Studies in Sustainability

New Chemical Bodies: A Conversation on Human Biomonitoring and Endocrine-Disrupting Chemicals
New Chemical Bodies: A Conversation on Human Biomonitoring and Endocrine–Disrupting Chemicals

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Executive Summary

This paper follows on the 2007 Gordon Cain Conference, “New Chemical Bodies: Biomonitoring, Body Burden, and the Uncertain Threat of Endocrine Disruptors” held at the Chemical Heritage Foundation in March 2007. The conference gathered together experts from academe, government, industry, and NGOs working in fields as diverse as public health, endocrinology, chemistry, sociology, history, and law in order to gather perspectives on current understandings of the ways human biomonitoring studies and research into the endocrine-disrupting effect of chemicals are changing the landscape and discourse of public health in the United States. This paper presents an outline of the conference and harnesses the discussion that took place in order to offer the thoughts and suggestions made by participants to interested parties working in fields directly related to or impacted by research into these two emerging fields of scientific investigation.
Introduction and Background

This paper discusses the new knowledge emerging from studies of both endocrine-disrupting chemicals and human biomonitoring. The convergence of results from both types of study provides us with new ways of understanding these complicated subjects. The potential for synthetic chemicals to mimic the function of hormones and to disrupt the normal operations of the endocrine systems of various organisms has been an issue of research and debate for more than a decade.

The topic may have reached its peak in the public’s conscious with the airing of the BBC documentary *Assault on the Male* in 1993 and the publishing of *Our Stolen Future* in 1996. However, that period also saw the beginning of a more serious undertaking by a variety of scientific and regulatory agencies to understand the phenomenon and to better determine what can and ought to be done about it. In an attempt to elucidate the core issues and to develop a systematic method to guide investigation, the Environmental Protection Agency (EPA) established the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC). However, the task proved more complicated than perhaps some had thought. After a decade the EPA has recently released its first list of potential endocrine-disrupting chemicals to be investigated. In the meantime results from research in various academic and industrial laboratories have continued to emerge on the scientific (and occasionally public) scene, but debate over how the science is done and what can be concluded from it has prevented more concrete actions.

As greater attention was being focused on the potential effects of synthetic chemicals on endocrine systems, researchers using new and more powerful analytical techniques began tracing a broader range of these chemicals into the tissues and fluids of humans. Advances in human biomonitoring have taken the technique beyond its original context in occupational health and moved it into the realm of public-health evaluation and monitoring. With the creation of the National Health and Nutrition Examination Survey (NHANES) in the early 1970s, the EPA, working in partnership with

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the Centers for Disease Control and Prevention (CDC), laid the groundwork for a systematic evaluation of chemical exposures in the general U.S. population. Over the subsequent three-plus decades NHANES spawned the CDC-guided “National Human Exposure Report.” In 2001 the CDC released the data from its first survey, with follow-up studies scheduled for release every two years and made publicly available through the CDC Web site on human exposures and biomonitoring. In that time the reports have grown in breadth and depth of analysis, expanding from twenty-seven chemicals in the original report to an anticipated three hundred in the fourth report (slated for release in 2008). The tremendous progress made in the field of human biomonitoring results from breakthroughs in both analytical capabilities (allowing researchers to find ever smaller traces of a chemical in a variety of biological mediums) and a greater understanding of the metabolic fate of many of these chemicals. The result has been a greater understanding among researchers of the extent to which synthetic chemicals find their way into our bodies.

How are studies of human biomonitoring and endocrine-disrupting chemicals linked to one another? Each raises questions about some of our basic assumptions concerning the relationship between ourselves, our world, and the objects we use to create that world. Old distinctions between sciences—chemistry, toxicology, epidemiology, endocrinology—are increasingly challenged by new research being conducted within these fields. It has become apparent that the effects of exploring the possible ways in which synthetic chemicals may disrupt the signaling of an organism’s hormonal system become magnified when the very same chemical can be found in appreciable quantities in nearly every human. The two work in concert. Concerns raised in one field of study become concerns amplified by the other. This converging scientific information may dramatically change the ways in which we think about ourselves and our world.

Because the potential for change is so great, a sustained and open dialogue concerning these matters is crucial. This report results from the attempt to create one such conversation and is also a plea for more of its kind. As traditional knowledge boundaries break down in the face of emerging data, we will need to draw on the insights and experiences of experts from a range of fields. The thoughts presented in this paper come from a diverse group of individuals working at a range of institutions who are all—broadly speaking—dealing with what has resulted, as well as what may result, from studies in these burgeoning scientific fields. Historians, chemists, endocrinologists, sociologists, lawyers—all offered their perspectives on the past, present, and future during a one-day workshop hosted by the Chemical Heritage Foundation. Perhaps more important than disciplinary diversity, participants came from academia, nongovernmental organizations, industry, and government to discuss their concerns frankly and to share their suggestions. The meeting demonstrated two important lessons: conversation is both possible and critical.

This paper attempts to retain the essence of what transpired at the workshop that brought this diverse cast of characters together. It is not a consensus statement: almost everyone who attended will likely find at least one thing here they disagree with to some extent. It is, however, intended to give the reader a sense of what the participants had to say. Although the outline of the workshop was provided, it was left to the participants to flesh out the topics themselves. Below, then, is a sketch of what that fleshed-out product looks like.
The Technical Aspects

The sixteenth-century Swiss proto-chemist Paracelsus provided the bedrock for modern toxicology with his now famous “the dose doth make the poison” insight. This phrase has come to characterize our understanding of the toxicity of the chemicals that surround us in our everyday lives. But we often accept the phrase without much thought for context, additional meaning, or well over four centuries of shifting and accumulating understandings of health and the body.

