SILENT SPRING INSTITUTE



RESEARCHING THE ENVIRONMENT AND WOMEN'S HEALTH

Is it safe? New ethics for reporting personal exposures

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Biomonitoring California Workshop on
Understanding and Interpreting Biomonitoring Results
March 17, 2011
Oakland, CA

Outline

Communicating uncertain science

- Our exposure and report back experience
- Ethics – moving beyond possible harms
- Six questions
- Matching messages to evidence
- Opportunities - who is high and why?

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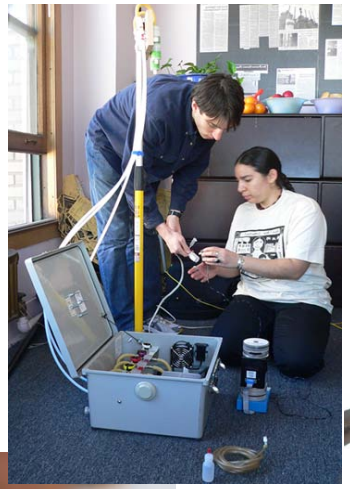
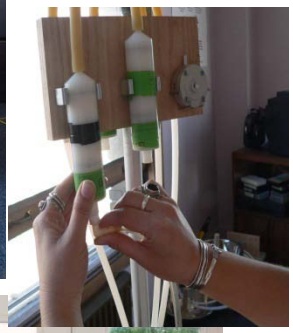
Household Exposure Study

- 170 homes

Household Exposure Study





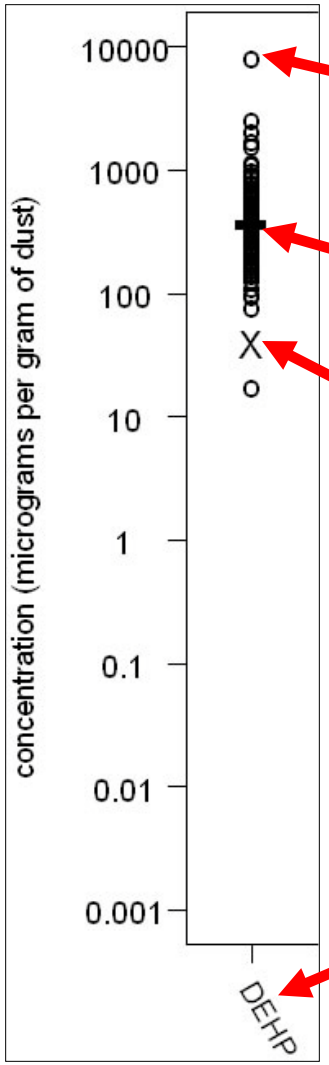
- 150 compounds
- 89+ endocrine disruptors
- Air
- Dust
- Urine

Rudel et al., ES&T, 2003

Brody et al., AJPH, 2009

Rudel et al., ES&T, 2010

How to read your results



Each o represents one other home in the study

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DEHP common uses: Plastics, inks, insect repellant, cosmetics, rubbing alcohol, liquid soap, detergents, lacquers, munitions, industrial lubricant.

Chemical abbreviation (di(2-ethylhexyl) phthalate)

Brody et al. *AJPH*, 2007

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

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

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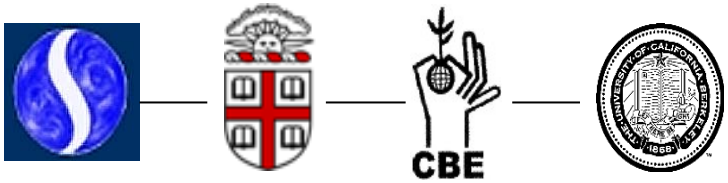

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- UC Berkeley: Rachel Morello-Frosch
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With science uncertain…

- **What (if anything) should researchers tell study participants about their own results?**
  - **Could reporting individual results to study participants do more harm than good?**

CDC's *Second National Report on Human Exposure to Environmental Chemicals*: Background

The *National Report on Human Exposure to Environmental Chemicals* is an ongoing assessment of the exposure of the U.S. population to environmental chemicals using biomonitoring. The first *Report* on 27 chemicals was issued in March 2001. This *Second Report*, released in January 2003, presents blood and urine levels of 116 environmental chemicals from a sample of people that represent the noninstitutionalized, civilian U.S. population during the two-year period 1999-2000.

