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Creating a Clearinghouse to Evaluate Environmental Risks to Fetal Development

KATE E. BLOCH*

In this Article, the Author explores current challenges to accessing and evaluating information about environmental risks to fetal development. She investigates these challenges within the context of the existing regulatory framework for environmental risks. As a result of this analysis, she highlights the need for and proposes creating an independent non-profit umbrella organization—a clearinghouse—to collect, distill, interpret, and make accessible the research on environmental threats to fetal development and to apply that research to evaluating relevant U.S. policy. The Author defines broadly the research on fetal development that lies within the charge of the clearinghouse to include not only research about chemical toxicant risks but also research involving environmental risks related to criminal and social justice policies.

* Professor of Law, University of California, Hastings College of the Law. My heartfelt thanks go to the many individuals and organizations that made the *Law & Policy of the Developing Brain: Neuroscience from Womb to Death* Symposium possible. I extend my gratitude in particular to Andrea Frey and Sarah Hooper of the UCSF/UC Hastings Consortium, to Dane Barca, Erica Connolly, and Jenna Kelleher of the *Hastings Law Journal*, to Chuck Marcus and Grace Takatani of the UC Hastings library, to my research assistants Emily Stehr and Katharina Jehle, to the rest of my wonderful colleagues at UC Hastings and Stanford whose efforts were pivotal in the planning and implementation process, and especially to the panelists and moderator on the Symposium's first panel, Dr. Khiara Bridges, Professor Teneille Brown, Dr. Gideon Koren, Dr. Megan Schwarzman, Dr. Mishka Terplan, and Dr. Tracey Woodruff. My thanks go also to Dr. Stephen Buchner, to Rory Little, and to my colleagues who read and provided invaluable insights on this article, namely Khiara Bridges, David Faigman, Jaime King, Gideon Koren, Meg Schwarzman, Mishka Terplan, and Lois Weithorn. Finally, this Symposium would not have evolved beyond a brief interstitial conversation at a faculty meeting had it not been for the dedicated efforts and enthusiasm of David Faigman, who transformed a casual suggestion into a fascinating interdisciplinary exchange.

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INTRODUCTION

I averted my eyes from the needle. It was the biggest one I had ever seen—about five inches long.¹ But this hollow tube designed for extracting cells from amniotic fluid would play a key role in answering many of my most pressing questions about the fetus I was carrying. Combined with an earlier ultrasound, it would supply critical information about the health of my child’s developing brain. Neuroscience, genetics, and the related field of epigenetics furnish heretofore undreamed of insights into the development of the human brain. This evolving understanding also sheds increasing light on the toxic chemicals and the behaviors that may profoundly alter or damage the fetal brain. As our understanding of the threats that can undermine healthy brain development and functioning grows, the question of regulating and reducing such damaging threats assumes greater prominence and urgency.²

1. Amniocentesis needles commonly range from 90 mm to 150 mm, or approximately 3.5 inches to 5.9 inches, in length. See, e.g., *Amniocentesis Needles with Stylets*, LABIVF, <http://www.labivf.com/index.cfm?GPID=93> (last visited July 1, 2012 by the editorial staff; this website reference and those in the notes that follow were last visited by the Author on varying dates on or before June 23, 2012).

2. See Philippe Grandjean et al., *The Faroes Statement: Human Health Effects of Developmental Exposure to Chemicals in Our Environment*, 102 BASIC & CLINICAL PHARMACOLOGY & TOXICOLOGY 73, 75 (2007) (“The accumulated research evidence suggests that prevention efforts against toxic exposures to environmental chemicals should focus on protecting the embryo, foetus and small child as highly vulnerable populations. Given the ubiquitous exposure to many environmental chemicals, there needs to be renewed efforts to prevent harm.”); see also Michael P. Wilson & Megan R. Schwarzman, *Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health*, 117 ENVTL. HEALTH PERSP. 1202, 1203–04 (2009).

Imagine a child is born who suffers from impaired language development, attention deficits, visual-spatial deficits, impaired fine motor function, and verbal memory deficits. Imagine too that the child's mother had followed all of the recommendations on the U.S. Food and Drug Administration ("FDA") and the U.S. Department of Health and Human Services ("HHS") websites during her pregnancy. This child's impairments do not stem from prenatal exposure to illegal drugs. In fact, her mother was scrupulously careful to avoid all over-the-counter and prescription medications. She exercised regularly and worked hard to maintain the diet recommended by the FDA and the HHS. The mother suffered from no illnesses during her pregnancy and consumed no alcohol. Her occupation did not expose her to any unusual levels of toxic chemicals. Neither she nor the father has a family history of similar difficulties. Her physician is at a loss to suggest any possible explanation for the child's limitations.³

The mother, who is contemplating having a second child, begins an extensive search for possible explanations. She discovers that research has associated the particular collection of limitations from which her child suffers with "[c]hronic, low-dose prenatal MeHg [methylmercury] exposure from maternal consumption of fish."⁴ But she was careful not to consume more than the FDA-recommendation of up to six ounces per week of albacore tuna during her pregnancy.⁵ With a bit of digging, she unearths a 2001 report from the Environmental Working Group about the contamination of fish by methylmercury. The report contends that

Research over the last several decades has demonstrated that the human brain's plasticity can enable remarkable self-repair or compensation in functionality after injury. *See, e.g.,* NORMAN DOIDGE, *THE BRAIN THAT CHANGES ITSELF* (2007). Still, "[t]he brain is particularly sensitive to toxic exposures during development, which involves a complex series of steps that must be completed in the right sequence and at the right time." Grandjean et al., *supra*, at 74. Perhaps some types of damage are much more difficult to repair, or perhaps we do not yet know how to invoke the brain's repair functions for those types of injuries.

3. My hypothetical physician is not familiar, at least initially, with the research correlating the child's deficits with possible methylmercury exposure. Many physicians, of course, could or would be.

4. COMM. ON THE TOXICOLOGICAL EFFECTS OF METHYLMERCURY, NAT'L RES. COUNCIL, *TOXICOLOGICAL EFFECTS OF METHYLMERCURY* 4 (2000) ("Chronic, low-dose prenatal MeHg exposure from maternal consumption of fish has been associated with more subtle end points of neurotoxicity in children. Those end points include poor performance on neurobehavioral tests, particularly on tests of attention, fine-motor function, language, visual-spatial abilities (e.g., drawing), and verbal memory."); *see* Gideon Koren et al., *Fetal Risks of Environmental Chemicals: The Motherisk Approach to the Organic Mercury-Fish Consumption Scare*, 63 *HASTINGS L.J.* 1605, 1605-07 (2012) ("While fish is rich in essential nutrients and women are encouraged to consume fish products, fish may contain methylmercury, which is an established neurotoxin to the fetus. . . . [S]ome species of fish contain methylmercury in sufficient amounts to cause adverse neurodevelopmental effects. . . . Methylmercury crosses the placenta and is found at higher concentrations in fetal blood than in the mother's blood." (citations omitted)).

5. U.S. FOOD & DRUG ADMIN. & U.S. ENVTL. PROT. AGENCY, EPA-823-R-04-005, *WHAT YOU NEED TO KNOW ABOUT MERCURY IN FISH AND SHELLFISH* 2 (2004) ("[Y]ou may eat up to 6 ounces (one average meal) of albacore tuna per week.").

“[t]en percent of American women enter pregnancy with elevated methylmercury levels, and current FDA safeguards, which are based on average exposures, do almost nothing to protect these high exposure pregnancies.”⁶ She intensifies her search, looking for other countries’ approaches to advising pregnant women about methylmercury exposure. She finds guidelines from Sweden on environmental risks during pregnancy.⁷ These address methylmercury and fish consumption as well, but they contend that, “[a]ccording to the recommendations of the Swedish National Food Administration . . . , pregnant and breastfeeding women, as well as women planning a pregnancy, should not eat . . . tuna more than at the most 2–3 times/year.”⁸ She also learns that according to the National Academy of Sciences Committee on the Toxicological Effects of Methylmercury, “[a]vailable consumption data and current population and fertility rates indicate that over 60,000 newborns annually might be at risk for adverse neurodevelopmental effects from in utero exposure to MeHg.”⁹

The mother persuades her physician to test her hair for methylmercury.¹⁰ Imagine that the test reveals elevated levels of methylmercury dating back to six months before her first pregnancy. The physician cannot ascertain whether these elevated methylmercury levels caused her child’s difficulties. The physician even points to a large study that did not find a correlation between low doses of methylmercury and learning deficits.¹¹ But one can imagine the mother lamenting how easy it would have been to consume her omega-3 fatty acids and protein in the months before and during her pregnancy from some source other than

6. JEREMIAH BAUMANN ET AL., ENVTL. WORKING GRP., BRAIN FOOD: WHAT WOMEN SHOULD KNOW ABOUT MERCURY CONTAMINATION OF FISH 3–4 (2001). This Brain Food report references a pre-2004 FDA allowance of twelve ounces of any type of fish (except four banned types) per week. *Id.* at 4. The current FDA recommendation continues to ban the four types of fish and to advise pregnant women to “[e]at up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury.” U.S. FOOD & DRUG ADMIN., *supra* note 5. The current twelve ounce recommendation includes canned light tuna, but recommends only up to six ounces of albacore tuna per week. *Id.* In contrast, the Baumann Brain Food report contends that the “FDA must restrict consumption of [certain] fish to no more than one meal per month, for all species combined: [including] [c]anned tuna.” BAUMANN ET AL., *supra*, at 4.

7. See generally LARS GERHARDSSON & LINNÉA LILLIENBERG, SAHLGRENSKA UNIV. HOSP., GUIDELINES FOR ASSESSMENT OF WORKING AND ENVIRONMENTAL RISKS DURING PREGNANCY (2009).

8. *Id.* at 3.

9. COMM. ON THE TOXICOLOGICAL EFFECTS OF METHYLMERCURY, *supra* note 4, at 325.

10. COLLEEN MOORE, CHILDREN AND POLLUTION: WHY SCIENTISTS DISAGREE 43 (2009) (“The amount of mercury a person has absorbed can be measured in hair.”).

11. See COMM. ON THE TOXICOLOGICAL EFFECTS OF METHYLMERCURY, *supra* note 4, at 4 (“Of three large epidemiological studies, two studies—one conducted in the Faroe Islands and one in New Zealand—found such associations, but those effects were not seen in a major study conducted in the Seychelles islands.”); *id.* at 1 (“Consumption of contaminated fish is the major source of human exposure to MeHg in the United States.”).

albacore tuna—perhaps a source like shrimp or nuts.¹² One can further imagine the mother thinking that if she had just known about the risks, she might have saved her child the daily struggles she now faces.

The mother will never know whether her daughter's limitations resulted from exposure to methylmercury in fish, this exposure in combination with other factors, or from something else entirely. What this hypothetical does suggest is that the information on which the mother could have based a more informed decision was scattered across the Internet from sources she, as a layperson, would have had to unearth and evaluate.¹³ Moreover, by relying on the official websites of the FDA and the HHS, she didn't realize that perhaps she should have been looking elsewhere for studies and guidelines on environmental hazards.¹⁴

12. Alternatively, one scholar has recommended that "routine gestational supplementation with purified fish oil or microalgae oil in addition to regular ALA [alpha linolenic acid] intake should be studied as a potential means to secure the benefits without the risks: adequate nutrition without toxicant exposure." Stephen J. Genuis, *To Sea or Not to Sea: Benefits and Risks of Gestational Fish Consumption*, 26 REPROD. TOXICOLOGY 81, 84 (2008). For a study discussing the benefits to fetuses of fish consumption generally in protecting against harm from ambient fine particulates, see Wieslaw Jedrychowski et al., *Higher Fish Consumption in Pregnancy May Confer Protection Against the Harmful Effect of Prenatal Exposure to Fine Particulate Matter*, 56 ANNALS NUTRITION & METABOLISM 119, 123 (2010) ("[O]ur study . . . did not collect information on the exact amount and type of fish consumed by the study participants.").