In order to apply the wisdom of Paracelsus one must have a deep understanding of the substance, its effects, and the very fine line that separates poisonous from harmless. That is, while it’s true that it is the dose that makes the poison, understanding why one dose and not another is an entirely different, and much more difficult, matter. When it comes to the toxicological nature of the tens of thousands of synthetic chemicals produced each year around the world, we understand woefully little. Our power to destroy, analyze, and rebuild molecules in fantastically novel ways has unfortunately developed without a parallel understanding of the effects of these activities. This is not purely accidental. We have ignored the ramifications of these actions until some effect has become manifest. One might argue that this state of affairs is tied directly to the model of innovation that has characterized the chemical and molecular sciences for at least the last century and a half.4

Despite the more recent development of infrastructures for toxicological testing for some of these chemicals, the data emerging from human biomonitoring studies and, more important, the fields examining potential endocrine-disrupting chemicals, have highlighted two places where the failure to be mindful of toxicity while synthesizing new chemicals has proven particularly problematic: the reliance on outdated toxicology paradigms and the disjunction between design for function and design for (non)toxicity.

Recent work in the fields of endocrinology, toxicology, and chemical signaling more generally has seemingly shown that it may be time to move beyond our sixteenth-century understanding of toxicology. Perhaps it is time to start asking why we still inhabit this old space and start looking for ways to leave it. What would a new model of toxicology look like in its evaluation of manufactured chemicals?

A shift in endpoints for our toxicological investigations is needed. According to the old paradigm, toxicol-

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ogy is equated with death; therefore, toxicological standards, models, experiments, and decisions have been based on an understanding of determining, roughly, how much of a substance would be fatal to enough of the population to prohibit continued exposure. More recently, toxicologists have begun to investigate other potential endpoints, most notably cancer. But with so much emphasis on lethal dose and the vagaries of cancer, researchers have been neglecting many other potent endpoints for chemical interactions with and within living organisms. It must be asked anew: in what ways will these interactions manifest themselves in the organisms that now contain them?

Change, to an extent yet to be determined, is under way. In June 2007 the EPA released its “Draft List of Chemicals for Initial Tier 1 Screening” as a part of its Endocrine Disruptor Screening Program. In addition to the endocrine-disrupting properties of some chemicals, research into chemical mutagenesis and toxicogenomics continues to evolve as well, pointing toward other potential endpoints that may have previously gone unnoticed. We might also consider as potential toxicological endpoints those that extend beyond the scope of adverse human health effects and incorporate threats to ecological systems through threats to individual or collective nonhuman species.

We encounter a more complicated problem in attempting to judge the potential toxicological effects of manufactured chemicals. This problem is exacerbated by our fractured regulatory structures: chemicals not produced as pharmaceuticals are by default presumed not to have pharmacological properties and thus receive far less scrutiny than their chemical brethren. Thus, the division of labor between the EPA and the Food and Drug Administration (FDA) also breeds a division of assumptions about the materials with which each agency works. In this case there are two prevalent assumptions: synthetic chemicals, regulated by the EPA, do not have pharmaceutical-like properties; and synthetic chemicals require higher doses of exposure in order to have appreciable adverse effects. However, current research challenges these two very basic assumptions. First, chemicals not intended to have druglike activity may very well have these properties in the right organic matrix. Second, the doses at which these chemicals can be found, and can potentially be found active, more clearly line up with the doses at which many if not most pharmaceuticals are intentionally designed to operate (in the range of the parts per trillion to parts per billion dose).

The situation outlined above becomes more crucial when we realize that toxicology rarely factors into the decision-making process of the synthetic chemist, as researchers such as John Warner, an early and persistent advocate for green chemistry, have been arguing for the last several years. Toxicological effects, it is presumed, will be managed once the product has been formed. The attention given to intended function (not unintentional effects), cost of production, and efficiency in terms of yield drives the design process.

While attention within emerging sectors of the chemical sciences has turned toward molecular design, analytical techniques and capabilities have made it possible to trace the fates of an increasingly diverse class of compounds. Advances at the intersection of chemistry and biology have given rise to new techniques for identifying the metabolic routes of many synthetic chemicals. On the instrument side more powerful detectors, more skilled researchers, and a greater availability of analytical labs have made it cheaper and faster (but neither cheap nor fast) to conduct biomonitoring studies in novel ways.

6 For more information on how these topics are being integrated into the research activities at the federal level, see Department of Health and Human Services, “National Toxicology Program,” ntp.niehs.nih.gov/index.cfm (accessed 4 December 2007).
Despite the myriad approaches developed over the last decade, such as green chemistry, life-cycle analysis, and industrial ecology, that have made it possible to begin talking differently about design, we still do not understand the more fundamental concepts of the toxicological effects of molecular structures. The behavior of the substances within individual organisms, populations, and entire ecological systems presents a terribly large knowledge gap. Terry Collins, of Carnegie Mellon University and a workshop participant, suggests a tiered approach to research that might help us move from the gains we have made in recent years to a chemistry that does not just talk about health in a broader way but actually incorporates it into its research practice. His plan shifts research from thinking only about efficiency in design to purposefully designing against adverse health effects.

We begin by designing for synthetic efficiency, which is a way to incorporate notions of atom economy into the design process for synthetic chemistry. From here, chemists must find a way to begin utilizing renewable feedstocks in their work, another “design for” issue. The final step, according to Collins, in this category involves the development and utilization of chemical and materials knowledge to design solar energy technologies. Moving beyond designing for strategies, Collins argues that in three areas chemists must “design against” specific inherent molecular properties and characteristics: the use of toxic elements; molecules that persist in the environment and our bodies; and molecules that possess endocrine-disrupting capabilities. This long-term strategy confronts specific areas of concern related to synthetic chemicals and health.