Scientists from CDC's Environmental Health Laboratory measured chemicals or their metabolites (breakdown products) in blood and urine samples from selected participants in the National Health and Nutrition Examination Survey (NHANES). Conducted by CDC's National Center for Health Statistics, NHANES is a series of surveys designed to collect data on the health and nutritional status of the U.S. population.

For this *Report*, an environmental chemical means a chemical compound or chemical element that is present in air, water, food, soil, dust, or other environmental media. Biomonitoring is the assessment of human exposure to chemicals by measuring the chemicals or their metabolites (breakdown products) in human specimens such as blood or urine. Blood and urine levels reflect the amount of the chemical in the environment that actually gets into the body.

This *Second Report* presents exposure data from NHANES 1999-2000 for 116 chemicals, including expanded information on the 27 chemicals listed in the first *Report* and 89 new chemicals. This *Report* also presents exposure data for the U.S. population by age, sex, and race/ethnicity.

The first *Report* provided data on lead, mercury, cadmium, and other metals; dialkylphosphate metabolites of organophosphate pesticides; cotinine; and phthalates. The *Second Report* includes data on these chemicals and adds the following:

- Polycyclic aromatic hydrocarbons (PAHs)
- Dioxins, furans, and coplanar polychlorinated biphenyls (PCBs)
- Non-coplanar PCBs
- Phytoestrogens
- Selected organophosphate pesticides
- Organochlorine pesticides
- Carbamate pesticides
- Herbicides
- Pest repellents and disinfectants

Public Health Uses of the *Report*

The overall purpose of the *Report* is to provide unique exposure information to physicians, scientists, and health officials to help prevent disease that results from exposure to environmental chemicals. The following are specific public health uses of the exposure information in the *Second Report*:

- To determine which chemicals get into Americans and at what concentrations.
- For each chemical with a known toxicity level, to determine the prevalence of people with levels above that toxicity level (e.g., a blood lead level greater than or equal to 10 micrograms per deciliter [µg/dL]).
- To establish reference ranges that can be used by physicians and scientists to determine whether or not a person or group of people has an unusually high exposure.
- To assess the effectiveness of public health efforts to reduce exposure of Americans to specific chemicals.
- To determine whether exposure levels are higher among minorities, children, women of childbearing age, or other potentially vulnerable groups.
- To track, over time, trends in levels of exposure in the population.
- To set priorities for research on human health effects.

Interpreting Data in the *Report*

Just because people have an environmental chemical in their blood or urine does not mean that the chemical causes disease. The toxicity of a chemical is related to its dose or concentration. Small amounts may be of no health consequence, whereas larger amounts may cause disease. Research studies, separate from the *Report*, are required to determine which levels of a chemical may cause disease and which levels are of negligible health concern. For some chemicals, such as lead, research studies provide a good understanding of health risks associated with various blood levels. For most of the environmental chemicals in the *Second Report*, more research is needed to determine whether exposure to the chemical at levels reported here is a cause for health concern. CDC conducts such research and provides biomonitoring measurements for this type of research in collaboration with other agencies and institutions.

The *Second Report* presents data collected to provide estimates of exposure for the civilian, noninstitutionalized U.S. population. The current survey design does not permit us to estimate exposure on a state-by-state or city-by-city basis. For example, it is not possible to extract a subset of data and examine levels of blood lead that represent a state population.

Why talk about science-in-progress?

Responsible communication is a human research ethical responsibility

To minimize harm, maximize benefit, support autonomy and justice

Human research ethics criteria

- **Possible harm**
  - Emotional distress
  - Individual privacy, community stigma
  - Expense, legal effect, ineffective action
- **Possible benefit**
  - Informed action
  - Environmental health literacy
  - Validate health concerns
- **Autonomy**
  - Ability to act consistent with own values
- **Justice**
  - Information disparity / power disparity

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Is It Safe?

