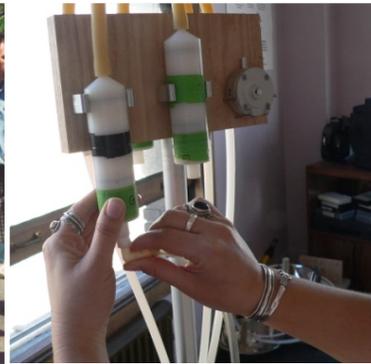




SILENT SPRING INSTITUTE



RESEARCHING THE ENVIRONMENT AND WOMEN'S HEALTH

# IRB Adventures In a Community-Based Environmental Exposure Study

Julia G. Brody, PhD  
NIEHS/OHRP SANC Conference, March 2012

[www.silentspring.org](http://www.silentspring.org)

# “A lab of our own”



*Brody et al., 2005*

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# Community critique

## Researchers were not focused on science and public health

- Not asking questions about prevention; driven by profit from new diagnosis and treatment
- Motivated by career and institutional advancement, operating competitively and within disciplinary boundaries
- Not sharing what they did know - disrespecting women's ability to make good decisions in the face of scientific uncertainty

# Research Paradigm for Prevention

**Biological  
mechanism**



**Human  
exposure**

**Basis for  
action**

**Strength of  
evidence,  
not “proof”**

**Educate  
Regulate  
Reformulate**

*Brody 2010*

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# Key IRB discomforts

- “Participants” are both individuals & communities when exposures are place-based or culture-based
- Environmental exposures often have uncertain health implications and remedies may require social action
- Partnerships mean protocols are negotiated and must be responsive
- Conceptions of partnership and shared data ownership imply sharing results
- Researchers may be based outside the university

# Sources

- **Our 15 years experience**
- **NIEHS Environmental Justice grantee meetings**
- **PERE Study workshop at Harvard Law School** (Personal Exposure Report-back Ethics Study, PI Brody)
- **Interviews**
  - 50 participants who received results
  - 25 researchers & IRB members

# Household Exposure Study

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- 170 homes



# Community Values

- Right-to-know
- Science-power to solve ignored problems





# Partners: Many IRBs & none



- **Silent Spring Institute**

Julia Brody, Ruthann Rudel



- **Brown University**

Phil Brown



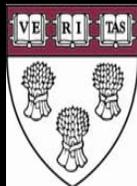
- **UC Berkeley**

Rachel Morello-Frosch



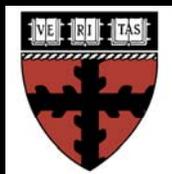
- **Communities for a Better Environment**

Jessica Tovar



- **Harvard Environmental Law Clinic**

Shaun Goho



- **Harvard Data Privacy Lab**

Latanya Sweeney

# What if the PI is outside a university?

- Can the university see its IRB as an opportunity for service to its larger community?

# Responsive, evolving protocol

- Community input:  
*"Fingerprint the oil refinery"*
- Problem-solving focus
- Ongoing relationship with participants, community partners

# Changes to the protocol

- **Added**
  - Analytes
  - Outdoor samples
  - Rural comparison community
  - Volunteer participants
- **Developed methods to report individual results**
- **Revisited some homes**

# IRB adventures

- Delays undermine community trust
- Threats to continuity – funding issues
  - MDPH asked us to destroy environmental samples, data at end of funding cycle before analysis was complete
  - Brown University unwilling to cover extension of study in which their co-I was not funded
- Threats to continuity – interpretation of consents
  - Excess reliance on re-consent
- Threats to scientific independence
  - MDPH
    - Blocked submission of a manuscript on a novel hypothesis, so our team was “scooped” by others.
    - Asked for prior review and editorial changes to individual reports to participants

