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Authors

Shamasunder, Bhavna
Morello-Frosch, Rachel

Publication Date

2015-03-01

DOI

10.1007/s13412-015-0233-0

Peer reviewed

J Environ Stud Sci
DOI 10.1007/s13412-015-0233-0

Scientific contestations over "toxic trespass": health and regulatory implications of chemical biomonitoring

Bhavna Shamasunder · Rachel Morello-Frosch

Abstract Biomonitoring has chronicled hundreds of synthetic chemicals in human bodies. With the proliferation of biomonitoring studies from diverse stakeholders comes the need to better understand the public health consequences of synthetic chemical exposures. Fundamental disagreements among scientific experts as to the nature and purpose of biomonitoring data guide our investigation in this paper. We examine interpretations of biomonitoring evidence through interviews with 42 expert scientists from industry, environmental health and justice movement organizations (EHJM), academia, and regulatory agencies and through participant observation in scientific meetings where biomonitoring evidence is under debate. Both social movements and industry stakeholders frame the meaning of scientific data in ways that advance their own interests. EHJM scientists argue that biomonitoring data demonstrates involuntary "toxic trespass" and underscores a policy failure that allows for the pervasive use of untested chemicals. Industry scientists seek to subsume biomonitoring data under existing regulatory risk assessment paradigms. Our analysis reveals one area of convergence (validity of Centers for Disease Control surveillance data) and seven areas of contestation regarding the scientific, public health, and policy implications of biomonitoring evidence, among regulatory, industry, and EHJM scientists including: chemical presence in bodies, biological mechanisms of health impact, use of biomonitoring equivalents, limits of targeted biomonitoring, limits of detection, policy influence of advocacy biomonitoring, and relevance of biomonitoring to motivate policy change. These areas of scientific contestation provide insight into the persistent challenges of regulating chemicals even in the midst of mounting evidence of widespread exposure to multiple compounds with implications for human health.

Keywords Biomonitoring · Contestation · Chemicals · Toxics · Expertise · Regulatory science

B. Shamasunder (✉)
Urban and Environmental Policy Department, Occidental College, 1600 Campus Road, Los Angeles, CA 90041, USA
e-mail: bhavna@oxy.edu

R. Morello-Frosch
Department of Environmental Science, Policy, and Management & School of Public Health, University of California, Berkeley, 130 Mulford Hall, Berkeley, CA 94720-3114, USA
e-mail: rmf@berkeley.edu

Introduction

Human biomonitoring, which measures chemicals or their metabolites in blood, urine, fat, breast milk, or other tissues, has proliferated in recent years driven by decreased costs, improved portability, and better detection and analytic capabilities (Namieśnik 2000). In the USA, the primary focus of this study, national surveillance conducted by the Centers for Disease Control and Prevention (CDC) reveals widespread population exposures to synthetic chemicals (CDC 2013). With an increase in the number of biomonitoring studies from diverse stakeholders including academic researchers, government agencies, environmental health and justice movement organizations (EHJM), and industry groups comes the need to better understand the public health consequences of exposures to synthetic chemicals. A growing body of research demonstrates adverse health effects for several chemicals, but there is a paucity of toxicological and human health data for most of the 84,000 chemicals that circulate in commerce (Judson et al 2009; Woodruff et al 2011a; Porta 2012). This

Published online: 01 March 2015

new "visibility" of ubiquitous chemical exposures in people reveals the shortcomings of the Toxic Substances Control Act of 1976 (TSCA), the policy that guides the regulation of industrial chemicals (Wilson and Schwarzman 2009). Many chemicals suspected of being hazardous to human health have been allowed under TSCA to remain in consumer products (Schettler 2006; Becker et al 2010). Biomonitoring evidence raises additional questions among many stakeholders about the policy structures that allow such widespread chemical exposures to persist.

Environmental health and justice organizations along with academic scientists have mobilized biomonitoring data to shed light on the extent of chemical exposures, with a particular emphasis on hazards posed to vulnerable populations such as newborns, pregnant women, and farmworkers (Schafer 2004; Environmental Working Group 2005). These "advocacy biomonitoring" studies aim to inform the public about pervasive exposures to synthetic chemicals, increase corporate accountability in production decisions (Scruggs et al 2014), and ultimately seek to influence state and national chemical policies to be more protective of public health (Morello-Frosch et al 2009). Advocacy biomonitoring has raised the stakes for interpreting biomonitoring evidence by receiving widespread media attention and raising questions about where responsibility for chemical exposure lies (MacKendrick 2010). EHJM groups increasingly harness scientific expertise to confront complex environmental challenges (McCormick 2009; Ottinger and Cohen 2012) and in the process have gained entry into expert arenas where biomonitoring research is debated. Conversely, industry and trade groups publicly dismiss the scientific credibility of advocacy biomonitoring studies while seeking to limit the use of biomonitoring evidence as a stand-alone determination of hazard (American Chemistry Council 2014).

Hazard-based versus risk-based interpretations of biomonitoring data reflect a long-standing dispute between EHJM advocates and industry, and between advocates and regulators as to how exposure evidence should be integrated into chemical regulations. Advocates typically argue for hazard-based responses which evaluate the potential for harm using existing human and animal studies, but generally without quantitative probability estimates of health effects, while industry emphasizes the importance of risk-based responses that quantify the probability of individual and population harm from chemical exposures (Bahadori et al 2007; LaKind et al 2008).

