won't Hurt You? The Problem of Substitutions and Limits of Detection

The Centers for Disease Control currently has analytical capability and the laboratory capacity to measure approximately 300 chemicals (CDC, 2009). This measurable number is a very small portion of the large number of chemicals in commerce, which number upwards of 80,000 (Tickner et al, 2005). In my interviews, almost every scientist regardless of sector mentioned that this is a serious limitation to relying on biomonitoring for decision-making. Industry scientists and advocacy scientists frame the reasons for this concern quite differently however. Industry scientists argue that it is dangerous to replace a known chemical for which there is extensive health effects data with an unknown chemical for which there is much less data simply because a chemical can be detected in the body. Many industry scientists gave the example of bisphenol A (BPA), a chemical in plastics, food packaging and can liners, that has been used for over a hundred years and is increasingly targeted because it has been measured in over 90% of the U.S. population and linked to adverse developmental health effects in animals at very low levels (vomSaal, 2007). Industry scientists argue that BPA has been demonstrated to be safe and there is no evidence that the alternatives are better, and in fact they could be found to be worse down the line (personal communication).

Public health scientists point out that the replacement of known chemicals with unknown and non-measurable chemicals is indeed a problem attributable to a regulatory system that does not test chemicals for commerce at the front end and is overly industry friendly (Personal Communication). An example of this problem is flame retardant chemicals. Brominated flame retardants have been extensively used to meet flammability requirements in furniture, clothing and electronics but are now known to be persistent and bioaccumulative in the environment (Easthope and Valeriano, 2007; Blum, 2007). In 1974, Firemaster flame retardants containing polybrominated biphenyls (PBBs) were pulled off of the market because of a poisoning incident in animal feed in Michigan and the toxicity concerns these chemicals posed. Firemaster chemicals, however, were replaced by similar flame-retardants (Woodruff et al, 2011). Pentabromodiphenyl ether (penta-BDE), one of the replacements, has been implicated in a wide range of adverse health effects in animals and as a result has been banned in many states in the U.S. as well as Europe. In 2004, Chemura, the sole U.S. manufacturer of penta-BDE's, voluntarily ceased production of the chemical and replaced it with Firemaster 550 with a new composition that is a trade secret. As a result, public health and academic scientists have conducted the expensive and time intensive work to reverse engineer Firemaster 550 in order to figure out the individual components, which have also been found to be ecotoxins and reproductive toxins (Shaw and Birnbaum, 2010).

The problem of unknown substitutions is compounded by methodological challenges related to limits of detection (LODs) in biomonitoring. The LOD is the lowest concentration of a compound that can be reliably detected by an analytical procedure. Advocacy scientists, in particular, fear an over-reliance on biomonitoring for decision-making because the technology is limited in its ability to detect numerous compounds at sufficiently low levels. One advocacy scientist stated,

One of the concerns I have is that if we don't have the analytical techniques for identifying some chemicals, and then we use biomonitoring to drive our prioritization, we're simply going to be ignoring the chemicals that we haven't yet learned how to measure. They may be in us at hazardous or risky levels, but we wouldn't know it if we can't measure it. (Advocacy Scientist, May 28, 2010; personal communication)

The LOD problem, which is inherent in biomonitoring science has been described as looking under the lamppost for lost keys, when in fact they lie elsewhere.

Advocacy scientists are also concerned that if biomonitoring becomes a primary source of exposure assessment, industry will simply switch to chemicals that analytical chemistry cannot or has not learned to "see". One advocacy scientist noted that there is precedent from pesticide air monitoring where potato growers in Minnesota switched fungicides to manam and mancozeb, which could not be detected in the air from chlorothalonil. She said, "I worry about that, where there's going to be a move towards chemicals where you can't measure them in the body. As long as you don't know, it's invisible" (Advocacy Scientist, March 2, 2010). In terms of regulation, both industry groups and advocacy organizations are concerned about the limits of detection for different reasons. Industry groups seek to limit regulation based on the ability to detect and advocacy groups are concerned that an over reliance on detection capacity could create a scenario where industry will increasingly "hide" chemical exposures in bodies and other media by formulating compounds that are less detectable through biomonitoring.

Dose-Response and Timing of Exposure

One of the most significant shifts in the toxicology field is in the understanding and characterizing of low dose effects. Historically, toxicology has relied on the rubric "the dose makes the poison" and chemicals regulation has been built upon this foundational assumption of chemical toxicity. However, in the past decade, there is increasing evidence that some chemicals, such as endocrine disrupting compounds that affect the hormone system, can exert toxic effects at extremely low levels of exposure—doses far below levels that are currently regulated (Vogel, 2008; Birnbaum and Jung, 2011). In recent years mounting evidence shows that many chemicals such as bisphenol A, a chemical in plastics, and atrazine, an herbicide, do not follow a linear dose-response curve, but rather exert their adverse biological and physiological effects at extremely low doses of exposure that are particularly troublesome in vulnerable windows of development (Birnbaum and Jung, 2011). For these chemicals, regulators are faced with the challenge of how to act.

As biomonitoring technology improves and increasingly detects the presence of chemicals at minute levels, the controversy over low dose health effects in vulnerable populations, such as children has become more urgent. There is a long history of industry efforts to influence the regulation of endocrine-disrupting chemicals by conducting research that contradicts low-dose academic studies that find adverse effects

(Vogel, 2009; Myers, 2009). In our interviews, industry scientists recognized the problem of low dose exposures but continued to focus on the importance of determining biological mechanisms. Advocacy scientists expressed frustration with regulation and policy inaction on the issue of endocrine disrupting chemicals and other chemicals that appear to have their most potent effects at very low doses. As a response, they have targeted their work towards public education and towards direct industry influence, since there has been little forthcoming action from the federal government on the challenges of low-dose exposures (Advocacy Scientist, June 4, 2010; See Chapter 2).

The Public Outcry Over Biomonitoring Data

The issues mapped above highlight the conflicting frames deployed by different scientific sectors. On one hand, industry asserts that presence of chemicals in bodies alone does not indicate harm and that characterization of risk is essential for scientifically sound regulatory decision-making. On the other hand, advocacy scientists and their community allies have put forth a public interpretation of biomonitoring data as proof of toxic trespass that starkly reveals the failures of US chemicals policy and regulation to protect public health. These heated expert debates about the contested science of biomonitoring have produced increasing uncertainty among members of the public about the use of science in regulatory decision-making (Weingart, 1999). In this context, community organizations and advocacy groups use biomonitoring science (and other tools) to democratize the interpretations and use of science, introduce lay knowledge and experiences within the project of scientific fact-making, and implement new policy-making logics, such as reforming existing chemicals policy to better protect public health (Parthasarathy, 2010; Wilson and Schwartzman, 2009; Morello-Frosch, 2009).

Advocacy biomonitoring studies reframe expert-oriented conversations by relaying results through storytelling about personal exposures, placing real faces on aggregate data, and disseminating data to the public in new and compelling ways through reports, informative websites, and the popular media. Scientific data presented in personal ways has generated a strong reaction in the public when they learn that they are undoubtedly and involuntarily contaminated by a host of synthetic chemicals, many of which have been linked to adverse health outcomes in animal studies. When scientific data is reported in the popular press, scientific experts in turn pay increased attention to the issue (Phillips et al, 1991).

While the personalization of biomonitoring data by advocacy organizations is far more compelling to the general public than the charts and graphs created by the CDC or in peer-reviewed studies (Washburn, 2009), industry and government scientists in our interviews routinely critiqued advocacy studies as not statistically rigorous since they included very small sample sizes. Nonetheless industry and government scientists also noted that advocacy groups used reputable laboratories approved by the CDC, so the chemical measurement findings of these small studies were not questioned. Industry scientists were often critical of advocacy studies as focused on garnering media attention while not “playing by the rules” and not submitting their research for peer review, which is the primary form of gaining legitimacy in the scientific community (Personal

Communication). While dismissing the scientific legitimacy of advocacy studies, industry scientists noted their strong public and policy impact.

They have had an impact in terms of raising awareness, but from a scientific perspective they don't provide much value. CDC studies provide the scientific gold standard. Some of the academic studies are closer to CDC and others are closer to these smaller NGO studies. Academic studies have been peer reviewed by journals. NGO studies aren't often peer-reviewed. However, they've been impactful in the policy arena. (Industry Scientist, June 15, 2009, personal communication)

Advocacy organizations responded to this critique by noting that their research followed IRB (Institutional Review Board) protocols for working with human subjects, used reputable laboratories, partnered with academic scientists, and were conducted in the public interest rather than primarily for publication in peer-reviewed journals (though some groups, such as Environmental Working Group, do publish their results in scientific publications) (Lunder et al, 2010). They noted that their findings held sway regardless of their study sample size and were aimed at promoting public education, corporate pressure, and large-scale policy change (Personal Communication). One advocate noted,

My sense is companies are listening and I think industry really listens too. They [industry] tend to want to discredit what we're doing because they say it's not scientific, they feel it's not statistically significant and we don't always have the capacity to test pathways of exposure.....but we learn by stories. People hear stories, they listen to them, they are moved by them in ways data will not move them. I've seen this time and time again. It's great if the data is there, too, that's best, absolutely best. (Advocate, July 7, 2010)

While industry trade groups, product manufacturers, and chemical companies emphasize the scientific shortcomings of advocacy biomonitoring studies and continually argue that chemical presence in the body alone does not merit action, our interviewees from advocacy and industry arenas noted that there are instances where chemical manufacturers, retailers, and product manufactures have made changes because of consumer or advocacy pressure such as stopping production of a particular chemical, removing problem chemicals from products, or discontinuing sales of products that have been found ubiquitously in bodies in the general population. Industries make these changes in order to maintain their corporate public image or to address exposures that can be directly linked with their products (see Chapter 2). While largely maintaining the claim that biomonitoring evidence cannot be linked with adverse health outcomes, some major companies have nonetheless responded to biomonitoring data about chemicals in their products. Environmental health advocates are pushing for an interpretation that exposures themselves matter, and this interpretation is gaining legitimacy and visibility. The case of PFOA (Perfluorooctanoic acid), demonstrates this trend.

In 2000, the company 3M discontinued the manufacture and sales of PFOA, a chemical that is a primary ingredient in stain resistant and anti-stick coatings, such as

Teflon. This chemical was also the primary ingredient for stain resistant coatings in carpets, clothing, and food packaging coatings. PFOA persists in the environment and as scientific evidence began to emerge that the chemical “fingerprint” of PFOA could be found in every single animal and human tested, 3M was forced to acknowledge the chemical’s persistence (Grossman, 2009; Industry Scientist, July 27, 2009). 3M publicly stated on their website that the chemical had no proven adverse health effects, but they discontinued the production and sale of PFOA because of its ubiquity and persistence (3M website, accessed July 27, 2010). 3M accounted for 98% of global production of PFOA and the company became increasingly aware that popular acceptance would never follow when their product was found in wildlife and people, and that the chemical bioaccumulation in bodies pointed directly back to the company. One industry scientist stated, “This was a \$500 million business. They were not going to be able to defend the company when the chemical was found in nesting bald eagles. 3M made a risk management decision to get out of the business.This is a classic example of how [biomonitoring] works really really well” (Industry Scientist, July 27, 2009).

Despite industry reluctance to concede that chemical presence matters, my interviews consistently found that industry does respond to public concern about chemical presence in bodies and they respond either at the level of discourse and debate in the regulatory arena, or in some cases making changes to their products. At the same time, industry scientists are critical of the public’s visceral response to biomonitoring data calling it “unscientific” and “emotional”. Yet, although industry groups maintain that chemical presence alone should not be a basis for decision-making, they also realize the limitations of communicating this message to the broader public. One industry scientist stated,

There is an emotional level of response. I knew it was inside you when it was in the air, you knew it was inside you, but when I say I measured it in your body, then mere presence becomes a basis for decision-making... And it’s difficult to have a debate because it does not translate into a sound bite. It comes across as, “I think its ok to have chemicals in your body’. It is not a winning sound bite (Personal communication, 10/15/2009).

Additionally, industry groups criticized activists and the media for quoting statistics from Centers for Disease Control survey percentages. For example, the chemical bisphenol A has become increasingly controversial both because it has been detected in almost everyone in the U.S. population and linked with adverse health outcomes at very low levels of exposure. Industry groups and trade associations argue that quoting these percentages is misleading and must be followed with specific interpretation. This critique leads back to industry arguments for biomonitoring equivalents which would establish a “level” that would be considered allowable in the body. To this end, one industry scientist argued, “... 93% of people, that must be important. And well, yeah, that maybe makes it interesting but it doesn’t make it important (Industry Scientist, 12/15/2009, Personal Communication). Advocacy biomonitoring that combines the deployment of established scientific expertise with storytelling about personal experiences with toxic trespass put faces on the statistics of

government biomonitoring surveillance, a strategy that has influenced larger industry and policy structures.

Discussion

Debates about regulatory science have centered on the meaning, interpretation, and ultimate utility of biomonitoring data for addressing toxic chemical exposures. The regulatory science response to biomonitoring evidence by federal agencies and policy-makers has been slow and often lacking. Regulatory agencies have been reluctant to act on information that toxic chemicals are building up in the general population. And, as concerns about the growing number of chemicals proliferate, there seems to be little clarity as to how regulatory agencies will address problems of toxic exposures. The U.S. regulatory process has been characterized as contentious and litigious (Brickman et al, 1985), a scenario that pushes regulators to seek out (or hide behind) strong scientific evidence that can be used as a justification for decision-making and shelter them from litigation. This regulatory climate has led to a process that is heavily reliant on the extensive and time-consuming collection of scientific evidence.

As new evidence continues to emerge from biomonitoring studies, there does not appear to be a clear regulatory path forward. Over the next few years, agencies and policy-makers will be faced with the task of incorporating growing evidence from biomonitoring research into chemicals regulation. They will need to make clear determinations on issues such as to what extent and how biomonitoring evidence will be incorporated into existing processes, such as exposure assessment and risk assessment, and whether these processes themselves are able to incorporate personal exposure data. The current regulatory structure also does not readily respond to emergent science such as low-dose science (Woodruff, 2007).

Yet, as biomonitoring evidence continues to uncover problems with a growing host of chemicals in everyday use, industry has been forced to address public concern. For example, earlier this year under growing market pressure, Colgate-Palmolive removed triclosan, an antibacterial pesticide used in many over-the-counter hand soaps, from most of its products because of growing media scrutiny. This chemical was linked with health problems such as skin irritation and exacerbation of antimicrobial resistance. Many media outlets that picked up the Colgate-Palmolive story noted that the CDC has found triclosan in the bodies of 75% of the U.S. population, pointing to the ongoing public interest in these types of statistics and the continued interest in biomonitoring as a way to understand personal and pervasive product exposures.

Scientific contestations over biomonitoring data and the pervasive presence of chemicals in the general population have important implications for the future of chemicals policy. Environmental health and justice advocates as well as public health scientists have long been critical of the existing chemicals regulatory structure (Tickner et al, 2005). The effort to gather biomonitoring evidence by environmental health movements has been a key strategy towards making the consequences of poor chemicals regulation more visible, as well as pushing us to better understand the extent of chemical

exposures. Advocacy biomonitoring and social movement organizing have brought issues of toxic trespass to public attention and raised general awareness about pervasive toxic exposures.

Over the past few years, environmental health advocacy groups have worked to introduce federal legislation that will reform the Toxic Substances Control Act and generally overhaul U.S. chemicals policy. In April 2011, Senator Frank Lautenberg introduced the “Safe Chemicals Act of 2011”, which would overhaul the 1976 Toxic Substances Control Act. In a publicly released video, Lautenberg stated, “ The average American has more than 200 industrial chemicals in their (sic) body, including dozens linked to cancer and other health problems. The shocking truth is that the current law does not require tests to ensure chemicals used in everyday household products are safe” (Lautenberg; April 14, 2011). While environmental health advocates continue to champion the legislation, with the U.S. government in financial crises and the country in a recession, the bill has not received much public attention. However, behind the scenes there continues to be extensive debate among scientists from different sectors as to how chemical policy reform will move forward, with industry recognizing that there will be some type of reform. Biomonitoring evidence has played a key role in pressing the case for the importance of chemicals policy reform for public health. However, it remains to be seen what the outcomes will be of scientific contestations over biomonitoring and whether biomonitoring evidence can shift the debates from a risk-driven approach to chemicals management to a more precautionary, hazards-based paradigm.

INFLUENCING CHEMICALS GOVERNANCE THROUGH MARKETS: THE CASE OF BISPHENOL A, BIOMONITORING DATA, AND THE NEW RIGHT-TO-KNOW

Abstract

Biomonitoring has emerged as an important data source for information about population exposures to toxic chemicals. While government, regulatory scientists and institutions have been slow to uptake and utilize biomonitoring data for regulatory decision-making, advocacy and academic biomonitoring studies referenced alongside the Centers for Disease Control's (CDC) National Biomonitoring Program data have pushed important transformations in chemicals governance through non-state market driven processes (NSMD) (GAO, 2009). Using the case of bisphenol A, this paper investigates how biomonitoring data is influencing chemicals governance in the U.S. despite a lack of government regulation. This study traces the role that non-profit organizations, academic scientists, industry actors, and regulatory institutions are playing in this process. Finally, biomonitoring data remains a contested science. There appears to be universal agreement that biomonitoring results indicate chemical exposure but there continues to be important contestations regarding the meaning, interpretation, and significance of biomonitoring exposure data. Despite this contestation, market efforts using biomonitoring data as key exposure evidence are having important impacts on chemicals governance and are considered a pathway by many interested stakeholders towards the longer-term goal of systemic chemicals policy reform.

Key Words: Bisphenol A, Biomonitoring, Governance, Market

The Sigg-BPA Controversy: A View into U.S. Chemicals Governance

In August 2009 Steve Wasik, then CEO of the Swiss reusable water bottle manufacturer, Sigg, announced on the company website that their water bottle liners contained trace amounts of the chemical bisphenol A (BPA), a suspected endocrine disruptor. The company had known about the use of BPA liners in their bottles since 2006 but continued to sell them through 2008. Wasik chose not to disclose this information citing the scientific controversy surrounding BPA, the lack of scientific consensus about its health effects, and the lack of government regulation. Instead, Sigg quietly developed BPA-free liners for their bottles, phasing out the old ones. The web posting might have gone unnoticed if not for shocked and angered consumers who posted and reposted the message to social media networks and blogs until the story was soon picked up by the mainstream media. Blog posts carried titles such as “Betrayed”, “Too Little Too Late”, and “Take Your BPA-Tainted, Soulless Sigg bottles back to major retailers”, pointing to Sigg’s efforts to replace old bottles with new BPA-free ones. Many of those who had purchased Sigg’s bottles had made the switch from Nalgene and other polycarbonate (hard plastic) bottles known to leach BPA.