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

American Journal of PUBLIC HEALTH

HEALTH POLICY AND ETHICS

Improving Disclosure and Consent

"Is It Safe?": New Ethics for Reporting Personal Exposures to Environmental Chemicals

Julia Green Brody, PhD, Rachel Morello-Frosch, PhD, MPH, Phil Brown, PhD, Ruthann A. Rudel, MS, Rebecca Gasior Altman, MA, Margaret Frye, BA, Cheryl A. Osimo, BS, Carla Pérez, BS, and Liesel M. Senyak, BS

The recent flood of research concerning pollutants in personal environmental and biological samples—blood, urine, breastmilk, household dust and air, umbilical cord blood, and other media—raises questions about whether and how to report results to individual study participants.

Clinical medicine provides an expert-driven framework, whereas community-based participatory research emphasizes participants' right to know and the potential to inform action even when health effects are uncertain. Activist efforts offer other models.

We consider ethical issues involved in the decision to report individual results in exposure studies and what information should be included. Our discussion is informed by our experience with 120 women in a study of 89 pollutants in homes and by interviews with other researchers and institutional review board staff. (*Am J Public Health*. 2007;97:1547–1554. doi: 10.2105/AJPH.2006.084913)

ON JANUARY 29, 2003, readers opened *The New York Times* to a full-page advertisement that featured a photograph of Andrea Martin, a 56-year-old mother and the founder of the Breast Cancer Fund, with a headline boxed like a cigarette label across her chest: "Warning: Andrea Martin Contains 59 Cancer-Causing Industrial Chemicals."[1] The ad reported on a study by Environmental Working Group (EWG) and Mt Sinai Medical School that reported finding an average of 90 pollutants in blood samples from 9 volunteers who were tested for 200 environmental chemicals. Details on the EWG Web site put a human face on "the pollution in people" by revealing each volunteer's test results.[2] A month later, the US Centers for Disease Control and Prevention (CDC) published its *Second National Report on Human Exposure to Environmental Chemicals*, an extensive assessment of personal exposure statistics for a representative sample of the US population, that included measurement of 116 pollutants in participants' blood and urine.[3]

These reports marked the beginning of a flood of personal exposure information. Scientific journals, activist Web sites, and the news media were soon reporting on contaminants in personal environmental and biological samples—for example, flame retardants in breastmilk,[4] pesticides in umbilical-cord blood,[5,6] endocrine-disrupting compounds in homes,[7] phthalates in cars,[8] and chemicals in a family tested by the *Oakland Tribune*.[9] The *Third National Report on Human Exposure to Environmental Chemicals* in 2005 reported on 148 chemicals in more than 5000 people.[10] National screening will expand to 473 chemicals in 2009, and biomonitoring programs are beginning in several states.

These efforts rest on new chemical analytic methods that enable the detection of ever-lower concentrations of an increasing number of chemicals for which animal and cell studies show troubling biological effects. However, human exposure concentrations, chemical sources, health effects, and exposure-reduction strategies are not yet understood. The new methods and data advance environmental epidemiology and environmental health policy, and they are powerful communication and mobilization tools. However, the methods and data raise ethical and technical issues about how to interpret and report results to study participants and their communities when the health implications of exposures are uncertain. The National Academy of Sciences' (NAS's) report, *Human Biomonitoring for Environmental Chemicals*, notes that chemical testing technologies have advanced faster than ethical guidelines and methods for interpreting and communicating results, and it recommends sharing information about multiple approaches in order to develop best practices.[11]