As the foundation of regulatory decision-making (Jasanoff 1990, 1999), such quantitative risk assessment generally precedes any action that restricts a chemical's use (Myers and Raffensperger 2006).

As biomonitoring research becomes an increasingly important to characterize human exposures and as a form of exposure evidence and the number of such studies grows, scientific experts and regulatory agencies are tasked to provide guidance regarding its meaning and to interpret results for individuals and communities. Fundamental disagreements among scientific experts as to the nature and purpose of biomonitoring data guide our investigation in this paper. We examine interpretations of biomonitoring evidence through interviews with 42 expert scientists from industry, EHJM organizations, academia, and regulatory agencies and through participant observation in scientific meetings where biomonitoring evidence is under debate. We identify significant categories of scientific disagreement and in so doing provide insight into the persistent challenges of regulating chemicals even in the midst of mounting evidence of widespread exposure to multiple compounds with significant implications for human health.

Methods

We conducted 42 semi-structured interviews with scientists who conduct biomonitoring research or utilize human biomonitoring data between January 2009 and August 2012. Sampling for this study was not random in that it involved scientists already involved in exposure research. We selected scientists based on their publications in the peer-reviewed literature or through their participation in government and industry meetings where biomonitoring was under debate indicating their interest and involvement in conversations over its use and interpretation. Most scientists agreed to participate in interviews; all provided information would be presented anonymously. We recruited scientists from industry, EHJM organizations, academia, and regulatory agencies. Scientists were from a variety of disciplinary backgrounds including toxicology, environmental health science, epidemiology, and exposure assessment, demonstrating the interdisciplinary landscape of biomonitoring debates. Our interviewees included scientists working with advocacy organizations (primarily employed by or aligned with EHJM groups) (9), government scientists (generally employed by or utilized by agencies as part of the regulatory or surveillance process) (15), industry scientists (working for trade associations and in chemical manufacturing) (14), and academic scientists (employed by universities) (4).

We conducted in-depth, semi-structured interviews with participants either in person or by telephone. The interviews focused on four categories of questions, which included the following: scientific issues raised by biomonitoring evidence for public health, influence of biomonitoring studies on chemical policy and regulation, legitimacy of advocacy biomonitoring studies, and methods of dissemination and response to biomonitoring results by study participants and the public. Interviews were recorded, transcribed, and analyzed using NVivo9. A coding structure was developed to reflect the format of the interview questionnaire using both top-level and subcodes. Top-level codes included characteristics of the

interviewee with subcodes, 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, the practice of biomonitoring (i.e., dissemination of results to participants or to key stakeholders), and policy implications (i.e., regulatory, industry, or policy-driven changes to chemicals decision-making).

In 2009–2012, we also conducted participant observation in public and scientific meetings where biomonitoring evidence was under debate, including meetings of Biomonitoring California, the first statewide biomonitoring program in the country as well as topically relevant industry meetings (see Appendix for a full list). Transcripts and meeting notes were also analyzed using NVivo9.

Democratization of the biomonitoring expertise

Population-level biomonitoring has a long tradition in several countries (e.g., Porta et al 2008; Aylward et al 2014). In the United States, for over a century, biomonitoring technology has been used by the government and industry to monitor worker exposures in industrial settings (Sexton et al 2004; Needham 2008). Biomonitoring was integrated into the public health infrastructure by 2001 when the CDC began publishing the *National Report on Human Exposure to Environmental Chemicals*, reporting data on chemical exposure from blood and urine measurements in a representative sample of the population. Today, the CDC tests samples for approximately 212 different chemicals (CDC 2013).

Meanwhile, in 2003 in a watershed moment in the emergence of advocacy biomonitoring, a full-page advertisement ran in *The New York Times* with the headline "Warning: Andrea Martin Contains 59 Cancer-Causing Industrial Chemicals" accompanied by a photograph of the mother and breast cancer activist. The advertisement reported on an advocacy biomonitoring study that included nine volunteer participants who had been tested for 200 different chemicals (Brody et al 2007a). In the decade since, EHJM organizations have continued to conduct biomonitoring research and publish study results online, through print reports, and in major newspapers utilizing storytelling and placing real faces on exposure data (Washburn 2009). Along with exposure results, each advocacy biomonitoring study raises questions of government failure to protect public health and industry culpability for exposures since many of these chemicals are found in everyday consumer products.

Past research describes how health social movements conduct their own research, produce scientific knowledge, and in doing so challenge traditional lines of scientific inquiry while pursuing policy advocacy goals (Brown and Zavestoski 2004). To translate research findings, social movement actors have developed interpretive schema that allows diverse publics to understand social, and in this case scientific, phenomena in a way that makes it accessible (Snow et al 1986). Interest groups develop "collective action frames" that resonate with their constituents' life experiences, respond to critics, and garner bystander support (Benford and Snow 2000). Advocacy scientists use biomonitoring to employ collective action frames that highlight the failures of current chemical policies. Both scientific and moral arguments encompass these frames: the moral frame asserts that chemical exposures constitute a bodily "toxic trespass," which is both involuntary and unjust; the scientific frame asserts that chemical body burden from multiple contaminant exposures is likely to adversely affect population health. Conversely, industry scientists construct their own frame regarding biomonitoring evidence. They assert that the mere presence of chemicals in humans does not necessarily imply harm to human health and that any regulatory action to reduce exposures must be based on quantitative risk assessments that establish a probability of adverse health effects at known exposure levels (Fig. 1).