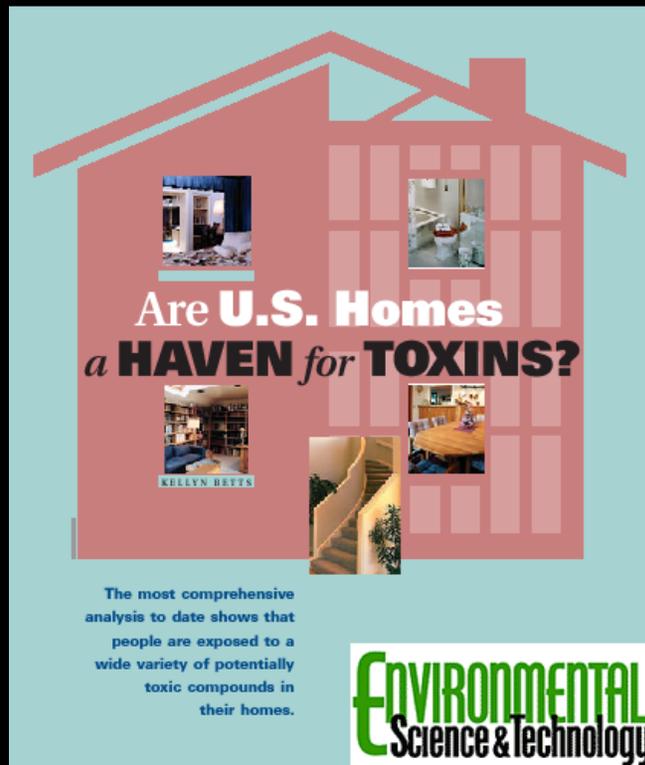
# Reporting personal exposures

- When health effects are uncertain

*Brody 2007, AJPH*  
*Morello-Frosch 2009, EH*

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# Cape Cod homes



- 67 EDCs
- Flame retardants 10X higher than Europe
- All homes, 15 chemicals above guidelines
- Some very high levels

*Rudel et al., 2003, ES&T;*

*Rudel et al., 2008, ES&T*

[www.silentspring.org](http://www.silentspring.org)

# California homes

Environ. Sci. Technol. 2008, 42, 8158-8164

## Elevated House Dust and Serum Concentrations of PBDEs in California: Unintended Consequences of Furniture Flammability Standards?

AMI R. ZOTA,<sup>1,2,3</sup> RUTHANN A. RUDEL,<sup>1</sup> RACHEL A. MORELLO-FROSCH,<sup>3</sup> AND JULIA GREEN BRODY<sup>1</sup>

<sup>1</sup>Silent Spring Institute, Newton, MA, <sup>2</sup>Department of Environmental Health, Harvard School of Public Health, Boston, MA, and <sup>3</sup>Department of Environmental Science, Policy and Management and School of Public Health, University of California, Berkeley, Berkeley, CA

with Europe (3, 4). Regional variation within the U.S. may result from more stringent furniture flammability standards in California than in other states; however, this possibility has not been evaluated.

Three major PBDE commercial mixtures have been commonly used in consumer products: deca-BDE, octa-BDE, and penta-BDE (5). Penta-BDE has been most often mixed into polyurethane foam (PUF) used in furniture, while octa- and deca-BDE are used in electronics and other plastic products (6). Penta-BDE is typically about 3–5% by weight in treated foam, and is easily liberated into dust because it is not chemically bound to the foam product. Penta-BDE has been used almost exclusively in the U.S. (6) and mostly in furniture for sale in California in order to comply with Technical Bulletin 117 (TB117), the state's 1975 performance-based furniture flammability standard (5, 7). Regional differences may be somewhat lessened, however, because some TB-117-compliant products are distributed nationwide (8), and not all furniture sold in California has complied with

### RESEARCH AND PRACTICE

## Linking Exposure Assessment Science With Policy Objectives for Environmental Justice and Breast Cancer Advocacy: The Northern California Household Exposure Study

Julia Green Brody, PhD, Rachel Morello-Frosch, PhD, MPH, Ami Zota, ScD, Phil Brown, PhD, Carla Pérez, BA, and Ruthann A. Rudel, MS

With a sprawling oil refinery in the background, Marleen Quint, Wanna Wright, and Etta Lunly stood on a hill overlooking Richmond, California, holding up a photograph of Quint's mastectomy scars.<sup>1</sup> The women were propelled by their breast cancer diagnoses to ask whether their own cancers as well as neighborhood problems with asthma, sore throats, rashes, other cancers, and children's development were related to chemical exposures from nearby industry and rail, truck, and marine shipping corridors. Their question is part of an emerging crossover of interests between environmental justice and breast cancer advocacy<sup>2–5</sup> that is driven not only by personal experiences but also by breast cancer statistics for ethnic minority women; environmental hypotheses that link the same pollutants to breast cancer and to health issues of concern in low-income, minority communities; and new partnerships between communities and scientists.<sup>6–9</sup>

**Objectives.** We compared an urban fence-line community (neighboring an oil refinery) and a nonindustrial community in an exposure study focusing on pollutants of interest with respect to breast cancer and environmental justice.