But getting from the first point (design for synthetic efficiency) to the final point (design against endocrine disruptors) is a long-term project. In the meantime researchers have already amassed results that assert intimate links between many of the synthetic chemicals being produced and a host of environmental health problems. For this reason attention cannot be focused solely on the technical issues involved in the redesign of the chemical sciences but must also focus on the institutional structures that mediate our everyday experiences with these products.
Research into endocrine-disrupting chemicals coupled with the vast expansion in the use and power of human biomonitoring have given rise to tremendous challenges to our view of chemicals from both legal and regulatory perspectives. A number of issues fit within this realm, including low-dose toxicity, the relevance of animal models, the problems of synergistic effects, and the sheer pervasiveness of many of these chemicals at what are deemed to be ecologically relevant doses. But perhaps more challenging legally and philosophically are the complicated issues of what constitutes a body and how chemicals trespass on or into these bodies.

Over the past several decades various procedures, rules, and regulations have evolved to help communities negotiate with corporations about the health-related concerns of the chemical industry. But human-biomonitoring studies threaten to disrupt this relationship. By focusing on the exposure of a single individual, that person has access in some cases to a very personal view of his or her own body's chemical burden—as unique perhaps as any other individual signature. Yet this fact is not always clear, and much depends on the way data is presented. While biomonitoring studies have the potential to give a highly personalized view of one's body, this personalization can also be prevented through the power of statistics, placing the individual back into the categories of the collective (e.g., male, Hispanic, age 30 to 50).\(^7\)

While human biomonitoring has thus far been used primarily as a tool for studying populations, it has the potential to become a tool for personalized health assessment and evaluation. However, just what bodies these techniques will be monitoring remains an unanswered question. And while the techniques have become more powerful, how these results can and ought to be used and interpreted has not yet been decided.

This situation creates a number of stinging legal problems. As an individual, what is a person to make of the presence of hundreds of synthetic chemicals in her body tissues and fluids? How did they get there? Who is responsible for having put them there?

At least two ways of evaluating this predicament exist. The first runs in tune with our current regulatory and legal structures: are the chemicals safe, and does ongoing exposure pose any risk? The terms *safe* and *risk* are slippery. An adequate answer requires a certain familiarity with the question and the context in which it has occurred as well as confidence in one’s understanding of the situation. That is, answering the question requires an awful lot of research. It presumes that we

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\(^7\) Take, for example, the ways in which human-biomonitoring information is communicated by the Environmental Working Group and the CDC.
know the difference between what will be safe and what will be unsafe and what is at risk and what the consequences of the risk might be, and that we have a certain amount of historical knowledge to help us navigate otherwise blurred boundaries.

In response to ongoing CDC reports on the nation’s collective and individual body burden, the American Chemistry Council is quick to point out that the presence of a chemical does not equal harm, typically by citing the CDC’s own language on the issue. Likewise, the CDC is careful to hedge its claims. While it is true that presence does not equal harm, it is equally true that presence does not equal non-harm.

Current research on some of the several hundred chemicals the CDC reports on in its studies suggests that there is at least some possibility for harm. But as the situation stands, most experts feel as though there simply is not enough information available to make judgments because we cannot predict what effects ongoing exposures will or will not have on our bodies. Thus judging safety and risk becomes virtually impossible at this stage based solely on scientific reasoning. The issue instead becomes one for moral and political reasoning and debate.

Alternatively, what if this issue was viewed not from the perspective of risk, safety, and harm but rather from the view of the individual body as a sovereign place, as Carl Cranor, a workshop participant, suggested? How does this view change our interpretation of the situation? The synthetic chemicals that have become a part of the body—literally—are now potentially viewed as invaders, the traces left behind of what might be referred to as “chemical trespass.” Moving from regulatory law, which is based on harm, and into the legal realm of private property, sovereignty, and trespass takes us into a wholly different understanding of what it might mean to find one’s body burdened with synthetic chemicals. Within a discourse of trespass it is enough to prove unlawful invasion regardless of any malicious intent to cause harm. In this scenario proof of presence does indeed matter.

Our current regulatory logic continues to be founded on principles of rights, risks, and harm. But again these concepts are difficult to pin down in this context. While harm must be proved, it is fairly clear at this point that we do not have enough information to make clear, irrefutable, or certain links between exposure and health effects. Within a system of risk analysis we face a tremendous problem: if we do not adequately understand the potential for harm, how can we develop models for assessing risk that provide clear options? Risk also becomes complicated because the risks are not traditionally shared equally, and those reaping the most benefit are rarely those asked to assume the greatest burden.

What rights are we considering when we regulate the production of certain objects? The obvious answers seem to be the perceived rights to health, clean water, and clean air. That is, we seemingly use regulation to protect the bodies of individuals, communities, and “the public” generally from unneeded or unnecessary harm. But in many cases these presumed rights have been tempered by the right that the corporate body claims to exist, to produce, and to generate profit. Regulation is

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9 Whether or not we can ever have this sort of knowledge is an issue, and what we do based on our “best” knowledge is also a subject for conversation.
10 While this observation has provided the underpinnings for the environmental justice movement, the information from human biomonitoring may offer a serious challenge, arguing instead that risk and exposure have been “democratized” through the profusion of these chemical species throughout the environment.
intended to protect not just the health of biological bodies but also corporate ones by ensuring them protection from the perhaps unintended consequences of their activities. The research coming out of endocrinology, toxicology, and associated fields in combination with human-biomonitoring studies is challenging this logical underpinning as studies introduce not just new ideas about our bodies but also new understandings of the relationships between these bodies.

The question may need to be changed to ask whether these new understandings of our bodies and their relations necessitate a new regulatory logic. Can our current regulations continue to function in light of this new knowledge? One answer is the development of the European Union’s chemicals regulations program adopted in December 2006, REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals). The new guidelines established in that protocol emerged from a growing concern that older regulations cannot adequately address what we now know to be the possible risks associated with chemical production, use, and afterlife.