Because scientific and technical decision-making shape environmental regulation, both social movements and industry stakeholders frame the meaning of scientific data in ways that advance their own interests. Meanwhile, regulatory agencies rely heavily on scientific data to make regulatory decisions more credible to diverse stakeholders (e.g., Jasanoff 1993, 2009; Brown 2013). Yet all too often, 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. Debates regarding the health risks of chemical exposures are often relegated solely to the scientific sphere and therefore dominated by experts, ensuring that battles over policy remain "objective" and divorced from their socioeconomic, moral, and political contexts. This practice slows down regulatory oversight of industrial production in ways that promote the interests of industries and the state over those of consumers, workers, and the broader public (Jasanoff 1987; Beck 1992). Often, the insatiable quest for "better science" and more data supports 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 et al 2009; Oreskes and Conway 2010).

Regulatory and policy decision-making tools have not kept pace with emerging scientific knowledge. The gaps between the ability to measure exposures and interpret these exposures unfold in the context of a contentious and litigious regulatory system (Jasanoff 1987). While regulatory strategies primarily aim to find a safe level for individual chemicals, science demonstrates that exposures to multiple chemicals can combine to produce effects experienced in the general population and that even some very low-dose exposures can carry risks, a

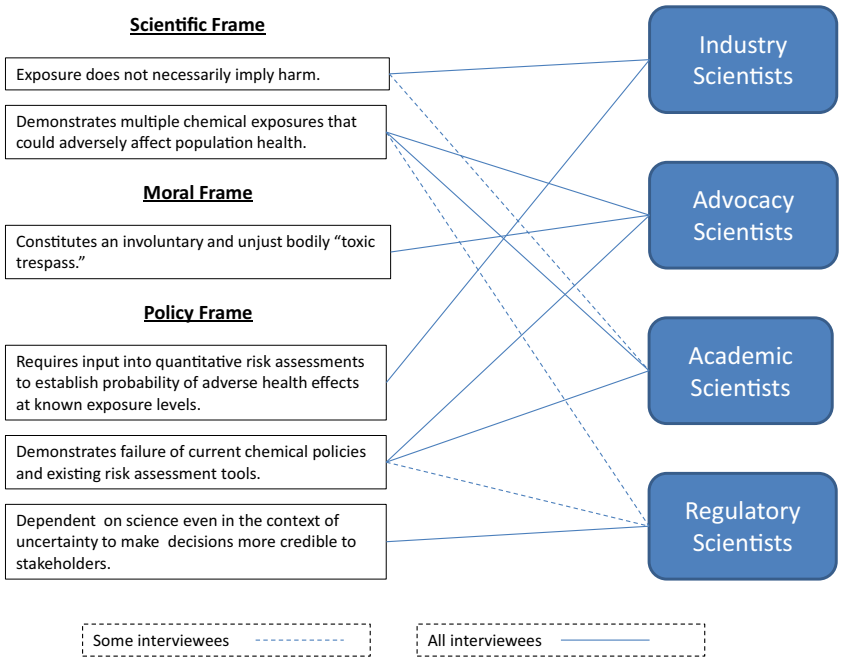

Fig. 1 Biomonitoring evidence of human exposures to environmental chemicals and expert scientists' theoretical frames

phenomenon that is not well accounted for in risk assessment calculations (National Research Council 2008; Vogel 2008). This type of mismatch between scientific knowledge and regulatory decision-making has led to calls among many stakeholders for updated policies to better protect public health (Wilson and Schwarzman 2009; Cranor 2011; Woodruff et al 2011a). In addition, the complexity and uncertainty in the science of chemical exposures lead to various interpretations and can often be influenced by financial motives (Woodruff et al. 2011a). EHJM organizations have demanded a greater role in environmental and health decision-making, pushing policymakers to incorporate lay knowledge alongside professional expertise (Corburn 2007). Social movements incorporate scientific expertise into their activism with the goal of introducing lay knowledge within the scientific enterprise and implementing new policy-making logics (Parthasarathy 2010; Ottinger and Cohen 2012). As EHJM scientific expertise grows, there is little analysis as to how advocacy scientists influence the scientific process through their participation in expert arenas and whether and how their participation might carry the potential for broadening the parameters of scientific debate.

Results

Our analysis reveals one area of convergence (validity of CDC surveillance data) and seven areas of contestation regarding the scientific, public health, and policy implications of biomonitoring evidence, among regulatory, industry, and EHJM scientists: chemical presence in bodies, biological mechanisms of health impact, use of biomonitoring equivalents, limits of targeted biomonitoring, limits of detection, policy influence of advocacy biomonitoring, and relevance of biomonitoring to motivate policy change. Sectoral affiliation influences perspectives in scientific controversies, particularly when links are being made between chemical exposures and harm (e.g., Brown 2013). Therefore, interviewee responses are categorized by sector since scientist perspectives typically aligned with organizational or company affiliation. Government scientists showed greater diversity in their answers, with some more aligned with EHJM scientists and others more aligned with industry scientist perspectives. However, government scientists were conscribed by their role within the regulatory structure and regardless of personal alignments typically represented this perspective (Table 1).