In the midst of the controversy *Advertising Age* noted, “Sigg, maker of the metal, reusable bottles that became a badge of consumer eco-consciousness and all-around cool, is in danger of becoming a poster child for brand deception and corporate dishonesty”. Sigg had become a “marketing darling” and had seen its business explode in 2007 because of consumer fears surrounding BPA leaching from plastic bottles. BPA avoidance in polycarbonate bottles began as early as 2003 when Sierra Club’s *Sierra Magazine* published the article “Hazards of Hydration: Choose Your Plastic Water Bottles Carefully” which profiled the work of Dr. Patricia Hunt, a geneticist at Case Western Reserve University who accidentally found that chromosomal abnormalities in her laboratory mice spiked from 1-2% to 40% when the mice’s polycarbonate cages were washed in a detergent that caused BPA to leach from them (Whittelsey, 2003). By 2007, advocacy groups such as the Work Group for Safe Markets and the Environmental Working Group drove additional high profile media coverage when they tested products such as cans and bottles for BPA leaching. Advocacy organizations also began conducting highly publicized small-scale biomonitoring studies that found high levels of BPA and hundreds of other chemicals in newborns and other populations across the country¹. These studies on products and people were cited alongside academic animal studies that linked the chemical to a host of developmental and reproductive problems. While there are no existing federal regulations on BPA, advocacy groups could compare their findings to the national biomonitoring data set published by the Centers for Disease Control’s National Health and Nutrition Examination Survey (NHANES) that showed BPA to be in 93% of the American population (CDC, 2009)

¹ There are several advocacy body burden studies that test for numerous chemicals. The Environmental Working Group has been most visibly conducting and publicizing body burden studies. For example see, *Pollution in People: Cord Blood Contaminants in Minority Newborns*; December 2, 2009; <http://www.ewg.org/minoritycordblood/home>

During this same time period, academic biomonitoring studies on BPA mounted. A Harvard study compared urinary BPA concentrations in students before and after drinking from polycarbonate plastic water bottles. After bottle use, urinary BPA concentrations increased by a dramatic 69% (Carwile et al, 2009). Animal evidence also increasingly showed health effects at low levels of chemical exposure. Several studies on BPA's estrogenic properties and its role as an endocrine disruptor were published by scientists Pete Myers and Frederick vom Saal, who became scientist advocates and publicly called for the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), the entities that regulate BPA in the environment and in food, to establish new regulatory standards that would consider data from low dose studies (the FDA regulates all food packaging uses of BPA, the primary route by which most people are exposed to the chemical; the EPA regulates the chemical's effect on the environment—for example, its effects on aquatic wildlife) (vom Saal and Hughes, 2005).² To date, both the EPA and the FDA are conducting more in-depth studies of the chemical and the FDA has indicated that it is a chemical of “some concern”. However, regulatory agencies have not to date enacted any new regulation for bisphenol A.

Biomonitoring and health effects data on BPA made its way into the mainstream media and drove consumer concern. Although sales figures are not publicly available, *Advertising Age* placed Sigg bottle sales at \$100 million, rising 250% between 2006 and 2007, even before the BPA controversy reached its peak (Zmuda, 2009). After receiving hundreds of emails from angry consumers, Wasik posted an apology stating, “I learned that many of you purchased Sigg bottles, not just because they were free from leaching and safe, but because you believed that Siggs contained no BPA....although Sigg never marketed the former liner as ‘BPA Free’”. In October 2009, Sigg replaced Wasik with Johnson & Johnson veteran Steven G.S. Taylor.

The Patchwork of United States Chemicals Governance

The Sigg-BPA story demonstrates the complex characteristics of United States chemicals governance. Governance has been defined as “new forms of regulation that differ from traditional hierarchal state activity”, referring to the efforts by entities outside of the national state to regulate ongoing and diverse social and economic issues, such as in this case chemicals. “Governance” is most often used in the context of global environmental politics and implies the participation of a diverse set of stakeholders including experts, corporations, and non-governmental organizations that work to change the course of events or the outcome of processes (Biermann and Pattberg, 2008). In the context of chemicals regulation, I use “governance” to include diverse strategies, particularly those focused on market-driven efforts to influence corporate behavior as well as state and federal policies. While this paper is situated in the U.S. context,

² Myers and vom Saal argued vehemently for new regulatory standards that would reflect BPA's adverse health effects at low doses, asking for changes to the LOAEL (lowest observed adverse effect level) as well as a new reference dose to be implemented for the chemical. The LOAEL refers to the lowest exposure level at which a chemical effect can be observed, most commonly determined through animal studies. These levels are then applied by the EPA to set chemical regulatory levels. A reference dose is an estimate of a daily oral exposure that is allowable over a lifetime without increased health effects

advocacy groups in the United States have long collaborated with and borrowed from their counterparts globally who have sought to influence chemicals policy, in recognition that the chemical industry is a global enterprise (Schwartzman and Wilson, 2009).

Academic research on chemicals has focused on governance comparisons between the United States and Europe, where stakeholders share strategies and information, despite different national regulatory frameworks. U.S. advocates have closely watched changes in the European Union as Europe has adopted precaution as one of the guiding principles for its environmental laws (Kriebel et al, 2001). Environmental health and justice organizations in the United States using multi-pronged efforts to change U.S. chemicals governance are particularly concerned with the lack of precaution guiding existing U.S. federal chemicals policy. One driving feature of U.S. advocacy efforts is to reverse the “burden of proof” which now falls on individuals and communities to prove adverse health impacts from chemicals exposures and place greater responsibility on industry to demonstrate that a chemical is safe before it is allowed on the market (Montague, 1998). Advocacy biomonitoring studies, which measure chemical levels in diverse constituencies, demonstrate the existing *public* burden, as the general public and vulnerable populations such as newborns carry high numbers and levels of synthetic chemicals in their bodies. Advocacy biomonitoring campaigns point to corporations and governments as having the power to reverse this trend.

One important development in chemicals governance has been the use of scientific data such as biomonitoring combined with strategies such as media campaigns by advocacy organizations to compel corporate changes directly. Non State Market Driven (NSMD) systems, also called civil regulation, are considered a relatively new form of business regulation and have been defined as, “deliberative and adaptive governance institutions designed to embed social and environmental norms in the global marketplace that derive authority directly from interested audiences, including those they seek to regulate, not from sovereign states”(Bernstein and Cashore, 2007). Efforts to govern chemicals using non-state market driven systems target priority or “bad actor” chemicals such as bisphenol A to raise awareness about widespread exposures to toxic chemicals, profile products formulated using bad actor chemicals, provide information to consumers, and push for industry change. These efforts ultimately seek to raise the necessary attention to drive more systemic regulatory and policy change at the state and federal level. Market pressures are often a way to build momentum and public awareness around an issue (Vogel, 2008). Biomonitoring campaigns, which test for synthetic chemicals or their breakdown products in human blood, breast milk, fat, or other bodily tissues, have recast debates among interested stakeholders from whether a chemical exposure exists to “what to do about the exposure” and “what the exposure means”. Biomonitoring evidence has important implications for shifting understandings of chemical exposure and, more broadly, is emerging as an important driver, alongside health effects studies, of market-driven transformations in U.S. chemicals governance. Biomonitoring data is consistently cited in media stories about bisphenol A. For example, *The Washington Post*, which covered the scientific controversies over bisphenol A more

than any other major newspaper between 2005 and 2009, cited urine biomonitoring data in nearly all of the BPA stories they ran over these years³.

To date, there is no national level government regulation of BPA anywhere in the world except for Canada, which banned the chemical in 2010. In the U.S., the use of BPA continues to be embroiled in debate about the extent to which it poses a health concern given its presence in over 90% of the population. However, it appears the market has responded to consumer concerns. In 2008 companies such as Nalgene discontinued the use of BPA in their water bottles and large retailers such as Wal-Mart and Toys R'Us removed baby bottles with BPA from their store shelves. Additionally, entirely new lines of "BPA-Free" baby bottles and water bottles were produced as a result of the consumer demand (Austen, 2008). Organizations have also worked at state and local levels to ban BPA in products for young children. Chicago, Connecticut, Minnesota, New York, Maine, Vermont, and Washington State have restricted BPA use in children's products and legislation has been introduced in thirty other states and localities across the country (Louisville Charter; www.louvillecharter.org)

What have been the major drivers of these market and state legislative changes? Why have major retailers discontinued the use of an unregulated chemical? This research project investigates the extent to which biomonitoring evidence, as a relatively new form of large-scale exposure evidence, has contributed to changes in U.S. chemicals governance, using the case study of bisphenol A. In particular, I explore how advocacy organizations and other stakeholders outside of regulatory arenas are utilizing advocacy biomonitoring as one tactic to push markets towards decreasing the use of targeted chemicals in consumer products. I examine whether biomonitoring data has played a role in BPA debates and to what extent biomonitoring data has contributed to market driven changes in the use and sales of BPA.

The first section provides background on the chemical bisphenol A and the BPA global market as an important case study for understanding the patchwork of current U.S. chemicals governance. The second section describes the existing U.S. federal regulatory system and situates non-state market driven approaches within the context of the failure of U.S. regulatory institutions to utilize emergent scientific data in their decision-making. The third section looks at how advocacy groups have entered into the foray to improve chemicals governance through market-driven efforts, utilizing a range of tactics including biomonitoring evidence to push for industry change and state-by-state policies in the regulatory vacuum left by federal policy. Finally, the conclusion analyzes the benefits and pitfalls of the non-state market driven approach and consumer politics as a vehicle towards larger scale chemical policy reforms.

Methods

³ Lexus Nexus search, U.S. Newspapers, Time Frame 2005-2009, search term "Bisphenol A". Search conducted September 25, 2009.

Research examining the role of biomonitoring in chemicals governance was conducted through a case study approach. Bisphenol A was chosen as an important chemical because it has become incredibly visible in media, non-governmental organization (NGO), and lay arenas. It has triggered a range of debates about chemicals policy effectiveness in the U.S, Canada, and Europe. It has been the subject of often acrimonious academic and policy debates and the subject of extensive biomonitoring through academic studies, government surveillance, and advocacy studies.

This case study was conducted through qualitative mixed-methods. Research included document analysis such as reports published by the Centers for Disease Control, the Government Accountability Office, academic scientific biomonitoring studies, and advocacy biomonitoring studies, produced by non-governmental organizations. A media analysis of trends in BPA news stories was conducted to better understand the links between media, reporting on BPA biomonitoring, consumer outcry, industry decisions to cease BPA sales, and state-level policy efforts to ban the chemical. The trade press was analyzed for industry reaction and debates about BPA. In addition, this project is part of a larger research study seeking to understand the role and impact of biomonitoring data as it has proliferated across academic, NGO, legal, and government arenas. For this project, I conducted semi-structured interviews with over forty scientists and decision-makers in academic, non-profit organizations, government, or industry who either conduct biomonitoring studies or use this information in their work. Interviewees were contacted through snowball sampling and through contact at professional or industry meetings. For this study, in particular, additional scientists and professionals who specifically address the chemical bisphenol A were interviewed.

Background on Bisphenol A

Sigg's story sits in the context of the larger story of bisphenol A, a 100+ year old chemical used in the manufacture of plastics. There are currently 82,000 chemicals in commerce in the U.S., very few of which have undergone testing for human health effects (Wilson and Schwartzman, 2009). BPA represents one of the most visible of these, entering into media and popular discourse and making it a useful chemical through which to look at issues of chemicals governance. BPA is unique because of its visibility, made so because it is ubiquitous in popular consumer products, widely used in children's products, and the subject of intense scientific debate regarding its toxicity. It is a poster child for debates on endocrine disruption, studies of adverse chemical effects to the endocrine system at low doses, doses much below levels considered in regulatory decision-making (vom Saal et al, 2005). Its widespread use in baby bottles and water bottles centers BPA in the arena of parents and outdoor enthusiasts, two groups that are vigilant consumers and brand ambassadors.

BPA is known to be weakly estrogenic and human exposure is considered to be largely through consumer products. Exposure in 93% of the U.S. population has been documented by the Centers for Disease Control's (CDC) biomonitoring program, a national effort to measure chemical exposures in a national sample. BPA's weakly estrogenic properties make it potentially disruptive to the endocrine system. The

Environmental Protection Agency (EPA) defines endocrine disruption as, "interfere[ing] with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body that are responsible for the maintenance of homeostasis (normal cell metabolism), reproduction, development, and/or behavior." The EPA stipulates that, "there is strong evidence that chemical exposure has been associated with adverse developmental and reproductive effects on fish and wildlife in particular locations. The relationship of human diseases of the endocrine system and exposure to environmental contaminants, however, is poorly understood and scientifically controversial" (EPA; www.epa.gov/endo/pubs/edspoverview/whatare).

This EPA statement encapsulates the central scientific controversy over BPA. While effects are widely observable in wildlife and through toxicological animal studies there is much disagreement as to how this translates to human health effects. EPA must also consider economic impacts and whether or not alternatives exist. Industry argues that few alternatives exist, especially for canned foods (Personal Communication, March 5, 2010). Industry also argues that it is better to stick with the use of bisphenol A since even less is known about its substitutes. Economically, BPA is hugely profitable in commerce, making the dominant interpretations of biomonitoring evidence and BPA's ubiquitous presence in human bodies an important battleground for industry.

BPA is of particular concern in food and beverage products, our main route of exposure to the chemical. It is used to make epoxy resins which coat the vast majority of food and beverage cans produced in the U.S. It is also used to make polycarbonate plastic, a nearly shatterproof and clear plastic used for baby and water bottles. Many retailers and manufacturers of polycarbonate bottles, particularly baby and water bottles, have reformulated their products without BPA due to a tide of consumer pressure. In March 2009, the six major baby bottle manufacturers reformulated their products. Shannon Jest of Philips Advent, the number one seller of baby bottles in the U.S. stated, "We made a business decision to move out of BPA. We felt like we had hit a tipping point with our consumers and with our retailers. Babies R Us was banning it, Target was going to, CVS was going to, and so the distribution channels were lessening and lessening" (Layton, 2009).

Epoxy resins in metal cans, including baby formula cans, represent the second largest application for BPA in food. The U.S. market consumed 545 million pounds of epoxy resins in 2006. Consumer pressure has not focused on metal can manufacturers to the same extent so these have not been reformulated, with a few exceptions such as canned foods sold by Eden Foods, a natural and organic food company and tomatoes sold by Muir Glen Organics. These companies, however, have not publicly disclosed the replacement chemical for BPA. Epoxy resins are a more difficult issue because only four companies dominate the U.S. metal can industry (Ball, Metal Container, Rexam, and Crown) and the economic and technological feasibility of substitutions varies on a case by case basis, meaning that few economically viable and widely accepted alternatives exist. BPA provides good canned food shelf life and has a strong safety record as a barrier to microbial contamination. Industry argues that there are no readily available alternatives to the use of BPA for epoxy resins, though advocates point to reformulation

by some companies as evidence to the contrary. In addition to beverage containers and baby bottles, which make up only 10% of the polycarbonate market, BPA is used to make optical digital media such as compact discs and DVDs, window coverings, medical equipment and a range of other products not used in food packaging (Bailin, 2008). Global demand for BPA is projected to exceed 5.5 million metric tons by 2011. Worldwide, BPA generates an estimated \$1 million per day in revenue for corporations such as Bayer, Dow Chemical, General Electric, Hexion Specialty Chemicals, and Sunoco Incorporated, companies that account for almost 70% of global BPA capacity (Byrne et al, 2008). As Sarah Vogel, a bisphenol A historian, notes, “the stakes in this battle are exceedingly high, economically, politically, and biologically”(Vogel, 2008).

Bisphenol A is a chemical with mounting biomonitoring evidence as well as health effects data. The Centers for Disease Control has conducted national biomonitoring for thirty years and now tests for 212 chemicals, including bisphenol A. The *Fourth National Report on Human Exposure to Environmental Chemicals* released by the CDC in 2009, which monitored participants age six and older, found BPA in “nearly all” of the people tested, indicating persistent widespread exposure. While the CDC conducts large-scale population surveillance, they do not have a hand in regulation. They produce population-wide exposure reports, akin to how the U.S. Census produces demographic information, which may or may not be considered in health protective regulations. In addition, there have been more than 125 studies on bisphenol A funded by government agencies such as the National Institutes of Health documenting a wide range of effects such as behavioral changes, disruption in hormone production, abnormalities in sperm production, and immune disorders.

Many of these studies have not been considered in regulatory assessments and there has been disagreement among different government branches regarding their interpretation of the scientific evidence and whether and how to regulate BPA (Erler, 2009). In May 2008, the Food and Drug Administration found levels of BPA leaching into food from containers to be safe, while in September 2008 the National Toxicological Program’s (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) concluded that current human exposure levels to BPA is of “some concern”(NTP, 2008). In particular, the NTP concluded that BPA could impact brain, behavior, and prostate glands in fetuses, infants, and children at current human exposures. Additionally, they found “minimal” concern for effects on mammary gland and early puberty for females in fetuses, infants, and children at current levels of exposure. More recently, in January 2010 the FDA reevaluated BPA under mounting public and government pressure and agreed with the NTP that it is a chemical of “some concern”. Nonetheless, they noted that they do not have the power to regulate BPA because it is classified as an “indirect food additive”(Kissinger, 2010). On its website, the FDA explains that BPA food contact uses were approved under food additive regulations issued more than forty years ago, and any manufacturer can use BPA in accordance with the regulation. There are hundreds of different formulations of BPA-epoxy linings and manufacturers are not required to disclose these formulations. The FDA, in order to alter the criteria under which BPA is currently allowed in use, would have to go through an extensive rule-making process to revoke any uses of BPA by redefining BPA (FDA, 2010).

Environmental health advocates are pressuring the FDA to change the criteria allowing BPA's pervasive use in food packaging.

Background on U.S. Toxics Regulation

This section addresses in greater detail the existing U.S. chemicals policy structure and the challenges to incorporating new scientific data from biomonitoring into decision-making. The problem of a glacially slow federal regulatory system has led advocates to address problems of chemical exposures through the market, going directly to corporations and appealing to the general public.

There has been less analysis of market processes that fall outside of state regulation, that have emerged largely as a result of a recalcitrant state that has not enacted regulatory reforms despite the existence of compelling, albeit equivocal scientific evidence of potential health concerns from chemical exposures (Geiser, Tickner and Torrie, 2009; Fung and O'Rourke, 2000). The result is that chemicals regulation is, "a series of different un-integrated policies at the federal, regional, state, and local levels" (Tickner et al, 2005). The Toxic Substances Control Act (TSCA) is the legislation that guides U.S. national chemicals regulation. Research on U.S. chemicals governance has primarily investigated the failure of TSCA to accomplish its goals to protect public health and the environment. Broadly, TSCA was passed in 1976 following a 1971 report from the White House Council on Environmental Quality on the lack of government oversight over chemical hazards. TSCA was intended to "prevent unreasonable risks to public health or the environment". TSCA is lengthy and includes many provisions, but the cornerstones of the Act are the requirement for manufacturers to notify the EPA at least 90 days before the manufacture and processing of any new chemical, authorizing the EPA to issue regulation if a chemical poses a threat of harm, and requiring the EPA to test chemicals and chemical mixtures where there is insufficient data to make a risk determination.

At the time TSCA was passed, 62,000 chemicals were on the market and these chemicals were grandfathered in with no additional testing requirements. These chemicals still make up more than 99% by volume of what is on the market today (Tickner et al, 2005). Research on TSCA's failure to protect public health and the environment has pointed to the grandfathering of chemicals that limited the incentive for companies to introduce new, less toxic chemicals and the incredibly high bar of scientific proof placed on the EPA to demonstrate a chemical's harm. This has led to a stalemate where very few chemicals are regulated while thousands of chemicals remain untested and in commerce (Wilson and Schwartzman, 2010). Scholars have referred to the data gap, the safety gap, and the technology gap in existing chemicals regulation and marketing. The data gap emerges because we know very little about the safety of existing chemicals since producers are not required to disclose information on the hazard traits of chemicals or products to the government, downstream users of the product, or the public. There is a safety gap because the government lacks the legal tools it needs to address or mitigate environmental health and safety concerns. The technology gap refers to the lack of upstream, government investment in less toxic chemicals or green chemistry (Wilson and Schwartzman, 2009). Additionally, the burden of proof lies with government

agencies such as the Environmental Protection Agency and the Food and Drug Administration, as well as the general public, to prove, on a chemical-by-chemical basis, that such chemicals will present an unreasonable risk. Moreover, the benefits of the regulation must outweigh costs to industry. This onerous burden leads to agency inaction. They often find it more beneficial to undertake consent agreements with individual companies to stop the production of problem chemicals on a voluntary basis than pursue regulatory solutions (Tickner et al, 2005).