**Methods.** We analyzed indoor and outdoor air from 40 homes in industrial Richmond, California, and 10 in rural Bolinas, California, for 153 compounds, including particulates and endocrine disruptors.

**Results.** Eighty compounds were detected outdoors in Richmond and 80 in Bolinas; Richmond concentrations were generally higher. Richmond's vanadium and nickel levels indicated effects of heavy oil combustion from oil refining and shipping; these levels were among the state's highest. In nearly half of Richmond homes, PM<sub>2.5</sub> exceeded California's annual ambient air quality standard. Paired outdoor-indoor measurements were significantly correlated for industry- and traffic-related PM<sub>2.5</sub>, polycyclic aromatic hydrocarbons, elemental carbon, metals, and sulfates ( $r=0.54-0.92$ ,  $P<.001$ ).

**Conclusions.** Indoor air quality is an important indicator of the cumulative impact of outdoor emissions in fence-line communities. Policies based on outdoor monitoring alone add to environmental injustice concerns in communities that host polluters. Community-based participatory exposure research can contribute to science and stimulate and inform action on the part of community residents and policymakers. (*Am J Public Health*. 2009;99:S600-S609. doi: 10.2105/AJPH.2008.149088)

- Unhealthy PM2.5 in almost 1/2 Richmond homes
- High vanadium, nickel from heavy oil
- Very high flame retardants
- EDCs from consumer products

Zota 2008 ES&T  
Brody 2009, AJPH  
Rudel 2010 ES&T

[www.silentspring.org](http://www.silentspring.org)

# Emerging contaminants: Clinical model doesn't fit

- Expert-driven (doctors decide)
  - But medical providers aren't the experts
- Response isn't medical
- Drawbacks when science is uncertain
  - Problems arise when knowledge advances after the study
  - Limits participants' learning and action
- Medical practice has evolved with more patient communication



# Human research ethics criteria

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- **Autonomy, respect for persons**
  - Right to know or not know
- **Justice**
  - Information disparity = power disparity
- **Minimize harm**
  - Emotional distress
  - Ineffective action
  - Stigma
  - Expense, legal effect
- **Maximize benefit**
  - Informed action
  - Environmental health literacy
  - Validate health concerns

# Report-back methods

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- **Individual data**
  - Informed consent
    - Set expectations: What can the study say?
    - Right to know or not know
  - Written report: text, graphs, context
  - Access to researcher
  - Exposure reduction resources

# Report-back methods

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- **Aggregated data**
  - Peer reviewed article
  - Fact sheet
  - Community meetings
  - News media
  - Web

# Is It Safe?

- What did you find?
- How much?
- Is that high?
- Is it safe?
- Where did it come from?
- What should I do?