But it might also be worth a deeper exploration of the extent to which our current tools have actually been used. Perhaps the problem is not inadequacy of regulation but rather the lack of enforcement of regulations already on the books. Perhaps TSCA, the Toxic Substances Control Act, could prove robust enough to accommodate our new understandings of chemical toxicity, persistence, and migration through environments and bodies, but perhaps not. Screening of products, however, appears to be one area that does require some reworking. We still do most of our chemical screening after a product has reached the market and after concerns have been raised. Developing a mechanism for premarket screening or slowing down the pipeline to market in order to allow the screening processes to keep pace appears to be an issue that requires further attention. We otherwise find ourselves the unwitting subjects of a number of global experiments.

In all these cases of possible legal and regulatory alterations the demand for more data comes as a unifying chorus. More results are needed to better understand the potential harm that these chemicals might pose, exactly what the risks are in order to develop a proper risk analysis, the ways in which chemicals persist in bodies, and how effects can persist over time and space. But at some point decisions have to be made.

The difficulty comes in negotiating the difference between what counts as adequate data in the scientific arena and what will count in a legal or regulatory one. There is no simple adoption of science into the regulatory framework. Rather, a consistent effort is needed to translate the information produced by science into the very different context of regulation.

The increasing complexity of the nature of our understanding of chemical products cannot be simply reduced into conformity with the requirements of the legal world. Our recent success stories might offer some guidance as to how this has been done as a way of thinking about how it can be done again, soon, and more consistently.
The research that informs much of what we know about endocrine-disrupting chemicals in the environment comes from ongoing experiments in various populations, not individuals. The nature of these experiments, however, differs greatly. As a part of our exploration of these topics workshop participants reviewed and discussed two such studies that highlight these differences.

The first concerned a more traditional laboratory-based experimental study reviewing the effects of a variety of synthetic chemicals on avian endocrine systems. The avian system under investigation acted as a model for several groups: avian populations whose endocrine systems may resemble and therefore react in similar ways to those under investigation and other animal species that may share specific key characteristics in physiology and the ways in which endocrine and reproductive systems can be altered by ecologically relevant doses of specific manufactured chemicals.

The second, less traditional study resulted from an informal network of physicians in Italy communicating about what they thought was an abnormally high incidence of a rare cancer—soft-tissue sarcoma. In this case the laboratory was a town (Mantua, Italy), the population under investigation its inhabitants, and the model still undefined.\textsuperscript{11}

Both these studies highlight the tensions within current attempts to elucidate environmental harm and toxic exposures while outlining many characteristics that may come to define a more robust science for tackling these emerging issues. Three points should be emphasized here:

• The role of experimental design (including how the design team itself is constituted) and communication (both within the research team and beyond);

• The role of data and endpoints, and our changing conceptions of what will count as “normal” in future studies; and

• The ways in which we might direct future research projects, including evaluating our past efforts and improving our ability to move beyond the snapshot results of our singular studies.

The call for more inter-, multi-, and cross-disciplinarity in scientific studies has become a hallmark of what may evolve into the key characteristic of twenty-first-century research. However, the practicality of making this sort of research happen remains a quandary. Rigorous boundaries within academia, half-century-old funding lines and institutions, and entrenched regulatory structures, guidelines, and protocols have made it difficult to facilitate the types of investigations that nearly everyone seems to want to see occur.

\textsuperscript{11} Unpublished materials were used in the workshop. Requests for materials should be sent to directly to the authors.
Despite the fact that institutionalized attempts to make these changes in research procedure have been hampered, reports such as those examined here are evidence that collaborative networks can and do exist. The question becomes then how to encourage this dynamic on a broader scale. One way to start is by examining some of the elements that made these research projects possible.

Conceptual innovation is a key aspect in these studies. The studies exhibit this both in the structure of the experiments and of data collection and in the networks used to conduct the work. In the study of Japanese quail, researchers worked to synthesize what has been a growing glut of information on the real and potential adverse effects of manufactured chemicals on the endocrine system of various biological systems. Most important, the researchers focused their efforts on pulling together a vast and diverse body of literature in order to begin the process of setting foundational techniques necessary for the establishment of an endocrine-disruptor screening program at the EPA.

In the case of the study of soft-tissue sarcoma in Mantua we see not only conceptual innovation but also the spontaneous collaboration of a diversity of actors to construct a research network. There were five important components in the construction of this network:

- First were the physicians whose degree of awareness of their local environment as well as their patients allowed them to take note of what appeared to be a suspiciously high number of cases of what was considered a rare condition.
- Individual physicians were able to communicate with one another in ways that allowed them to conceptually map the extent of disease manifestation.
- Working with area environmental planners, the physicians were able to chart geographically their patient-based evidence onto the territorial maps of Mantua and the surrounding area. The planners were also able to help pinpoint possible sources for the disease in the surrounding area.
- Through communication with and by the public media the physicians (and environmental planners as well) were able to solicit support from the local populations in order to increase their sample sizes, collect further data, and enroll the locals’ assistance in drawing more official recognition to the potential problem.
- Increased attention, support, and concern created an opportunity to enlist the aid of international elements, resulting in the role of the American CDC in analyzing the samples for dioxin exposure.

The openness of the design and the participants allowed for emerging collaborations and negotiations among professionals as well as for a place where the public can be directly involved. Most interesting, however, is the role played by the physicians.

In the United States at least, physicians are not routinely acknowledged as playing a significant role in identifying and tracing out exposure-effect vectors in local communities or in studies of environmental health exposures or their consequences. This fact is odd not only because of the locally grounded, patient-focused attention that physicians offer but also because of their historical role in identifying environmental hazards throughout the twentieth century that otherwise might have gone unnoticed.

The effects of thalidomide and diethylstilbestrol (DES) were both recognized early on by physicians, and Minamata disease, associated with severe mercury poisoning, was also heavily investigated by a physician. Finding ways to train physicians to spot potential problems as well as creating pathways for them to communicate their findings will be critical to creating a

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new protocol for understanding environmental exposures and health consequences.