13. In Dr. Gideon Koren's article for this Symposium, he notes with respect to pregnant women's consumption of fish and the methylmercury concern that "[t]here has been broad media coverage on the topic, presenting contradictory information regarding the benefits and risks of fish consumption. Contradictory information presented simultaneously can lead to confusion in the public that includes skepticism about the media source, anxiety, and stress." Koren et al., *supra* note 4, at 1607–08 (footnotes omitted). In some cases, a mother's health care provider would, of course, probably be helping to search, parse, and interpret the research.

14. For an article analyzing information on federal advisories on methylmercury and U.S. consumption of canned tuna, see Beth Pallo & Marlene Barken, *The Domestic and International Dimensions of Methylmercury Contamination in Tuna: An Analysis of the Efficacy of the Fish Advisory Standards of Two Federal Agencies*, 18 RES. SOC. PROBS. & PUB. POL'Y 179 (2010) (arguing that current federal advisories about canned tuna are inadequate). *Consumer Reports* has also conducted research on canned tuna. See *Mercury in Canned Tuna Still a Concern: New Tests Reinforce a Need for Some People to Limit Consumption*, CONSUMER REPORTS, <http://www.consumerreports.org/cro/magazine-archive/2011/january/food/mercury-in-tuna/overview/index.htm> (last visited July 1, 2012) ("Children and women of childbearing age can easily consume more mercury than the Environmental Protection Agency considers advisable simply by eating one serving of canned white tuna or two servings of light tuna per week."). *Consumer Reports* recommends, as a precautionary measure, that pregnant women not consume tuna at all. *Id.*

For a study examining fish consumption and levels of awareness of cautionary advisories about fish consumption, see generally Elana Silver et al., *Fish Consumption and Advisory Awareness Among Low-Income Women in California's Sacramento-San Joaquin Delta*, 104 ENVTL. RES. 410 (2007). The authors of this study reported that more "than one-quarter of women (29%) [in the study] exceeded the joint FDA/EPA advisory limit via a combination of sport and commercial fish consumption." *Id.* at 416. The authors also found that "pregnant women were 2.2 times more likely to consume fish within the joint FDA/EPA advisory limit . . . than non-pregnant women." *Id.* With respect to awareness of fish consumption advisories, the authors reported that almost "half of the study participants (45%) had general advisory awareness," *id.*, meaning they answered affirmatively

But even if the hypothetical mother described above had been aware of the potential hazards for women consuming methylmercury during pregnancy, particularly with an already elevated methylmercury exposure, research on other potential hazards to her developing fetus might still have been at too early a stage to have provoked media attention, triggered an FDA caution, or otherwise entered into the general public consciousness. Moreover, even with early warning, some hazards, such as polychlorinated biphenyls, which were once used in many common items like paints and varnishes and sealants, may so broadly permeate our environment that pregnant women cannot reasonably avoid them without external regulation of those hazards.¹⁵ In fact, researchers in one empirical study extracted blood from the umbilical cords of newborns and detected 287 pollutants and synthetic chemicals, suggesting the extent to which toxic chemicals permeate our environment.¹⁶ Of those, the researchers opined: “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 exposure to this complex mixture of carcinogens, developmental toxins and neurotoxins have never been studied.”¹⁷

when asked if they were “aware of any health warnings about eating fish or shellfish for women of childbearing age.” *Id.* at 412. A recent study by FDA researchers, using a national sample of women, found that, in their pregnant, postpartum, and control groups of women, a “majority of all 3 groups of women were aware of mercury as a problem in food and that virtually all women in all 3 groups were consuming fish at levels consistent with the 2004 joint FDA/EPA advice for not consuming too much or certain types of fish. However, most women were not eating the amount of low mercury fish recommended” Amy M. Lando, et al., *Awareness of Methylmercury in Fish and Fish Consumption Among Pregnant and Postpartum Women and Women of Childbearing Age in the United States*, 116 ENVTL. RES. 85, 90 (2012).

15. MOORE, *supra* note 10, at 68–103. “PCBs are extremely stable chemicals. Like mercury, they are distributed around the globe and biomagnify up the food chain.” *Id.* at 68. PCBs have been used in a variety of substances including varnishes, paint, electrical transformers, flame proofing of textiles, sealants, and plasticizers. *Id.* at 70 (citing Martin G. Broadhurst, *Use and Replaceability of Polychlorinated Biphenyls*, 1 ENVTL. HEALTH PERSP. 81 (1972); J. Wister Meigs et al., *Chloracne from an Unusual Exposure to Arochlor*, 154 JAMA 1417 (1954)); see JANE HOULIHAN ET AL., *BODY BURDEN: THE POLLUTION IN NEWBORNS* 33–34 (2005) (“[F]etal exposure to industrial chemicals is contributing to adverse health effects in the human population. This is cause for concern. But experience shows us that it is never too late to take action. Blood levels of PCBs and pesticides like DDT are lower today than 30 years ago when they were banned.”).

16. HOULIHAN ET AL., *supra* note 15, at 13–14.

17. *Id.* Research in recent decades has enhanced available information and resources that relate to potential environmental threats to children more generally. See, e.g., TRACEY WOODRUFF ET AL., U.S. ENVTL. PROT. AGENCY, EPA 240-R-03-001, *AMERICA’S CHILDREN AND THE ENVIRONMENT: MEASURES OF CONTAMINANTS, BODY BURDENS, AND ILLNESSES* (2003); *Pediatric Environmental Health Specialty Units: A Network of Experts in Children’s Environmental Health*, PEHSU, <http://aoec.org/pehsu/aboutus.html> (last visited July 1, 2012) (“The Pediatric Environmental Health Specialty Units (PEHSU) are a source of medical information and advice on environmental conditions that influence children’s health. PEHSU are academically based, typically at university medical

This Article reflects upon the insights of physicians, medical researchers, and legal policy analysts who gathered at a recent Symposium to discuss the current state of research on environmental threats to the fetal brain as well as approaches to regulating them.¹⁸ From their collective insights as well as research from individuals and organizations focused on various facets of the regulation question, this Article highlights the need for and proposes developing an umbrella entity charged explicitly with (1) comprehensive data gathering and analysis, (2) evaluation of U.S. legal approaches and policy in the context of the relevant evolving research, and (3) information sharing about risks and proposed responses to environmental threats to the fetal brain and to fetal development more generally.¹⁹

A number of federal and state agencies, as well as many independent and industry researchers, currently study and address potential risks and sometimes propose policy changes in this field. But the varied missions of these individuals and entities, the difficulty in accessing and interpreting data, and the variety of audiences to whom these data and policies are relevant suggest that an independent non-profit umbrella entity focused

centers, and are located across the United States, Canada and Mexico. These PEHSU form a network that is capable of responding to requests for information throughout North America and offering advice on prevention, diagnosis, management, and treatment of environmentally-related health effects in children.”).

18. University of California, Hastings College of the Law, Law & Policy of the Developing Brain: Neuroscience from Womb to Death, Panel #1: Assaults on Prenatal and Early Childhood Brain Development: What Can Be Done? Limits on Autonomy and Government Regulation (Feb. 10, 2012). The panelists were Dr. Khiara Bridges, Dr. Gideon Koren, Dr. Megan Schwarzman, Dr. Mishka Terplan, and Dr. Tracey Woodruff.

19. Scholars in the realm of public health have emphasized the need for increased awareness of the risks of environmental toxicants on fetal development. See ELIZABETH HARRISON ET AL., JOHNS HOPKINS WOMEN’S & CHILDREN’S HEALTH POL’Y CTR., ENVTL. TOXICANTS AND MATERNAL AND CHILD HEALTH: AN EMERGING PUBLIC HEALTH CHALLENGE I (2009) (“Widespread awareness of environmental toxicants and their effects on reproductive and perinatal outcomes is essential in order to decrease preconception and prenatal exposure.”). The authors of the same article also report that “[t]he heterogeneity of toxicants poses a challenge in educating women about risk and how to reduce exposures. For example, a substantial exploration of the Internet in 2007 did not reveal any national, state, or local organized efforts specifically targeting pregnant and/or childbearing age women about pesticides and how to reduce their exposures.” *Id.* at 4; see Holly A. Grason & Dawn P. Misra, *Reducing Exposure to Environmental Toxicants Before Birth: Moving from Risk Perception to Risk Reduction*, 124 PUB. HEALTH REP. 629, 634 (2009) (The authors contend that there “appears to be general consensus that clinicians are not well-versed on the subject of environmental exposures.”) [hereinafter Grason & Misra, *Reducing Exposure*]. For useful charts describing available Internet resources as of 2007 on “Environmental Hazards Relevant to Reproductive and Perinatal Health,” see Holly Grason & Dawn Misra, *Summary Tables: Internet-Posted Information on Environmental Hazards Relevant to Reproductive and Perinatal Health*, JOHNS HOPKINS BLOOMBURG SCH. OF PUB. HEALTH, http://www.jhsph.edu/wchpc/publications/perinatal_envIRON_hazards_web.pdf (last visited July 1, 2012) (“The . . . tables describe findings from a systematic search of web-available materials conducted between June and August 2007 using the search terms ‘pregnancy,’ ‘pregnant women,’ ‘reproductive health,’ ‘environmental exposures,’ ‘environmental hazards,’ and ‘environmental toxins.’”) [hereinafter Grason & Misra, *Summary Tables*].

specifically on the question of risks and responses to environmental threats to fetal development could bring greater accessibility and coherence to the evaluation of risks and the creation of informed decisions and cohesive policy responses.²⁰

In Part I, this Article surveys a few of the sources of potential environmental threats to the fetal brain. Although the focus is on the fetal brain, the fetus more generally is at risk from many of the same environmental toxicants. Thus, the Article ultimately proposes a clearinghouse that addresses environmental threats not only to the fetal brain but to overall fetal development. Part II canvasses current structural avenues of regulation. Part III speaks to the challenges of maternal self-regulation. Part IV concludes with a proposal for a think tank clearinghouse, The Clearinghouse to Evaluate Environmental Risks to Fetal Development (the “Clearinghouse”), to collect, evaluate, and share the research about environmental threats to fetal development. Part IV also raises a number of the concerns that such a clearinghouse might engender.

I. THREATS TO THE FETAL BRAIN

Environmental threats to fetal brain development and subsequent functioning range from those that have been extensively researched and documented, to those currently under substantial scrutiny, to those not yet under serious scrutiny. This discussion about these threats is not meant to be exhaustive.²¹ Instead, it aims to highlight the spectrum of research and how this spectrum reveals a need for a more integrated and comprehensive approach to gathering, evaluating, and presenting the data on potential damage-causing agents to fetal health.