Brody 2007, AJP

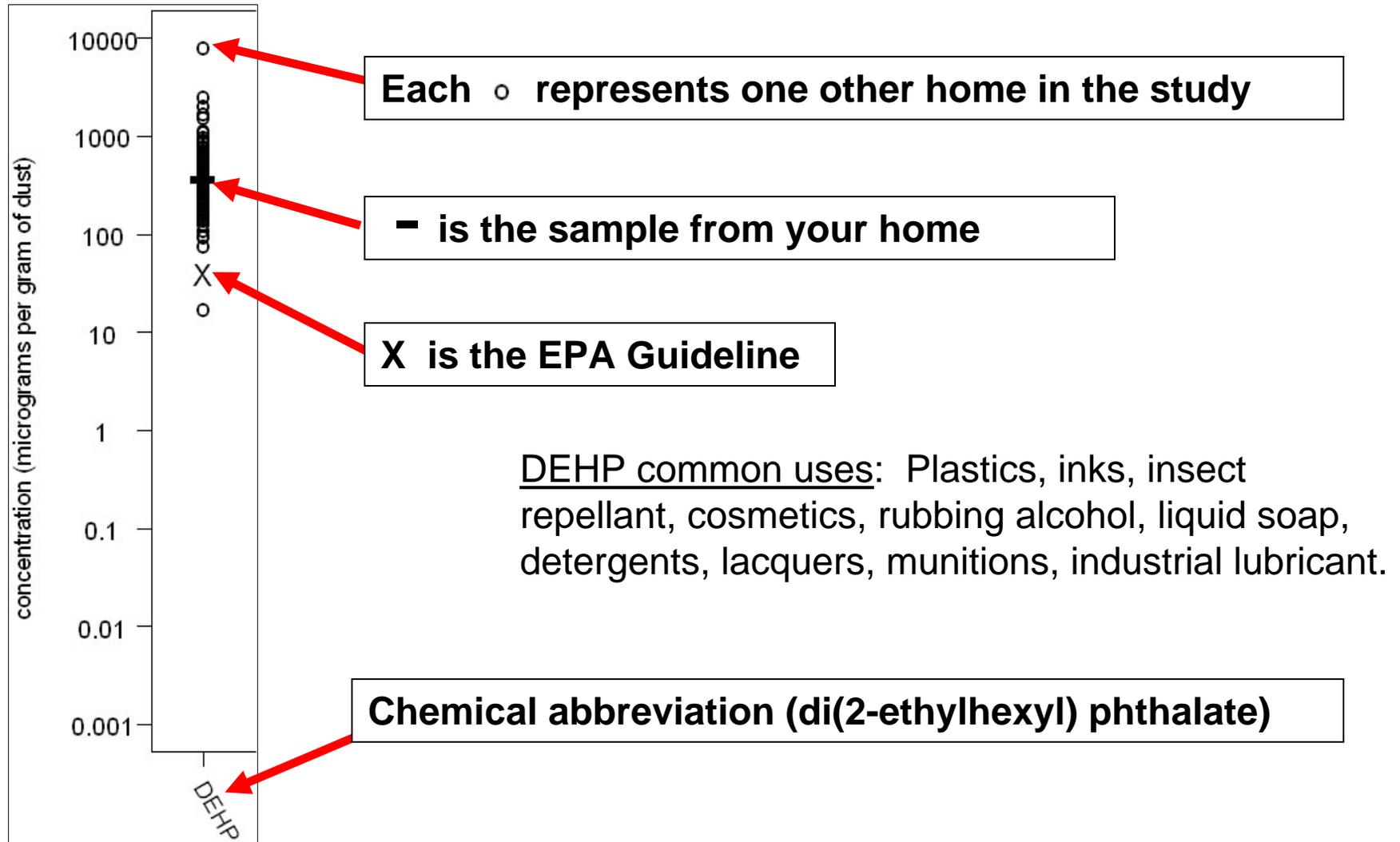
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# Narrative excerpt

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- “We detected many chemicals in every home in the study”
- “One of the chemicals we found in your urine is a weed killer.... If you are using a weed killer in your yard, you could reduce your exposure by controlling weeds without these chemicals.”
- “We are studying this chemical because....”