The two studies also highlight the problem related to data: both its dearth and glut. The studies demonstrate just how little researchers actually understand biological systems, their hormonal systems, chemical signaling, environmental exposures, the role of genetics, synthetic chemicals, relevant doses, exposure timings, transgenerational complications, synergistic activity, and more. The studies also underscore the inadequacy of many of our current models as well as the possible futility of using animal models at all (for reasons other than understanding how a specific species will in fact react). In all, they challenge our overly reductive models that attempt to boil down a tremendously complex ecological system into something that can be controlled, measured, and studied on a laboratory scale.

That being said, an enormous amount has already been learned. While generalized standards have not yet been established, many labs have simply developed their own through trial and error. The consistency of their results, the similarity in predictions and outcomes, and the architecture that has begun to form around new theories have all provided enough information to argue that while we may want to know more, we certainly know enough to start acting.

Endocrine disruption should be classified as a regulatory endpoint. The phenomenon of hormesis should be further investigated and should probably be seen as a more robust understanding of the relationship between dose and response. And, as the Mantua case shows, we need to be concerned about what we are using as our baseline for comparative studies. Residents’ dioxin levels seemed perfectly in-line with the general population until they were compared with the levels found in the citizens of Seveso, Italy, and Midland, Michigan—places already acknowledged to have elevated levels of dioxin in the environment and the population.

Perhaps most important, we have learned enough to know that many of our previous assumptions are wrong (or at the very least incomplete), that our work needs to change its focus, and that our current infrastructure for judging the relative safety and harm of synthetic chemicals is woefully out of date.

Discussion of these studies not only highlights some of the troubles we face within our current system but also suggests some ways forward. This is not the first time that the national and international publics have faced new information on the role of manufactured chemicals’ effects on the environment and the body. The stories of lead and secondhand smoke are the two examples that most clearly demonstrate the power of collective political will.

According to CDC data, the presence of these chemicals in the blood and urine samples of the general U.S. populace has dropped precipitously since the institution of regulations either banning or restricting their entry into the environment.13 For example, after the planned phaseout of lead in gasoline in 1973, researchers anticipated a gradual drop in the amount of lead found in the general population. Instead, researchers found a parallel drop in blood-lead levels compared with the lead-gasoline removal.

The dramatic results encouraged the EPA to seek even lower limits. While lead remains a critical problem for those still living in places with lead-based paints and lead pipes, the fact that a corrective was instituted following the acknowledgment of a severe public-health threat remains a model for what can be done when political will is strong.

While we have some examples to assist in planning future moves, too many of those examples come from the 1970s. We need to find a way to forge ahead with a new agenda. As new research emerges to challenge

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many of our current understandings, we must consider what other perspectives might be incorporated into our modes of testing, regulation, and ultimately production of synthetic chemicals.

Some suggested considerations are:

• The need to move beyond humans as the sole regulatory endpoint with respect to environmental toxicology;

• The need to increase funding to the National Institute of Environmental Health Sciences (NIEHS) to help expand research in such emerging topics as toxicogenomics, environmental connections to cancer, and chemical mutagenesis; and

• The need to find a way to collate results from the many diverse studies already under way and make them meaningful for other researchers, for regulators and lawmakers, and for the public that is exposed during the course of their daily lives.

Together the studies on avian endocrine systems and cancer clusters in Mantua, Italy, point to the need for nontraditional collaborations, increasing roles for science and health journalists, further studies, increased public outreach and participation, and—ultimately—action.
Personal Landscapes

From the macroscopic view of populations we move to the microscale of the individual and the personal experience of human biomonitoring with its tangled issues of exposure, risk, and harm. The health of the body becomes deeply intimate but has the potential for tremendous effects on communities, particularly those facing health and exposure-based discrimination. On the level of the individual body we see many of the same concepts and concerns discussed earlier but from an altered perspective.

How does an individual make sense of personalized biomonitoring data? What does it mean to find this synthetic matter within one’s body? In what ways does this data imply a personal violation? In what ways are we now polluted? The personal landscape of human biomonitoring challenges us on two fronts: the technical efforts required to detect, monitor, and evaluate, and the personal struggle of making sense of the data, the risk, and ultimately the self.

The growing use of human biomonitoring studies in recent years (as well as the concomitant growth in calls for more studies) is due in no small part to the increasing technical proficiency with which these studies can be conducted. Over the course of just four years (from 2001 to 2005) the number of chemicals included in CDC reports has more than tripled, and it will double again as the fourth report emerges during the course of 2008, bringing the likely total number of chemicals included to over three hundred.

However, despite the exponential growth witnessed in recent years, a report documenting potential exposure to three hundred chemicals hardly keeps pace with the few thousand high-production-volume chemicals manufactured in the United States each year or the scores of thousands more that are produced and used on smaller scales. Thus, these reports are limited by the extent to which chemicals can be feasibly—technically and financially—analyzed.

Even while the tests grow in depth and breadth, a number of challenges linger, threatening to hamper our ability to use this information in public-health contexts. Breakthroughs in both technique and cost are required to give biomonitoring a more stable presence in discussions of public health. Current reports rely heavily on samples taken from human blood and urine, yet we know these are not the only pathways by which we (or, more important, fetuses) are exposed. Research in these areas continues to explore ways of testing other fluid mediums for the presence of synthetic chemicals: cord blood, amniotic fluid, and breast milk are examples.

The trajectory of the past several years, then, has been moving research on human biomonitoring away from its traditional concern with occupational exposures only and into the realm of everyday-life exposures. Bringing the costs down and making the tests more accessible will not only put the results into the hands of more people but may also cause increased demand for more testing. This in turn may lead to...
increased funding possibilities and again to more demand to make these sorts of studies more accessible to a more diverse set of audiences.