Toxic chemicals such as lead and methylmercury find their place in the first category of extensively researched toxicants. But that was not

20. For a discussion of some of the organizations focused on environmental threats to human health, see *infra* notes 101–119 and accompanying text. The research reported in Dr. Gideon Koren’s Article in this Symposium issue speaks to the need for a respected interpreter of studies and information on methylmercury and pregnancy. Dr. Koren reports on research that his organization, Motherisk, conducted with women who had contacted Motherisk for advice about fish consumption during pregnancy during 2006–2007. Koren et al., *supra* note 4, at 1608 (“The Motherisk Program provides information and counseling services that assess maternal and fetal risks following exposure to medications, recreational drugs, and various environmental chemicals during pregnancy and lactation.”). For a more detailed discussion of Dr. Koren’s research, see *infra* notes 86–87 and accompanying text. Motherisk evaluates research on the impact of radiation and diseases on fetal health, research beyond chemical toxicants. The charge of the Clearinghouse discussed in Part IV could include the gathering and evaluation of such research.

21. To the contrary, this Article points out only a few of the many potential or confirmed environmental (primarily chemical) threats to the fetal brain. This Article also does not address inadvertent or intentional infliction of violence on the fetal brain.

always the case, and debate about their toxicity in low levels persists.²² Alcohol and tobacco use during pregnancy similarly fall into the extensively researched category. Alcohol's effect on pregnancy, in particular that ingestion of alcohol during pregnancy is the cause of Fetal Alcohol Spectrum Disorders, now represents a well-documented and accepted tenet of neurobiology.²³ These disorders are marked by findings that range from atypical facial features, to learning disabilities and poor coordination, to low IQ, and to heart, kidney, and bone problems.²⁴ Similarly, the effects of cigarette smoke on fetal development have received extensive study.²⁵ Studies over the years have repeatedly associated smoking during pregnancy with fetal morbidity, such as low birth-weight babies, as well as fetal mortality.²⁶

Even for extensively researched hazardous chemicals, the road to serious scrutiny and significant regulation has commonly been paved with delay and political hurdles, particularly when an industry producing or disseminating the toxicant is fundamental to the economy or is otherwise highly politically influential.²⁷ Scholars point, for example, to the decades-long process that was required to ban leaded gasoline.²⁸ But overcoming

22. See MOORE, *supra* note 10, at 29, 3–36 (“Scientists still disagree about low-level lead exposure, in spite of all the evidence that it harms children’s development. Scientists do agree that lead in high doses is toxic.”); Amy Norton, *No “Safe” Lead Level Seen for Fetal Brain*, REUTERS HEALTH (Jan. 19, 2006), <http://www.ewg.org/news/no-safe-lead-level-seen-fetal-brain>.

23. *Facts About FASDs*, CTNS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/ncbddd/fasd/facts.html> (last visited July 1, 2012). (“[Fetal Alcohol Spectrum Disorders] are caused by a woman drinking alcohol during pregnancy.”); see *Fetal Alcohol Syndrome*, MAYO CLINIC, <http://www.mayoclinic.com/health/fetal-alcohol-syndrome/DS00184/DSECTION=risk-factors> (last visited July 1, 2012) (“Although doctors aren’t sure how much alcohol you’d have to drink to place your baby at risk, they do know that the more you drink, the greater the chance of problems. Because there’s no known safe amount of alcohol consumption during pregnancy, don’t drink alcohol if you are or think you are pregnant or you’re attempting to become pregnant. You could put your baby at risk even before you realize you’re pregnant.”).

24. *Facts About FASDs*, *supra* note 23.

25. See, e.g., *Highlights: Impact on Unborn Babies, Infants, Children, and Adolescents*, CTNS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/sgr/2004/highlights/children/index.htm (last visited July 1, 2004) (“Research has shown that women’s smoking during pregnancy increases the risk of pregnancy complications, premature delivery, low birth-weight infants, stillbirth, and sudden infant death syndrome (SIDS).”).

26. See, e.g., Hamisu M. Salihu & Roneé E. Wilson, *Epidemiology of Prenatal Smoking and Perinatal Outcomes*, 11 EARLY HUM. DEV. 713, 713 (2007) (“[P]renatal smoking remains a common habit and accounts for a significant proportion of fetal morbidity and mortality through both a direct (fetal) and an indirect (placental) effect.”); *Highlights*, *supra* note 25.

27. See, e.g., MOORE, *supra* note 10, at 3–36 (describing the influence of industry and/or industry-funded scientific research on the efforts to ban tetraethyl lead in gasoline).

28. *Id.* On the issue of the delay in implementing programs for reducing lead exposure for children, see Philippe Grandjean & Phillip J. Landrigan, *Developmental Neurotoxicity of Industrial Chemicals*, 368 LANCET 2167, 2167 (2006) (“Previous evidence-based programmes of exposure prevention, such as those directed against children’s exposure to lead, have been highly successful, although they were initiated after substantial delay.”).

the hurdles and producing useful regulations can have a remarkable impact. Scholars report a “90% reduction in childhood blood-lead concentrations follow[ing] the termination of lead additives in petrol.”²⁹

Beyond hurdles to regulation erected or fostered by industry, regulation also sometimes conflicts with consumer demand and autonomy. For example, alcohol consumption and smoking are legal activities for adults. Depriving adults of access to those activities raises autonomy and discrimination concerns, particularly if the deprivation is specifically linked to a woman’s pregnancy.³⁰

Cocaine might also fall within the category of environmental threats that have already been subject to extensive research.³¹ Controversy about the effects of cocaine on fetal health, however, remains. In an open-access, peer-reviewed, digital discussion of the effects of cocaine on the fetal brain, Dr. Steven E. Hyman explains:

Multiple studies have attempted to identify the effects of cocaine and other commonly abused drugs on fetal brain development and behavior in clinical populations. The attribution of risk to specific drugs remains challenging, however, because women addicted to cocaine often use other illegal drugs as well as alcohol and tobacco. Moreover, they tend to have poor nutrition, low levels of prenatal care, and other problems that confound analysis.³²

But Dr. Hyman concludes that “[o]verall, however, children exposed to cocaine prenatally appear to have neurological and cognitive deficits.”³³ In contrast, the authors of a systematic review of a collection of studies on prenatal cocaine exposure report that “[t]here is little impact of prenatal cocaine exposure on children’s scores on nationally normed assessments of cognitive development.”³⁴

Like alcohol and tobacco, cocaine is also associated with addiction, engendering a plethora of additional concerns in the regulatory realm.

29. Grandjean & Landrigan, *supra* note 28, at 2169–70.

30. Laws that treat women differently based on their pregnancy status may be subject to constitutional challenge, particularly under the Equal Protection Clause. *See, e.g.*, Pregnancy Discrimination Act of 1978, Pub. L. No. 95-555, 92 Stat. 2076 (amending “Title VII of the Civil Rights Act of 1964 to prohibit sex discrimination on the basis of pregnancy” in the context of employment). For a discussion of equal protection and pregnancy, see, for example, Nora Christie Sandstad, *Pregnant Women and the Fourteenth Amendment: A Feminist Examination of the Trend to Eliminate Women’s Rights During Pregnancy*, 26 LAW & INEQ. 171, 189–95 (2008).

31. *See, e.g.*, Irena Nulman et al., *The Effects of Intrauterine Cocaine Exposure on Neurodevelopment of Adopted Children: The Toronto Adoption Study*, 65 CLINICAL PHARMACOLOGY & THERAPEUTICS 138, 138 (1999) (discussing several studies of children’s neurodevelopment following *in utero* cocaine exposure).

32. Steven E. Hyman, *How Might Cocaine Interfere with Brain Development?*, 5 PLoS MED. 857, 857 (2008).

33. *Id.*

34. Deborah A. Frank et al., *Growth, Development, and Behavior in Early Childhood Following Prenatal Cocaine Exposure: A Systematic Review*, 285 JAMA 1613, 1615 (2001).

Unlike alcohol and tobacco, criminal provisions ban possession and use of cocaine by persons of any age in the United States.³⁵ Because of the illegal nature of the drug, much more intensive scrutiny often accompanies cocaine use by pregnant women.³⁶ This scrutiny has raised serious social justice concerns, some of which are discussed in Part III.

A second category of research addresses potential environmental threats, such as Bisphenol A (“BPA”), which are currently under substantial scrutiny and about which debate rages.³⁷ BPA “is a chemical that has been used for more than 40 years in the manufacture of many hard plastic food containers, such as baby bottles and reusable cups and the lining of metal food and beverage cans, including canned liquid infant formula. Trace amounts of BPA can be found in some foods packaged in these containers.”³⁸ To give some perspective on the debate and the evolving approach to BPA, consider the FDA’s website’s informational summary concerning BPA:

BPA (Bisphenol A) is a chemical used in certain food contact materials and first approved by FDA in the early 1960s. In recent years, concerns have been raised about BPA’s safety. In August 2008, FDA released a draft report finding that BPA remains safe in food contact materials. On October 31, 2008, a subcommittee of FDA’s science board raised questions about whether FDA’s review had adequately considered the most recent scientific information available. On January 15, 2010 and again on March 30, 2012, the FDA issued an interim update on BPA.³⁹

In the March 30th update, the FDA indicated that,

35. See, e.g., 21 U.S.C. § 844 (2010) (“It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order . . .”).

36. See, e.g., Dorothy E. Roberts, *Punishing Drug Addicts Who Have Babies: Women of Color, Equality, and the Right of Privacy*, 104 HARV. L. REV. 1419, 1428–31 (1991) (“Some child protection agencies institute neglect proceedings to obtain custody of babies with positive toxicologies based solely on these tests. . . . [G]overnment authorities are also removing drug-exposed newborns from their mothers immediately after birth pending an investigation of parental fitness. In these investigations, positive neonatal toxicologies often raise a strong presumption of parental unfitness, which circumvents the inquiry into the mother’s ability to care for her child that is customarily necessary to deprive a parent of custody.” (footnotes omitted)).

37. See Khadijah Rentas, *To Ban or Not to Ban, Bisphenol-A in Food Is OK with FDA, But Not with Some Scientists*, COLUMBIA MISSOURIAN, Jan. 9, 2009, available at <http://www.columbiainmissourian.com/stories/2009/01/09/to-ban-or-not-to-ban/> (presenting the views of a scientist who researches BPA and expresses substantial health concerns about human ingestion of BPA).

38. *Bisphenol A (BPA) Information for Parents*, U.S. DEP’T OF HEALTH & HUM. SERVS., <http://www.hhs.gov/safety/bpa/> (last visited July 1, 2012).

39. *Food: Bisphenol A (BPA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/foodingredientspackaging/ucm166145.htm> (last visited July 1, 2012) (footnotes omitted). The FDA website also links to a European report: EUR. FOOD SAFETY AUTH., STATEMENT OF EFSA ON A STUDY ASSOCIATING BISPHENOL A WITH MEDICAL DISORDERS I (2008) (“EFSA concluded that this single study does not provide sufficient proof for a causal link between exposure to BPA and the health conditions mentioned in the study, i.e. heart disease, diabetes and elevated liver-enzyme activities. Therefore, EFSA considers that there is no need to revise the TDI as derived by the AFC Panel in 2006.”).

[a]t this interim stage, FDA shares the perspective of the National Toxicology Program that recent studies provide reason for some concern about the potential effects of BPA on the brain, behavior, and prostate gland of fetuses, infants and children. FDA also recognizes substantial uncertainties with respect to the overall interpretation of these studies and their potential implications for human health effects of BPA exposure.⁴⁰

As these materials indicate, divergent views among scientists within the FDA provoked a revisiting of the issue and a changing perspective on BPA. Concurrently, the FDA and the HHS have promulgated advice to parents for reducing infant exposure to BPA.⁴¹ The HHS site now explains that “recent studies have reported subtle effects of low doses of BPA in laboratory animals. While BPA is not proven to harm children or adults, these newer studies have led federal health officials to express some concern about the safety of BPA.”⁴² Investment in new research and acknowledgement of the need for this revisiting of the potential hazards of BPA represent important modifications to the FDA’s approach to BPA.⁴³

The debate over the potential hazards of BPA has also apparently spawned a rethinking of the way scientists conduct studies on BPA in academic environments.⁴⁴ With the recent influx of thirty million dollars in funding to study BPA, the FDA apparently has revised protocols for conducting these experiments.⁴⁵ The aim is to produce studies where the protocols coincide, and comparing the results thus involves comparing apples to apples.⁴⁶ In the meantime, while the federal approach continues to evolve, a number of states are banning BPA use in various products.⁴⁷

40. *Bisphenol A: Use in Food Contact Application*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm> (last visited July 1, 2012).