# How to read your results



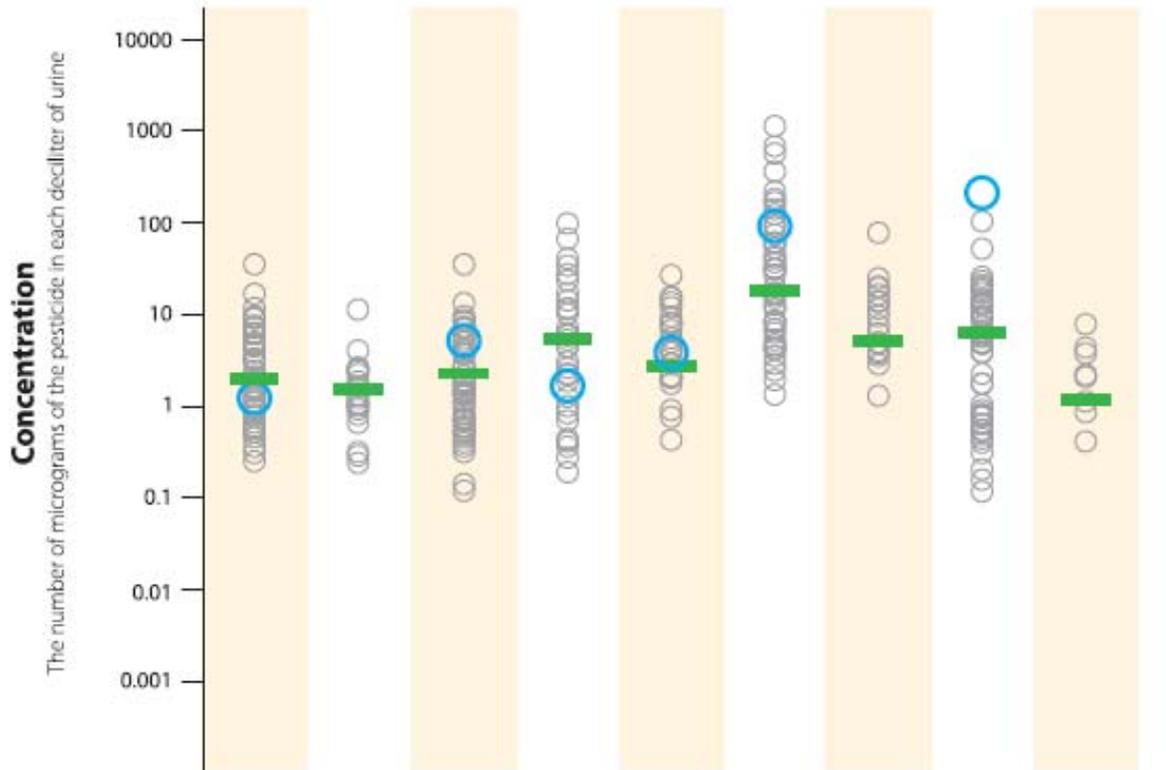
Brody et al. *AJPH*, 2007

[www.silentspring.org](http://www.silentspring.org)