Validity of CDC surveillance data

All interviewees in our study cited data sources as key criteria for assessing the validity of biomonitoring evidence, with all stakeholder scientists citing the CDC national chemical body burden surveillance data as the "gold standard" for characterizing population-level exposures. There is widespread reliance on the CDC's National Biomonitoring Program by expert scientists from all sectors to set standards for biomonitoring detection methods. While the CDC regularly reports chemical biomonitoring data on a representative sample of the US population, the Agency does not interpret the public health

Table 1 Summary of results: Convergence and contestations over interpretation and regulatory significance of biomonitoring among expert scientists

	Advocacy	Industry	Academic	Regulatory
Validity of CDC data	Yes. In certain cases provides sufficient evidence along with toxicological data to motivate policy action to reduce exposures.	Yes. Not sufficient alone to motivate policy action to reduce exposures.	Yes. In certain cases provides sufficient evidence along with toxicology data to motivate policy action to reduce exposures.	Yes. In certain cases provides sufficient evidence along with toxicology data to motivate policy action to reduce exposures.
Chemical presence in bodies	Yes. Measureable exposures should motivate actions to reduce or eliminate exposures.	No. Chemical presence alone provides little or no basis for action.	Yes. In certain cases, there is sufficient evidence for action when combined with toxicology data, and exposures are ubiquitous.	Under debate. Currently, no regulatory benchmarks for majority of detectable chemicals.
Biological mechanism of health impact	No. Long time frames required to fully understand mechanism of health effects prevent precautionary action based on existing scientific evidence.	Yes. Any action based on biomonitoring data must be connected to chemical's biological mechanism of effect.	No. Public health approach can utilize existing human exposure evidence and animal toxicology data to guide decision-making and promote regulatory action.	Under debate. Can help facilitate action but expensive and time consuming.
Use of biomonitoring equivalents	No. Undermines a precautionary approach, due to timeframe for developing BEs.	Yes. Enables input into risk assessment or risk management evaluations.	No. A preliminary benchmark but not for use as a single measure as it can obfuscate uncertainties.	Under debate.
Targeted biomonitoring	Mixed. Overreliance could ignore potentially unmeasured chemicals that could pose harm.	No. Often unfairly stigmatizes well-studied chemical.	Mixed. Need for a comprehensive nontargeted method ("exposome approach") to fully characterize broad range of environmental chemical exposures.	Mixed. Lack of information about chemical use and substitution makes it difficult to predict, track, and make regulatory decisions.
Detection	Yes. Detection should motivate action. But ability to detect should not drive chemical prioritization.	No. Analytical ability to detect should not drive decision-making about a chemical. Chemical exposures are not new, only the analytical capacity to measure them.	Mixed. Detection provides evidence of exposure and in certain cases provides sufficient evidence along with toxicology data to motivate policy action to reduce exposures.	Mixed. Provides evidence of exposure but insufficient alone due to lack of regulatory benchmarks for majority of detectable chemicals.
Policy influence of advocacy biomonitoring	Yes. Policymakers respond to real stories and constituency concerns over chemical exposures.	No. Advocacy studies raise public awareness but are not scientifically rigorous and should not be taken into account for policy.	Mixed. Has increased the visibility and public awareness ofbiomonitoring evidence but policy change has followed in few instances.	Mixed. At times effective in pressuring companies and raising public awareness, thereby pressuring decision-makers.
Relevance ofbiomonitoring to promote policy change	Yes. Points to the need for large-scale chemical policy reform. In absence of effective chemical regulation, has pushed for changes in industry and government.	No. In a few cases, such as lead and PFOA, biomonitoring has led to industry or policy change. But typically insufficient to change policy.	Yes. Provides important exposure data and can motivate policy change with additional scientific evidence of harm.	Under debate. Lead is an important example. But difficult to incorporate into decisions since regulatory benchmarks do not exist for majority of chemicals.

significance of these exposures. As a result, some advocacy scientists have pointed to this Agency reticence as one reason why biomonitoring data has not been fully leveraged to promote regulatory and policy change. Nevertheless, nearly all of the scientists we interviewed described the important role biomonitoring evidence played in transforming national policy limiting lead exposures. As the USA phased out the use of lead—a known neurotoxicant—in gasoline and house paint between 1973 and 1980, CDC biomonitoring data showed corresponding and consistent declines in population blood lead levels (Jackson et al 2002). As biomonitoring technology improved, lead could be measured in blood at lower levels, and these measurable levels were then also linked to adverse neurological outcomes, particularly in young children. Regulatory guidelines for defining childhood lead poisoning were steadily lowered as a result, from 60 μg per deciliter of blood in 1960 to the current benchmark of 5 μg per deciliter of blood (Needleman 2004; National Center for Environmental Health 2012; Centers for Disease Control and Prevention, CDC 2013). The leveraging of biomonitoring data to strengthen the regulation of lead was due to the overwhelming scientific evidence of its adverse neurological effects, particularly in children. However, for most measureable chemicals, the quantification of exposures in biological samples precedes scientific understanding of their potential health effects (Morello-Frosch et al 2009). This raises questions about how to utilize biomonitoring for policy and disagreements over whether and how to use biomonitoring to motivate policy change in the absence of toxicological or other health data (discussed below). The following sections describe divergent framings and key areas of contestation among stakeholder scientists over the meaning and interpretation of biomonitoring data for use in regulation.