Making biomonitoring studies work in the context of endocrine-disruptor research will involve finding ways to analyze direct fetal exposure as well as the development of a more reliable technical infrastructure for analytical purposes. Research into the first of these factors is under way. As for the construction of a research infrastructure, efforts have been hindered in recent years by both technical and financial factors.

Despite calls in the 1990s by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) to develop a new set of validated assays for the testing of potential endocrine-disrupting chemicals, we still have little to use as a foundational touchstone for analysis. The ongoing failure of this program would appear mostly political, but nonetheless research has continued in some pockets of the EPA. In June 2007 the EPA released their first draft of a list of chemicals to be screened. But with no technical infrastructure currently in place to conduct these tests, much preparation is needed before we can adequately handle the information emerging from human-biomonitoring studies.

This is especially true since the results relate to the tremendous potential for many of these chemicals to affect seriously the development of those exposed. The failure to construct these analytical tools creates a frustrating situation for researchers charged with performing the difficult task of translating exposure data into risk data. But for those exposed the frustration is even greater, as they face the prospect of living with the effects of this undone science. This situation comes about in part as a result of our preconceived notions of pollution.

Those of us raised in the post–World War II era have grown accustomed to the notion of pollution. But the concept of pollution has always contained an element of the “outside”: national parks, rivers, skylines of a distant city, and poor communities and countries. The widespread use of human biomonitoring has turned this logic on its head, moving the pollution from “out there” to “in here” in a way that remains mostly indecipherable to exposed populations (which at the moment seems to be all of us to lesser and greater degrees). This inversion of pollution from external to internal presents a number of challenges to our understanding of both environmental and public-health issues.

As we move from place-based pollution narratives toward those of a more personal, yet also placeless nature, we can expect a number of different reactions from concerned individuals and groups. The lack of information available on the possible harm that could result from ongoing and persistent contact with synthetic chemicals could lead to a decrease in scientists’ credibility. Further, individuals may question current regulatory practices and their ability to protect the public from the effluence of society. We have become accustomed to the ongoing monitoring of our air, water, and soil for toxic contaminants. But as these same tests are applied to our bodies and the developing bodies of our fetuses and children, monitoring takes on an entirely different meaning. Exposure assessments will mean little without an adequate ability to perceive risk—something that is currently woefully lacking.

The internalization of pollution narratives may also have a number of effects on our perceptions of environmental justice. As we uncover the ubiquity of exposure, we may be tempted to see a democratization of risk. We may even begin to equate affluence with direct exposure to effluence: that is, the more we have, the more we are exposed. In some cases this may be true. But as recent research has shown, we continue to spread the effluence of our affluence around the world, distributing known toxins literally into the hands of others, increasing their direct exposure to these compounds.14 Thus,
while we may all be polluted, we are polluted to varying degrees, and our exposure routes may differ remarkably and their impacts even more so. That being said, there is the possibility that greater awareness of the ubiquity of exposure (by whatever means) will garner more attention and support for environmental justice. How this might happen remains to be seen, but the answer may be in how we choose to see the data and thus how we choose to see ourselves.

How people respond to human biomonitoring will in large part be guided by the ways in which the information is communicated to them. Here again we see the push and pull between the technical and the personal aspects of these studies. Take two examples: the CDC “National Report on Human Exposure to Environmental Chemicals” (e.g., 2005) and “Body Burden: The Pollution in Newborns” from the Environmental Working Group (EWG).

As Rachel Washburn, of the University of California, San Francisco, and a workshop participant, points out, the CDC report is characterized by those qualities one might expect in a government document: charts, graphs, tables, and lists. Chemicals tested for are grouped, divided, and statistically analyzed. Exposures are given in terms of representative percentages. Claims are qualified. The report, a wonderfully data-dense document, appears to be missing just one element: people. The contrast could not be greater, Washburn notes, with the reports issued by the EWG. While the EWG does publish its report, to get the complete experience one must visit the Web site in order to interact with the information. The report breaks down each exposure not only by chemical but also by individual: the data remains personal, focused on an individual body rather than abstracted from it as in the CDC report. It not only provides a face with the data; the data itself can be mined to place a source with the chemical. Thus, the data remains both technical and personal.

But the technical and personal dichotomies persist. It is perhaps only within the context of the aggregated individuals—in the realm of communities—that the two can function more conjointly. The challenges remain: on one side are biomonitoring and continuing research on endocrine disruptors; on the other are frustrated individuals waiting for decisions and wanting action. Together, as communities, individuals can underscore the relationships between their own exposure and more systemic inequalities related to exposures, hazards, and health care more generally. Together they can push for more research but also demand action. Within communities the bodies accommodate both place-based and personal pollution narratives.

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15 Or it may be that the burdens of all mask the specific and disproportionate burdens borne by others.


17 The EWG project has morphed into the “Human Toxome Project” available at www.ewg.org/sites/humantoxome/ (accessed 4 December 2007).
The 2006 Boston Consensus Conference (BCC) on human biomonitoring explored the role consensus conferences might play in reaching out to diverse communities, educating individuals, and, perhaps most important, receiving feedback from groups on their concerns about the issues. This mechanism is one of the few available that allows for a community group to deliberate and deliver their own conclusions. However, we face both a definitional and an ethical dilemma in deciding what and how to communicate, and whether we should even bother to communicate.

In dealing with human biomonitoring we face a particularly puzzling problem: do researchers, manufacturers, and the government have a greater obligation to inform communities of their exposure despite the fact that there is little information about what that exposure data means in terms of health risks? Or are communities better served by not receiving partial information from which no clear action can be taken? In many ways this is a false dilemma.

There are at least two reasons why the information ought to be communicated to affected communities despite its seeming incompleteness. The first is that as an extension of right-to-know legislation, communities and individuals alike have a right to know what chemicals they are being exposed to despite the lack of information about its possible effects. The second is the role that informed communities play in the democratic process.