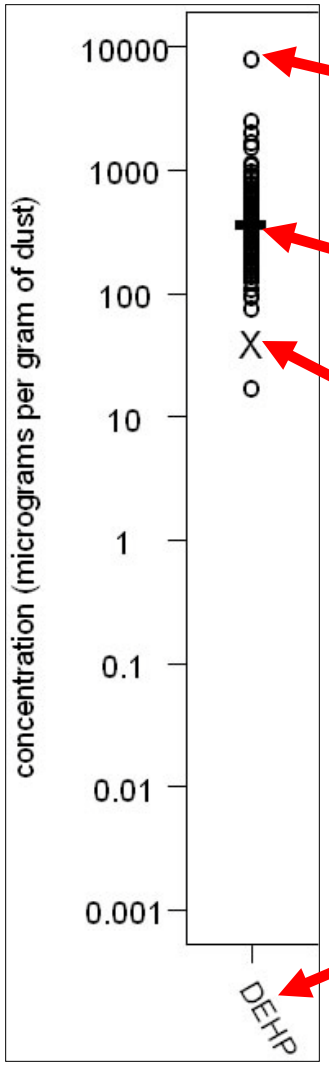
These issues are of particular importance to our study team because of the household exposure study of endocrine-disrupting compounds we are conducting. As part of the Cape Cod (Massachusetts) Breast Cancer and Environment Study,[12–16] we tested for 89 endocrine-disrupting compounds in household air and dust from 120 homes and tested a urine sample from the woman in each home who participated in the breast cancer study. The endocrine-disrupting compounds tested for included phthalates, alkylphenols, parabens, polychlorinated biphenyls (PCBs),

September 2007, Vol 97, No. 9 | American Journal of Public Health

Brody et al. | Peer Reviewed | Health Policy and Ethics | 1547

Brody et al, 2007, AJPH

How to read your results



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Narrative example

- “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….”

Interviews with participants

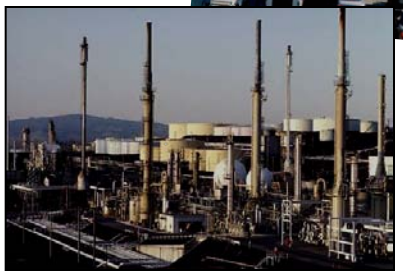
- 57 participants
- 60-90 minutes, in-person
- Transcribed
- Coded in NVivo

- How do people assign meaning to their results?
- What is their experience?

Brody, 2007, AJPH
Altman, 2008 JHSB
Morello-Frosch, 2009, EH
Adams, in press, JHSB

Key understandings

- Many chemicals are detected in homes
- Banned substances are found today
- Many sources
- Comparisons to study distributions and EPA guidelines
- Common household chemicals are unregulated, understudied



Key experiences

- Participants wanted their results
- Increased trust in researchers
- Pride in contributing to science and their community
- Frustration at information gaps
- Evolving interpretations, brainstorming
- Motivation to reduce exposure