TSCA's regulatory holes have led to efforts over the years that seek to fill in the gaps. Some efforts have focused on "information-based regulation", which have sought to reduce industrial emissions by disclosing information on pollution sources to corporate managers, regulators, and the public. One example of such state actions is Proposition 65 in California, which requires a warning label to be placed on sites and products containing known carcinogens and reproductive toxins. Another case is the Massachusetts Toxics Use Reduction Act (TURA), which uses information disclosure and mandatory planning to push for voluntary industry toxics reduction measures. Research on TURA has found while right-to-know initiatives can indeed spur and achieve toxics reduction, firms can decide against adopting toxics reduction practices (O'Rourke and Lee, 2004). Biomonitoring data could be considered an additional form of "right-to-know", where there has been a growing push to enumerate the extent of bodily exposures as the endpoint of a largely unregulated chemicals economy. In the absence of federal regulation, advocates have also pushed state-by-state policies to address chemicals such as bisphenol A.

Biomonitoring Data and Endocrine Disruption Science: U.S. Regulatory Recalcitrance to Emergent Scientific Data

Bisphenol A has risen to chemical prominence for two interrelated scientific reasons. First, numerous scientific studies have chronicled bisphenol A's role as an endocrine disruptor, altering the body's hormone systems at very low levels of exposure (vom Saal et al, 2007). Second, bisphenol A has been biomonitoring both by the federal government through the Centers for Disease Control surveillance program and through academic and advocacy studies that have found bisphenol A in the majority of the U.S. population. Academic dietary intervention studies have repeatedly shown BPA levels in urine to dramatically reduce when ceasing the use of polycarbonate bottles or products with plastic packaging (Rudel et al, 2011; Carwile, 2009).

Endocrine disruptors challenge the monotonic (the higher the dose, the greater the effect) dose-response relationship that has long been the cornerstone of toxicology and chemicals regulation. Interruptions to delicate hormonal processes can occur at even low levels of exposure. Endocrine disruptor research has further shown that the "timing makes the poison" with increased vulnerability in windows of rapid physical development such as the fetal period. Existing regulatory structures do not account for these low levels of exposure that could impact vulnerable windows of development. So, bisphenol A is known to be problematic for health at low levels *and* it has been found in

bodies everywhere at these low levels—raising important questions about how we should regulate such a chemical.

Biomonitoring and Chemicals Regulation

The proliferation of human biomonitoring data presents a challenge to existing chemicals regulation. This is somewhat surprising since biomonitoring data is not new to standard setting. It has been used in occupational health contexts since the 1890's to monitor workers and set exposure guidelines in the workplace (Needham, 2008). The opposite has been true in terms of regulation outside of the workplace. In 2009, the Government Accountability Office released a study that chronicled the federal government's shortcomings on biomonitoring titled, "EPA Could Make Better Use of Biomonitoring Data" (GAO, 2009). This study found that the EPA had made very limited use of biomonitoring in its assessments of risks posed by commercial chemicals and recommended the EPA improve its use of such data.

The GAO considered EPA's challenges in that they have limited access to biomonitoring data on the entire U.S. population for the 6,000 chemicals that companies produce in quantities of 25,000 pounds or more per year. There is biomonitoring data available for only 212 of these chemicals. The GAO also acknowledged that biomonitoring data alone does not provide information on source, route, and timing of exposure, making risk management difficult. But the GAO pointed out that a core problem is EPA's lack of research coordination with other government agencies conducting biomonitoring and lack of understanding of its own authority to obtain biomonitoring data from industries under the Toxic Substances Control Act. The GAO recommended that EPA develop a comprehensive strategy to improve its ability to use biomonitoring in risk assessments, to determine its legal authority under TSCA, and if needed to request additional authority from Congress to collect pertinent data from industry and other government agencies. The GAO report represents an important step in acknowledging the increasing relevance of biomonitoring as a source of exposure data for environmental health policy-making. However, there is little indication to date that the EPA has implemented GAO's guidelines.

The challenge of incorporating new data from biomonitoring into regulatory practices is a reflection of the larger challenges of the U.S. policy-making process. The comparative study *Controlling Chemicals* offered one of the earliest critiques of this messy process, which is "costly, confrontational, litigious, formal, and unusually open to participation". In this environment, government scientists have come to heavily rely on quantitative data through risk assessments and exposure assessments for regulatory decision-making (Brickman, Jasanoff, and Ilgen, 1985). Brickman, Jasanoff, and Ilgen found the U.S. process to be much more open to participation by both community groups and industry than its European counterpart, and for this reason regulators felt the need to buttress their decisions by relying on quantitative representations of risk, the use of mathematical models to measure and characterize exposure to toxic substances, extrapolating human risk estimates from animal studies, and setting "*de minimus*" (no need for action) levels of risk (Jasanoff, 1990). This structure has led to a regulatory

system lacking in precautionary policies and heavily dependent on evidence-based data (Vogel, 2003).

In an article on the benefits of biomonitoring data for toxic chemicals regulation, Richard Jackson, who while at the CDC instituted the existing effort to biomonitor chemicals in the U.S. population, noted,

biomonitoring measures (rather than predicts) the toxicants that actually get into people and the concentrations of those toxicants. The value of biomonitoring lies in decreasing uncertainty associated with assessing human risk and vastly improving the ability to make timely and appropriate public health decisions and regulations. As a result, scarce resources can be used to address serious problems rather than those that are of negligible health concern (Jackson et al, 2002).

This perspective on “decreasing uncertainty” is not shared by industry groups such as the American Chemistry Council, who acknowledge that biomonitoring data will increasingly drive environmental health policy-making but argue that significant knowledge gaps make this data unusable for policy decision-making,

Research is needed to link biomonitoring data quantitatively to the potential for adverse health risks, either through associations with health outcomes or using information on the concentration and duration of exposure, which can then be linked to health guidelines (Vogel, 2008).

This debate on whether biomonitoring data should be used as a precautionary tool to make informed public health decisions or whether new research should be relied on to make explicit links between exposure levels and health outcomes is ongoing in the regulatory arena.

The GAO study touches on important challenges at the intersection of science and policy for the use of biomonitoring data, including the specific problem of biomonitoring data coupled with endocrine disruption science. Biomonitoring technology allows for the measurement of chemicals at lower and lower levels. The endocrine disruptor hypothesis argues that these low levels of exposure can lead to adverse health effects. Vom Saal and other scientists have repeatedly called for BPA regulators to set lower exposure thresholds in recognition of the lower levels at which BPA operates. Scientific debates around endocrine disruption have centered on whether levels of contamination revealed in population level monitoring are high enough to generate concern and stricter regulation. Industry groups such as the BPA Polycarbonate Global Group argue that the body metabolizes BPA quickly and it exits rapidly through urine and therefore does not pose a health threat. Advocacy groups point to the very high numbers of people who show exposures in population level surveillance and argue that these numbers indicate people are continually exposed and re-exposed. For this reason, despite its rapid metabolism, BPA acts more like a chronic exposure in the body (Personal Communication). Advocacy groups and many scientists are especially concerned with exposure during vulnerable windows of development.

An additional problem with biomonitoring chemicals such as bisphenol A are that there are no regulatory benchmarks to which biomonitoring data can be compared since none have been set through regulation. For this reason, many advocacy and academic biomonitoring studies compare biomonitoring data gathered through smaller cohort studies with national population level data gathered by the CDC in order to have some way to comparatively understand exposures.

Endocrine-Disruption and Chemical Regulation

The challenge of endocrine disrupting chemicals (EDC), like the case of biomonitoring data, provides a strong example of the limitations of existing government regulation in the face of new scientific evidence. In 1996, the Environmental Protection Agency established the Endocrine Disruptor Screening Program (EDSP) to address a mandate by Congress to test endocrine-disrupting chemicals as a part of the Food Quality Protection Act (FQPA). Endocrine disrupting chemicals are chemicals that can mimic natural hormone systems, stimulate or inhibit the endocrine system, and can result in development and reproduction problems (Environmental Protection Agency; www.epa.gov/endo/pubs/edspoverview/primer). Through the EDSP, the EPA acknowledged that very little is known about endocrine disrupting properties of the existing 82,000 chemicals in commerce.

Vogel in his research on the EDSP argues that the program cannot effectively protect public health and the environment from EDC's for four reasons. The EPA cannot practically evaluate thousands of chemicals in a reasonable amount of time and efforts to prioritize them are problematic; it is very difficult to establish a relationship between EDCs and health hazards, particularly since EDCs break the established rules of toxicology that have guided chemical regulation; exposure complexity is a real problem since low-dose and transient effects can be hazardous; and while Congress mandated the testing for EDCs, no new regulatory authority was created to actually manage and address EDCs, which will lead to fragmentary efforts across multiple departments (Vogel, 2005).

Woodruff, an environmental health scientist, has noted that the regulatory process for EDC's is moving forward but is slow and fragmented. She makes specific suggestions that can improve the EDSP. She argues for a multi-pronged strategy that would develop new methods for high-throughput screening of EDCs in order to deal with the enormous number of chemicals that need to be tested; a better use of existing data and information in order to have a more flexible weight of the evidence for identifying EDCs; an increased emphasis on ambient monitoring and the identification of sources of EDCs; new models for comprehensive chemicals evaluation; and the need to improve chemicals regulation policy more generally (Woodruff, 2007). Despite these suggestions, a comparative analysis of EDC regulation in the U.S. versus Europe by Ansell and Balsiger found that the scientific testing programs in the U.S. are particularly inappropriate for EDCs and other forms of new data, science, and technology since there is a clash between "emergent" concerns and "mature" systems or regulatory frameworks (Ansell

and Balsinger, 2009). They argue that the U.S. regulatory system is a mature system, meaning that it is extensively institutionalized, which results bureaucratic machinations that are slow, painful, and generally resistant to change.

For the case of the endocrine disruptor bisphenol A, the scientific and regulatory saga has been extensively chronicled elsewhere and can be recounted here briefly (Vogel, 2009). Most accounts begin with the research of Frederick vom Saal who published research in 1997 that demonstrated that bisphenol A exposure in pregnant mice leads to enlarged prostates in their male offspring. Surprised by these findings, he then published additional research showing BPA exposure shrinks seminal vesicles and enlarges glands that produce sex pheromones. The chemical industry took notice and, according to vom Saal, hired scientists to replicate and try to discredit his work (Gross, 2007). Since BPA is in mass circulation and conflicting scientific reports continued to emerge, the EPA asked the National Toxicological Program (NTP) to review the evidence on BPA. The NTP's assessment would have important implications since if the panel decided the evidence about BPA was compelling, it would call into question the EPA's existing risk-assessment practices based on "the dose makes the poison" toxicological paradigm. It would also raise the issue of safety of thousands of chemicals sold by pesticide and chemical companies.

In its initial 2001 report entitled *Report of the Endocrine Disruptors Low Dose Peer Review*, the NTP decided that there was "credible evidence" that low doses of BPA could cause adverse health effects. But the NTP did not believe these effects were strong enough to be conclusive and reproducible. They did, however, call for a new testing paradigm recognizing the growing consensus that endocrine-disrupting chemicals might not follow the monotonic dose-response relationship (NTP, 2001). In response, the American Plastics Council commissioned its own review from the Harvard Center for Risk Analysis, which received funding from all the major BPA producers and their trade groups (Gross, 2007). This report concluded that the weight of the evidence was very weak. Since the NTP's first assessment in 2001, there have been five additional reviews of the scientific literature. In 2008, the Center for the Evaluation of Risks to Human Reproduction (CERHR) located within the NTP released its final report and found BPA to be of "some concern for effects on the brain, behavior, and prostate glands in fetuses, infants, and children at current human exposures to BPA" (NTP, 2008).

In August 2008, faced with mounting public and political pressure because of its role in regulating bisphenol A in food and beverage contact items and its lack of action in reviewing the science, the Food and Drug Administration released a draft assessment of the reproductive and developmental toxicity and carcinogenicity of bisphenol A, and found "no observed adverse effect level". However, the FDA had not included hundreds of studies published in the peer-reviewed literature that had found adverse effects from BPA at low levels.⁴ The FDA was accused of being captured by industry because they had relied heavily on two multigenerational studies that were industry funded. Even the

⁴ For an extensive account of the BPA controversy, see Vogel, Sarah A.; "The Politics of Plastics: The Making and Unmaking of Bisphenol A 'Safety'"; v99, No33, Supplement 3; *American Journal of Public Health*; 2009

Science Subcommittee of the FDA disagreed with the FDA's methods. In response, the FDA agreed to look at the issue of BPA in more depth, and currently on its website the FDA states that it "shares the perspective of the National Toxicology Program". But the FDA also stresses that there are many uncertainties about BPA and they are pursuing "additional studies" (FDA, 2010).

These scientific debates over biomonitoring data, over endocrine-disrupting chemicals, and over bisphenol A have led to a growing sense by advocacy groups, the general public, and even some state legislatures of regulatory paralysis through over-analysis. Advocacy organizations and consumers have become incredibly frustrated with the state of federal chemicals policy and, rather than continually wait for a definitive regulatory outcome, they have waged public and market campaigns to address problems of chemicals in an array of consumer products and in human bodies.

Non-State Market Driven Efforts to Target Bisphenol A

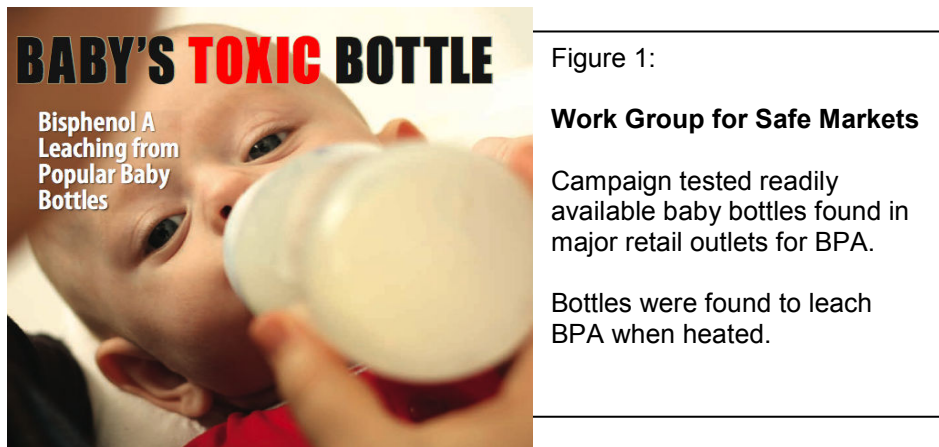
Because regulatory agencies have not taken action on bisphenol A and many other bad actor chemicals, non-profit organizations and other stakeholders have been conducting small-scale biomonitoring studies, independent product testing, and media campaigns to take the problem directly to consumers and corporations. As noted above, the use of scientific data and media strategies by advocacy organizations to compel corporate changes are a form of non-state market driven systems or civil regulation (Bernstein and Cashore, 2007). Civil regulation governs the social and environmental impacts of firms and markets without state enforcement. Efforts to govern chemicals such as Bisphenol A through non-state market systems target priority chemicals in order to raise awareness about widespread exposures to toxic chemicals in the general public, profile products formulated using these chemicals, push corporations to pull or reformulate products, provide information to consumers, and ultimately work for awareness that could bring larger scale changes in policy.

Despite little evidence that market campaigns affect company profits, businesses such as Philips Advent and other companies that reformulated their BPA baby bottles *do* often respond to non-state market driven campaigns, for a variety of reasons. These include pressure from advocacy organizations that have become increasingly sophisticated at employing public shaming strategies, an increase in politically oriented consumerism, changes to their own corporate strategies, and the changing realities of business norms and values (Vogel, 2008). Little research has been done on civil regulation and non-state market driven strategies and the research that does exist largely comes from the forestry sector (Cashore et al, 2004). Efforts promote corporate change through consumer action has also been notable in the realm of anti-sweat shop movements where, for example, student boycotts of sweatshop-produced clothing on college campuses drove awareness of factory conditions in the U.S. and abroad (Fung et al, 2001).

Studies of market-driven efforts have shown that successful campaigns to target and ostracize products share some important characteristics. These campaigns take on a

product that is easily identifiable by consumers, target as few brands as possible, select publicly visible targets, and choose products that have readily available substitutes (Friedman, 2008). These characteristics explain how bisphenol A has risen to chemical fame through its use in high profile products such as baby bottles. Bisphenol A is used in a huge array of products, but in order to be successful, advocates must narrow their campaigns to profile only one or two product categories. Advocacy efforts to ostracize bisphenol A have taken on high profile water and baby bottles, which are made by a handful of companies, where BPA-free substitutes are already on the market or can be readily reformulated by bottle makers. Canned goods, which are actually a more pervasive source of bisphenol A exposures, are more difficult to target because they represent a huge range of food products, are canned and sold by a large variety of companies (even though the cans themselves are relatively narrowly produced), and do not have ready substitutes.

In an example of this strategy in the case of BPA, in 2007 the Work Group for Safe Markets, a coalition of public health and environmental NGO's in the U.S. and Canada, published the report *Baby's Toxic Bottle: Bisphenol A Leaching From Popular Baby Bottles* (Figure 1), profiling popular and easily available bottles from retail stores. The coalition worked with the laboratory of famed BPA researcher Frederick vom Saal to simulate repeated bottle washing and measure how much BPA leached from the bottles when heated (as when washed in a standard dishwasher). Leachates were then shown to end up in babies' bodies, particularly when consuming apple juice or milk, which are acidic and can cause an already compromised bottle to leach BPA. They also profiled retailers, stating, "Major retailers including Babies R'Us, CVS, Target, Toys R'Us, Walgreens, and Wal-Mart, sell baby bottles that leach BPA when heated". Though a biomonitoring study was not conducted in this particular campaign, they cited CDC surveillance data that found BPA in 93% of people tested, making the connection between leaching from baby bottles and pervasive presence in bodies (Work Group for Safe Markets, 2007).



Efforts such as these have raised the profile of BPA, leading to the eventual removal of BPA bottles and other baby products from retail outlets and shifted

manufacturing to include BPA-free bottles and other children's eating containers. These groups have also successfully championed state and local legislation to remove BPA in children's food container products in an effort to circumvent lackluster federal reform.

Advocacy market efforts have made key inroads towards passing local and state regulations. Staffers in the California state legislature, which has repeatedly introduced legislation to remove BPA from children's products, noted that the market is often driven by advocacy groups and moves ahead of the legislative process. The legislative process takes a cue from what is doable in the market place (Personal Communication; March 23, 2010). Legislative staffers noted that the market plays an important role, but it is fickle and not comprehensive, which is why advocates then pursue legislation. However, they note that state legislation is limited by political feasibility and industry ability to sway the discourse.

Consumers are a challenge because they are not always clear in their goals. In the case of canned food, "consumers want something that can sit on their shelves for three years and they don't know what goes into a can for it to be usable for three years". In this case, children's products have far more traction for state bills than canned goods. Legislative staffers noted that, "being politically doable is more important than anything else. Kids, babies, pregnant moms resonate with the larger population"(Personal Communication; March 23, 2010). In terms of deciding how to take on one piece of chemical legislation versus another, they note their strategy is to "shake like a wet dog and see what sticks".