It is precisely because we do not know the full scope of the effects of our chemical exposures that we ought to be told of them. Individuals and communities with incomplete information will demand to know more, pushing a representative government to call on its regulatory agencies to demand more information from both its own research entities and the manufacturers of the suspect chemicals.

Only through our free access to information—however incomplete—can we maintain the democratic structure of our government-citizen-corporation relationship. And this is precisely what can be seen as a result of the BCC process. The consensus-conference participants, when presented with the best available information about their possible exposures and the

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known and unknown effects, demanded action from their representatives to find out more.

The sharing of information, however incomplete, not only facilitates a more democratic process but also encourages and supports a more trusting relationship between all parties—particularly between affected communities and manufacturers. As the National Academies report on human biomonitoring indicates, communities that have access to information as well as future plans to fill in the missing gaps are much more accepting of the fact that those gaps exist and will be more patient in awaiting an outcome.19

While such simple ideas might seem obvious, we unfortunately have a long history of half-truths, misinformation campaigns, and purposeful concealment of information that has generated over the past century an antagonistic relationship between these parties. The BCC offered a rare opportunity for direct engagement between representatives of the community with various experts in the field. The meetings worked not only to facilitate the communication of information across community boundaries but also to help establish new relationships based on trust and collaboration. The BCC also provided the opportunity for community members to raise their own concerns rather than simply hearing what concerns they ought to have about human biomonitoring.

The conclusions of the members of the BCC were largely unremarkable in that they might have been predicted before the conference began. Members wanted more information and more research. They called on representatives to find ways to further the efforts by government agencies such as the CDC in their evaluation of our exposures.

But the committee also came up with some unexpected—or perhaps unanticipated—conclusions and concerns. Primary among these was its concern about the handling of data from human-biomonitoring studies, which was somewhat similar in nature to worries about the handling of genetic information. Participants wanted to know what would happen to the very personal information gleaned from human-biomonitoring studies. Where will the information be stored? Who will have access to it? Will it appear on medical records? Will it be used to discriminate in the allocation of health insurance or employment opportunities?

These concerns surprised many of the “experts” who participated in the consensus conference, in part because it was assumed that an informed public would want to know the risks associated with exposure (which, of course, they did). But community members also wanted to know about the risk of participation and exposure of a very different sort. While exposure to manufactured chemicals carries certain unknown risks to the health of the individual, exposure of one’s personal information carries the risk of decreased access to health-related services.

There is a strange and unfortunate irony to all of this: just as manufacturers and corporate trade groups are quick to point out that there are no known health effects caused by the presence of these chemicals in our bodies, that same uncertainty can be used by insurance companies to create a class of potential “at-risk” persons. That is, the combination of uncertainty in health effects combined with the uncertainty of access to health care (particularly in the United States) creates a dilemma for individuals and communities. They are forced to weigh the risk of continued exposure without action on the one hand against the risk of the loss of access to health care on the other if they do participate in monitoring studies designed to build a case for reassessing our collective exposure levels.

The surprising twist that accompanied the consensus conference adds further weight to the arguments demanding greater participation by a greater number of individuals and communities in scientific and technical

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19 See National Research Council (cit. n. 3), especially chapter 6.
issues, especially those that relate to immediate health and environmental concerns. Greater involvement by a diversity of groups—and not just experts—adds an additional dimension to such issues as these. The democratized process not only adds additional insight to proposed solutions, but can lead to alternative problem definitions. In a situation where everyone faces some degree of exposure and therefore some degree of risk, ensuring access to information and deliberation is essential.
Landscapes of the Future

This section summarizes the workshop participants’ discussions during the final session and the possible implications for groups directly affected by the continuing research in the areas of human biomonitoring and the endocrine-disrupting effects of manufactured chemicals. The points made should not be confused with conclusions. Just as the scientific and technical aspects that provide the infrastructure for our continued evaluation of these topics evolves, so too do our understandings of the future implications of this research. However, it behooves us not to wait idly for more information before beginning serious discussions about what we already know and what actions we can take now.

Though we need more data, we have enough to begin taking action. But for those involved in various aspects of research related to human biomonitoring and endocrine-disrupting chemicals, it is difficult to know what steps to take next. While there are numerous examples of research done on the “micro” level of information gathering and generation, there has been a tremendous lack of research aimed at the “meta” level: aggregated studies are needed that find ways to synthesize the work happening in disparate fields. Not since Theo Colborn’s work on the environmental endocrine hypothesis have we seen this sort of effort with respect to endocrine-disrupting information. And we have yet to see anything that would fruitfully combine research from chemistry, toxicology, epidemiology, endocrinology, and the like with the vast amounts of information coming from human-biomonitoring studies, such as those the CDC has been conducting for years. What is missing is a sustained call for more work on the meta-analytical level: a way must be found to make sense of the vast amount of information that is now available but remains largely unmanageable and therefore inaccessible to nearly everyone—especially nonspecialists.

One way to begin addressing the inaccessibility of the data and to begin moving toward a more meta-level project analysis involves finding ways of aggregating information into databases that can keep track of the vast amounts of research currently under way. Such a system may contain an even greater benefit: through storing information about what we know, we can also begin the construction of a catalogue of what we do not know. These databases could help guide research questions, experimental designs, points of contention, and still-to-be-uncovered areas of concern. We could set an agenda for the future, a process that has long been used in various scientific pursuits from the investigation for new chemical elements to the semiconductor industry.

Developing strategic plans is crucial not only for understanding what needs to be accomplished but also for guiding the construction of the socio-technical infrastructure necessary to make the plan a reality. Interdisciplinary research and collaboration must be
enhanced. At a time of disciplinary crisis within the chemical sciences, another call for interdisciplinarity might be viewed as both threatening and meaningless: threatening because of concerns that the disciplinary core of the chemical sciences has already been eroding, and meaningless because the continued calls for interdisciplinarity usually provide no clear explanation of what is meant.