41. *Id.*; *Bisphenol A (BPA) Information for Parents*, *supra* note 38 (“It is clear that the government and scientists and doctors need more research to better understand the potential human health effects of exposure to BPA, especially when it comes to the impact of BPA exposure on young children. The Department of Health and Human Services—through its Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA)—is investing in important new health studies in both animals and humans to better determine and evaluate the potential health effects of BPA exposure, including \$30 million in studies at NIH. We expect to have the results of this scientific research in approximately 18 to 24 months. While we learn more, the Food and Drug Administration is supporting current efforts by industry to stop the manufacture of infant bottles and feeding cups made with BPA from the U.S. market. The FDA is also seeking to strengthen its oversight of BPA so the agency can respond quickly, if necessary, when more scientific evidence becomes available.”).

42. *Bisphenol A (BPA) Information for Parents*, *supra* note 38.

43. For a discussion of the investment in research, see *supra* note 41.

44. See generally Brendan Borrell, *The Big Test for Bisphenol A*, 464 NATURE 1122 (2010).

45. *Id.* at 1124.

46. *Id.*

47. See, e.g., *California BPA Ban Signed into Law*, FOOD SAFETY NEWS, Oct. 6, 2011, <http://www.foodsafetynews.com/2011/10/california-bpa-ban-signed-by-gov-brown/> (reporting on California’s BPA ban, scheduled to become effective in July 2013).

Along the spectrum of research on environmental threats, some potential threats have yet to trigger regulatory control. Though these potential threats may not yet invoke substantial regulatory action, they may merit public attention. In May 2011, the American Academy of Pediatrics issued a report condemning the lack of access to important information about chemicals introduced and currently in use in the United States.⁴⁸ The report criticizes current constraints on the Environmental Protection Agency (“EPA”) that prevent the EPA from revealing information about potential hazards associated with certain chemicals.⁴⁹ The report explains:

[C]oncerns about chemicals are permitted to be kept from the public. In their notifications to the EPA, chemical companies may declare large amounts of information to be “confidential business information.” This broad exemption has effectively prevented the EPA from sharing information about potentially hazardous chemicals with community groups, local and state governments, and foreign governments or international organizations.⁵⁰

Pregnant women, physicians, and policymakers should be able to access information, early research, and a credible evaluation of such research even if the research results are not sufficiently persuasive to trigger cautionary advisories or condemnation by the government. After all, in 2008, the FDA assured the world that BPA was safe in food contact materials, despite multiple studies suggesting otherwise.⁵¹ Where scientific consensus will land in the debate on the potential hazards of BPA remains to be seen. But pregnant women and their physicians, among others, need more comprehensive and earlier access to emerging information about potential hazards. The risk threshold of pregnant women may be much lower than the FDA’s. And, as suggested by the methylmercury hypothetical above, their actual risk can be much higher than the average risk level that may underlie FDA regulation.

48. Am. Acad. of Pediatrics, *Policy Statement—Chemical-Management Policy: Prioritizing Children’s Health*, 127 PEDIATRICS 983 (2011).

49. *Id.* at 985.

50. *Id.*

51. *See, e.g., Oversight on EPA Toxic Chemical Policies: Hearing Before the S. Comm. on Env’t & Pub. Works*, 110th Cong. (2008) (statement of Dr. Linda C. Giudice, Professor, University of California, San Francisco) (“In a series of important studies by Dr. Pat Hunt at Washington State University, pregnant mice were exposed to BPA, which resulted in exposure to the developing fetus. This exposure to BPA damaged female fetus’s new eggs, known as oocytes. The daughter’s eggs were more likely to have chromosomal abnormalities, which increased the likelihood of a granddaughter with genetic defects.”); *see also* Borrell, *supra* note 44, at 1122–24 (discussing scientists and studies raising concern about BPA); Rentas, *supra* note 37 (writing about a scientist who expresses substantial health concerns about human ingestion of BPA).

II. STRUCTURAL CONSTRAINTS AND AVENUES OF REGULATION

Regulation entails more than a determination that the environmental agent is correlated with or even causes harm. It also depends on at least three additional critical factors: (1) regulatory constraints, including the “tilt” principle applied to the task before the regulator, with the term “tilt” suggesting the lens or perspective through which potentially hazardous chemicals are evaluated; (2) translating the science into policy, which includes a cost-benefit analysis of any harms against any benefits; and (3) the identity and role of the regulator.

A. REGULATORY CONSTRAINTS AND THE “TILT” PRINCIPLE

Regulation of potential threats to the prenatal brain depends first on the constraints imposed on the regulator.⁵² Take, for example, the EPA.⁵³ The EPA possesses regulatory authority over approximately 80,000 chemicals in U.S. commerce.⁵⁴ Even advocates for reform of regulatory policy acknowledge the U.S. chemical industry’s contributions to “economic growth, employment, and improvements in life expectancy, health, and living conditions.”⁵⁵ But with trillions of pounds of chemicals manufactured in or imported into the United States each year,⁵⁶ the need for careful regulation of the safety of such chemicals is essential. Constraints on such regulation here include the enabling legislation that drives and cabins the EPA’s authority. With respect to regulation of potentially toxic chemicals, much of its animating authority derives from the Toxic Substances Control Act (“TSCA”) enacted by Congress in 1976.⁵⁷ Scholars note that, pursuant to TSCA,

the U.S. EPA has been able, since 1976, to use its formal rule-making authority to partially regulate five existing chemicals (or chemical classes): polychlorinated biphenyls (PCBs), chlorofluorocarbons, dioxins, asbestos, and hexavalent chromium. Of these, an amendment by Congress to TSCA required regulation of PCBs, and the U.S. EPA’s

52. This Article construes the term “regulator” broadly to include not only governmental entities but also private entities and the pregnant woman herself. Each of the organizations or persons can exert control and potentially regulate aspects of fetal health.

53. For an informative discussion of limitations on the EPA’s regulation of environmental chemicals, see generally Wilson & Schwarzman, *supra* note 2.

54. *Id.* at 1203.

55. *Id.*

56. *Id.*

57. Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601–29 (1976); U.S. Gov’t ACCOUNTABILITY OFFICE, GAO-05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA’S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM I (2005) (“TSCA addresses those chemicals manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States, but excludes certain substances including, among other things, pesticides that are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and food; food additives; drugs; cosmetics or devices that are regulated under the Federal Food, Drug and Cosmetic Act (FFDCA).”).

asbestos regulation, promulgated after the agency spent 10 years building its case, was overturned in its most significant aspects by the 5th Circuit Court of Appeals, which concluded that the U.S. EPA had failed to meet its burdens of proof under TSCA.⁵⁸

Regulation of this type that is limited to these few chemicals or chemical classes does not result from research and convincing proof that the remaining thousands of chemicals are safe. Rather, a report to Congress suggests that it results from the constraints imposed by TSCA on the regulator.⁵⁹ The following excerpt from the Government Accountability Office's report to Congress underscores the constraints inherent in TSCA:

TSCA generally places the burden of obtaining data on existing chemicals on EPA, rather than on the companies that produce the chemicals. For example, the act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the roughly 80,000 industrial chemicals in use. Moreover, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce annually for their toxicity, and companies generally do not voluntarily perform such testing. Further, the procedures EPA must follow in obtaining test data from companies can take years to complete. . . .

While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet present a legal threshold that has proven difficult for EPA and discourages the agency from using these authorities. For example, EPA must demonstrate "unreasonable risk," which EPA believes requires it to conduct extensive cost-benefit analyses to ban or limit chemical production. . . . GAO has previously recommended that Congress amend TSCA to reduce the evidentiary burden EPA must meet to control toxic substances and continues to believe such change warrants consideration.⁶⁰

These regulatory constraints illustrate the larger overarching "tilt" principle through which TSCA operates. The regulatory tilt in this paradigm is sometimes referred to as the "smoking gun principle."⁶¹ This tilt suggests that regulatory agencies should permit the target substance's

58. Wilson & Schwarzman, *supra* note 2, at 1205 (citation omitted); see Am. Acad. of Pediatrics, *supra* note 48, at 983.

59. See generally U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-428T, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT (2009).

60. *Id.* at i ("Since 1976, EPA has issued regulations to control only five existing chemicals determined to present an unreasonable risk. Further, its 1989 regulation phasing out most uses of asbestos was vacated by a federal appeals court in 1991 because it was not based on 'substantial evidence.' In contrast, the European Union and a number of other countries have largely banned asbestos, a known human carcinogen that can cause lung cancer and other diseases.").

61. MOORE, *supra* note 10, at 7.

use unless there has been a showing that the substance is a health hazard.⁶² As indicated by the report above, the EPA must demonstrate a specified level of risk before it can take action to ban a chemical. This implies that the EPA is subject to a smoking gun tilt in regulating under TSCA. A second paradigm, generally referred to as the “Precautionary Principle,” operates from a very different starting point: “[W]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof.”⁶³ Adoption of one paradigm versus the other can tilt the result 180 degrees, with one paradigm permitting introduction of the chemical into commerce with little or no testing and the other requiring precautionary measures, such as requiring the introducing party to shoulder some burden of information production or proof regarding safety.

Scholars in the field, as well as the Government Accountability Office’s report quoted above, have encouraged Congress to adopt a more precautionary tilt and to emulate to a greater extent models like the European Union model of Registration, Evaluation, Authorization, and Restriction of Chemicals (“REACH”).⁶⁴ According to authorities who study regulatory approaches, REACH is structurally distinct from TSCA.⁶⁵ REACH requires that the importers and manufacturers of the chemical, rather than the government, supply “basic information on the identity and physical properties of [approximately] 30,000 chemicals sold in volumes of more than one metric ton per year, per producer.”⁶⁶ REACH also contemplates special treatment for “Substances of Very High Concern.”⁶⁷ For these substances, the burden on the introducing party for continued use depends “on producers’ demonstrating the safety of each intended use, or that in the absence of suitable alternatives, the socioeconomic benefits outweigh the health and environmental risks.”⁶⁸

62. *Id.*

63. *Wingspread Conference on the Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK (Jan. 26, 1998), <http://www.sehn.org/wing.html>; see MOORE, *supra* note 10, at 8.

64. See, e.g., U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 59, at 14 (“REACH requires greater public disclosure of certain information, such as basic chemical properties. Furthermore, REACH places greater restrictions on the kinds of information chemical companies may claim as confidential. For example, REACH includes a provision for public access to basic chemical information, including brief profiles of hazardous properties and authorized uses. The European Union’s approach to [the] public’s access to information combines a variety of ways that the interests of the public’s right to know is balanced with the need to keep certain information confidential.”); Megan R. Schwarzman & Michael P. Wilson, *New Science for Chemicals Policy*, 326 SCI. 1065, 1065 (2009).

65. Schwarzman & Wilson, *supra* note 64, at 1065 (citation omitted).

66. *Id.*

67. *Id.*

68. *Id.*

REACH appears to incorporate much more of a precautionary tilt than does TSCA.