Boycotts and product targeting campaigns have been useful because they have raised awareness about bisphenol A in the general population and have been successful in pushing industry to make changes to highly visible and identifiable products. When advocacy groups such as the Work Group for Safe Markets targeted bisphenol A in baby bottles and the retailers that were selling these bottles, Wal-Mart, Toys R' Us, and Target responded and removed baby bottles with BPA from their shelves in 2008. These retailers cited consumer concern and manufacturers noted the increasing difficulty of finding retail outlets. Since these efforts are less successful for targeting more general product categories without readily available substitutes, widespread exposures to BPA continues to persist and is difficult to eradicate through market pressure alone.

However, it should be noted that the story of BPA removal from baby bottles in the U.S. is more complex than consumer demand and boycotts. The decision by U.S. retailers seems to have been helped along by a Canadian government ban on BPA use in baby bottles in April 2008 (Personal Communication, June 7, 2010). U.S. retailers followed suit in July 2008. This timeline of events raises questions as to whether industry claims of responsiveness to consumer concerns in the U.S. were actually a calculated economic response to national policy in Canada, making it easier and cheaper for Wal-Mart and others to address the bottles in North America more generally. Indeed, a Wal-Mart staffer responsible for sustainability noted,

It was originally the Canada stores that did that and we followed. It is hard for us to get involved with science or politics either way....We are a retailer and its our

goal to provide what our customer wants....Canada did it first and we quickly did it too.. BPA is very hard because the FDA hasn't banned it. There wasn't anything and they are still evaluating it and the FDA is still working on studies. You have another retailer that is going to pull it off the shelves and so sometimes you follow. (Personal Communication, June 7, 2010)

The sustainability staffer did *not* note that Canada Wal-Mart removed the bottles due to a government ban. He did note that Toys R' Us and other retailers did not want to be left behind Wal-Mart, and so they followed suit.

Overall, studies of consumer politics in the U.S. have found that corporate behavior has not changed as a result of consumer or market pressures but has primarily been a result of government regulation (Vogel, 2008). Political expression through the marketplace is considered an important contributor to making changes in the regulatory and policy process, since it places issues that otherwise would not be there on the political agenda. But it is ultimately government policy and regulations that have been found to change corporate conduct (Vogel, 2008).

In the case of bisphenol A, government regulation in Canada (driven by cross-national NGO efforts such as the Work Group for Safe Markets) pushed local corporate changes that rippled into the U.S. In 2010, Canada used the existing scientific data and pressure to list BPA as a "toxic chemical", opening the door for a larger scale chemical ban. Despite evidence that the Canada baby bottle decision gave U.S. retailers a nudge forward, there is little evidence that the EPA or the FDA in the U.S. will similarly declare BPA to be toxic. What is evident from the chart below is that market decisions have led the way in addressing BPA in the U.S, federal agencies have demonstrated an unwillingness to act, and local and state governments have responded in lieu of federal action (see Figure 2).

Figure 2: BPA Milestones: Market, Local, State, and Federal Decisions

January 2006	<i>(Market)</i>	Whole Foods stops sale of BPA baby bottles and sippy cups
April 2008	<i>(Federal/International)</i>	Health Canada concludes BPA dangerous; first country to ban BPA from baby bottles
April 2008	<i>(Market)</i>	Wal-Mart Canada pulls BPA baby products; Wal-Mart USA, Target, Toys R' Us, CVS, and Babies R' Us announce they will cease sales of baby bottles and other children's food containers with BPA
May 2008	<i>(U.S. Federal)</i>	FDA declares BPA "safe"
September 2008	<i>(U.S./Federal)</i>	National Toxicology Program issues final report finding "some concern" over BPA
March 2009	<i>(Local/Regional)</i>	Suffolk County, NY first jurisdiction to ban BPA in children's beverage containers
May 2009	<i>(Local/Regional)</i>	Chicago passes first municipal ban on baby bottles and sippy cups manufactured with BPA
May 2009	<i>(State)</i>	Toxic Free Kids Act. Minnesota is first state to ban BPA in sippy cups and baby bottles
June 2009	<i>(State)</i>	Connecticut bans BPA from infant formula, baby food cans and jars, reusable food and beverage containers. Considered nation's most stringent BPA ban.
August 2009	<i>(Local/Regional)</i>	Albany County, NY bans BPA in baby bottles in sippy cups
August 2009	<i>(Local/Regional)</i>	Schenectady County, NY bans BPA in children's beverage containers
January 2010	<i>(U.S./Federal)</i>	FDA finds BPA of "some concern"
March 2010	<i>(State)</i>	Wisconsin bans BPA in baby bottles and sippy cups
March 2010	<i>(State)</i>	Washington State passes Safe Baby Bottle Act: BPA banned in baby bottles, sippy cups, children's dishware, sports bottles
April 2010	<i>(State)</i>	Maryland bans BPA in children's products
May 2010	<i>(State)</i>	Vermont bans BPA in baby bottles, spill proof cups, reusable food and beverage containers; 2 nd most stringent ban after CT.
June 2010	<i>(State)</i>	New York State bans BPA in pacifiers, baby bottles, sippy cups, and straws
October 2010	<i>(Federal/International)</i>	Canada declares BPA a "toxic chemical"
April 2011	<i>(State)</i>	Maine bans BPA from baby bottles, sippy cups, water bottles, and reusable food storage containers

Advocacy Biomonitoring Studies as a Subset of Non-State Market Driven Politics

Biomonitoring technology has become increasingly affordable, making it more accessible to a wider range of organizations, including advocacy organizations (Morello-Frosch, 2009; Altman, 2008). Advocacy groups, particularly environmental health and justice groups, have conducted small-scale biomonitoring studies in politically salient populations such as babies, pregnant women, fence-line communities, and people living far from any source of industrial emissions and publicize their findings through consumer advocacy and the lay media (Morello-Frosch et al, 2009). Advocacy biomonitoring studies seek to link toxins in consumer products, regulatory science, and environmental health problems (Iles, 2007; Urban Habitat, 2004). Organizations such as Commonweal, Alaska Community Against Toxics, and the Washington Toxics Coalition conduct biomonitoring studies to address the problem of poor chemicals management and to demonstrate the ubiquitous chemical presence in human bodies.

The goals of advocacy biomonitoring studies, in this way, are entirely different from academic studies and government surveillance since they have a mission to educate the general public, profile hazardous chemicals, and pressure industry and government changes in chemical policies. This type of scientific research deployed by advocacy groups has been termed “data-judo”, “a strategy in which study design and individual results communication are shaped primarily by policy goals to improve chemical regulation.... Environmental advocacy groups and communities marshal their own scientific resources and expertise to conduct research, and report-back strategies are specifically aimed to advance regulatory and policy change” (Morello-Frosch et al, 2009, p.6).

Advocacy biomonitoring studies have gained traction because they individualize and personalize science. Unlike the Centers for Disease Control, which publishes population level data in tables and charts or academic studies that are often published in inaccessible peer-reviewed journals, advocacy groups publish their biomonitoring results in accessible reports alongside names, faces, geographies, photos, and histories, and they discuss problems of “toxic trespass” and involuntary body burden. Though their sample sizes are small, the results are personal. These studies have effectively linked biomonitoring science with human faces, making biomonitoring data compelling to the average person. An advocate at Commonweal, one of the non-profit organizations that continue to be at the forefront of advocacy biomonitoring, stated,

the average person has become much more sensitized to the importance of the data, importance of the information. It’s actually quite sobering to learn what chemicals you have in you and I think we’ve seen, somewhat universally, among individuals who get personally biomonitoring that they know to some degree of confidence that ‘yeah, I know I’m going to have chemicals in my body, I’m prepared for that.’ The actual numbers still kind of take them aback. So I don’t think there’s very many people in the public who learn about biomonitoring data and immediately pooh pooh it. I think in fact, the opposite is true; the more information about it that gets out, the more people are concerned about

it, the more they would like to see more discussion and reasonable solutions put forward to reduce the risk that chemical exposure has (Personal Communication, May 6, 2009).

Advocacy groups have been very successful at making palpable connections between biomonitoring science, personal exposures, and possible solutions that could address the problems of chemical exposure. As noted by Commonweal, most people already know that they will have a “body burden” but hearing their own personal results is still alarming and a cause for subsequent action. People want to know what to do when faced with biomonitoring evidence. They want to take personal action in the things they purchase, address exposures in their homes, limit their families’ exposures to chemicals, and even participate in larger scale actions to address problems with chemicals policy. Advocacy biomonitoring data and the way it is presented is a call to action.

In the case of bisphenol A, advocacy biomonitoring studies have been routinely covered in the mainstream press and have led to a new crops of advocacy organizations such as Making Our Milk Safe (MOMS) who repost biomonitoring studies on their websites. For example MOMS state their mission to be, “eliminating the growing threat of toxic chemicals and industrial pollutants in human breast milk”. Groups such as Environmental Working Group and Commonweal have used both biomonitoring and product testing to make the case of chemical trespass. In July 2005, EWG and Commonweal published a study titled, “Body Burden: The Pollution in Newborns” which found 200 different industrial chemicals in the cord blood of newborns. In March 2007, EWG surveyed the epoxy linings of 97 cans of vegetables, fruit, and soda and found BPA levels to be unsafe based on government mandated levels of exposure at the rate of 1 out of every 10 canned food product and 1 out of every 3 infant formula product. They tied these exposures back to Centers for Disease Control data as well as to the growing number of studies pointing to BPA’s role as an endocrine disruptor. In May 2009, EWG released a report titled, “Pollution in 5 Extraordinary Women: The Chemical Body Burden of Environmental Justice Leaders” documenting 48 chemicals, including bisphenol A, found in these women (EWG, <http://www.ewg.org/featured/15>). EWG also publishes articles such as “Tips to Avoid BPA” such as using BPA free baby bottles, rinsing canned fruits and vegetables before ingestion, avoiding polycarbonate plastics, and washing these plastics on the top rack of the dishwasher or by hand (EWG, <http://www.ewg.org/bpa/tipstoavoidbpa>).

Some industry trade groups have dismissed advocacy biomonitoring on bisphenol A as being incomplete and un-rigorous. One industry scientist argued that advocacy studies do not provide enough information because their sample sizes are too small the measurements have been made in urine rather than in blood. He argued that blood measurements are actual measurements of the parent chemical while urine measurements are of the metabolites. A major thrust of his work on BPA has been focused on delegitimizing urine measurements of BPA, despite the use of urine as the measure by the CDC (Personal Communication, December 15, 2010). Advocacy groups admit that their sample sizes are not statistically significant, and that their primary goal is not to publish in the peer-reviewed press (though some organizations have done so), it is rather to build public awareness and push for change. Despite industry efforts to dismiss the legitimacy of advocacy studies, one industry lawyer noted, “I think that people or businesses are

affirmatively deselecting BPA now because of the fear of consequence down the road... BPA is not about noncompliance with environmental standards but it's all about fear of consequence in the use of the product that is widely perceived intergalactically to be a bad actor. So people are affirmatively deselecting it rather than endure the possible consequence of continued use". Its perception as a bad actor has been driven by advocacy biomonitoring studies, academic research, and strong consumer response (Personal Communication, February 26, 2010). One academic scientist noted the connections between biomonitoring studies, advocacy organizing, and industry response: "I think there's certainly been an indirect ripple effect as chemicals like bisphenol A and perchlorate pop up in almost everybody in the whole population, and then NGOs start freaking out about the high prevalence in everybody's bodies and then the public pressure ultimately on industry makes them rethink their product composition" (Personal Communication; April 20, 2009).

Indeed, consultants that make their money advising companies about toxic exposures tell their clients to support state level legislation on BPA to benefit their own reputation, since there is so much evidence about BPA building up in human bodies (Personal Communication, March 5, 2010). Not surprisingly, companies whose brands are tied to their reputation for healthy food and healthy living, such as Whole Foods and Patagonia, took early action to eradicate bisphenol A from products in their stores (Personal Communication, December 15, 2009). These companies received credit for their early response from their consumers, who have been particularly vociferous about their concerns about BPA.

The case of Patagonia points to an additional phenomenon of scientists taking a cue from NGOs and going directly to companies. For example, Frederick vom Saal and Pete Myers, who have gotten little traction in the regulatory arena, went directly to Patagonia and introduced them to the problem of bisphenol A leaching out of the polycarbonate water bottles sold in their stores. It was because of these scientists that Patagonia replaced their Nalgene bottles and searched out another vendor that turned out to be Sigg (Personal Communication, December 15, 2009). These cross-sector interconnections in decision-making are crucial to understanding the full picture of how biomonitoring data and other emergent scientific data is used in the market to propel changes in chemicals governance.

As noted above, legislative actions often follow advocacy studies that put pressure on the market as well as on state politics. In California, where Environmental Working Group has an office and where Commonweal is based, advocacy biomonitoring efforts clearly drove the passage of Senate Bill 1379, which created the first statewide biomonitoring program in the country, the California Environmental Contaminant Biomonitoring Program (CECBP), now known as Biomonitoring California. Environmental health advocacy organizations worked several years for the passage of this legislation and effectively made the point that statewide biomonitoring was important for California's public health. The goals of the CECBP are focused on systematically improving public health by determining the levels of environmental chemicals in a representative sample of Californians, establishing chemical trends over time, and

assessing the effectiveness of public health efforts and regulatory programs to decrease exposures to specific chemicals (OEHHA; oehha.ca.gov/multimedia/biomon/index.html). California legislative staffers noted, “The NGO data is a great first shot on the emerging stuff.... It’s great to pull us to something that needs more attention. They were really influential for the California biomonitoring legislation that we think is so promising” (Personal Communication, March 23, 2010).

Advocacy efforts to address chemical exposures and the marketplace of chemicals have found real traction through non-state market driven strategies to intervene in chemicals governance. Regulatory scientists and policy-makers have been in a holding pattern, immobilized by newly emergent science and industry pressure, and have done little to address the problems of ubiquitous chemical exposures. In the case of bisphenol A, the NTP, the FDA, and the EPA have stalled decision-making by conducting additional studies. In this regulatory vacuum, advocacy organizations have leveraged CDC data, highly respected by all scientists, as a comparison point for their own small-scale biomonitoring studies that individualize names, faces, and locations of people who have been measured for toxic trespass. Advocacy biomonitoring studies have been useful as a part of larger chemical policy reform campaigns that have pushed for industry reformulations of water and baby bottles. They have successfully pushed some canned food companies to remove BPA from their cans as a matter of brand reputation, pressured retailers to remove baby bottles with BPA from store shelves, passed local and state bans on children’s food products with BPA, and pushed through statewide biomonitoring in California. Advocacy biomonitoring studies exemplify non-state market driven efforts that successfully and compellingly connect scientific data, personal exposures, industry culpability, and the need for regulatory and policy change.

Challenges of Consumer Choice as a Route to Chemicals Policy Reform

Research on market movements shows that very little is known about how and why consumers make the decisions they make in the marketplace nor the confluence of reasons that lead to consumer, corporate, and entire market shifts (O’Rourke, 2005). Nonetheless, advocacy efforts to pressure the market are an important trend in pushing for changes in governance. O’Rourke, in his research on NGO-driven market movements writes, “in the past, where NGOs would have targeted government decision-making and regulation through lobbying, they now target consumers and corporations as the key decision makers regarding production and consumption. Through these campaigns, advocacy groups seek both to drive consumer preferences and deploy existing consumer concerns in the cause of influencing corporations”(O’Rourke, 2005).

Despite a lack of knowledge on consumer reasoning, these NSMD approaches have shown traction in U.S. chemicals governance. Industry acknowledges that advocacy organizing through science campaigns involving media outreach influences consumer preferences, and industry responds. Industry has increasingly tried to remove BPA from their products and when they do so, they profile these changes through “BPA-free” labeling. Industry advisors note that companies can avoid a litany of business risks, such

as being locked out of the market through regulation, and litigation by being proactive (Personal Communication, March 5, 2010). Despite a lack of regulatory movement on BPA, advocacy “data judo” strategies appear to have played a part in moving firms to reformulate products in response to consumer demand and concern regarding exposures and potential health impacts in vulnerable groups. Yet, this strategy has significant limitations.

BPA continues to be ubiquitous in canned food and beverage products and with few alternatives and no vigilant consumer base to advocate for its removal, it is unlikely that BPA will be removed from canned products anytime soon. It is likely that the main route of BPA exposure is from residues in food, likely to be leaching from can liners. This issue has not caught on in the same way as the baby and water bottle containers and, according to NGO and industry scientists, this could be due to lack of feasible alternatives in canned foods and industry claims that removing BPA would see the rise of deadly microbial illness, far worse than the unproven health effects of low-level chemical exposures. Indeed, it is a trade-off that none would choose.

Equally troubling, BPA seems to be being replaced with other bisphenols such as bisphenol F and bisphenol B, chemicals that science knows much less about than BPA. What little evidence there is seems to implicate these replacements as endocrine disrupters as well, a problem that cannot be addressed through market driven pressures that cannot mandate research on substitutions (Browning, 2011). These larger challenges lead back to the data gap (where little is known about chemicals or their substitutions) and the technology gap (where there has not been a large scale investment to seek out alternatives to the use of BPA in canned goods though there are ongoing smaller efforts).

Some scholars have criticized the trend in targeting consumer preferences as encouraging an individualized response to collective threat. Szasz argues that social movements are collective in their goals, defining problems collectively and pushing for systemic change, while market efforts are not. He argues that, “a person who buys some products because those products promise to shield them from trouble is not at that moment a political actor. He or she is, instead, in the modality of a consumer, responding to a felt need- in this case the need to be protected from harm- by buying certain goods that promise to satisfy that need” (Szasz, 2007). Despite this complaint, consumer action, especially vociferous or large-scale action, has shown to lead to political change. And the reality is that consumer-engaged and market-driven movements are often a last choice option for social movements that have had little success at the regulatory and policy level (Pulido, 1996). According to NGO’s, their ultimate goal is not to influence the market but to change chemicals policies (Personal Communication). The challenge of market-driven efforts is translating individual consumer preferences into larger-scale regulatory, policy, and industry change.

In addition, since market movements must strategically target individual, visible, and replaceable products, they tend to focus on single chemicals and high profile product categories, which can obfuscate the larger goals of dealing with the thousands of problematic but less visible chemicals. There is also a danger of NSMD campaigns to

focus on individual rather than community or national risk. Since biomonitoring data is a “downstream” measure of exposures that have already occurred, some groups, particularly environmental justice communities where place-based exposures compound exposures in consumer products, are concerned that biomonitoring could place individuals and communities as “environmental hazard detectors”. In such a scenario, communities would need to prove their body burdens or extent of exposures prior to any regulatory action being taken (Morello-Frosch et al, 2009).

How the media portrays advocacy biomonitoring studies and biomonitoring data more generally plays an important role in the responses to chemical contamination. A study of media framing of body burden stories in high circulation Canadian news media from 1986 to 2006 found that it was uniformly characterized as a problem. The trend in the media over time, however, has been to focus on “precautionary consumption” rather than stronger regulations, chemical reduction policies, and the improvement of risk assessments. The media increasingly suggested that personal choices and behavioral changes could reduce personal exposure to potentially harmful chemicals. The majority of the articles did not address the issue of responsibility for chemical contamination at all, referring neither to industry nor to government regulation. The failure to identify responsible parties situates body burden as a “blameless phenomenon”, and the onus for protection then devolves to the individual (MacKendrick, 2010). However, advocacy organizations emphasize they must be comprehensive in their approach, informing consumers and advising them on how to protect themselves in the short term and pushing for larger-scale change in the longer term. The ongoing challenge is that individualized messages have power and consumers tend to assume they are protecting themselves through purchasing, while it is impossible to completely avoid chemicals such as BPA.