The term *interdisciplinary* has instead become a buzzword deployed to make a specific scientific or technical pursuit appear more cutting edge. While the first concern may be legitimate, the crisis in chemistry is partly a result of the emerging research in fields like endocrine disruptors. Therefore, this crisis serves as a perfect opportunity to begin refashioning the chemical sciences to include many of the observations, techniques, and methods of these other fields.

As to the problem of interdisciplinarity, we cannot hope to fit everything we need to know under one disciplinary roof because relevant research often happens in such disparate locations. At the very least, our interdisciplinary roof must be raised. Too often when we speak of interdisciplinarity in the sciences we mean a constellation of other physical and biological sciences coming together to share research methods, models, protocols, and data. But in the case of the issues arising from human biomonitoring and endocrine disruptors we have a host of “extra-scientific” issues to deal with that cannot be managed in isolation from the research that is highlighting their importance: environmental justice, public health, the history and future of chemicals regulation, communication between and with stakeholders and exposed communities, business history, and perceptions of the self in a world where the synthetic mixes with the natural on an everyday and intimate level. Thus, when we speak of the need for interdisciplinary collaborations, we ought to mean an effort to extend them beyond their traditional scope to include historians, sociologists, public health professionals, legal scholars, philosophers, policy makers, and others.

One goal of such interdisciplinary collaborations then is to spur the creation of a new, updated framework for the regulation of chemicals that includes science and publics in the regulatory decision-making process. The difficulty comes in defining precisely what those regulations might look like. While we might not have set ideas on this, we do have some ideas about how things have worked up to this point. We can think about how the system has been broken down by such challenges as those presented by more continuous human-biomonitoring projects and by the considerations and consequences of endocrine-disrupting chemicals. Sources of the problem aside, it seems clear that we need three things from our regulatory system for the proper control of hazardous chemicals:

- The system must be robust enough to accommodate a variety of chemicals, exposure pathways, and potential effects (e.g., we need to make room for new regulatory endpoints).
- The system should be flexible enough to accommodate new research as it emerges, thus getting around the dual problems of having fixed regulations that no longer represent our current level of understanding and having to wait until all of the information is obtained before taking action.
- The system should work proactively, not reactively, in its evaluation of chemicals and the hazards they do or may pose.

Whether we can do this with current regulations remains to be seen.

The final recommendation brings all these topics together in order to create a model of research and regulation that engages more effectively with stakeholders of all stripes—including community groups, exposed communities, and the public. While a perfect model for doing this does not exist, we do have some ideas about what projects might work. We have seen through the BCC that it is possible to bring together a representative sampling of a community, give them access to resources and experts, and receive back important and meaningful
considerations of what they would like to see done in the future. But while this model proved possible, there are questions about its practicality. The consensus conference required the mobilization of a large number of resources, extensive planning, and a hefty time commitment. While it appears to have had positive results, participants at this workshop wondered about its feasibility on a much larger scale.

We must also ask to what end we want to engage with the public. In this case the answer seems to be that the public could create support for further exploration of the possible connections between everyday and ubiquitous exposure to thousands of synthetic chemicals and the potential effects this may have on broad ecological systems. In order to garner that sort of support, advocates of this research need to offer at least two things: 1) information—access to it, the ability to use it, and the opportunity to question it, and 2) partnership—in supplying information and expertise and in helping to set research agendas.

The first is crucial for building a critical mass of people who can understand the potential problems they are faced with and for recruiting other interested parties. The second helps to maintain the participation of these parties. The more involved a community feels in matters of significance, the more likely they will be to continue to devote their time to the issue.

Finally, academics themselves must be reminded that they too are part of the public and that any action on the part of the public necessarily will involve them as well. Academics, as members of the public with access to information not readily available to many others, can play an important role as advocates.

There is an unfortunate custom (within the United States at least) that encourages academics and other professionals to distinguish between their occupation and their place as a member of the public. This is unfortunate not only because it plays a role in the fracturing of our society into classes of experts and laypeople but also because it encourages a laissez-faire approach on the part of many of our researchers and intellectuals when it comes to matters of public concern. In matters that have the potential to have tremendous effects on all of us, as does the diffusion of synthetic chemicals into our everyday lives, we will remain incomplete unless we can find a way to involve all elements of the public.
## Workshop Participants

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About the Chemical Heritage Foundation
The Chemical Heritage Foundation (CHF) serves the community of the chemical and molecular sciences, and the wider public, by treasuring the past, educating the present, and inspiring the future. CHF maintains a world-class collection of materials that document the history and heritage of the chemical and molecular sciences, technologies, and industries; encourages research in CHF collections; and carries out a program of outreach and interpretation in order to advance an understanding of the role of the chemical and molecular sciences, technologies, and industries in shaping society.

About CHF’s Center for Contemporary History and Policy
The Center for Contemporary History and Policy offers historically grounded perspectives on issues related to the molecular sciences and technologies. The center’s programmatic initiatives draw on diverse historical and contemporary source materials to provide knowledge, perspective, and advice to stakeholders from industry, academia, government, and citizen groups.

About the series
Studies in Sustainability examines the complex social, political, economic, and technical tools involved in building a sustainable society. In particular, this series serves as a forum for dialogue at the intersection of the molecular sciences with environmental and human health concerns.

About the author
Jody A. Roberts manages the Environmental History and Policy Program in the Center for Contemporary History and Policy at the Chemical Heritage Foundation. He holds M.S. and Ph.D. degrees in science and technology studies from Virginia Tech and a B.S. in chemistry from Saint Vincent College. His work focuses on the intersection of the molecular sciences and sustainability.

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