Chemical presence in bodies

All interviewees noted that the analytical capacity to detect chemicals in the body has improved overtime. Advocacy scientists framed ubiquitous chemical exposure as a call to action. They found that measurable exposures in human bodies cause deeper concern among individuals and communities than chemicals measured in media such as air or water. As one advocacy scientist stated:

> 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 biomonitored 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 …

Conversely, industry scientists framed chemical presence in the body as providing little or no basis for action, because more information about the chemical and its effect in the body must be understood. One industry scientist stated:

> 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 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.

Chemicals such as bisphenol a (BPA), which is used to make different plastic products, have become the target of consumers and advocates since it has been found in nearly everyone (93 %) (CDC 2013). However, industry scientists typically dismissed these large percentages. As one industry scientist argued, "93 % of people [exposed] …that must be important. And well, yeah, that maybe makes it interesting but it doesn't make it important."

Biological mechanism of health impact

All industry scientist interviewees insisted that biomonitoring data must be connected to an understanding of a chemical's biological mechanism, including how it is metabolized in the body and interacts with other physiological processes, also called pharmacokinetics. Pharmacokinetics provides a mathematical basis for the time course of a chemical, its health effects, and metabolism in the body (Dhillon and Kostrzewski 2006). Industry scientists emphasized that this mechanism must be elucidated prior to any type of regulatory action. One chemical industry scientist asserted, "We don't care about exposure for exposure's sake." Another explained this point further:

> One question….. is about a female who says they [sic] are pregnant, and if this is going to affect the fetus. 1) Does it cross the placenta? 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.

Advocacy scientists disagreed with this focus because of the long time frames required to fully elucidate a chemical's biological mechanism. Some described the toxicity assessments that the US EPA began in the 1980s for highly toxic chemicals such as dioxin that took decades to complete

(National Research Council 2006). Meanwhile, little would be known about impacts of in utero exposures to a developing fetus which could have lifelong consequences (Stein et al 2002) or the cumulative impacts of chemical mixtures. For example, an advocacy biomonitoring study of ten newborns noted:

> 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 (Environmental Working Group 2005).

Scholars have previously shown that environmental chemicals have been detected in virtually all pregnant women in the USA (e.g., Woodruff et al. 2011b) with animal and human evidence suggesting links between chemical exposures and reductions in fetal growth (Fei et al 2008; Washino et al 2009; Kodavanti et al 2010; Harley et al 2011). In vivo and in vitro animal studies, for example, show adverse developmental and reproductive effects from chemicals such as brominated flame retardants found in consumer products (Schecter et al 2005). Therefore, EHJM scientists emphasize the need for a public health approach to chemical regulation that utilizes existing evidence of widespread human exposures and animal toxicology evidence of adverse effects to guide decision-making and promote regulatory action.

Existing risk methodologies are built on a foundational toxicological assumption of "the dose makes the poison" and have come under criticism as evidence mounts that some chemical categories notably endocrine-disrupting compounds can disrupt hormone function in humans and exert toxic effects at low exposure levels. These can be particularly harmful during critical windows of development such as the prenatal period (Vogel 2008; Birnbaum and Jung 2011). For example, BPA and the widely used agricultural pesticide atrazine disrupt the body's hormone system at very low doses (Birnbaum and Jung 2011; Vandenberg et al 2012). Industry has forestalled regulations of endocrine-disrupting chemicals despite numerous studies showing adverse effects from low-dose exposures (e.g., Vogel 2009; Myers et al. 2009). In our interviews, industry scientists emphasized determining the biological mechanism for endocrine-disrupting chemicals and discussed mechanism in the context of single measures rather than through the frame of critical windows of vulnerability. Also, no industry scientist mentioned the importance of timing of exposure. One scientist working with the chemical BPA stated:

> You hear so much about BPA in various places, in food and so on but that's qualitative information and to put it into a scientific context not just qualitative, but what level and what does it mean. It turns out the levels are extremely low. So, it's actually, it's not alarming data at all, its reassuring data.

Use of biomonitoring equivalents

Biomonitoring equivalents (BE) are the proposed methodology, developed and funded by industry groups such as American Chemistry Council and the American Petroleum Institute, to facilitate the use of biomonitoring in risk assessments. Biomonitoring equivalents are at the center of ongoing disputes among stakeholder scientists over hazard- versus risk-based approaches regarding regulatory applications of biomonitoring evidence. BEs are defined by trade groups as, "a basic, screening level approach for putting biomonitoring data into a health risk context" (Hays et al 2008). Biomonitoring data describe chemical levels found in the body, which are affected by varying absorption rates, metabolism, and excretion. Biomonitoring measurements reflect the amount of a chemical in the body at the time the measurement is taken, whereas risk assessments set regulatory thresholds based on the amount of the chemical a person is exposed to. Biomonitoring equivalents emphasize pharmacokinetics with the goal of comparing the concentration of a chemical in the body to regulatory reference doses (RfD) set by the EPA, which are the maximum allowable levels of oral exposure of different chemicals in the body. In a presentation at a Biomonitoring California Workshop, an industry scientist framed the utility of biomonitoring equivalents for regulation:

> 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 BEs [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 (OEHHA 2011)

Conversely, EHJM scientists viewed the use of biomonitoring equivalents as a strategy that undermines a precautionary approach to applying biomonitoring evidence to better protect public health. Scholars have criticized risk assessment for overlooking discriminatory social, economic, and racially biased regulatory practices (Wigley and Shrader-Frechette 1996; O'Brien 2000), and EHJM scientists point to BEs as another tool that would deter the pursuit of more complex understandings of these socially determined exposure

dynamics. Academic scientists too have publicly argued that sole use of biomonitoring equivalents would communicate false precision for an inexact risk assessment process. One academic toxicologist at the same Biomonitoring California workshop criticized the systemic uncertainty embedded in risk assessment as "Scientific Wild Ass Guess (SWAG)," criticizing the tendency of both risk assessment and biomonitoring equivalents to emphasize one data point which obfuscates the many uncertainties that play into estimating potentially toxic effects in diverse populations:

> I mean, I think that they [Biomonitoring Equivalents] offer a preliminary benchmark … [but] be clear and honest with folks about what you can and can't say with reasonable confidence … measurements have this appearance of precision. And I think it's hard not to convey this single—the confidence that it does of a single point value (OEHHA 2011).

Research reviewed by the National Academy of Sciences recommends that risk assessment be improved to reflect newer science on the relationship between exposure and adverse health effects, such as including complexities of differential susceptibility and vulnerability (National Research Council 2009). To address the limitations of risk assessment, some public health scientists propose making regulatory decisions on the basis of available, albeit incomplete, evidence such as information on chemical structure and other indicators of potential hazard. One government scientist working in a government surveillance program expressed deep frustration with the limitations on regulatory programs stating:

> [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 working 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.

Limits of targeted biomonitoring

Analysis that characterizes the full range of human chemical exposures remains in its infancy despite significant technological advances. This is in part due to a key limitation to current targeted biomonitoring methods. Chemicals to be monitored are defined a priori and only cover about 250–300 (or 10 %) of the chemicals in US commerce. Considerations such as production volume are often used to select chemicals for targeted biomonitoring (Judson et al 2009; Egeghy et al 2012). However, the lack of information about where, how, and the extent to which chemicals are used and substituted in different products makes it difficult to predict and track which chemical exposures are most important with respect to human development and health risks. Nearly all interviewees mentioned this as a serious limitation for biomonitoring though they framed their concerns differently. Industry scientists were concerned with targeted biomonitoring since this method could "unfairly stigmatize a known chemical" that has long been used in consumer and other products and that has some toxicological data. Four industry interviewees cited the example of bisphenol a (BPA) that, as a result of consumer and environmental health activism, has been removed from baby items such as bottles and sippy cups. Once a chemical such as BPA is removed, it is often substituted with an unknown chemical or one that is similar in chemical structure such as BPS (Viñas and Watson 2013). Interviewees from industry made strong arguments in favor of protecting use of existing chemicals as safer than unknown alternatives.

EHJM scientists also argue that so-called "bad actor" chemicals should not be replaced with similar or unknown chemicals. Yet they also expressed concern about the chemical-by-chemical approach of targeted biomonitoring and seek reforms in chemical policy that would require safety testing of chemicals before new compounds are used in consumer products. EHJM scientists also emphasize the need to advance innovative non-targeted biomonitoring methods to more fully characterize the scope of population exposures to multiple environmental chemicals that have not yet been identified through traditional targeted approaches. Fewer than 10 % of the 3000 high production volume (HPV) chemicals are currently measured in large-scale human biomonitoring studies. A more systematic and comprehensive non-targeted approach that identifies a wide array of environmental chemicals potentially present in human biological specimens would address this knowledge gap. This nontargeted strategy is now recognized by academic scientists as an integral part of an "exposome" approach (Rappaport 2011; Wild 2012).

Limits of detection

Targeted biomonitoring is driven by the ability to detect contaminants in biological media. The limit of detection (LOD) is the lowest concentration of a compound that can be reliably detected by an analytical procedure. This technological limitation also limits the utility of biomonitoring to those chemicals that can be detected and measured. All of the industry scientist interviewees argued that the analytical capacity to detect a chemical should not drive decision-making about a chemical. As one trade industry scientist stated:

> Trace chemicals we are picking up are not unexpected. This is a challenge to communicate and to help people understand and inform policy-makers. Now because

> you can detect chemicals, from 9 to 300, people think more chemicals are "getting into us more often." The reality is that many of these chemicals have been in our bodies for a while, but now we have the capacity to measure them.

On the flip side, EHJM scientists are concerned with detection becoming a requirement for action since the majority of chemicals are unmeasurable or have not been examined. The lack of biomonitoring data on these other chemicals is a critical impediment to understanding the full range of population health risks. As one EHJM scientist argued:

> 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 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.