Conclusion

As biomonitoring technology has become more accessible, it has proliferated in advocacy, academic, and government arenas. In the case of bisphenol A, CDC surveillance biomonitoring proves ubiquitous and continuous exposure to the chemical while academic studies demonstrate the chemical to be potentially damaging at very low levels of exposure. This information has been deployed by environmental health movements that have used biomonitoring technology to conduct strategic advocacy biomonitoring to demonstrate extensive exposure to not only BPA but to a host of chemicals. While government regulatory agencies have been slow to respond to biomonitoring data, consumer demand and market pressure have pushed product manufacturers and retailers to discontinue BPA water and baby bottle sales and develop alternatives. While this strategy addresses some routes of exposure, it has not addressed the systemic problem of exposure to BPA, largely through canned foods, nor does it address the larger universe of chemicals policy of which BPA is a part.

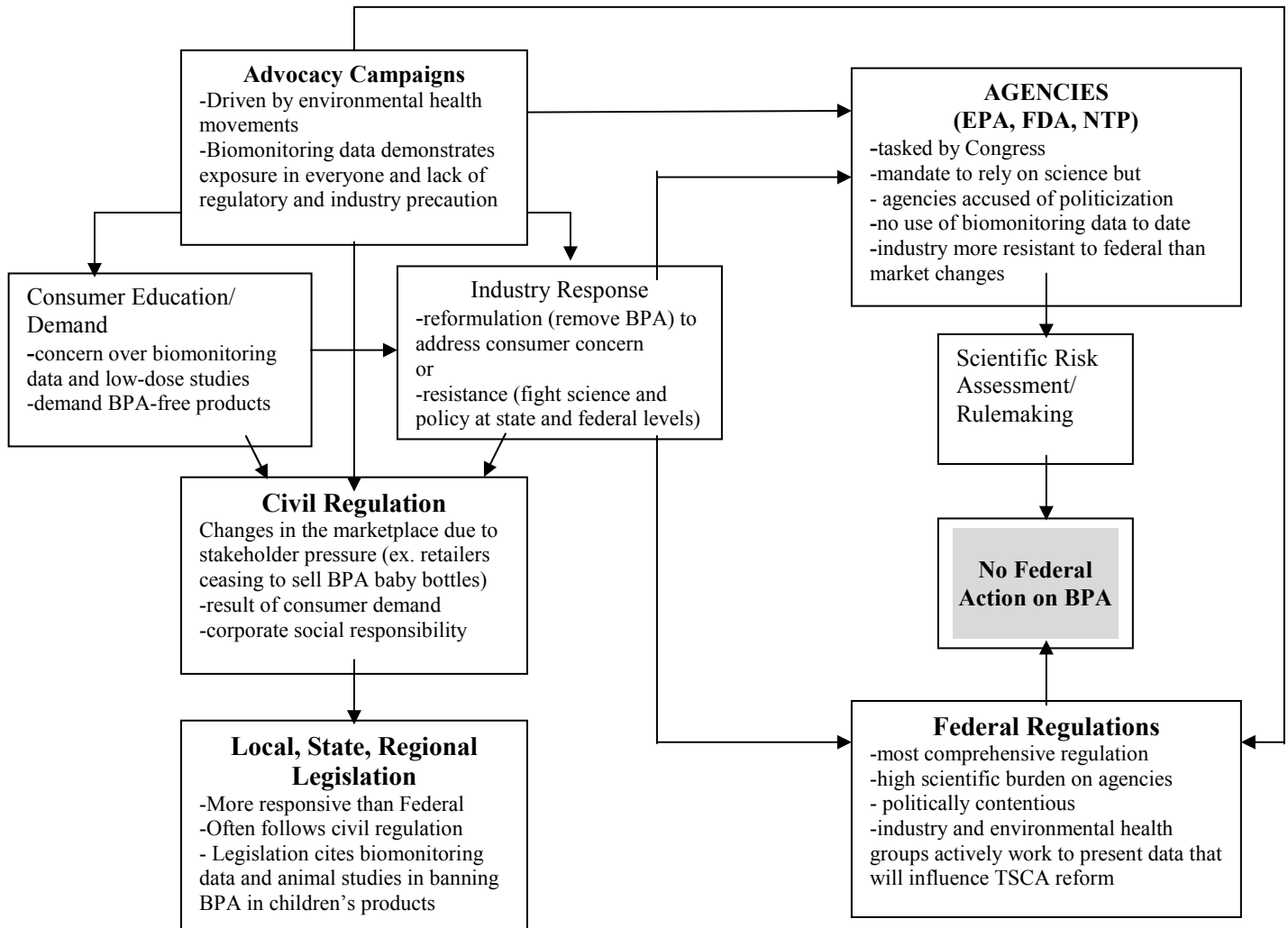
However, in the absence of government action despite mounting information, direct consumer education to reduce chemical exposures and highlight toxic chemicals such as bisphenol A in consumer products, and efforts to enact state bans have been important routes for change. Non-state market driven efforts by advocacy groups have been effective in providing change in some categories of products and most importantly

in putting the issue of chemicals policy reform on the political agenda. But NSDM strategies have the pitfall of “individualizing risk” and pushing debates into ones of consumer choice rather than emphasizing involuntary exposures that cannot often be addressed through single chemical market efforts. While recognizing these shortcomings, advocacy biomonitoring that directly targets consumers and industries do so because of an entrenched state regulatory system that has not provided leadership on chemicals management in decades.

As of this writing, the FDA and NTP have released no additional research nor proposed any additional forms of regulation for BPA. At the federal level, Senator Frank Lautenberg (D, N.J.) introduced the Safe Chemicals Act of 2011, a bill that would mandate companies to confirm chemical safety before introducing them onto the market. The bill is similar to one that failed last year. The Safe Chemicals Act, though it is in its third iteration, is evidence that TSCA reform, a main agenda for advocacy groups, is on the federal political agenda with the hope of actual reform over the next few years.

Figure 2

The Use of Biomonitoring in Bisphenol A Governance



TRACKING REGULATORY FAILURE THROUGH CHEMICAL BIOMONITORING: THE HISTORICAL AND CONTEMPORARY CASE OF CHLORPYRIFOS

Abstract

Chlorpyrifos is an organophosphate insecticide known to be a neurotoxin and a suspected endocrine disruptor. Social movements have waged campaigns to limit or ban chlorpyrifos use but efforts to ban the chemical have often proceeded through uncoordinated social movement strategies and are consistently curbed by economic concerns from industry. Environmental health advocacy efforts succeeded in limiting chlorpyrifos by demonstrating its profound toxicity to children and the chemical was discontinued for consumer sale in 2000. However, its use persists in agriculture at 8-10 million pounds/year. Biomonitoring evidence, emerging from advocacy, academic, and government arenas, has tracked chlorpyrifos exposures in farmworkers, agricultural fenceline communities, and consumers, showing widespread exposure to chlorpyrifos in the general population while workers and agricultural communities face exposures far in excess of the national average. Chlorpyrifos biomonitoring studies challenge the notion that consumers can be protected through product bans while excluding protections for workers or fenceline communities located at the source of the exposure. I argue that chlorpyrifos biomonitoring data provides strong evidence of systemic regulatory failure even in groups targeted for protection under the chlorpyrifos regulatory ban. Biomonitoring exposure evidence demonstrates the need for comprehensive rather than piecemeal regulatory protections that can better address the complex routes of chemical exposures to truly protect public health. Chemical biomonitoring across constituencies also suggests opportunities for cross-movement, cross-constituency organizing strategies.

Key Words: Pesticide, Chlorpyrifos, Biomonitoring, Farmworkers, Drift, Consumers

Introduction

Biomonitoring is fast becoming a key technology for determining exposure to toxic chemicals. Biomonitoring, or body burden research, is the measurement of a chemical, its metabolite, or its reaction product in human blood, urine, fat, hair, breast milk, or other tissues (Black, 2006). Chlorpyrifos, a neurotoxic organophosphate insecticide, has become the subject of several academic, industry, government, and advocacy biomonitoring research studies since it is the most widely used organophosphate pesticide in the U.S. (EPA, 2006). This paper traces key peer-reviewed, government, and advocacy chlorpyrifos biomonitoring studies conducted in workers, communities living on the fenceline of intensive agricultural production, and consumers. Through biomonitoring studies, I follow the trajectory of the chlorpyrifos molecule in bodies from points of agricultural production among workers, points of drift or unintended dispersion in agricultural fenceline communities, and points of consumption among consumers.

Chlorpyrifos biomonitoring studies have not been collectively examined in both the social sciences or environmental health sciences literatures. An analysis of chlorpyrifos biomonitoring in different groups is a pathway to better understanding the chemical's exposure footprint. Chlorpyrifos biomonitoring studies tend to be published in the environmental health sciences peer-reviewed literature or as government reports and self-published reports by advocacy organizations. This range of studies, written for different audiences and over several years' span, provides valuable information for social scientists interested in problems of chemical exposure. These studies collectively tell the story of a chemical molecule that travels and can be measured in human bodies at every point along its journey from field to food plate. Monica Casper in her essay *Chemical Matters* argues for "following the molecule" as a necessary means for understanding the complex interplay of industrial chemicals as they move across a multitude of sites where they have come to inhabit and affect people, communities, and institutions (Casper, 2003).

This perspective emphasizes that humans both shape and are shaped by the movement of chemicals. Historically, social scientists have most often studied place-based community efforts to fight chemical exposures disparately contaminating communities and adversely affecting community health (Bullard, 1993; Brown, 1997). But, industrial chemicals are increasingly persistent, becoming embedded in bodies and ecosystems around the globe regardless of place. In this way, chemicals have come to straddle the boundary between "nature" and "culture" (Roberts and Langston, 2008). Biomonitoring technology allows for a literal "following" of the molecule, pushing forward our conceptual and discursive understandings of chemicals across constituencies. By making chemicals in human bodies more "visible", biomonitoring provides measurable evidence that a chemical exposure exists. For chlorpyrifos and other biomonitored chemicals the crucial question has become *at what level* the chemical is harmful and where regulatory benchmarks are set to address this harm.

In this paper, I discuss the ways that biomonitoring data connects the often disconnected worlds inhabited by farmworkers, agricultural fenceline communities, and consumers.

Biomonitoring evidence shows that the pesticide regulatory apparatus has not accounted for the persistent movement of chemicals from agricultural fields into consumer bodies, primarily through the food chain, and has not accounted for low-level health effects resulting from chronic exposures. National surveillance data shows chlorpyrifos to be in the bodies of more than 93% of the general population (CDC, 2005). Chlorpyrifos regulatory exposure standards, which are based on an outdated dose-response regulatory paradigm (Vogel, 2008), have not kept pace with the science of low-level effects. Studies on low-level effects demonstrate that organophosphate pesticides can lead to neurological and developmental damage, making pervasive exposures a public health threat, particularly to children who are in vulnerable stages of growth and development (Schettler, 2001).

A key challenge to systematically addressing pesticide exposures is the fragmentation of pesticide regulation along local, state, and federal lines coupled with the growing focus on market and voluntary solutions, which often do not address the most exposed and vulnerable populations (Harrison, 2008). The broad chlorpyrifos agreement between DowAgrosciences and the Environmental Protection Agency (EPA), which led to the discontinuance of chlorpyrifos sales in consumer products, permitted a lengthy time period for chlorpyrifos phase-out. It also allowed continued use for agriculture, golf courses, communities with mosquito spray programs, and containerized baits for cockroach control (Feldman, 2000).

Beginning with DDT, there is a long history of social movement organizing to address pesticide exposures. These pesticide efforts reflect the fragmentation of pesticide regulation, with separate efforts to address worker health, consumer health, and ecosystem degradation. Environmental justice, workers rights, environmental, and environmental health movements have often strategically parted ways in the fight to curb pesticide use due to differing movement priorities and structural challenges posed by complex regulatory mechanisms differing for workers and consumers. One overarching commonality has been the lack of sustained attention by environmental movements to farmworkers' multiple vulnerabilities despite their acute and chronic exposures to the pesticides that pose much lower exposures for consumers (Pulido, 1996; Allen, 2003). Biomonitoring helps trace pesticide exposures across social constituencies, demonstrating that harmful exposures in workers leads to exposures in consumers, increasingly recognized as harmful. This evidence could give social movements additional data leverage to better incorporate worker concerns into fights for environmental protection, environmental health, and consumer safety.

In the following sections, I first provide background on chlorpyrifos, its health effects, and circumstances surrounding the 2000 regulatory decision. Then, I address relevant chlorpyrifos biomonitoring studies as they have been conducted in workers, agricultural fence-line communities, and consumers. Worker cholinesterase monitoring (biomonitoring of effect) comprises some of the earliest chlorpyrifos testing and continues to be the primary form of biomonitoring in workers. Cholinesterase testing is also the process by which farmworkers are afforded some protections in states such as Washington and California. Agricultural fence-line biomonitoring studies have been the focus of longer-term prospective academic biomonitoring studies and the focal point for advocacy biomonitoring and anti-drift organizing. Chlorpyrifos

consumer studies have focused largely on children and pregnant women. These academic studies began before the 2000 chlorpyrifos ban and show the profound, long-term negative health consequences for children exposed to insecticides in the home. In the final sections, I address the promises and limits of biomonitoring in the context of chlorpyrifos regulation and social movement organizing. In particular, I argue that biomonitoring strategies that have enabled transformations in consumer products (see Chapter 2) have not had the same traction in providing worker protections, even when considering the same chemical.

Chlorpyrifos Biomonitoring in the Context of Pesticide Regulation

For over a hundred years, the U.S. government and industrial workplaces have used biomonitoring as a technocratic tool to measure and monitor workers for signs of excessively high workplace exposures and chemically related illnesses (Sexton et al, 2004). The Centers for Disease Control (CDC) routinely measures chemicals in the U.S. population as a part of the National Health and Nutrition Examination Survey (NHANES) and publishes the *National Report on Human Exposures to Environmental Chemicals* detailing chemicals, testing methods, and levels (CDC, 2009). The CDC has been monitoring chemicals for nearly three decades and the number of chemicals they have the laboratory capacity and methodology to monitor for has steadily increased. In 2001, they monitored for 21 chemicals and they now monitor for 212 different chemicals, one of which is chlorpyrifos.

The CDC data is well-respected by scientists regardless of sector and is used as a baseline for smaller population study comparisons.⁵ In the most recent report documenting 2008 chemical levels, the CDC measured chlorpyrifos in more than 90% of the U.S. population (Needham, 2005).⁶ The human body relatively quickly metabolizes chlorpyrifos, which is most often measured through its breakdown product in urine, TCPy, though it can also be directly measured in blood. Industry groups such as the Western Growers Association take issue with CDC's use of metabolite measurements in urine and argue for direct measurements of the chemical itself in red blood cells (Western Growers Association, 2000). Academic researchers do sometimes measure chlorpyrifos directly in blood though it is widely agreed that exposure can be captured through urine measurements, which are less invasive and easier to collect. Since the body metabolizes chlorpyrifos relatively quickly, the ubiquitous presence of TCPy in the general population indicates continual re-exposure to chlorpyrifos, most likely consumed through food. The studies cited in this paper largely utilize urine measurements of TCPy, though some academic studies of urban populations in New York have relied on blood samples (Barr and Angerer, 2006).

⁵ Interview data; Scientists from non-profit, industry, academia, and government consistently referred to CDC data as the “gold standard” and cited it as an important baseline for study results comparisons.

⁶ The fourth report noted that chlorpyrifos levels were roughly similar to the 2nd and 3rd reports. The 91% statistic comes from the 2nd Report, which is difficult to find online. CDC 2003. Second National Report on Human Exposure to Environmental Chemicals. Atlanta, GA: Centers for Disease Control and Prevention.

Much of the biomonitoring social science literature emerges from the environmental health movement literature. This literature addresses the theoretical and practical considerations of taking chemical body burden measurements (Altman et al, 2008; Iles, 2007; Morello-Frosch et al, 2009; Roberts and Langston, 2008). The environmental health and contested illness literature describes community efforts to combat polluted environments, community efforts to link illness incidence to point source contamination, and lay efforts to challenge expert notions about illness and disease for diseases such as breast cancer (Brown et al, 2004; Brown, 2007). The use of biomonitoring as an advocacy tool has led to research that examines the implications of its uptake by environmental health advocacy organizations. Advocates have published biomonitoring studies conducted in small samples of newborns, pregnant women, those living far from polluting industries, and fence-line communities, as evidence of widespread “toxic trespass”, i.e., pollution in everyone. Scholars have coined the phrase, “data judo” to describe activist use of science to educate consumers and fight to overhaul existing chemical policies (Morello-Frosch et al, 2009). Advocacy biomonitoring and CDC surveillance, together revealing hundreds of chemicals in a single human body and across the U.S. population, are part of an emerging complex of evidence demonstrating the endpoints of thousands of untested and unregulated chemicals currently on the market.

Pesticide biomonitoring studies have also proven to be models of productive community-based participatory research, typically conducted through strong partnerships between environmental health, community organizations, and academic scientists in an effort to making pesticide body burden data accessible to communities living near pesticide drift. These studies have creatively coupled biomonitoring data with air monitoring data, have publicized results in the media, and profiled personal stories of community residents to demonstrate that agricultural communities shoulder exposure burdens far above those seen in the general population (PANNA, 2004).

Researchers have focused particularly on ethical issues related to community biomonitoring. Many measurable chemicals have not been studied for health effects so reporting these results can involve unique challenges. Most biomonitored chemicals are also unregulated bodily measurements cannot be linked back to regulatory action levels. Research has examined the ethical dilemma scientists face when reporting results that are not associated with any form of regulatory protection. Researchers have found that individuals and communities most often want to know their chemical levels, prompting a need for community-engaged collaborations to determine how different groups can better understand, engage, and potentially address study results (Morello-Frosch et al, 2009). Groups such as the Pesticide Action Network North America (PANNA) have organized individual and community discussions of biomonitoring results while providing a comparative baseline of community numbers alongside the CDC national sample. Unlike many biomonitored chemicals, chlorpyrifos *does* have extensive health effects data at higher levels of exposure but as research continues to emerge for low-level effects, report-back on chlorpyrifos has become more challenging.

The most far-reaching health protections from chlorpyrifos exposure are a direct result of federal regulation that discontinued chlorpyrifos sales to consumers in 2000. Emerging scientific

evidence finds continuing exposures from agriculture to be widespread however, with the prospect of enacting a wholesale ban eleven years later an unlikely possibility. Environmental advocacy groups argue that the voluntary agreement with DowAgrosciences ultimately failed to secure widespread protection, because it was unwilling to prohibit *all* uses of the known neurotoxin (Feldman, 2000). In this context of an implausible ban, social movements have increasingly turned to the market, counseling consumers to avoid the most pesticide intensive food products. The literature on voluntary and market-driven environmentalism, which comes from a broad base of scholarship in law, management, sociology, business ethics, geography, and development studies, collectively describe a scenario where corporations respond to social criticism, activism, and individual concern by adopting self-regulation and market-based sustainability instruments, preferring these regulatory tools to state intervention (Vogel, 2008; O'Rourke, 2005; Cashore, 2002).