The tilt principle and other constraints that are often involved in the political process that produces federal regulation support the need for voices external to the regulating agency on the question of regulation. These constraints suggest the need for an organization that can provide an independent, comprehensive review across disciplines such as science, law, and economics for evaluation and information sharing about risks and proposed responses to potential threats to fetal health.

B. TRANSLATING SCIENCE FOR USE IN POLICY AND LAW

Beyond the tilt and general regulatory constraints, there remains the challenge of translating science for use in policy and law. Tomes have been written on this topic.⁶⁹ Here, at a minimum, it is worth noting that science produces various types of evidence, many of which do not necessarily translate directly into policy. How much and what types of evidence are enough to warrant intervention? What level of certainty is needed for regulatory action? What types of regulatory action are appropriate in the face of the evidence?

For instance, even a comprehensive and unassailable scientific result—one based on multiple studies that a particular substance has been correlated with specific learning deficits in one percent of children—does not immediately dictate the parameters or contents of regulatory legislation. Regulatory policy also considers, for example, the benefits, if any, of the chemical. Let's hypothesize that the chemical is critical for space travel or deep-sea exploration. Does the legislation ban all future manufacturing of the chemical or limit its dissemination? Does it govern recall of all the products into which the chemical has already been incorporated? Does it govern disposal of those recalled products? Regulation here should evaluate and depend upon scientific inquiry, but it also embraces considerations beyond research results. Value judgments and economic considerations, among others, infuse the regulatory process. Moreover, government regulation emerges from a political vortex, with different constituencies vying for influence. Making the science count in the complex equation that produces regulation is a significant challenge.

C. THE IDENTITY AND ROLE OF THE REGULATOR

Regulation depends not only on the constraints of the animating forces behind the regulation and the complexity of translating science into

69. See, e.g., DAVID L. FAIGMAN ET AL., *MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY* (2011); DAVID L. FAIGMAN ET AL., *MODERN SCIENTIFIC EVIDENCE: STANDARDS, STATISTICS, AND RESEARCH METHODS* (2008).

policy or law, but also on the identity and role of the regulator. This Subpart considers a number of regulators external to the mother. External legal regulators assume two primary forms: governmental and non-governmental actors.

Many governmental actors play roles in the regulation of environmental threats to the fetal brain. In the scholarly literature, one often finds them divided into two contingents. First, a substantial contingent participates in the direct regulation of the industries that manufacture, transport, and produce products associated with the threats, particularly potentially toxic chemicals.⁷⁰ These include agencies such as the EPA and the FDA.⁷¹ Regulation here might also include federal prosecutors pursuing civil or criminal charges against industry violators of federal law under, for example, TSCA.⁷² These and other government agencies also participate indirectly in the regulation of industry through public education. A second contingent of governmental actors has been employing criminal justice vehicles to attempt to regulate maternal behavior. Primarily, these are state prosecutors who, under a variety of theories, have prosecuted mothers for the transmission of illegal drugs to their fetuses or newborn children.⁷³ Pregnant women, perhaps particularly poor women, may be even more likely to encounter another set of government regulators: those in the realm of dependency and child protective services.⁷⁴

70. See, e.g., Schwarzman & Wilson, *supra* note 64, at 1065 (“The U.S. Toxic Substances Control Act (TSCA) is the primary mechanism by which the Environmental Protection Agency (EPA) is expected to oversee more than 80,000 chemicals.”).

71. See, e.g., *id.*

72. For an example of civil enforcement, see *Vidiksis v. E.P.A.*, 612 F.3d 1150 (11th Cir. 2010) (upholding a finding of liability and a civil penalty of \$97,545 on sixty-nine violations of TSCA section 409 alleged in the EPA’s administrative complaint against John P. Vidiksis). TSCA also provides for criminal enforcement of its provisions: 15 U.S.C. § 2615(b) (2010) (“Any person who knowingly or willfully violates any provision of section 2614 or 2689 of this title, shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than one year, or both.”).

73. See, e.g., *Whitner v. State*, 492 S.E. 2d 777 (S.C. 1997) (finding that it was not a violation of the petitioner’s constitutional right to privacy to prosecute her for child abuse and endangerment for taking cocaine while pregnant); *Synopsis of State Case and Statutory Law*, 1 YALE J. HEALTH POL’Y L. & ETHICS 237 (2001) (providing a detailed state-by-state summary of provisions related to statutes and criminal cases addressing pregnant women and the prenatal use of alcohol and illegal drugs); Ada Calhoun, *The Criminalization of Bad Mothers*, N.Y. TIMES, Apr. 25, 2012, at MM30 (focusing on the prosecution of mothers for their ingestion of illegal drugs during pregnancy).

74. Cf. Ian Vandewalker, *Taking the Baby Before It’s Born: Termination of the Parental Rights of Women Who Use Illegal Drugs While Pregnant*, 32 N.Y.U. REV. L. & SOC. CHANGE 423, 425 (2008) (“Sixteen states have statutes providing that the use of illicit or controlled substances during pregnancy is child abuse. Other states allow prenatal drug use to be considered in determinations of child status as abused, neglected, dependent, in need of assistance, or the like, even without a statutory mandate. While only one state, Illinois, has a statute explicitly providing for termination due to

Apart from government actors, private parties and non-governmental organizations also serve as regulators. In addition to roles as educators and enablers or disputants of formal governmental policy, these actors regulate the womb through private civil law suits, in particular class action suits.⁷⁵ Consumers as private actors also regulate the extent and frequency of some potential environmental threats through their wallets, by buying or declining to purchase products that contain potentially toxic chemicals. For instance, the movement over the past few years toward retail stocking of BPA-free reusable plastic bottles seems to have been driven by consumer preference, rather than formal government regulation.⁷⁶ This, of course, is an indirect, but ultimately highly persuasive, form of regulation for certain types of products. Consumer regulation of this form may result in the removal of a particular suspected toxic chemical from products, but it does not necessarily govern the safety of any substituted or replacement chemicals.

The media, of course, may also play a significant role in regulating potential threats to the fetal brain by bringing research to light and unearthing hidden biases and economic or political ties.⁷⁷ Other private actors, particularly health care providers through their advice to prospective parents and pregnant women, regulate potential threats to fetal health.⁷⁸ A 2011 report from the American Academy of Pediatricians encourages pediatricians to

familiarize themselves with the information about chemicals in the environment and their effects on child health. Many chemicals are reviewed in the American Academy of Pediatrics manual *Pediatric Environmental Health*. . . .

Pediatricians should learn about the resources contained in the Environmental Health and Toxicology pages of the National Library of

prenatal drug use, child welfare laws in all states may be used by judges or social services agencies to permanently remove children from mothers who used drugs while pregnant.” (footnotes omitted)).

75. The morning sickness drug, Bendectin, provides an example. The drug was pulled from the market in the wake of lawsuits claiming it caused birth defects. See Gina Kolata, *Controversial Drug Makes a Comeback*, N.Y. TIMES, Sept. 26, 2000, at F1. Diclectin, apparently made with the same ingredients as Bendectin, see *id.*, is now available in Canada to treat morning sickness. See *Diclectin*, DUCHESNAY INC., <http://www.diclectin.com/> (last visited July 1, 2012).

76. See, e.g., *Editorial on Banning Bisphenol A from Food Containers: FDA Should Do Its Job*, S.F. CHRON., Mar. 25, 2012, at E10 (noting that a number of retailers already often decline to stock products with BPA and relating that change to consumer preferences and industry approaches).

77. Some media reports have also been criticized for raising potentially unnecessary alarm in their reporting about possible environmental toxicant harm to fetal development. See, e.g., Rebecca Goldin, *Media Claims Phthalates (Might) Cause Genital Defects*, STATS (May 27, 2005), http://stats.org/stories/2005/media_claims_phthala_may27_05.htm (criticizing a media report about phthalate study).

78. Efforts to bring current research about environmental risks to reproductive health to clinical health care providers are a focus, for example, of the UCSF Program on Reproductive Health and the Environment. *Expanding Clinical Practice*, PROGRAM ON REPROD. HEALTH & THE ENV'T, <http://coe.ucsf.edu/prhe/clinical/index.html> (last visited July 1, 2012).

Medicine Web site. Those portions that will be of most use in counseling families include Lact-Med (a peer reviewed and fully referenced database of drugs to which breastfeeding mothers could be exposed) and the Household Products Database (which links >8000 consumer brands to chemicals they may contain on the basis of Material Safety Data Sheets provided by the manufacturers).⁷⁹

These recommendations also reference several useful online resources. Would not their valuable recommendations serve more audiences if prepared as part of a single online resource and presented in ways accessible not only to physicians but also to expectant parents, breastfeeding mothers, and non-physician policymakers?

Most important, all of the above actors need current, well-digested, evaluated, and accessible information about environmental threats to fetal development so that they can make informed decisions. Pregnant women need information in this form as they are the first-line decisionmakers, regulators, and protectors of themselves and their fetuses. Busy front-line physicians need an independent gatherer and interpreter of research on fetal development that is not subject to the influence of special interest groups in the political process. Actors beyond pregnant women and their physicians who interact with and attempt to regulate maternal behavior need accurate understandings of research on fetal development. If, for example, experience and research suggest that prosecuting mothers for transmission of illegal drugs to their fetuses translates into fewer mothers seeking prenatal care,⁸⁰ and if the research further indicates worse outcomes for the fetus without prenatal care⁸¹ even if the

79. Am. Acad. of Pediatrics, *supra* note 48, at 988–89 nn.1–2 (citations omitted).

80. See, e.g., Emily Figdor & Lisa Kaeser, *Concerns Mount over Punitive Approaches to Substance Abuse Among Pregnant Women*, GUTTMACHER REP. PUB. POL'Y., Oct. 1998, at 3, 4 (“[A]ccording to the South Carolina Association of Alcoholism and Drug Abuse Counselors, drug treatment programs in South Carolina experienced as much as an 80% decline in the admission of pregnant women in the year following the state supreme court’s highly publicized decision [of *Whitner v. State*, 492 S.E. 2d 777 (S.C. 1997)].”). *Whitner* upheld a woman’s guilty plea “to criminal child neglect for causing her baby to be born with cocaine metabolites in its system by reason of *Whitner*’s ingestion of crack cocaine during the third trimester of her pregnancy.” 492 S.E. 2d at 778–79 (citation omitted); see also Krista Stone-Manista, *Protecting Pregnant Women: A Guide to Successfully Challenging Criminal Child Abuse Prosecutions of Pregnant Drug Addicts*, 99 J. CRIM. L. & CRIMINOLOGY 823, 836 (2009) (“Moreover, public health officials generally discourage these prosecutions, believing that pregnant women tend to react to the threat of prosecution not by terminating their drug use, but by avoiding prenatal care.”).