Further, EHJM scientists are concerned that without premarket testing requirements, industries could simply switch to using new chemicals for which analytical methods have not yet been developed to measure them in human tissues. One EHJM scientist noted the precedent for this type of industry action in the case of pesticide air monitoring where potato growers in Minnesota switched from chlorothalonil fungicides to the pesticides maneb and mancozeb, which could not be detected in the air. 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."

Policy influence of advocacy biomonitoring

Science does not operate in a vacuum but interacts constantly with the wider social world, influencing public policy and the media, which in turn can (re) shape scientific ideas. The debates mapped above highlight conflicting frames employed by scientists from different sectors. These debates play out in public arenas due to organizing efforts of environmental health advocacy groups and industry lobbying. Public biomonitoring debates highlight the concept of the "public hypothesis," whereby new scientific paradigms are the subject of public deliberations and involve the lay public, advocacy groups, and scientific experts (Krimsky 2000). In part by using the media, advocacy groups seek to democratize science, introduce lay knowledge within the scientific enterprise, and implement new policy-making logics, such as reforming existing chemical policies to better protect public health (Morello-Frosch et al. 2009; Parthasarathy 2010; Wilson and Schwarzman 2009). Advocacy groups publicize biomonitoring results through storytelling, placing real faces on aggregated exposure data, and disseminating this information in diverse ways ranging from peer-reviewed journals to interactive websites (Washburn 2009). This strategy forces regulatory scientists and industry to pay increased attention to the issue as they respond to the concerns of tested individuals, families, and communities who learn they are involuntarily exposed to synthetic chemicals, many of which are in everyday consumer products.

One outcome of public dissemination of biomonitoring evidence is industry criticism of advocacy studies. Industry and some government scientists question the scientific credibility of advocacy studies because of their focus on media attention and for not "playing by the rules" by not submitting their research for peer review, and for a lack of statistical rigor and generalizability due to the small sample size of their biomonitoring studies. While dismissing the scientific relevance of advocacy studies, industry scientists state that these strategies do generate publicity about biomonitoring: One industry scientist stated:

> I'd have to consider that these studies were done for publicity reasons, not scientific ones….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 [non-governmental organization] 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.

EHJM scientists countered criticisms of a lack of peer-review by arguing that their research follows Institutional Review Board protocols for working with human subjects, use reputable laboratories with valid sampling protocols, and benefits public interest through diverse dissemination strategies that are not limited to peer-reviewed publications. One advocacy scientist responded to industry criticisms stating:

> There is never going to be statistically representative data in an [EHJM] study. It's not our point, it's not what our funding is about, and it doesn't serve our purpose. It's really descriptive. It's pilot research……It's definitely for public awareness and public education, public engagement with the issues. But it's often trying to fill a data gap or impress upon people the results or risks of inaction…..So what happens if you're pairing cord blood measurements with mercury and you realize that most American children also have an existing body burden of PCBs and PBDEs and pesticides that might all affect the same pathways?… almost never are epidemiologists doing anything to acknowledge the co-existence of other chemicals.

Relevance of biomonitoring to motivate policy change

EHJM scientists expressed frustration with government inaction on chemical policy, so they also educate consumers and try to influence product manufacturing decisions directly. One EHJM scientist stated:

> I think that 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. I'd be curious whether companies are keeping a close enough eye on which of their products are showing up in biomonitoring studies. Some of them probably are and when it shows up, are they rethinking their product line? Or are they waiting and holding their breath to see if there's going to be a big hue and cry about it, and if there isn't, they'll figure they're good. I don't have enough insight as to what's going on to know for sure but there are some chemicals that are popping up in biomonitoring where I am seeing companies taking actions and there are others where I'm not seeing it.

Some companies respond to biomonitoring evidence and have phased out certain compounds. For example, in 2000, the company 3M discontinued the manufacture and sale of perfluorooctanoic acid (PFOA), a chemical that is a primary ingredient in water-resistant and anti-stick coatings, such as Teflon. One industry scientist described widespread biomonitoring evidence showing PFOA's persistence in the environment, including their own studies, that revealed a PFOA "fingerprint" in every single animal and human tested.

> 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. 3 M made a risk management decision to get out of the business. … This is a classic example of how [biomonitoring] works really, really well.

Based on biomonitoring evidence, 3M was compelled to acknowledge the chemical's ubiquity and persistence in the environment. They stated on their website that although PFOA had no proven adverse health effects, they chose to discontinue production because of its persistence (3M 2014). 3M's manufacturing accounted for 98 % of PFOA global production, and the company determined that popular acceptance of PFOA products would decline once their product was found in wildlife and people.

In another example, Colgate-Palmolive removed the chemical triclosan, an antibacterial pesticide used in many over-the-counter hand soaps, from most of its products. The CDC detected this persistent, endocrine-disrupting chemical in 75 % of the US population (Calafat et al 2008). Despite one company's decision, triclosan remains unregulated and in widespread use. Public awareness, consumer pressure, and industry wariness of liability have brought some change to the most visible products such as PFOA. But phaseouts of chemicals such as BPA have been limited to high-visibility products such as baby bottles, and BPA otherwise remains in widespread use. Industry scientists we interviewed resisted making changes to consumer products based on the public's reaction to biomonitoring evidence, calling it "unscientific" and "emotional." But they recognize the unpopularity of this position. 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 it's ok to have chemicals in your body.' It is not a winning sound bite.