Indeed, in the case of DowAgrosciences, the company was faced with the imminent lowering of regulatory levels as chlorpyrifos underwent re-registration. Rather than have the chemical be banned, they worked with the EPA to limit consumer uses and retain agricultural and other non-consumer uses. Dow preferred the agreement to be considered a voluntary one. Dow's chlorpyrifos website states, "Chlorpyrifos has never been banned in the U.S.... In 2000 by agreement with EPA, Dow AgroSciences began the phase-out of U.S. residential uses of chlorpyrifos in response to stringent new EPA standards...Dow AgroSciences continues to sell chlorpyrifos for agricultural use in the U.S. consistent with the EPA's favorable assessments of the product's health and environmental profile with exposures from authorized use" (DowAgrosciences, www.chlorpyrifos.com/myths-vs-facts.htm; accessed, June 10, 2011). EPA's agreement with Dow drew ire from advocacy organizations, which saw it as only partially protective. There is an ongoing effort by environmental law organizations such as Earthjustice and the Natural Resources Defense Council, alongside pesticide advocacy groups such as PANNA, to petition and sue the EPA to ban the chemical (www.docs.nrdc.org/health/hea_10072201.asp)

As social movements increasingly turn to the media and the market to communicate biomonitoring data, there are concerns that biomonitoring evidence will become a tool for individual product avoidance and self-protection without prompting community public health benefits. The increasingly consumer-driven and voluntary nature of environmental regulation threatens to push biomonitoring into the narrow margins of debates on individual risks and consumer choice, valuing "precautionary consumption" over regulatory reforms (Shostak, 2004; MacKendrick, 2010). This phenomenon has been prominent in the pesticide realm where organic foods are now a luxury commodity through which consumers can practice precautionary consumption and self-protection. Advocacy biomonitoring studies seek to inform consumers but ultimately seek improved state and federal government chemical regulations, though the latter goal is consistently challenged and co-opted by market-driven initiatives (Personal communication, 2010; Campbell, 2001). The literature on pesticides and agrifood activism points to an increasingly neoliberal and market-driven agenda by both the federal government and environmental and food-centered social movements, where consumer choice and the ability to purchase organic foods are prioritized over worker concerns (Guthman, 2004). Studies of

pesticide drift have found that market-based efforts actually exacerbate drift and worker exposures. For example, the EPA does not expect to curb chlorpyrifos use any further, having already banned it in consumer products. Workers are expected to be protected through safety equipment and reentry periods. Ultimately, market efforts do not address systemic pesticide exposures. Additionally, there is regulatory resistance to restrict drift-prone pesticides since these chemicals are often less persistent in the environment despite their often greater acute toxicity to workers (Harrison, 2008). For example, the pesticide methyl bromide was banned because it was found to deplete the ozone layer but growers seek to replace it with methyl iodide, which does not deplete ozone but is far more toxic to workers.

Given these tendencies in the realm of pesticide protections toward consumer and market-driven reforms, biomonitoring evidence demonstrates that worker exposures lead down the line to consumer exposures. So, consumer protections alone are not enough to ensure comprehensive public health protections against toxic pesticide exposures.

Methods

Semi-structured interviews were conducted with scientists from advocacy, academic, industry, and government sectors (n=42) who conduct or utilize biomonitoring in their work. Interviews were also conducted with scientists who are specifically focused on chlorpyrifos academic research, government regulation, and advocacy biomonitoring. Interviews were conducted with government scientists working at state and federal levels. To locate scientists engaged in cholinesterase testing, I contacted government scientists working on implementing worker testing programs in California and Washington State. California has the oldest cholinesterase monitoring program in the country, which began in the 1970s. Washington State is considered one of the best programs, which began in 2006. Advocacy, academic, and government scientists were contacted first through a purposive sample, locating them through their published research followed by a snowball sample. Scientists were contacted through industry and professional meetings. In addition to interviews, I conducted document analysis of the peer-reviewed scientific literature, government reports, and advocacy reports, and reviewed public comments solicited for chlorpyrifos reregistration through the Environmental Protection Agency (EPA). Public comments for the 2000 regulatory decision were gathered from the EPA document library in Washington, DC. Subsequent public comments from 2002 onwards were found online at www.regulations.gov.

Background on Chlorpyrifos

Chlorpyrifos has long been a chemical of concern for advocacy groups, researchers, and governments. It is an organophosphate insecticide and known neurotoxin developed during World War II by the Dow Chemical Company (Doyle, 2004). After DDT was banned in the United States in 1972, chlorpyrifos became the dominant replacement pesticide. Chlorpyrifos was sold under the names Dursban and Lorsban and was found in 800 other associated consumer

products such as flea sprays and roach killers. When the Environmental Protection Agency announced a broad agreement with chemical manufacturers to phase out chlorpyrifos for home and garden uses in 2000, it was the most extensively used home and garden pesticide, with approximately 200 million household related applications (Browner, 2000; <http://www.epa.gov/history/topics/legal/03.htm>). The agreement permitted chlorpyrifos to remain in all food uses (except tomatoes), golf courses, greenhouses, and mosquito and fire ant control. In the U.S., 8-10 million pounds of chlorpyrifos continue to be applied each year, primarily in agriculture, and many more millions of pounds are sold globally (Feldman, 2000).

Health Effects

There is extensive evidence of chlorpyrifos' adverse health effects. Chlorpyrifos inhibits the action of the enzyme acetylcholinesterase (AChE) in the nervous system, causing a buildup of acetylcholine and resulting in the overstimulation of the nervous system (Kwong, 2002). As early as the 1960's, Dow Chemical secretly conducted testing on human subjects using 16 prisoners at the Clinton Correctional Facility in Dannemora, New York. At higher exposure levels, Dow noted sharp drops in plasma cholinesterase levels (Doyle, 2004). These physical effects from chlorpyrifos exposure have since been well-documented in the peer-reviewed literature and higher levels of exposure are known to result in acutely neurotoxic effects (Richardson, 1995). There are various symptoms of acute exposure, which can include salivation, irregular heartbeat, convulsions and death. Low dose exposures documented in farmworkers include impaired memory and concentration, disorientation, severe depression, irritability, confusion, headaches, nightmares, sleepwalking, drowsiness, insomnia, and flu-like conditions (Barr and Jurgen, 2006).

One key challenge of multiple possible symptoms is that physicians can mistake chlorpyrifos exposure for the common flu, leading to misdiagnoses and underreporting of farmworker pesticide poisoning cases (Nash, 2004). Recent studies have associated chlorpyrifos exposure with developmental delays and prenatal exposures have been linked with attention deficit and hyperactivity disorder problems (Lovasi et al, 2010; Rauh et al, 2006). Developmental neurotoxicity effects can extend beyond the prenatal period and into adolescence (Slotkin and Seidler, 2007). There is also growing animal evidence pointing to chlorpyrifos' role as an endocrine disruptor, a class of toxins that disrupt hormone systems associated with reproduction and development at very low exposure levels (Haviland, Butz, and Porter, 2010). The exposure levels that influence behavior, reproduction, memory, and development are far below those that trigger cholinesterase inhibition and also below levels at which the pesticide is regulated for either workers or the general public.

The 2000 Chlorpyrifos Reregistration Decision: Why not Ag?

Two federal statutes, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Food Quality Protection Act (FQPA), regulate chlorpyrifos. FIFRA provides the basis for the regulation, sale, distribution, and use of pesticides. In 1996, the FQPA amended FIFRA and set more stringent safety standards for new and old pesticides, creating more uniform requirements for processed and unprocessed foods (EPA.gov; accessed March 22, 2011). The

FQPA required the EPA to set standards for the amount of pesticides allowable as residues on food, to consider risks to infants and children when setting these standards (termed tolerances), to consider “aggregate risk” from an exposure to one pesticide from multiple sources, and to address “cumulative risk” for pesticides that share a common mechanism of toxicity, which includes the class of organophosphate pesticides like chlorpyrifos (www.EPA.gov ; accessed March 29, 2011)). Some have heralded the FQPA as groundbreaking since it is the first federal environmental statute to consider the unique exposures and vulnerabilities of fetuses, infants, and children rather than addressing only adult exposures. The FQPA is the core reason for the ban of chlorpyrifos in consumer products (Landrigan and Goldman, 2011). However, others, while acknowledging the improvements made by the FQPA, some have argued that EPA has been given broad discretion through this statute to regulate and curb pesticide use but has rarely done so (Personal Communication, 2010).

Chlorpyrifos’ scientific assessment has been called the most extensive and contentious for a pesticide in history (Brown and Warrick, 2000). In April 2000, twelve prominent scientists including Philip Landrigan, a pediatrician and former EPA executive, penned a letter to then EPA Administrator Carol Browner calling on the EPA to “tightly restrict” agricultural uses of chlorpyrifos and “ban outright” its uses in schools and homes. In October 1999, the EPA had proposed lowering the acceptable exposure level for the chemical to one-third of its then allowable level and finally restricted it to one-tenth of its then allowable level. Normally, the EPA sets safety exposure levels for pesticides such as chlorpyrifos at one one-hundredth of the maximum concentration at which there are no detectable effects on an adult animal. Under the FQPA, the hundred-fold safety margin increases ten-fold more if evidence is found that there are any impacts on infants and children. Studies leading up to the decision showed children absorbed more pesticides from their environment than adults, chlorpyrifos persisted in furniture, rugs, and other household items, and children were less able to excrete and detoxify themselves through natural bodily processes than adults (Landrigan, 1999). These physical and behavioral patterns of children, combined with evidence that chlorpyrifos could likely be a developmental and behavioral neurotoxin, greatly pressured the EPA to take action. The new standard essentially eliminated home uses and lowered the amount of residue allowed on food.

Thousands of public comments were submitted, emphasizing the country’s economic dependence on chlorpyrifos, protesting the limiting of the chemical’s sale, and chiding the EPA for limiting its ban to consumers alone. For example, the State of California’s Department of Food and Agriculture, which is linked to the nation’s largest agri-industry, took issue with the EPA decision, stating it would affect “consumers who depend upon an affordable, reliable food supply” (Lyons, 2000). In addition, numerous advocacy organizations challenged the EPA’s lack of attention to pervasive general population exposures from agriculture.

While human biomonitoring data was not considered in the decision, the Attorney General of the State of New York submitted extensive public comment critiquing the continued use in agricultural and residual presence on food. The New York AG argued that the Final Risk Assessment (FRA) failed to address the metabolite of chlorpyrifos TCP found in 92% of adults and 100% of children tested. They also emphasized the failure to address neurological and

developmental impacts at low-levels and a serious lack of consideration for environmental justice by not addressing farmworker exposure and communities affected by drift (State of New York, 2000). These comments reflected many of the concerns by advocacy groups who are still angry with the agency's failure to ban the pesticide altogether.

When asked about the agreement with Dow, a Federal EPA scientist was surprised and upset by the criticism by advocacy organizations. She stated,

In risk management, it's really our practice to sit down with companies and get them to voluntarily withdraw chemicals when there's a problem. The reason we do that is because it happens pretty quickly and in fact we got chlorpyrifos out of people's houses in record time with the help of industry. If they don't agree, our recourse is to go to court. We're doing that on carbofuran right now and four years later its still being used, so from a management perspective of getting the hazard away from people, that's how you do it. And I don't think that people realize that. It hurts me to hear that it's an industry friendly deal because we think that we got it away from houses as quickly as possible. I don't think there was any way we could've done that any faster than we did. I mean we actually cancelled the products, changed the numbers so the products couldn't be used (Government Scientist, Personal Communication, 4/16/2010)

The EPA is currently in a period called "registration review" for chlorpyrifos, which will be decided in 2014. In California, a Department of Pesticide Regulation scientist noted that the main issues being considered now for future decisions are for effects on neural development (Personal Communication, 3/20/2010).

In the meantime, three biomonitoring studies carried out at three different universities appeared in April 2011 showing the impacts of prenatal exposures to organophosphate pesticides on neurological development of children. All three studies biomonitored pregnant women's exposures to organophosphate pesticides via umbilical cord blood. The studies at Columbia University and University of California, Berkeley found dramatic IQ deficits in exposed children living in low-income public housing and in exposed farmworker children. The Mt. Sinai School of Medicine study measured prenatal organophosphate metabolite urine and blood samples in 404 pregnant women and also found a decline in mental function due to pesticide exposure. Dr. Phil Landrigan, who was instrumental in the 2000 consumer ban, called these new findings "shocking" in a *New York Times* health blog (Parker-Pope, 2011) and stated, "when we took lead out of gasoline, we reduced lead poisoning by 90 percent, and we raised the I.Q. of a whole generation of children four or five points. I think these findings about pesticides should generate similar controversy, but I'm cautiously optimistic that they will have the effect of having the EPA sharply reduce the use of organophosphate pesticides." Biomonitoring studies of organophosphate pesticides have emerged as a key site of data that must be considered in future EPA decisions on chlorpyrifos (Personal Communication, 4/16/2010).

Following the Molecule: Workers, Farm Towns, and Consumers

While we can surround ourselves with the very latest epidemiological and scientific data on hazardous exposures, we need to look beyond these data—themselves often quite contested—to environments, bodies, communities, and nations. In short, we need to follow the molecule from its point of origin, if that can be calculated, through all the other places and spaces that it travels. The information we gather can help to shed light on how bodies and whole ecosystems might be affected. (Casper, 2003)

The following sections trace the chlorpyrifos molecule, documented through biomonitoring studies, as it travels from agricultural fields into farm towns, finally landing in consumer's bodies. These sections follow the molecule's geographic route, synthesizing molecule-by-molecule and community-by-community research into a more complete picture of the implications of chemical trespass for both humans and the environment.

Cholinesterase Monitoring in Workers

I would say the impact of cholinesterase monitoring has been quite noticeable and well-documented. It did highlight the number of workers who were being exposed over what we would consider an acceptable dose. The first year we had over 20% of our workers over the action threshold. It really caught people's attention. The beauty of biomonitoring is that with things like cholinesterase monitoring that you're catching exposure before symptoms show up.

– Washington State Department of Health Scientist, May 21, 2010

I think there's a divide between occupational exposure and exposure of consumers. I think it's wrongly termed as "involuntary exposure" of the consumer versus "occupational exposure" in workers. Workers seem to accept a certain level of risk...I don't prescribe to that theory...Medical monitoring has been occurring in workers and workers are exposed to a certain level but that hasn't resulted in so much regulatory change. But those same chemicals measured in consumers or people who aren't working in those chemicals might result in change.
-Scientist, California Department of Public Health, December 16, 2009

In order to be relevant to people affected by chemical contamination, the latest scientific data must be considered alongside its broader social and economic implications. The story of chlorpyrifos is a legacy of the story of DDT, the most infamous of all pesticides. DDT was a widely applied agricultural insecticide and used to control malaria beginning in World War II. Pesticide biomonitoring began with DDT in countries such as Sweden, one of the first countries to conduct long-term population level chemical biomonitoring. Studies found that DDT is persistent and bioaccumulative, meaning that it concentrates in fat and tissues, moves up through the food chain, and the body does not easily rid itself of the chemical. It is found in humans and animals in far-flung regions of the world, even in non-industrialized areas in the circumpolar North through transboundary transport in the food chain and broader ecosystem. Bans on DDT have been enacted by countries around the world, and international agreements such as the Stockholm Convention continue to use biomonitoring to document declines in DDT in breast

milk around the globe. For this type of population-level chemical tracking, biomonitoring has become a valuable tool for evaluating policy effectiveness at both national and international levels (Noren and Meironyte, 2000). During the 1960s in the United States, the battle against DDT was fought all over the country by environmental organizations, consumer groups, and most famously the United Farmworkers Campaign (UFW) in California (Pulido, 1996). The UFW were the first to organize around pesticide exposures for workers. DDT was finally banned in the U.S. in 1972.

California's agricultural system is extensively industrialized, driven by large-scale corporate agricultural interests, and deeply dependent on the use of pesticides. The state's agricultural history is rooted in the massive exploitation of natural resources and the subordination of immigrant workers who suffer from tenuous economic and political circumstances (Walker, 2004, McWilliams, 1939). The system is absolutely dependent on temporary and marginalized farm labor. Even efforts that work for alternatives to the industrialized system, such as community supported agriculture or organic farming, are dependent on a steady supply of mostly immigrant and undocumented farmworkers. This heavy reliance on vulnerable workers in all agricultural sectors makes the system at its core unwilling to address poor working conditions (Allen, 2003; Guthman, 2004). When DDT was banned, it was quickly replaced by organophosphate pesticides. As evidence mounted that workers suffered severe neurotoxic effects from chlorpyrifos exposure, California became the first state in the country to adopt cholinesterase monitoring in 1974. Cholinesterase testing sought to manage against the worst health effects from organophosphate poisoning in workers. Nonetheless, the California program is now widely considered to be a failure since it is lax, there is no central reporting, and industries only participate on a voluntary basis (Personal Communication).

In the United States, the problem of DDT bioaccumulation in birds and other wildlife, the subject of Rachel Carson's acclaimed book *Silent Spring*, heralded the environmental health movement of the 1970s, which galvanized a base of interested consumers and citizens to the cause of addressing toxic chemical contamination. In order to connect their poor working conditions to consumers interests so the movement could gain national traction, the United Farmworkers' Campaign organized the national grape boycott. Most consumers came to know of UFW workers' plight through their grape boycott. Observers of UFW's legacy, however, argue the failure of farmworkers to secure long-term protections for their material and physical safety lies in their efforts to mobilize consumer support (Prouty, 2010). This turned out to be a serious miscalculation, stretching the UFW too thin, moving the best organizers away from the fields and into urban centers. Efforts at farmworker organizing in the fields suffered (Bardache, 2011). The evolution of consumer movements, which have been largely disconnected from farmworker concern is a legacy of UFW organizing efforts, despite the short period of time when these worker to consumer connections were made in the market.

Mainstream environmental organizations such as the Sierra Club sought to ban DDT but did not support the UFW (Gordon, 1999). The UFW had a clear economic and social agenda that would address their material and physical suffering due to racial discrimination, ill-treatment in the fields, lack of economic security, and continual exposure to harmful chemicals. Mainstream

environmental groups saw these issues as too removed from their goals of protecting wilderness. They considered the UFW's agenda to be the "conservation problems of special minority groups" (Gordon, 1999). Large environmental groups focused on the particulars of the DDT ban rather than on the use of toxic pesticides in agriculture generally. Once DDT was banned, environmental groups retreated from the pesticide-related issues for many years. In the meantime, DDT was replaced by organophosphate pesticides that are less bioaccumulative in the environment and in human bodies but are more drift prone and more acutely toxic to workers (Pulido, 1996).⁷ In acknowledgement of this toxicity, in California, the Department of Pesticide Regulation (DPR) in collaboration with the Office of Environmental Health and Hazard Assessment (OEHHA) established pesticide illness surveillance and cholinesterase medical monitoring.

Cholinesterase Testing (Biomonitoring of Effect)

Cholinesterase monitoring (biomonitoring of effect) is one of the only forms of protection for workers exposed to organophosphate pesticides (DiCaprio, 1997).⁸ Cholinesterase monitoring measures workers' physiological reaction to exposure, removing them from the field when they begin to show a physiological response. All workers who work with Class I and Class II organophosphate or carbamate pesticides with more than six days of exposure in a month are to be tested. Reentry periods have been established to define how long a worker must wait to resume work to give their plasma cholinesterase levels an opportunity to rebound (Lessenger, 2005). In Washington state, a cholinesterase monitoring program was established when pesticide poisoned farmworker Juan Rios sued the Department of Labor & Industries, which administers the Washington Industrial Safety and Health Act. In 2002, the Washington State Supreme Court found the Department had violated the Washington Industrial Safety and Health Act of 1973 when it denied the farmworkers' request for a mandatory cholinesterase monitoring program.⁹ In so doing, they had failed to comply with their own mandate to protect workers. The program now has a network of state workers and physicians who provide services to farmworkers.