81. Frank et al., *supra* note 34, at 1621 (“[F]ear of prosecution may discourage pregnant and parenting women from seeking prenatal care and drug treatment, which have been shown to optimize infant outcome.” (citations omitted)); Derk B.K. VanRaalte IV, *Punitive Policies: Constitutional Hazards of Non-Consensual Testing of Women for Prenatal Drug Use*, 5 HEALTH MATRIX 443, 457 (1995) (“The [Association of Maternal and Child Health] Policy Statement on punitive measures concluded that ‘[c]riminal prosecution of chemically dependent women will have the overall result of deterring such women from seeking both prenatal care and chemical dependency treatment, thereby increasing, rather than preventing, harm to children and society as a whole.’ . . . Given that evidence suggests that prenatal care may be more important than maternal drug use in determining fetal health, punitive approaches appear to do more harm than good.” (footnotes and citation omitted)).

mother continues to ingest illegal drugs during her pregnancy, then that is research governmental actors should have access to and consider. Research about the relative benefits or detriments of criminal justice interventions, such as drug courts⁸² or incarceration during pregnancy,⁸³ also fits within the province of an entity gathering research about potential environmental threats to fetal health. Because this type of research is relevant to audiences concerned with fetal development and environmental hazards, a think tank clearinghouse should collect and interpret research on social justice issues involving fetal health. For example, what does the empirical research suggest about disparate impacts of regulation on poor women and women of color?⁸⁴ How can that research better inform fetal health law and policy? Instead of combing through dozens and perhaps hundreds of websites, consumers, pregnant women, physicians, policymakers, other regulators, and the public more generally could locate carefully evaluated and accessibly presented research and implementation implications about fetal health on the website of one independent think tank.

III. MOTHERS' SELF-REGULATION

Challenges to a mother's self-regulation abound. The hypothetical mother's experience described in the Introduction illustrates one aspect of the daunting challenge to self-regulation—the complexities of when and where to look for reliable information. A related challenge involves the dearth of accessible and comprehensible information about prenatal threats. For instance, even if one locates an important scientific journal article on the topic in question, one often needs a subscription or to pay a fee to read the full article.⁸⁵ And even if the searcher achieves physical

82. See, e.g., Mishka Terplan et al., "Compassionate Coercion": Factors Associated with Court-Mandated Drug and Alcohol Treatment in Pregnancy 1994–2005, 4 J. ADDICT. MED. 147 (2010) (describing trends in criminal justice referrals of pregnant women for treatment).

83. See, e.g., Jennifer G. Clarke & Eli Y. Adashi, *Perinatal Care for Incarcerated Patients: A 25-Year-Old Woman Pregnant in Jail*, 305 JAMA 923, 926 (2011) ("A systematic review of pregnancy outcomes for incarcerated women (7 of 10 U.S. studies) reveals that when compared with similarly disadvantaged populations, maternal and fetal outcomes improve with increasing lengths of incarceration. One study observed that on average, for each day spent in prison during pregnancy, infant birth weight was 1.49 g greater than among infants born to women incarcerated at times other than during their pregnancies. . . . These studies do not imply that prisons constitute the optimal environment for pregnant women; rather, the women in question have a poor preincarceration environment, often characterized by poverty, drugs, chaos, and danger, as well as inadequate nutrition and lack of safe shelter." (footnotes omitted)).

84. See, e.g., KHIARA M. BRIDGES, *REPRODUCING RACE: AN ETHNOGRAPHY OF PREGNANCY AS A SITE OF RACIALIZATION* (2011); see generally Khiara M. Bridges, *Poor Women and the Protective State*, 63 HASTINGS L.J. 1619 (2012); Roberts, *supra* note 36.

85. For example, in researching Mishka Terplan and Tricia Wright's article, *The Effects of Cocaine and Amphetamine Use During Pregnancy on the Newborn: Myth Versus Reality*, 30 J. ADDICTIVE DISEASES 1 (2010), co-authored by one of the panelists at the Symposium, I was unable to access the full

access, specialized knowledge may be necessary for genuine accessibility. In addition, respected scientists who publish their research results in journal articles may arrive at conflicting conclusions about a topic.

At the same time that inaccessibility limits the availability of some types of important information, such as scientific research results, there exists a plethora of information available on the Internet about fetal health. While I invented the hypothetical mother confronting the issue of fish consumption during pregnancy in this Article's introduction, Dr. Gideon Koren's empirical research described in his article in this Symposium issue documents the confusion of real women in the face of conflicting and often overwhelming information about methylmercury and fish consumption during pregnancy. His organization, Motherisk, conducted research with women who had contacted Motherisk regarding their concerns about "the reproductive safety of consuming fish during pregnancy."⁸⁶ Dr. Koren notes that

[h]alf of the participants stated that they initially became aware of the issue of mercury in fish through electronic and printed media . . . and almost all had called for clarity after what they had heard from these sources. Those who had searched the Internet found a vast amount of information, some of which was described by them as dramatic and overstated After reading the controversial and varied opinions, they wanted clarity.⁸⁷

Where does one look? To whom does one turn when sources conflict? How does one interpret complex scientific research and determine what it means? With the Internet information overload, trusted guides and interpreters become crucial.⁸⁸

Self-regulation for some pregnant women means navigating the terrible challenges of pregnancy amidst poverty.⁸⁹ For some, it means

text without having login privileges. See TAYLOR & FRANCIS ONLINE, <http://www.tandfonline.com/doi/pdf/10.1080/10550887.2011.532048> (last visited July 1, 2012). I was informed, "Sorry, you do not have access to this article" and given options as to how to access the article. *Id.* The site suggested I could "[r]ecommend to [my] librarian that [my] institution purchase access to this publication." *Id.* Or, I could pay \$36 for access to the article or pay \$269 for permanent access to the full issue. *Id.*

86. Koren et al., *supra* note 4, at 1608.

87. *Id.* at 1610–11.

88. Fortunately for the women in Dr. Koren's study who contacted Motherisk, they found a respected interpreter on the studies and information on methylmercury. Such a respected interpreter should be available to everyone on topics of importance to fetal health. The umbrella entity proposed here is designed to serve as that interpreter on a broad range of issues related to environmental risks to fetal health.

89. Poverty also creates barriers to Internet access, constructing an additional hurdle for self-regulation for these women. More, but not yet enough, free Internet opportunities are developing. Today, public libraries are often the free source of computers with Internet access. INFO. INST., FLA. ST. UNIV., INTERNET CONNECTIVITY IN U.S. PUBLIC LIBRARIES: U.S. PUBLIC LIBRARIES PROVIDE CRITICAL ACCESS TO INTERNET SERVICES 1 (2008) ("Nearly all of America's 16,543 public library buildings offer free public access to computers, to the Internet and to trained staff equipped to help library users gain technology skills and find the information they need for school, work and more. This public service provides a critical

confronting the enslavement of addiction. For others, it means facing the escalation of domestic violence that sometimes accompanies pregnancy.⁹⁰ Research relevant to these issues and others that bears on environmental risks to fetal health, as well as information on resources available for addressing them, should be within the purview of a single entity.

IV. CREATING THE THINK TANK CLEARINGHOUSE

A. NEED

The need for a think tank clearinghouse derives from a variety of circumstances. The need arises both from the inaccessibility of some types of research information about fetal health and from the simultaneous inundation of other information about fetal health. As noted above, some research, often important empirical studies, can be highly challenging to locate and even then access must sometimes be purchased.⁹¹ As authors at the Johns Hopkins Women's and Children's Health Policy Center explain: "A critical challenge for both consumers and clinicians is the inaccessible and dispersed nature of information about environmental toxicants and pregnancy available online."⁹² They opine that "[f]ederal agencies, professional organization[s], and other groups have created websites and briefs on environmental toxicants. However, these sites are often highly technical and detailed, difficult to navigate, and include a very broad array of substances. Most important, the information is not organized with reproductive health concerns in mind."⁹³

source for millions of Americans as nearly three-quarters of public libraries (72.5 percent) reported in a 2007–2008 study that they are the ONLY provider of free access to the Internet in their community.”). For a discussion of the intersection of pregnancy, poor women, and state regulation in the context of potentially toxic chemicals and social justice, see generally Bridges, *supra* note 84.

90. See, e.g., Jay G. Silverman et al., *Intimate Partner Victimization Prior to and During Pregnancy Among Women Residing in 26 States: Associations with Maternal and Neonatal Health*, 195 AM. J. OBSTETRICS & GYNECOLOGY 140, 140 (2006) (“Women experiencing intimate partner violence both prior to and during pregnancy are at risk for multiple poor maternal and infant health outcomes, suggesting prenatal risks to children from mothers’ abusive partners.”); Deborah Tuerkheimer, *Conceptualizing Violence Against Pregnant Women*, 81 IND. L.J. 667, 667 (2006) (“Victims of domestic violence often describe a history of battering that begins, or escalates, during pregnancy. . . . It becomes obvious to anyone who works with pregnant victims of domestic violence that battering during pregnancy is a problem of immense proportions.”).

91. Abstracts are commonly available without subscription or fee, but accessing the full article often requires subscription or payment. See, e.g., Sheela Sathayanarayana et al., *Environmental Exposures: How to Counsel Preconception and Prenatal Rights in the Clinical Setting*, AM. J. OBSTETRICS & GYNECOLOGY, <http://www.ajog.org/article/S0002-9378%2812%2900151-2/abstract> (last visited July 1, 2012) (providing a free abstract, but requiring login privileges or paying a purchase price of \$30 for access to the full article).

92. HARRISON ET AL., *supra* note 19, at 4.

93. *Id.* Some websites that currently address environmental toxicants are, however, generally more accessible and do focus on reproductive health. See, e.g., MARCH OF DIMES, <http://www.marchofdimmes.com/> (last visited July 1, 2012).

These challenges of accessibility suggest the value of an entity that would access and evaluate this research and that would translate the results of its evaluation into accessible content.⁹⁴ In contrast to the dearth and inaccessibility of some types of data, the sheer quantity of information available on the Internet about fetal health is overwhelming. One search engine claimed to find about 42,300,000 results for a search on “fetal health.”⁹⁵ Sifting through such an avalanche of information can be daunting. This abundance of information as well as the need to parse and evaluate that information reinforces the need for an interpretive, evaluative entity.

The need for the Clearinghouse also stems from a desire to create an evidence-based, independent evaluator whose charge focuses broadly on environmental risks to fetal health. In commenting specifically about TSCA, the American Academy of Pediatrics notes that “TSCA has created a non-evidence-based system for chemical management.”⁹⁶ A think tank clearinghouse would rely on an evidence-based system for evaluation of research.

In some ways, one of the strongest arguments for an umbrella entity is the ability to look more holistically at hazardous chemicals and related fetal health concerns. As Professor Colleen Moore, an authority in the realm of environmental toxicants and their effects on the development of children, explains: “We know very little about how different toxic exposures combine—lead plus mercury plus PCBs, plus pesticides, and so on.”⁹⁷ Similarly, the empirical study quoted earlier indicated that the interaction and effect of the 287 pollutants and synthetic chemicals found in the umbilical cord blood of newborns have never been studied as a collected set of chemicals.⁹⁸ Work on assessing exposure has begun. For instance, a study reported in 2011 investigated “biomonitoring data for pregnant women from [the National Health and Nutritional Examination Survey] to characterize exposure to individual and multiple chemicals and their metabolites in pregnant women.”⁹⁹ Research documenting exposure is an important step and arguably a prerequisite to assessing impact. An umbrella entity could aid in investigating such interactions by identifying new and continuing unmet research needs (and perhaps funding sources). Similarly, such an entity could gather and evaluate

94. A number of existing governmental and non-governmental organizations do access and translate research about various environmental risks. See, e.g., *infra* notes 100–119 and accompanying text.