# Part 2: Pesticides in Urine Results Chart

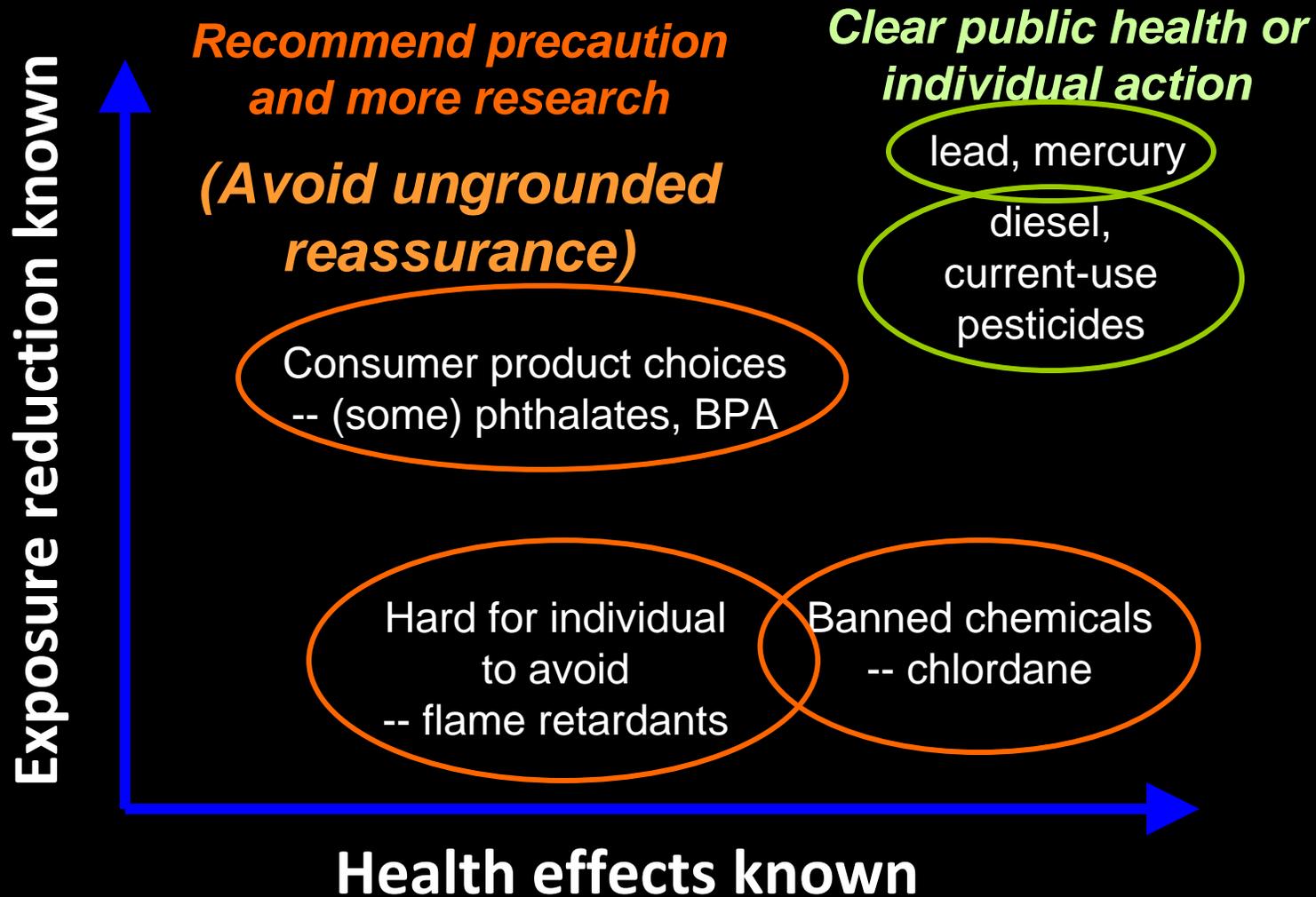
Participant number: 43

○ **Your level** There is no blue circle if we did not find this chemical in your sample.  
○ **Other people's levels** Each circle represents a person in the study.  
■ **National average** The most common level in pregnant women.



Pesticides	1. 3-PBA	2. OC	3. TN	4. DDT	5. DDE	6. DAPs	7. DEP	8. DMP	9. TCPy
<b>Your exact levels</b>	1.17	Not Found	7.92	2.32	5.40	105	Not Found	328	Not Found

# What should I do?



# Experiences of our participants

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## **Pollution Comes Home and Gets Personal: Women's Experience of Household Chemical Exposure\***

REBECCA GASIOR ALTMAN

*Brown University*

RACHEL MORELLO-FROSCH

*University of California at Berkeley*

JULIA GREEN BRODY

RUTHANN RUDEL

*Silent Spring Institute*

PHIL BROWN

MARA AVERICK

*Brown University*

*Altman et al., 2008, Journal of  
Health and Social Behavior*

*Adams et al., 2010, Journal of  
Health and Social Behavior*

Journal of Health and Social Behavior 2008, Vol 49 (December): 417-435

*We report on interviews conducted with participants in a novel study about environmental chemicals in body fluids and household air and dust. Interviews reveal how personal and collective environmental history influence the interpretation of exposure data, and how participants fashion an emergent understanding of environmental health problems from the articulation of science and experience. To the illness experience literature, we contribute a framework for analyzing a new category of embodied narratives—"exposure experience"—that examines the mediating role of science. We update social scientific knowledge about social responses to toxic chemicals during a period in which science alters public understanding of chemical pollution. This article is among the first published accounts of participants' responses to learning personal exposure data, research identified as critical to environmental science and public health. Our findings raise the importance of reporting even uncertain science and underscore the value of a community-based reporting strategy.*

spring.org

# Interviews with participants

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- Participants wanted their results
- Increased trust in researchers
- Pride in contributing to science and health
- Learning, conceptual shifts about pollution
- Reflections on illnesses, “toxic trespass”
- Frustration at information gaps
- Evolving interpretations, brainstorming
- Motivation to reduce exposure
- Differences X community context

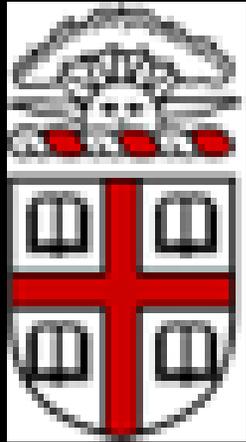
# Challenges

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- Timing
- Consensus on benchmarks
- Managing overload for the participant
- Automating processes for the researcher

# What we need

- Guidance and training that makes CBPR “normal”
- Coverage for CBOs in researcher roles
- Strategies that reduce re-review and re-consent
- Empirical observation of effects
- Courage!



**Special thanks to the  
Brown University IRB**



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### Endocrine Disruptors and Asthma-Associated Chemicals in Consumer Products

Robin E. Dodson, Marcia Nishioka, Laurel J. Standley, Laura J. Perovich, Julia Green Brody, Ruthann A. Rudel

<http://dx.doi.org/10.1289/ehp.1104052>

8 March 2012



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