Linda Nash writes extensively on the history of pesticide-related illness among farmworkers in California. Environmental illness was rendered invisible for decades because regulators saw human bodies as separate from their environments. When workers came down with illness, they were accused of uncleanliness, lack of hygiene, and not following proper farm

⁷ For detailed chronicle of the United Farmworkers Pesticide Campaign, see the chapter "The Pesticide Campaign of the UFW Organizing Committee, 1965-71" in Pulido, Laura; *Environmentalism and Economic Justice: Two Chicano Struggles in the Southwest*; The University of Arizona Press; 1996.

⁸ There are three distinct forms of biomonitoring. Biomonitoring for exposure the subject of the majority of this paper, biomonitoring for effect which measures the physical effects of chemical exposures, and biomonitoring for susceptibility which monitors for inherent vulnerabilities and individual might have that would make them more vulnerable to a chemical exposure

⁹ For more information on this program, see the Washington State Department of Labor & Industries; <http://www.lni.wa.gov/WISHA/Rules/agriculture/HTML/part-j-1.htm>

protocols. This focuses blame on individuals rather than on the systemic problems of employer and regulatory neglect. Cholinesterase testing, emerging in the late 1950's and early 1960's, was a move towards acknowledging the body as intimately connected to the environment. It provided a litmus test for exposure and provided occupational health regulators with stronger toxicological knowledge of pesticide-related illness. However, prediction proved unwieldy since baseline cholinesterase levels vary widely among individuals and levels in the blood are sometimes a poor approximation for levels in the brain (Nash, 2004). Additionally, highly technocratic but rather arbitrary regulations emerged to determine "reentry levels" so neurotoxic pesticides could continue to be used while "protecting" worker health. Complex monitoring systems were put in place in lieu of regulations to limit pesticide use.

Despite these limitations, cholinesterase testing can be a powerful scientific tool to corroborate workers' experiences and protect farmworkers from the worst effects of pesticide exposure, though it is widely agreed that these programs are limited since they are voluntary and exist in very few states (Advocacy Scientist, 6/2/2010). These programs also do not account for increasing evidence of adverse chronic, low-level effects. The Washington State program has been held up by the Centers for Disease Control as, "one of the best pesticide poisoning surveillance programs in the country" (Beyond Pesticides, 2009). Still, there is no federal farmworker program to regulate pesticide overexposure. Physicians who work closely with farmworkers see cholinesterase testing as necessary but insufficient, since neurotoxic pesticide use will always cause some amount of worker poisoning (Academic Scientist, May 28, 2010).

There is also poor employer compliance with physician recommendations (Fillmore and Lessenger, 1993). Even in Washington State where the program is much stronger than in California, state workers profess that while the program increases access to testing and medical care, its non-mandatory structure leaves many workers exposed and untreated. Most farmworkers lack legal status, so they fear the visibility of seeking out testing. This leads to a very low return rate of farmworkers for testing even if they might have registered for the program (Government Scientist, May 21, 2010). Some state workers also note the pervasive feeling that, "people just don't care about farmworkers", so poor industry response and regulatory inaction are the norm despite any testing programs that may exist (Government Scientist, December 16, 2009). Finally, the state rather than growers shoulders the economic burden of administering the program, making it vulnerable to budget cuts. Many farmworker advocates consider this an injustice, since taxpayers pay health costs while growers profit by externalizing their costs onto the public (Farmworker Advocate, June 1, 2010).

Farmworkers themselves, as evidenced by the Juan Rios lawsuit, are seemingly dissuaded from pursuing pesticide bans. Farmworkers have not sought out solidarity through consumer or other forms of national pesticide regulation, as had been the case for DDT. Rather, they focus on not getting sick. Farmworkers routinely show evidence of pesticide poisoning so, at least in Washington, they demanded access to testing as one means of protecting themselves. On the national front, large environmental organizations such as Earthjustice and the Natural Resources Defense Council have found some common ground with farmworker movements and are petitioning the EPA to discontinue all uses of chlorpyrifos. Agrifood activism and the organic

food movement, probably the most visible front of anti-pesticide organizing, have spoken broadly about food justice without successfully merging rhetoric with practice. According to food scholars, they have done little to address the concerns of the poorest and most vulnerable in the food system (Allen, 2008).

The most notable social movement working to address pesticide exposures in vulnerable populations are anti-drift activists, who organize in communities living on the fenceline of intensive agricultural production. There are few regulatory protections against pesticide drift. In this context, biomonitoring has emerged as an important organizing companion strategy to demonstrate the exposures in agricultural fenceline communities. Ultimately these groups seek to address pesticide drift through improved regulatory controls.

Drift: Communities: Living on the Agricultural Fenceline

Look at what the general population is exposed to just from eating food and look at what farmworker children are getting exposed to and realize that these kids are getting hit directly through the air, from hugging their parents when they get home, and through playing in their house and in their yards, which are contaminated (Farmworker Advocate, June 2,2010)

The chlorpyrifos molecule leads us from workers into agricultural fenceline communities. Agricultural pesticide drift is the offsite, airborne movement of pesticides away from their target location. Drift lands in towns adjacent and downwind from areas where pesticides are applied. Chlorpyrifos is a high use insecticide that poses significant drift problems. In California in 2008, there were 334 documented reports of illness and injury associated with drift, of which 229 were considered by the California Department of Pesticide Regulation to be definitely or probably due to exposure to pesticide drift (CDPR, 2011).¹⁰ In Washington State, the Department of Health found that, “agricultural drift accounted for a disproportionately high number of illnesses per event compared to other sources of exposure. . . . Non-agriculturally employed bystanders comprised 26% of all the exposures plausibly related to agricultural drift in 2008” (WSDP, 2009). This data suggests that illness and injury from pesticide drift exposure is a crucial problem, creating increased medical needs in drift-prone areas.

Reported illness from pesticide drift reveals only the surface of the problem. Most drift related illnesses go unreported since, as mentioned earlier, pesticide exposures can present much like the flu or a variety of other illnesses. In addition, there has been a poor response rate by local governments to community complaints about drift (Harrison, 2006). Pesticide drift is poorly regulated and even routinely minimized as the small and technical side effect of pesticide application (Harrison, 2008). Harrison’s research in California reveals that pesticide drift is a longstanding problem, which rather than being addressed as such, is framed as a series of “accidents” and isolated incidents. This regulatory framing renders the problem invisible and is followed by general inaction by regulatory officials. Though the California pesticide

¹⁰ These numbers are based on data from the Pesticide Illness Surveillance Program which maintains and publishes data online; <http://www.cdpr.ca.gov/docs/whs/2008pisp.htm>; accessed February 24, 2011

regulatory apparatus is elaborate and large, it is highly devolved and fragmented, is often captured by industry, and has been weakened by market-oriented approaches to environmental problem solving. As a result, there is extensive data collected by multiple offices, there is little actually done to reduce and address harm (Harrison, 2006).

In the face of continuing drift exposures and little regulatory response, environmental health advocacy groups, working with community-based organizations, have set out to demonstrate that agricultural fenceline communities face much higher exposure levels than the national average. Studies have documented chlorpyrifos exposure to be much higher in agricultural communities than in the general population. Advocacy scientists have worked alongside communities to biomonitor residents living adjacent to sprayed fields in California’s Central Valley. These studies find that farm communities, from young children to the elderly, are exposed to alarming levels of chlorpyrifos. In 2004, PANNA released a report titled *Chemical Trespass: Pesticides in Our Bodies and Corporate Accountability*. PANNA measured the chlorpyrifos metabolite TCPy using the same age categories as the Centers for Disease Control, ranging from young children to adults (Figure 1). In every age category, the community levels were higher than the “acceptable dose” set by federal regulation.¹¹

DowAgrosciences discredited the study as not being scientifically valid because of a small sample size. Advocacy scientists countered that even with a small sample the results were “highly statistically significant” (Advocacy Scientist, March 2, 2010).

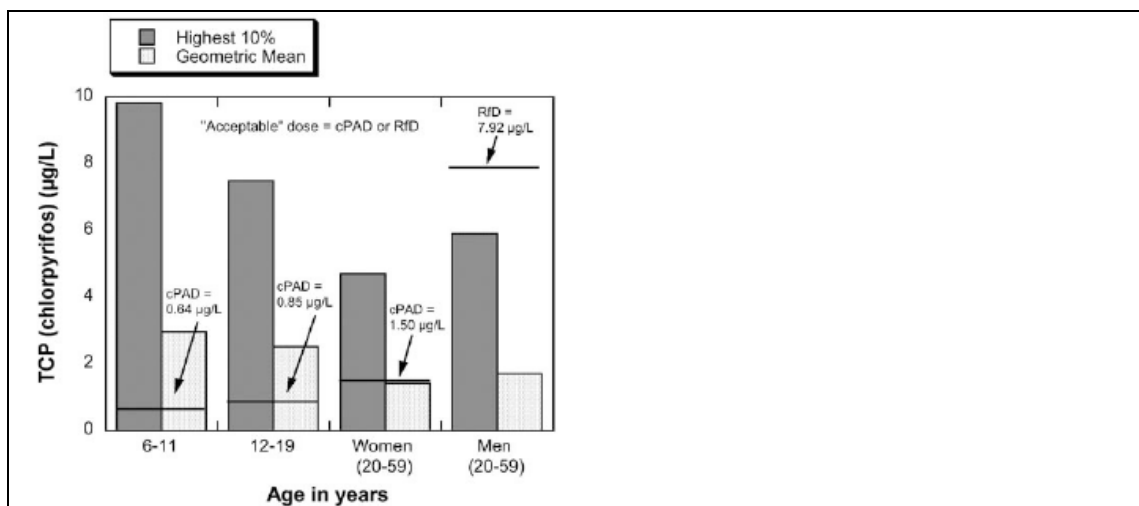


Figure 1: From *Chemical Trespass*, Pesticide Action Network North America
 In each age range, community member living adjacent to pesticide drift show levels of TCPy at levels much higher than the national average and above levels set by the Environmental Protection Agency as an “acceptable dose”.

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¹¹ “Acceptable Dose” is defined as the maximum level at which the chemical poses no health or environmental hazard.

mic long-term cohort biomonitoring studies have also found high chlorpyrifos levels in agricultural communities. The most comprehensive organophosphate pesticide exposure study in an agricultural community is the CHAMACOS study, the Center for the Health Assessment of Mothers and Children of Salinas, a partnership between researchers at the University of California, Berkeley, Natividad Medical Center, Clinica de Salud del Valle de Salinas, and other community organizations. Salinas Valley is a rich agricultural area on the central coast of California with a 2 billion dollar per year agricultural industry that employs over 35,000 farmworkers. CHAMACOS has produced a wealth of studies examining worker protections, household contamination, and pesticide exposures in children.

Beginning in 2000, the CHAMACOS longitudinal study followed 536 infants for seven years, whose mothers were enrolled while pregnant. Biomonitoring data from this study has been extraordinarily valuable in understanding the long-term adverse developmental impacts of organophosphate exposure. Through CHAMACOS, biomonitoring has come to be considered the best available method for assessing children's exposure to pesticides (www.cerch.org). Maternal exposures have also been found to be particularly important for understanding infant health (Fenske, Bradman et al, 2005). Pregnant women in this community showed higher levels of urinary organophosphate metabolites than women in the national NHANES sample. Higher metabolite levels were associated with shorter gestation periods (Bradman et al, 2005; Eskenazi et al, 2004). Neonates, whose mothers had higher pesticide levels, were also more likely to have abnormal reflexes and poorer mental development by the age of 2 (Young et al, 2005; Eskenazi et al, 2007). Children can face lifelong social and mental challenges as a result of prenatal and early exposures.

Advocacy and academic biomonitoring studies provide compelling evidence that poor communities and communities of color living near intensive agricultural production face disparate pesticide exposures. Armed with exposure data, community and advocacy organizations appealed to local, state, and federal governments. In particular, communities have sought out local protections in the absence of state and federal protections. Local community organizations alongside PANNA fought for buffer zones that would limit spray times and allowable spraying distance near schools and homes. One advocacy scientist noted,

Biomonitoring helped pass a new policy to get buffer zones in place around aerial applications of restricted use pesticides, which is a pretty narrow victory but it's a step in the right direction. And the community worked really hard for that, negotiated with the commissioner, the county board of supervisors. I mean there was a big organizing effort that went along with it. And the biomonitoring data was back up saying, "look, we're being exposed to this stuff and our kids are and it's not good to have this near schools and homes" so that helped get it through. Even though chlorpyrifos use wasn't aerial or restricted use (Advocacy Scientist, 3/2/2010)

As noted, the buffer zone effort became an important organizing drive but has ultimately provided limited protection. One reason for this is that preemption laws in California and in many other states around the country disallow local, county and municipal governments from creating more protective regulations for pesticides than what is mandated at the state level. In

Tulare County, for example, buffer zones prohibited aerial applications of restricted use pesticides at a distance of one-quarter mile around schools in session, occupied farm labor camps, and residential areas (Clarren, 2008). However, these requirements only apply to restricted use pesticides, pesticides that require a permit to apply. Chlorpyrifos is not a restricted use pesticide and can be applied without a permit, so it is not subject to buffer zone requirements. However, communities realized that, “even though it wasn’t their particular chemical, that better protection from other pesticides was better than nothing” (Advocate, November 24, 2009).

Community and advocacy organizations use biomonitoring to make their case for prohibiting pesticide applications near sensitive land uses. Nonetheless, they are aware of the technology’s limitations and wary of continually needing to prove community exposures through ever better technology. Anti-drift organizers are also acutely aware of industry’s ability to circumvent detection by developing “invisible” pesticides, which might not be as easily detected in the body, as has been the trend for pesticides measurable in the air (Advocacy Scientist, March 2, 2010).

With little federal movement on pesticide regulation and community groups stifled from making real progress even at local levels because of preemption laws, consumer and market-driven efforts are perceived to be a next best possible route for change. Anti-drift advocates note that consumer-based and food justice movements had not shown much solidarity with pesticide drift issues but hope that over time this highly visible movement will engage worker and agricultural communities. Much of mainstream America’s pesticide knowledge comes from the organic food movement. This movement has focused on making foods safer for consumers, increasing organic options, and limiting direct-to-consumer pesticide sales. Much like BPA-free baby bottles described in chapter two, organic foods have become a consumer-driven substitute for larger scale chemical regulatory failures. In a federal government climate that prefers voluntary regulations, market-driven efforts have been easier to enact than government regulations. Biomonitoring data provides strong evidence that pesticides applied in the field ultimately travel into consumers’ bodies, despite the ban on chlorpyrifos as a consumer product.

Consumer Biomonitoring Studies

Consumer studies get all the attention. I mean certainly biomonitoring is used in regulation in occupational health, lead being the primary example but there are probably other ones. Cholinesterase being one. So, there are examples in which biomonitoring has reached the stature of being a tool that is actually used to enforce regulations. But the general research studies haven’t had a lot of impact, I would say. I mean it takes years for them to have that kind of an impact...There have been studies for years, breath monitoring, urine monitoring, blood monitoring, even other things like in air for metals and things.. but if you step back and look, you see that very few have actually reached the point of being recognized.

Academic Scientist, May 20, 2010

Perhaps the most profound finding from chlorpyrifos biomonitoring studies is that consumers continue to be exposed to potentially harmful levels of chlorpyrifos, despite regulatory efforts aimed at better protecting them. Consumer biomonitoring studies indicate that, despite discontinuing direct sales of chlorpyrifos products to consumers, ubiquitous exposures in the general population continue. Existing regulatory structures do not adequately account for the movement of pesticides from farms to tables. The CDC's NHANES surveillance found chlorpyrifos in over ninety percent of those tested. This is of concern because regulatory benchmarks do not account for studies showing that chlorpyrifos causes developmental and neurological problems at very low levels of exposure.

Consumer biomonitoring studies have largely consisted of children's dietary intake studies conducted at University of Washington. In addition, studies of exposures *in utero* have been conducted by Columbia Center for Children's Environmental Health (CCCEH). Like the CHAMACOS drift studies in the Salinas Valley, since 1998 the Columbia research group has tracked a cohort of inner city, urban, New York children from in utero through school age. Their early work examined extent of chlorpyrifos exposure and its health effects. Mothers and their newborn infants who were tested for chlorpyrifos showed similar levels, demonstrating that chlorpyrifos rapidly transfers from mother to baby during pregnancy.

At the time, chlorpyrifos was one of the most heavily applied indoor pesticides in urban areas. Columbia researchers found that insecticide levels in the blood of their study participants rapidly decreased between 1998 and 2001 (chlorpyrifos was discontinued for sale in 2000) (Whyatt et al, 2003; Carlton et al, 2004), thus documenting the immediate effectiveness of regulatory interventions. More recently, the Columbia group showed that children who were exposed to higher levels of pesticides have measurable neurodevelopmental problems, such as weakened motor skills, developmental delays, developmental disorders, and increased risk of ADHD (Attention Deficit Hyperactivity Disorder) (Lovasi et al, 2010).

Pesticide residues in food are considered to be the major source of exposure for infants and young children, populations that are vulnerable to pesticide-related health risks, since they are in a phase of intense physical and mental development. Dietary studies track chlorpyrifos exposures from the consumption of fruits, vegetables, and nuts. In 2006, a study conducted at the University of Washington tested the urine of 23 children between the ages of 3 and 11 who attend public elementary and Montessori schools in suburban Seattle, Washington (Lu et al, 2006). These children consumed only conventional diets and were recruited for a three-phase biomonitoring study. In the first phase, children consumed their regular diets; in the second phase, organic diets were substituted for the children's fruit, vegetables, wheat, and corn-based foods; and in the third phase, the children resumed their old diets. While on an organic diet, pesticide metabolite levels in the children's urine significantly dropped and then increased again when they resumed their original conventional diets. Reducing pesticide exposure by consuming organic foods was dramatic and immediate.

The implications of this research are far reaching. They find that: 1) consumer bans on very toxic chemicals are important and probably the most effective form of health protection; 2)

early exposures can have long-term adverse health implications, even when exposures are thought to be low; 3) low-income and communities of color that live in substandard housing must grapple with problems such as cockroaches, but the use of very toxic pesticides has long-term consequences for children's health. By banning pesticides, vulnerable consumers were protected. However, poor housing stock that prompt the use of indoor pesticides in the first place are problems of structural inequality. This group of studies also found that one toxic pesticide (chlorpyrifos) is often replaced with another unregulated toxic pesticide. The current chemicals regulatory system does not address the problem of replacement chemicals, which are most often also toxic. Consumer studies and surveillance show that we are all exposed to chlorpyrifos, primarily through our food system, despite bans on home use pesticides.

Exposures through food are ubiquitous and difficult to avoid. Many environmental health organizations are reluctant to simply promote a "buy organic" agenda since this strategy individualizes a broadly systemic risk. It also does not account for families that cannot access or afford organic foods. This challenge environmental health organizations face extends to the broader problem of reducing exposures to toxins in consumer products. As one environmental health advocate noted, "It's deeply embarrassing for people to learn about environmental contaminants and the uncertainty and the broad health concerns and then be given advice about vacuuming their house or washing their hands. It doesn't feel like it measures up to agitating for reform of TSCA [Toxic Substances Control Act]".

Nevertheless, environmental health groups and consumer safety organizations promote green purchasing. There has been a proliferation of information-based websites and green blogs where consumers can find better and safer products for their families. Organizations such as Environmental Working Group (EWG) have pursued a multi-pronged strategy to push the FDA and the EPA to better address chemicals through regulation, while also chronicling and profiling safety guides for products such as make-up and sunscreen. For example, EWG has put together a Shopper's Guide detailing the "dirty dozen" fruits and vegetables, such as apples, celery, and strawberries, that are highest in pesticide residues and should be purchased organic. This effort is targeted at families who might not be able to purchase or find primarily organic produce (EWG, 2011).