95. The search was run on Google.com on February 26, 2012.

96. Am. Acad. of Pediatrics, *supra* note 48, at 985.

97. MOORE, *supra* note 10, at 64.

98. HOULIHAN ET AL., *supra* note 15, at 13–14.

99. Tracey J. Woodruff et al., *Environmental Chemicals in Pregnant Women in the United States: NHANES 2003–2004*, 119 ENVTL. HEALTH PERSP. 878, 878 (2011).

studies that look at collective effects and at the timing of exposure or the windows of susceptibility during pregnancy.¹⁰⁰ The ability to access all these studies in one place could foster meta-analyses that could combine information from many sources. An umbrella entity might enable researchers and policy makers to see the forest and the trees, so to speak, in ways not previously possible.¹⁰¹

Such an entity, with its focus on fetal health but also with a broad mandate to look at research beyond potential chemical toxicity and into social justice and other fetal, environmental health related research, could provide a resource for a wide variety of policymakers and regulators. It might also enable policymakers and regulators to understand the relationship among disciplines in ways not previously emphasized. An enhanced understanding of the impact of maternal incarceration and drug courts on fetal health, and of the social justice demographics of the interaction of pregnant women with child protective services and the criminal justice system, for example, could enable a broader contingent of actors to make better informed choices about programs and options that promote fetal health. The Clearinghouse could provide that understanding and those perspectives.

B. DESIGN AND COMPOSITION

The Clearinghouse would need content independence from government regulation. It would need independence from industry. It would need a confirmed and consistent funding source, which is perhaps the greatest challenge. One might imagine funding from private foundations, for example, or from the National Institutes of Health supplying at least a portion of the necessary financial support. Some existing partial analogues for such an entity may already exist. Some

100. Work on windows of particular susceptibility is underway. See, e.g., *Targeted Research*, PROGRAM ON REPRODUCTIVE HEALTH & ENV'T, <http://prhe.ucsf.edu/prhe/research/index.html> (last visited July 1, 2012).

101. There has been enhanced recent attention to the importance of cumulative impacts. The California EPA's Office of Environmental Health Hazard Assessment created a work group devoted to studying cumulative impacts, the Cumulative Impacts and Precautionary Approaches work group, which published a report in December 2010. See LINDA S. ADAMS & JOAN E. DENTON, CAL. ENVTL. PROT. AGENCY, *CUMULATIVE IMPACTS: BUILDING A SCIENTIFIC FOUNDATION* iii (2010) ("This report presents the first step in developing a screening methodology to evaluate the cumulative impacts of multiple sources of pollution in specific communities or geographic areas."). In addition, a recently established website called the Cumulative Impacts Project focuses on the cumulative effects of environmental chemical threats to human health. See CUMULATIVE IMPACTS PROJECT, <http://cumulativeimpacts.org/> (last visited July 1, 2012). For additional information about cumulative impacts and the new cumulative impacts website, see Nancy Myers, *The Networker: A New Cumulative Impacts Website*, 16 SCI. & ENVTL. HEALTH NETWORK 4, http://www.sehn.org/Volume_16-4.html (last visited July 1, 2012).

features of organizations like the March of Dimes,¹⁰² or academic institutes or programs that evaluate reproductive health research, such as the University of California at San Francisco's Program on Reproductive Health,¹⁰³ might help inform the design of the Clearinghouse. The design, composition, and operation of such an entity would also benefit from research about the approaches of any similar entities internationally, perhaps one like the Motherisk program in Canada.¹⁰⁴ I welcome the insights of others more knowledgeable about the creation of such entities for further proposals on the specifics of the design and composition of the Clearinghouse.

C. EVALUATORS IN RELATED DOMAINS

Evidence-based independent evaluators currently exist in relevant domains.¹⁰⁵ For example, there are a variety of evaluators that focus on environmental hazards and health. The University of California Center for Occupational and Environmental Health and its sister centers, for instance, arose from legislation passed in 1978 establishing these entities to "serve government, industry, schools, health professionals, and the general public through programs and partnerships designed to deepen understanding of occupational and environmental hazards and to prevent disease, fatalities, and injuries."¹⁰⁶ The centers focus on environmental health, but their charge includes substantial realms outside fetal development. Cochrane Reviews offers independent evaluations and describes its work as "systematic reviews of primary research in human health care and health policy."¹⁰⁷ It provides reviews of environmental hazards and fetal development but aims to address human health policy throughout the human lifespan. Another organization that researches the impact of environmental chemicals on health is the Silent Spring Institute. It focuses on links between environmental chemicals and women's health, particularly breast cancer, rather than on fetal development per se.¹⁰⁸

102. MARCH OF DIMES, *supra* note 93 (providing information about fetal health to the general public, including pregnant women and medical professionals, as well as funding research about fetal health).

103. *Targeted Research*, *supra* note 100.

104. *Motherisk News: Oh Baby! . . . Motherisk Turns 25!*, MOTHERISK, http://www.motherisk.org/prof/commonDetail.jsp?content_id=932 (last visited July 1, 2012).

105. See *supra* and *infra* notes 100–119 and accompanying text.

106. *COEH at a Glance*, UNIV. OF CAL. CTR. FOR OCCUPATIONAL & ENVTL. HEALTH, <http://coeh.berkeley.edu/about/default.htm> (last visited July 1, 2012).

107. *Cochrane Reviews*, COCHRANE COLLABORATION, <http://www.cochrane.org/cochrane-reviews> (last visited July 1, 2012).

108. *About Us*, SILENT SPRING INST., <http://www.silent-spring.org/about-us> (last visited July 1, 2012) ("We partner with physicians, public health and community advocates and other scientists to identify and break the links between environmental chemicals and women's health, especially breast cancer.").

Other evaluators do focus substantially on environmental threats to fetal health, or more accurately, maternal-fetal health. In Canada, for example, the Motherisk program at the Hospital for Sick Kids describes its program as the “pre-eminent international centre for the study of the safety or risk of medications used during pregnancy and breastfeeding. Motherisk provides information and guidance to pregnant or breastfeeding women and health-care professionals regarding risks to the fetus or infant from exposure to drugs, chemicals, diseases, radiation and environmental agents.”¹⁰⁹ The program both conducts its own research and evaluates existing research.¹¹⁰ Motherisk also conducts some social justice research,¹¹¹ although that does not appear to be the focus of the program. Motherisk provides a related analogue to the proposed Clearinghouse, except that Motherisk, an organization based in Canada, does not focus on the evaluation of U.S. law and policy. Further, Motherisk provides extensive direct services to expectant mothers as patients and is also a primary research facility. The Clearinghouse would not provide in-person direct patient services, although it might provide, depending on staffing, an e-mail or phone interpretive service to explain, apply, or clarify its online materials. The Clearinghouse also would not serve as a center for conducting front line empirical research.

Organizations in the United States also direct their research and services toward the intersection of environmental risks and maternal-fetal health. First, for example, like Motherisk, the University of California, San Francisco’s Program on Reproductive Health and the Environment (“PRHE”) offers another analogue to the Clearinghouse. Its mission is to “create a healthier environment for human reproduction and development through advancing scientific inquiry, clinical care and health policies that prevent exposures to harmful chemicals in our environment.”¹¹² PRHE both conducts and evaluates research on potential environmental threats to reproductive health.¹¹³ To establish scientifically based policy proposals and share information, PRHE synthesizes research results and develops and advances policy solutions

109. MOTHERISK, *supra* note 104.

110. *Id.*

111. *Motherisk News: New Research Questions Automatic Removal of Children Living in Grow Ops*, MOTHERISK, http://www.motherisk.org/prof/commonDetail.jsp?content_id=945 (last visited July 1, 2012) (studying children in homes where marijuana was being grown and concluding that automatic removal may not be warranted and that removal should be based on a case-by-case evaluation of the situation). Although much of the information available on the Motherisk website is of interest internationally, the site limits its intended audience with the following disclaimer: “This is a Canadian website and its content is intended for Canadian residents only.” *Disclaimer*, MOTHERISK, <http://www.motherisk.org/prof/disclaimer.jsp> (last visited July 1, 2012).

112. *Targeted Research*, *supra* note 100.

113. *Id.*

on reproductive health and the environment, including fetal health.¹¹⁴ While PHRE's important work offers a useful model for informing the creation of the Clearinghouse, it differs from the proposed entity in several ways. PRHE's focus on reproductive health includes health issues beyond environmental threats to fetal development. PRHE also conducts primary research as part of its research mission, and its evaluation of research does not appear to emphasize research in the social justice sphere.

Second, the Organization of Teratology Information Specialists ("OTIS") also represents an important example analogue and service. OTIS "is a non-profit organization made up of individual services (TIS) throughout North America... dedicated to providing accurate evidence-based, clinical information to patients and health care professionals about exposures during pregnancy and lactation."¹¹⁵ Patients and health care providers can read online fact sheets and call, without fee, to consult with a specialist about environmental exposures and their likely effect on a pregnancy.¹¹⁶ OTIS is a direct service and research organization focused on original research and supplying information to patients and their health care providers. Unlike the Clearinghouse, OTIS's mission does not appear to target applying its research to evaluating legislation and U.S. policy generally. Nor does it appear that OTIS focuses on social and criminal justice research.

In another domain related to the proposed scope of the Clearinghouse, the Campbell Collaboration reviews research in the realms of criminal justice, education, and social welfare.¹¹⁷ Some of this research, including articles evaluating drug courts, may be relevant to fetal development and environmental toxicants.¹¹⁸ But this organization does not focus primarily on either fetal development or environmental toxicants.

All of the organizations described in this Section are entities whose approaches may represent analogues related to the mission of the proposed Clearinghouse, but the goals of these organizations generally include aims outside or different from the mission of the Clearinghouse.¹¹⁹

114. *Advancing Science-Based Policy Solutions*, PROGRAM ON REPROD. HEALTH & ENV'T, <http://prhe.ucsf.edu/prhe/policy/index.html> (last visited July 1, 2012).

115. OTIS PREGNANCY, <http://www.otispregnancy.org/> (last visited July 1, 2012).

116. *Id.*

117. *About Us*, CAMPBELL COLLABORATION, http://www.campbellcollaboration.org/about_us/index.php (last visited July 1, 2012) ("The Campbell Collaboration (C2) helps people make well-informed decisions by preparing, maintaining and disseminating systematic reviews in education, crime and justice, and social welfare... The Campbell Collaboration is an international research network that produces systematic reviews of the effects of social interventions.").

118. An example of the research reviewed, this one on drug courts, can be found at *Crime and Justice Reviews*, THE CAMPBELL COLLABORATION, http://www.campbellcollaboration.org/reviews_crime_justice/index.php (last visited July 1, 2012).