Discussion and conclusion

Debates among scientific experts over biomonitoring aim to interpret evidence, with particular attention to demarcating the role of biomonitoring in understanding human exposures to a host of synthetic chemicals and how it might be integrated into regulatory and policy-making structures. Risk versus hazard frames dominates battles between EHJM scientists and industry scientists. Industry scientists seek to limit biomonitoring to risk-based frameworks and channel funding and effort towards developing methods to facilitate this, such as promoting the use of biomonitoring equivalents that take a chemical-by-chemical approach to risk management and set thresholds for internal exposures. EHJM scientists, while wary of overreliance on biomonitoring, seek to integrate biomonitoring evidence into a broader hazards driven framework of exposure assessment. Advocacy scientists frame biomonitoring within the context of a new approach to chemical management that would integrate the science of low-dose exposures, recognize disparate effects on vulnerable populations, and utilize methods to understand multiple chemical exposures. One important consideration in biomonitoring studies is the issue of ethical report back. We do not include debates among experts over report back strategies, which is a limitation of this study as it is a critical component of all biomonitoring research. While discussion of report back is beyond the scope of this study, we have written extensively on this topic previously (Brody et al 2007a, b; Morello-Frosch et al 2009; Adams et al 2011).

Our research highlights the reliance of all scientists engaged in biomonitoring on CDC national surveillance data as an important standard bearer for biomonitoring studies. Despite national surveillance activities, government use of biomonitoring evidence has been slow and often lacking. In 2009, the US Government Accountability Office criticized the EPA's limited use of biomonitoring evidence and encouraged the EPA to develop a national coordinated research strategy (U.S. Government Accountability Office 2009). The US regulatory process, which tends to be contentious and litigious (Jasanoff 1987), pushes regulators to rely on extensive and time-consuming evaluation of scientific evidence, which discourages regulatory action. Indeed, despite new forms of evidence, government scientists continue to feel pressure to amass exposure data to demonstrate a problem, and there is still little coordinated effort on biomonitoring.

Scientific debates over biomonitoring have moved into public arenas. EHJM organizations pursue a multipronged strategy to mobilize communities and consumers, influence the scientific enterprise, change industrial production processes, and motivate policy change at local and state levels. Industry scientists remain wary of the public's emotional response to biomonitoring data and delegitimize studies conducted by EHJM groups. EHJM biomonitoring informs the public and policymakers about biomonitoring. These efforts have opened up a space for national dialog about pervasive human exposures to environmental chemicals and the need for chemical policy reform (Lautenberg 2011).

There has been an overall limited and at best mixed impact of biomonitoring evidence towards promoting policy change or limiting a chemical's use, even with evidence of widespread exposure. Biomonitoring evidence, in the case of lead, relied on extensive knowledge of this compound's adverse neurological impacts before lowering regulatory thresholds. For the majority of chemicals without sufficient health or toxicological data, there has been little to no regulatory action even with extensive exposure evidence. Rather, industry has voluntarily removed some chemicals from a limited range of products, such as BPA in baby bottles or PFOA in cooking products, that it sees as unpopular or a liability with consumers.

Biomonitoring, while a powerful tool for elucidating chemical exposures, is not yet integrated into the chemical policy decision-making apparatus. The differing interpretations identified in these interviews reveal sectoral influence on scientists' interpretation of chemical exposures. The involvement of EHJM scientists expands the parameters of scientific debate over biomonitoring towards more precautionary interpretations and introduces proactive approaches to chemical management. By describing key areas of scientific contestation over the interpretation of biomonitoring, the findings from this research explain some of the persistent challenges to regulating chemicals even in the midst of mounting evidence of widespread population exposures.

Acknowledgments This research was supported by the National Science Foundation Award [# 0822724], a National Science Foundation Graduate Research Fellowship, and this work was supported by the National Institute of Environmental Health Sciences (R01ES017514). Thank you to Dr. Phil Brown and the Social Science Environmental Health Research Institute at Northeastern University for valuable feedback on the manuscript.

Appendix

Table 2 Scientific meetings attended (see "Methods")

Biomonitoring California Scientific Guidance Panel Meetings (13 meetings were held over this time period. Oakland meetings were attended in person; Sacramento meetings were attended virtually. http://www.biomonitoring.ca.gov/meetings)	January 2009–August 2012
American Chemistry Council, International Council of Chemical Associations (ICCA) Long-Range Research Initiative (LRI) Connecting Innovations in Biological, Exposure, and Risk Sciences	Charleston, North Carolina, 2009
Workshop on the Ethics of Reporting Personal Environmental Exposures (See also our paper on this http://www.ehjournal.net/content/13/1/40#B7)	Harvard University, 2010
Biomonitoring California Workshop, Understanding and Interpreting Biomonitoring Results (http://www.biomonitoring.ca.gov/events/biomonitoring-california-workshop-march-2011)	Oakland, California, March 2011
National Conversation Leadership Council: Addressing Public Health and Chemical Exposures: An Action Agenda. In the National Conversation on Public Health and Chemical Exposures. Centers for Disease Control/ATSDR (Agency for Toxic Substances and Disease Registry)	Atlanta, 2011

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