As in the case of bisphenol A (Chapter 2), information-based strategies have been effective at raising public awareness about sources of chemical exposures, personalizing and giving a face to chemical exposures, and targeting particular foods and consumer products. One important challenge for advocacy organizations is that these efforts can shift the focus for public health protections from government agencies to individual consumers. This shift can harness individuals with the task of self-protection and allow corporations to profit from voluntary market changes. Meanwhile, the federal government does little to address the larger systemic problems of chemical trespass.

Ulrich Beck has described this trend as a "risk society" where government institutions have abdicated responsibility for protecting citizens and instead relegated the responsibility for protection to the market. In this atmosphere, individuals are given the unfair burden for

managing their own exposure to risks and hazards (Beck, 2006). Increasing globalization of production systems has been linked with a deepening sense of individualization (Giddens, 1991). Individuals have become increasingly disconnected from the global processes that can damage their local environment and personal health. Since individuals can feel disempowered and ill-positioned to address global problems, they attempt to take on greater *personal* responsibility as a way to interact with and/or change inherently global processes. Szasz describes the trend towards deepening individualization in the environmental movement as “inverted quarantine”, where consumers are encouraged to make individualized decisions to protect their health and the environment through actions such as purchasing bottled water or organic foods rather than engaging in community organizing or other forms of activism that could garner larger-scale, systemic regulatory or policy reform (Szasz, 2007). However, even very committed environmental movement activists do practice green consumption since consumption can often be the most visceral individual connection towards change (Connolly and Prothero, 2008).

Many chemicals simply cannot be avoided through differential purchasing. Trending towards market-based regulatory instruments in the absence of government regulation neglects this crucial gap, outside of even the most ardent environmental consumer’s grasp. While it is possible to reduce exposures, it is almost impossible to eradicate them. In their study on women’s experiences of household chemical exposure, Altman et al. describe this as the “consumption fallacy”. Differential purchasing cannot change exposures to chemicals, such as flame-retardants that are mandated by law or pesticides used in a multitude of crops. It also does not address chemicals that do not appear on product labels (Altman et al., 2008).

Environmental health advocacy organizations, who work on information-based campaigns, continually struggle with the challenge of providing improved information to consumers while working for systemic government change, since their efforts can quickly be narrowed or co-opted into a focus on individual consumption preferences. Individuals and advocacy organizations use multi-pronged strategies in the void of federal protections. Still, the most vulnerable in the system, poor communities and workers, have seen little respite from chemical exposures. Biomonitoring advocacy, which has been highly effective in consumer battles (see Chapter 2), has had little traction for farmworkers. This same trend is reflected in the realm of food politics. There has been a lack of sustained connection made between social consumption of food and the political economy of food production (Guthman, 2002). Scholarship has focused on how individual consumption choices and personal taste translate into production in terms of rent and landed agriculture. Nonetheless, little attention has been paid to the chemical industrial complex and the stronghold it has held over agriculture since World War II.

Conclusion

Chlorpyrifos biomonitoring studies, when viewed as the story of a chemical molecule traveling from points of production, to points of unintended dispersion and points of consumption, provide a comprehensive picture of pervasive regulatory failure at every point

along the trajectory. Workers on the frontlines of pesticide exposures are consistently exposed and regulatory structures do not adequately protect them. Exposures in the field are compounded by economic, social, and political vulnerabilities. The voluntary structure of cholinesterase monitoring misses many worker pesticide poisoning cases. Workers remain the most vulnerable and unprotected group for pesticide poisonings and biomonitoring data, which has been collected on workers since the 1970s, shows chronic and acute forms of illness, with only band-aid protections to address these ongoing problems. New biomonitoring evidence has still not afforded workers greater regulatory protections.

Agricultural fenceline communities are also chronically and disproportionately exposed to chlorpyrifos. Regulatory structures do not protect the predominantly low-income communities and communities of color living near fields. Biomonitoring evidence has helped propel local efforts by demonstrating higher than average exposure levels. However, promising local efforts such as buffer zones are stymied by state and federal preemption laws, leaving these communities, too, chronically exposed.

In consumers, exposure levels have been set to protect food buyers. Children, in particular, are recognized by the FQPA to be a vulnerable population. Yet, children continue to receive most of their pesticide exposure through residues in food. Pesticide exposures in young children have been linked with adverse neurological impacts at even low levels of exposure. Chlorpyrifos used in the field has been shown through biomonitoring to make its way through food production systems and into the bodies of the general population. Regulation has not protected even consumers from chronic chlorpyrifos exposures.

Social movements have tried to address pesticide exposures from various vantage points. While environmental health movements have pushed for systemic regulatory change, evidence shows that consumer-driven and market-driven efforts have seen the most traction. Workers rights have particularly suffered under a market-driven paradigm, both in food justice and environmental health arenas (Allen et al, 2003). Mainstream environmental organizations have resorted to lawsuits against the EPA, with little success. In 2007, Natural Resources Defense Council, Pesticide Action Network North America, and Earthjustice submitted a petition for the EPA to cancel chlorpyrifos. After no answer, in July 2010 they sued the EPA for “unreasonable delay and failing to act”. Until chemical policy is overhauled, these types of efforts will have little legal traction. Even with extensive scientific evidence, the standards of scientific proof required for changes in chemical use remains unrealistically high. In this climate, farmworkers have pursued strategies to protect their individual health rather than target a national and outright chemical ban.

Biomonitoring has been powerful and visceral for the general population, for information about exposures in consumer products, and for affected communities who are concerned about involuntary and unsolicited exposures. In an era of increasingly market-focused government regulation issues that are not consumer-focused have not seen much regulatory change. Disappointingly, biomonitoring data, which powerfully demonstrates exposure, has not been enough to help win regulatory changes for the most vulnerable and disenfranchised communities.

The challenge for social movements to pursuing an integrated response for chemicals policy must recognize government unwillingness to enact systemic regulatory change in the face of corporate power. With the threat of lawsuits, the EPA prefers to address problems through voluntary agreements with corporations. Local agencies are also unwilling to act since these have often been captured by powerful corporate interests (Harrison, 2006).

Regardless, if leveraged by consumer and market-driven efforts, biomonitoring could be an opportunity to demonstrate that consumer-focused regulation alone cannot protect public health, and is particularly detrimental to children's health. While this argument may appear simplistic, as scientific evidence mounts that chlorpyrifos is harmful at low exposure levels, there are important public health reasons to address chemical exposures from production through consumption, rather than attempting to intervene for consumers alone.

Social movements, given the fragmented landscape of local, state, and federal regulations, could leverage biomonitoring data as a way to demonstrate sustained exposures across constituencies. This scientific data, as one prong of a larger strategic effort could bring attention to fights for more systemic public health protections. Biomonitoring has limitations, such as the overreliance on an expensive technology and the need to continually prove exposures through ever more sophisticated technologies. There is also a danger of "scientization", the effort to address non-scientific issues such as injustice done to workers through scientific tools. Chlorpyrifos, a neurotoxic chemical with extensive health effects data, ubiquitous exposures prompt an interrogation of existing public health protections. Biomonitoring evidence presents an opportunity to better understanding chemical exposures as a chemical's molecules travel through the agricultural chain.

Examples of Regulatory Structures to Address Pesticide Exposures

Governing Regulation	Intended to Protect	Regulates	Jurisdiction	Mandates Biomonitoring	Regulatory Failure
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), first passed 1947	Everyone; Provisions for worker protection (ex. illegal to spray while workers in field)	Pesticide registration, distribution, sale, and use	Federal	No	Found in 96% of the general population (Centers for Disease Control), workers disparately exposed; (CDC, 2009)
Food Quality Protection Act (FQPA) amended FIFRA in 1996	Consumers; General Public; special consideration for infants and small children; Specifically <i>excludes</i> occupational exposures	More stringent safety provisions than FIFRA, Specifically covers residue levels on food; consideration of “aggregate risks” from exposure to organophosphate pesticides Manages adverse health effects from some pesticides, including chlorpyrifos.	Federal	No	Pervasive general exposure through food. Dietary intake studies show food is primary source of chlorpyrifos exposure for young children. (Lu et al,2006; Lovasi et al,2010)
Cholinesterase Monitoring	Workers		State	Yes; measures physiological effect of exposure	Workers disparately exposed despite protections; voluntary programs, only in very few states (ex. WA and CA) (Lessenger,2005; Busby and Eckstein,2009)
Buffer Zones	Living near agricultural production	Mandates allowable spraying buffers, application times, protects schools and communities from pesticide drift	Local	No	Drift communities face higher exposure levels than general population; state laws supersede local efforts; applies to restricted use pesticides only so does not include chlorpyrifos; enacted in very few areas; (Bradman et al,2005; Eskenazi et al,2007; Schafer et al,2004)

CONCLUSION

On June 8, 2011, the Environmental Protection Agency made public the identities of 150 chemicals contained in 104 health and safety studies that had earlier been claimed as confidential by industry. The EPA website states, “over the past several months [the EPA] has taken a number of other steps to make chemical information more readily available. The agency has provided the public, for the first time ever, with free access to the consolidated TSCA Inventory on the epa.gov and data.gov websites” (EPA, 2011). For many who have worked on chemical transparency issues for years, this revelation came as welcome news. The federal government, under the Obama administration, seems to be making some strides to improve public access to chemical information.

Biomonitoring evidence has played a central role in raising awareness, both inside and outside of government, about the endpoints of unregulated chemicals. Environmental health and justice movements have successfully claimed biomonitoring, a historically technocratic tool, to better educate the public about chemicals, increase corporate transparency, and pressure governments to address ineffective chemical policies. Biomonitoring has become a powerful exposure tool because it documents a dizzying array of unwanted and uninvited chemicals in bodies. In this context, there is widespread agreement among industry and advocacy scientists that chemical policy reform is imminent (Personal Communication, 2009 and 2010). The eventual implementation of reform remains unknown, since industry and environmental health advocates are most often on opposite sides of the table on key issues of transparency and precaution.

This year, following two previous failed attempts to introduce chemicals policy reform legislation, U.S. Senator Frank Lautenberg introduced the Safe Chemicals Act of 2010, a bill seeking to overhaul of the Toxic Substances Control Act of 1976. The press release directly points to biomonitoring and the chemical burden placed on the public’s health. It states, “America’s system for regulating industrial chemicals is broken. Parents are afraid because hundreds of untested chemicals are found in their children’s bodies. EPA does not have the tools to act on dangerous chemicals and the chemical industry has asked for stronger laws so their customers are assured their products are safe”. This bill would place a greater burden of proof on industry to prove chemicals are safe prior to marketing them, provide the EPA with increased power and information, call for faster action to address the highest risk chemicals first, create open public access to chemical information, and foster the development of safe chemical alternatives.

As biomonitoring research has proliferated in academic, advocacy, and government arenas, my research investigates the theoretical and practical impacts of increased personal exposure data on chemicals governance. While scientific contestations about the meaning and interpretation of biomonitoring are ongoing (chapter 1), biomonitoring evidence has, in the meantime, been leveraged by social movements as an organizing tool. These efforts have primarily taken the form of raising public awareness and pressuring corporations and the state and federal government towards product reforms and better chemical regulation.

Biomonitoring has achieved mixed success in achieving measurable changes to chemicals regulation. However, it has become increasingly valuable in documenting exposure and shifting the public's consciousness about chemicals in products. As a core strategy, environmental health and justice organizations have successfully framed biomonitoring evidence as "toxic trespass". They have personalized chemical exposures by connecting data with real names, faces, and places. With little or no federal government response to problems of chemical trespass, advocacy organizations have used biomonitoring to force a debate about chemical exposures. By publicizing advocacy studies in the popular media, advocates have shifted the venue of conversations away from the sole purview of technocratic regulatory agencies and corporations seeking to market products. By popularizing issues of chemical exposures, advocates have opened up a national conversation about the public health and environmental consequences of unregulated chemicals.

Since there has been little traction for advocacy efforts through national politics, advocates have also used biomonitoring to shift their political strategy. They have focused on influencing state laws and partnering with international efforts, sidestepping national politics. The federal government has found itself squeezed in between changing international response to chemicals, particularly in the European Union, and a state-by-state adoption of chemical-by-chemical bans and regulations.

The broader questions about the use of biomonitoring for social change include: In what arenas have environmental health advocacy groups found most success in leveraging biomonitoring data for change? When is biomonitoring evidence most effective as an organizing tool? The cases of bisphenol A and chlorpyrifos provide some indication of the contexts in which biomonitoring evidence can be most successfully deployed for chemical policy reforms. Advocacy biomonitoring efforts seem to have the most traction when the following combination of factors exist:

- Chemicals must have evidence of adverse health effects for biomonitoring evidence to matter to either politicians or the general public. While biomonitoring can detect hundreds of chemicals, many of these have not been studied. Both bisphenol A and chlorpyrifos have been the subject of scores of health studies. There is significant evidence that exposure to these chemicals can result in illness, developmental delays, and other forms of harm. However, health effects data is insufficient. Chlorpyrifos has significant evidence of adverse health effects but this evidence alone has not been effective in banning all uses of chlorpyrifos.
- Evidence of exposure must be able to mobilize action (e.g., the primarily affected groups are babies, as in the case of BPA in baby bottles). The context of exposure significantly affects the ability for social movements to organize. Avoidable exposures to children, in particular, have been key focal points for several

effective statewide campaigns to ban the sale of products with bisphenol A in children's food containers.

- Since environmental health advocates must employ a state-by-state organizing strategy combined with corporate pressure, there must also be some form of policy change that can be enacted at the state level. In addition, an alternative to the chemical must be available for state-level efforts to be successful. In the case of chlorpyrifos, a local organizing campaign could not prevail since localities are preempted by state laws. There is almost no traction at the state level to ban chlorpyrifos, since growers argue that there are no comparable alternatives. The agricultural lobby in California, for example, is extraordinarily powerful and has consistently argued that chlorpyrifos has no replacements. In the case of bisphenol A, substitutes already existed and advocates could pursue policies to limit BPA sales for children at the state level. Corporations and politicians could be publicly shamed for permitting avoidable and unnecessary exposures to young children. Still, state policies have not banned the most pervasive exposure to BPA from canned foods since, as in point two, the context of exposure, has not mobilized action.

As an advocacy tool, biomonitoring has found most immediate success in consumer campaigns, particularly when young children are involved. Biomonitoring evidence has been less effective in campaigns for workers and fenceline communities. The reasons for this are complex, including the lack of political and economic power these constituencies wield to advocate for change for themselves. The diminishing power of worker movements in the U.S. also plays an important role in the ability of farmworkers to organize. Further, movements such as the organic food movement have not effectively included workers rights issues.

As a policy issue, while some worker protections can be enacted at the state level, such as cholinesterase monitoring, the chemical itself must be banned at the federal level by the EPA. National organizations such as Earthjustice continue to push for a federal ban by filing lawsuits that interrogate EPA's risk assessment. Currently, the EPA must make a decision on the existing uses of chlorpyrifos by November 23, 2011 as per a settlement agreement with Earthjustice. In an effort to educate the public, Earthjustice cites biomonitoring data to more effectively engage and educate the general population, connecting chronic personal exposures to acute exposures for farmworkers. In a recent blog entry, Earthjustice lawyer Matthew Gerhart writes, "according to CDC data, you probably have chlorpyrifos in your body—because you probably have been regularly exposed to it since you were developing in the womb. Chlorpyrifos is part of a class of pesticides, the organophosphates, that are most frequently reported as the cause of acute poisonings of farm workers" (earthjustice.org, October 10, 2011).

As biomonitoring data becomes a primary form of exposure evidence, there are important considerations for scientists and social movements. Biomonitoring still follows a chemical-by-chemical measuring paradigm. However, efforts must address multiple and cumulative exposures, which better reflect actual exposures in the body. There are ongoing efforts to more

quickly address the high volume and number of chemicals on the market by figuring out high throughput biomonitoring strategies. There are also efforts to incorporate biomonitoring into “green” chemistry, producing chemicals in the laboratory that do not end up in human bodies and in ecosystems. Over the coming years, as biomonitoring data becomes more routine, it remains to be seen whether its uses will narrow, as has been the case with chemical risk assessment, or whether it will actually be a tool that can help usher in more precautionary regulation and policies. In the meantime, it is clear that biomonitoring data, leveraged by social movements, has made strides, slowly but surely, in pushing for changes to chemicals governance.

APPENDIX 1 – Qualitative Data Analysis

Interview Coding Themes and Labels

Top Level Codes

Characteristics
Biomonitoring by Sector
Methods
Interpretation of study results
Report Back Format
Case Studies by Chemical
Practice of Biomonitoring
Governance Implications

Characteristics - sub codes

Scientific Discipline
Sector
Does/Did Biomonitoring

Scientific Discipline – sub codes

Epidemiology
Toxicology
Risk Assessment/Exposure Assessment
Analytical chemistry
Medical Doctor

Sector – sub codes

Industry

- Chemical Manufacturer
- Product Manufacturer
- Product Retailer

Academia/University
Advocacy Organization
Government or Regulatory
Member of Biomonitoring California’s Scientific Guidance Panel

Biomonitoring by Sector - sub codes

Government or Regulatory Biomonitoring
Academic Biomonitoring
Advocacy Biomonitoring
Industry Biomonitoring

Government or Regulatory Biomonitoring – sub codes

Growth

Proliferation

State versus federal programs

Impact

- Characterize Exposure
- Elucidate Sources
- Evaluate Exposure Reduction Intervention
- Identify Emerging Contaminants
- Inform Advisory Groups
- Inform Policy Makers
- Inform Chemicals Policy
- Inform Regulators
- Inform Public Health Interventions
- Inform Industry
- Inform Retailers
- Inform the Public

Academic Biomonitoring – sub codes

Growth

Proliferation

Impact

- Characterize Exposure
- Elucidate Sources
- Evaluate Exposure Reduction Intervention
- Identify Emerging Contaminants
- Inform Advisory Groups
- Inform Policy Makers
- Inform Chemicals Policy
- Inform Regulators
- Inform Public Health Interventions
- Inform Industry
- Inform the Public

Advocacy Biomonitoring- sub codes

Growth

Methodological Approach

Validity of

Impact

- Inform Policy Makers

- Inform Regulators
- Influence Chemicals Policy
- Inform Public Health Interventions
- Inform Industry
- Inform the Public
- Surveillance

Media coverage

Industry Biomonitoring – sub codes

Growth

Impact

- Inform Regulators
- Inform Policy-makers
- Inform Public
- Inform Industry
- Media
- Inform Retailers

Product Changes

Methods – sub codes

Sampling strategy

Cost considerations

Analyte decisions

Laboratory capacity

Participation of constituencies

Participation of stakeholders

Interpretation of study results – sub codes

Scientific validity

Industry data sources

Peer review

Sample Size

Uncertainty

Report Back Format – sub codes

Aggregate report-back

Individual report-back

Publication & Dissemination of Results (Communication)

Media

Case Studies by Chemical – sub codes

Bisphenol A
Chlorpyrifos

Practice of Biomonitoring – sub codes

Lay involvement
Cost
Study size
Recruitment
Population characteristics
Report-back-- Aggregate
Report-back—Individual
Report-back—Response to
Dissemination—Peers
Dissemination—Regulators
Dissemination—Public
Dissemination—Media

Governance Implications- sub codes

Regulatory Governance
Industry Governance
Policy Governance

Regulatory Governance – sub codes

Exposure assessment
Risk assessment
Risk management
Legislative and agency action
Surveillance systems

Industry Governance – sub codes

Chemical Manufacturing Decisions
Consumer product manufacturers
Retail Decisions
Public Communication/Public Image

Policy Governance

Local policies
State level policies
Federal Influence/Chemical Polic

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