119. Additional existing related resources include: *Health Assessment and Translation (Formerly*

D. CRITIQUES

The existence of a range of entities, such as those described above, which conduct or review research in relevant domains, raises the question of whether the proposed Clearinghouse would be superfluous. Based upon research conducted thus far, none of the existing entities shares the specific charge that would vitalize the Clearinghouse.¹²⁰ What I

CERHR), NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUM. SERVS., <http://ntp.niehs.nih.gov?objectid=497BF6E6-D00C-C4E6-423E8917D64B6A20> (last visited July 1, 2012) ("The NTP and the National Institute of Environmental Health Sciences established the NTP Office of Health Assessment and Translation (OHAT) to serve as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as 'substances') cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. Assessments of potential adverse effects of environmental substances on reproduction or development carried out by the Center for the Evaluation of Risks to Human Reproduction from 1998–2010, will now be carried out by OHAT." The Center for the Evaluation of Risks to Human Reproduction maintained a core committee of representatives with scientific expertise from various government agencies. Its aim, during its first five years, was to evaluate two to three chemicals per year. Gloria D. Jankhe et al., *Center for the Evaluation of Risks to Human Reproduction—The First Five Years*, 74 BIRTH DEFECTS RES. 1, 2, 7 (2005)); MARCH OF DIMES, *supra* note 93 (providing information about fetal health to the general public, including pregnant women and medical professionals, and funding research about fetal health); *National Guideline Clearinghouse*, U.S. DEP'T OF HEALTH & HUM. SERVS., <http://www.guideline.gov/search/search.aspx?term=prenatal+health> (last visited July 1, 2012) (NGC "is a public resource for evidence-based clinical practice guidelines" that reviews research and offers guidelines on health-related topics, including fetal health); *PubMed Help*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (last visited July 1, 2012), <http://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp> ("PubMed comprises over 21 million citations for biomedical literature from MEDLINE, life science journals, and online books. PubMed citations and abstracts include the fields of biomedicine and health, covering portions of the life sciences, behavioral sciences, chemical sciences, and bioengineering. PubMed also provides access to additional relevant web sites and links to the other NCBI molecular biology resources. PubMed is a free resource that is developed and maintained by the National Center for Biotechnology Information (NCBI), at the U.S. National Library of Medicine (NLM), located at the National Institutes of Health (NIH)."); U.S. PREVENTIVE SERVS. TASK FORCE, <http://www.uspreventiveservicestaskforce.org> (last visited July 1, 2012) ("The USPSTF is an independent panel of non-Federal experts in prevention and evidence-based medicine and is composed of primary care providers (such as internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and health behavior specialists). The USPSTF conducts scientific evidence reviews of a broad range of clinical preventive health care services (such as screening, counseling, and preventive medications) and develops recommendations for primary care clinicians and health systems. These recommendations are published in the form of 'Recommendation Statements.'"). In addition, Search Medica is a general database for medical professionals and provides a search feature. See SEARCH MEDICA, <http://goto.searchmedica.com/search.html> (last visited July 1, 2012). Additional resources are summarized in Grason & Misra, *Summary Tables*, *supra* note 19. There has also been a substantial influx of federal government support for various studies and environmental health research centers. See generally Michael Szpir, *New Thinking on Neurodevelopment*, 114 ENVTL. HEALTH PERSP. A100 (2006) (describing studies on various confirmed and suspected environmental toxicants and the relatively recent government funding of new studies and centers).

120. The goal of the Clearinghouse is to serve as the "go to" resource for everyone from women contemplating pregnancy to primary-care physicians to policy makers about environmental threats to fetal development. If an entity like the Clearinghouse does somehow exist out there and my research

am proposing is both broader and more focused than what is currently available. The charge of the Clearinghouse would be to evaluate a wide range of research and policy related to fetal health, including research on environmental toxicity and nutrition, as well as research on existing and proposed criminal justice and social justice policy implications related to environmental threats. Its charge would include gathering and evaluating data and research from a broad swath of sources about fetal health and environmental risks and interpreting and presenting that research in multiple formats accessible and responsive to the information needs of various audiences.¹²¹ The entity would also evaluate existing U.S. policies and legislation in light of the evolving research on fetal health.

But the Clearinghouse would not seek to furnish in-person direct clinical services to individual patients, nor would it serve as a front line empirical research facility conducting its own original research.¹²² In-person patient care and conducting original research are, of course, extraordinarily valuable roles. But those are roles outside the Clearinghouse's role as an interpreter. Each of those roles requires different funding and focus.

The creation of such a Clearinghouse should not, of course, operate to silence other voices engaging in, contributing to, and evaluating the research and policy decision making in this field. To the contrary, many individuals and organizations, like those discussed in this Part IV, currently serve as valuable checks on and influential voices in the discussion. Their voices will continue to serve critical roles both independently, as they do now, and by informing the work of the Clearinghouse. The goal is to create a synergistic relationship among the Clearinghouse, researchers, regulators, and others to yield reductions in environmental risks to fetal development.

In addition to the question of the need for the Clearinghouse, another potential critique is that umbrella entities that gather health information may raise "Big Brother" types of concerns.¹²³ Here, the worry would be that enormous amounts of data are collected in one repository and that such a database could be mined in intrusive and inappropriate ways. The Clearinghouse's charge does not, however,

has failed to uncover it, this suggests that it is not fulfilling the mission that the Clearinghouse aims to fulfill.

¹²¹ Motherisk, for example, offers one clickable icon for providing information to pregnant and lactating women and a separate icon for health care professionals. See *MOTHERISK*, *supra* note 104.

¹²² One might distinguish conducting original empirical research from engaging in meta-analyses of the research of other scientists.

¹²³ For a discussion of some concerns potentially raised by databases containing personal information, see, for example, Emily Stehr, *Next Generation Identification—Not a DNA Database, but Just as Problematic*, *BIOPOLITICAL TIMES* (July 19, 2011) <http://www.biopoliticaltimes.org/article.php?id=5788>.

contemplate that it gather personally identifiable information on individuals, like genetic profiles or even residential addresses or birthdates. The Clearinghouse is designed to serve as an interpreter, not an entity that conducts empirical research and collects personally identifiable confidential information on research subjects or patients. Certainly, however, were such information to be part of the Clearinghouse's repository, oversight and compliance with requirements such as the Privacy Rule of the Health Insurance Portability and Accountability Act¹²⁴ and perhaps the Genetic Information Nondiscrimination Act¹²⁵ might be necessary.¹²⁶

A third critique is that the role of the Clearinghouse is too limited. Reducing the potential harm of environmental threats to fetal development requires more than interpreting information and making it accessible. Scholars in the field of public health have in recent years called for much more comprehensive initiatives.¹²⁷ Such initiatives include, as “an initial step, better management of information, including information vehicles,”¹²⁸ but extend well beyond that. They include supplying “care specific to hazardous environmental exposures related to perinatal health.”¹²⁹ They would also involve providing “guidance for medical education,”¹³⁰ developing “[n]ational shared goals”¹³¹ as well as a

124. OFFICE FOR CIVIL RIGHTS, U.S. DEP'T OF HEALTH & HUM. SERVS., SUMMARY OF THE HIPAA PRIVACY RULE ii (2003) (“The *Standards for Privacy of Individually Identifiable Health Information* (‘Privacy Rule’) establishes, for the first time, a set of national standards for the protection of certain health information. The U.S. Department of Health and Human Services (‘HHS’) issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 (‘HIPAA’). The Privacy Rule standards address the use and disclosure of individuals’ health information—called ‘protected health information’ by organizations subject to the Privacy Rule—called ‘covered entities,’ as well as standards for individuals’ privacy rights to understand and control how their health information is used.”).

125. Pub. L. No. 110-233, 122 Stat. 881 (2008) (providing regulations on nondiscrimination based on personal genetic information in the contexts of insurance and employment). For information about GINA, see *Genetic Information Nondiscrimination Act (GINA) of 2008*, NAT'L HUM. GENOME RESEARCH INST., <http://www.genome.gov/24519851> (last visited July 1, 2012).

126. An additional critique, or at least a question about the proposal, might involve why the Clearinghouse is limited to the intersection of threats of environmental toxicants and fetal development as opposed to childhood or adolescent development or adulthood. At least two responses merit mention. First, it appears that fetal development is a period of especially heightened susceptibility to environmental toxicants, as are embryonic (which would seem to fall within the Clearinghouse's mission) and early childhood development (which exceeds the specific Clearinghouse mission). See, e.g., Grandjean, *supra* note 2. Second, an even broader mission for the entity would dilute its focus on fetal development and likely would require more extensive resources to succeed.

127. Grason & Misra, *Reducing Exposure*, *supra* note 19, at 637-40 (2009) (“We [describe] a wide range of policy strategies [including short-term actions and longer-term initiatives] that could be implemented to address environmental toxicants in the context of perinatal health.”).

128. *Id.* at 637.

129. *Id.* at 639.

130. *Id.* Grason and Misra recommend modeling “an organized system of information and care specific to hazardous environmental exposures related to perinatal health” on the “system used by

“prevention model that incorporates a lifespan perspective through primary (information and education), secondary (risk identification), and tertiary (counseling) prevention services”¹³² and “communication mechanisms that link all components and strengthen accountability . . . for improved outcomes for women and children consistent with the shared goals articulated.”¹³³ Certainly, these scholars are correct that more comprehensive approaches will be needed to effectively grapple with reducing environmental threats to fetal development. But accurate, reliably interpreted, and accessible information about those potential threats and their implications supports and is arguably a prerequisite to significant progress in reducing those threats. The Clearinghouse could thus serve as the foundation for the advancement of more comprehensive initiatives.

A fourth critique of the Clearinghouse relates to its Internet-based nature. Its online presence does allow for rapid and real-time updates of information, but not everyone has access to or uses computers to gather health information. For example, one study conducted in 1999–2000 documented disparities in the use of Internet resources based on demographics.¹³⁴ The researchers “conducted a population-based study to examine women’s use of health information resources.”¹³⁵ They found that “women with higher incomes (>\$50,000) had 2.2 times greater odds of using computer-based resources compared with women with a household income of ≤50,000.”¹³⁶ In addition, their analysis indicated that, of the women surveyed, the White women were more likely than the Black women to use computer-based resources to access health information.¹³⁷ With respect to computer access, the American Library Association reports that nearly “all of America’s 16,543 public library buildings offer free public access to computers, to the Internet and to trained staff equipped to help library users gain technology skills and find

U.S. poison control centers.” *Id.*

131. *Id.*

132. *Id.*

133. *Id.*

134. Wanda K. Nicholson et al., *The Relationship of Race to Women’s Use of Health Information Resources*, 188 AM. J. OBSTETRICS & GYNECOLOGY 580 (2003) The study researchers noted that their “survey only asked whether the respondents used computer-based resources.” *Id.* at 584. The researchers did not ask “respondents about their access to computers through employment or family and friends.” *Id.*

135. *Id.* at 581.

136. *Id.* at 582.

137. *Id.* at 584. The researchers explain that this difference in the likelihood that the women surveyed would use computer-based resources to access health information manifested even after the researchers adjusted “for income, education, marital status, age, and employment in the logistic regression model,” *id.*, with the Black women in the study “60% less likely than [the White] women to use computer-based resources.” *Id.*

the information they need.”¹³⁸ This suggests that access to computer resources is improving. Even if public access becomes or is available, however, accessing personal health information in a public space may still not be an inviting prospect. Moreover, women may not use computers to obtain health information for reasons unrelated to computer access. But, even for women who may not personally use a computer to access health information, because it is in a public space or for other reasons, the establishment of the Clearinghouse may nonetheless augment their access to reliable and current evidence-based health information because some of these women may seek information from their health care providers, who will probably have access to a computer and may use the resources of the Clearinghouse. Still, the Clearinghouse should explore additional avenues for making its resources available to the public.

CONCLUSION

Extraordinary advances in neuroscience and related fields contribute to a growing understanding of the environmental threats that can impair fetal (and, consequently, often lifelong) health. As we learn more about these threats, often the desire as well as the ability to protect against the damage the threats may cause multiplies. In a world of information dearth and avalanche, informed and evaluative interpreters of information about fetal health become critical. For the mother I imagined at the start of this Article who had elevated levels of methylmercury, the proposed Clearinghouse could have equipped her with knowledge about the toxic properties of methylmercury from research beyond the reassuring recommendations about albacore tuna on the FDA and HHS websites. The Clearinghouse might have spared her child the impairments described, or at least—by equipping the mother with and enabling her to act on the best information available—spared her the unremitting uncertainty of a possible role in having caused her child’s impairments. The Clearinghouse proposed here responds to the need for informed, independent, and evaluative interpreters to transform the concurrent information inaccessibility and overload into accessible, interpreted, and useful databases that can effectively inform policy makers, pregnant women, physicians, and anyone else with an interest in or a need to know about environmental risks to fetal development.

138. *See supra* note 89.