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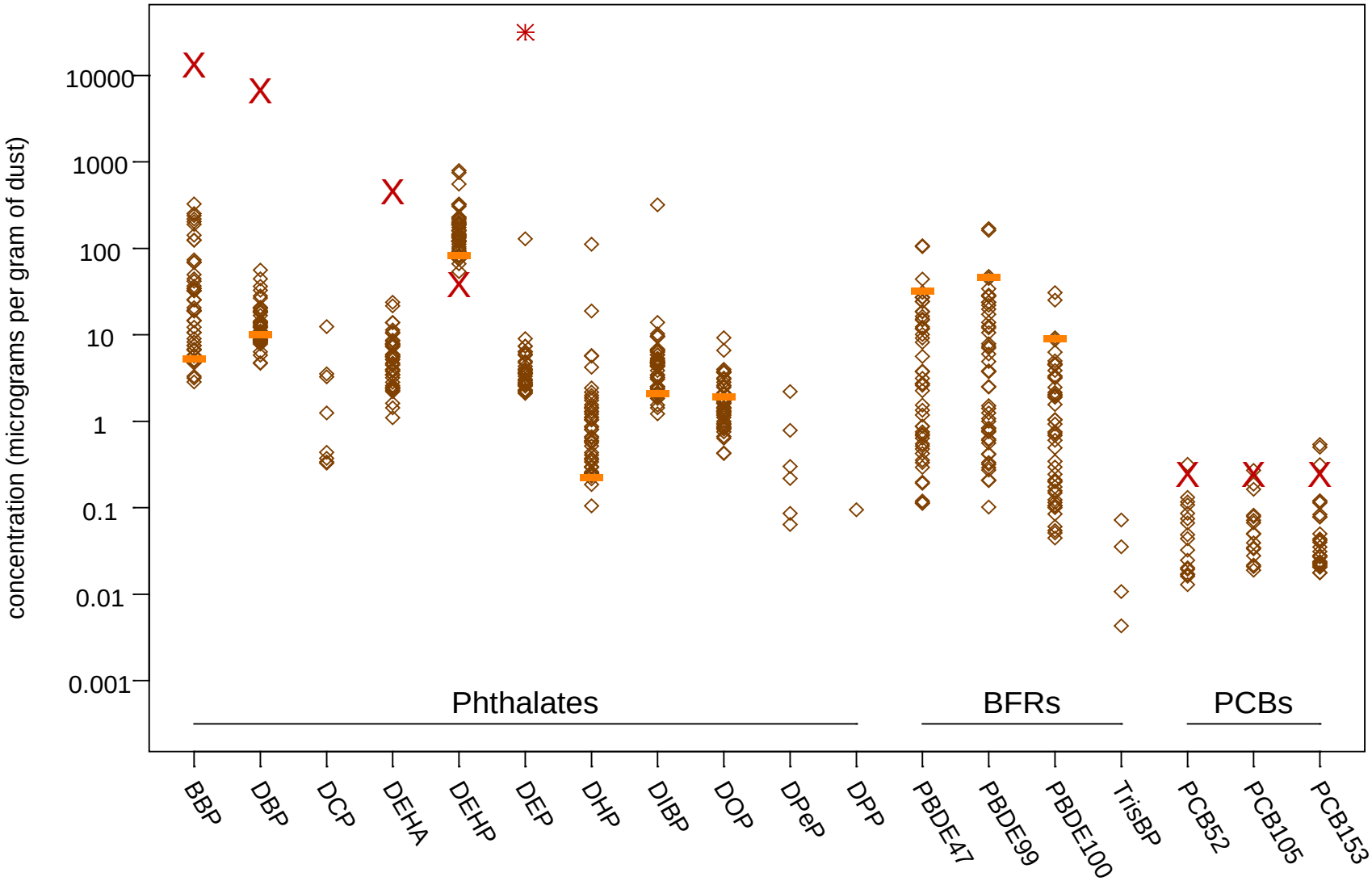
Phthalates, BFRs & PCBs in Dust

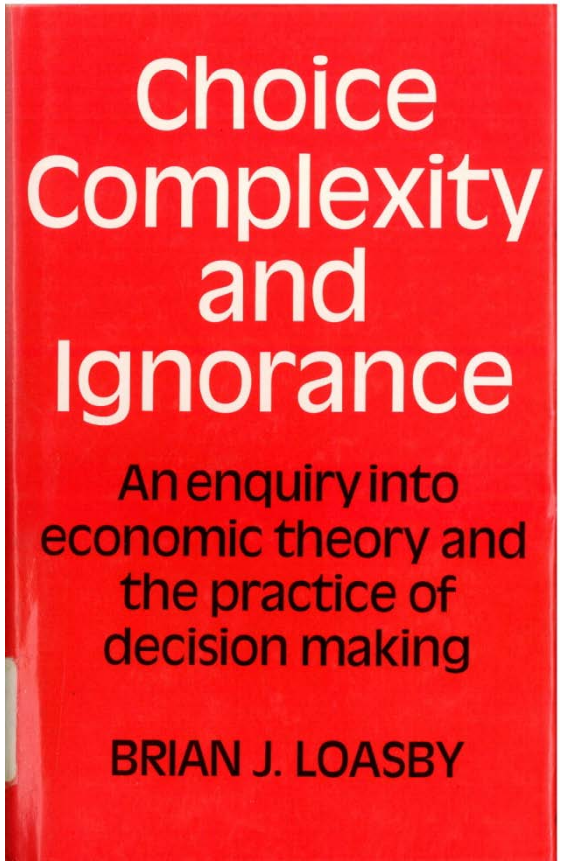


Risk-based guidelines

- Useful – we want a health-based benchmark . . . but

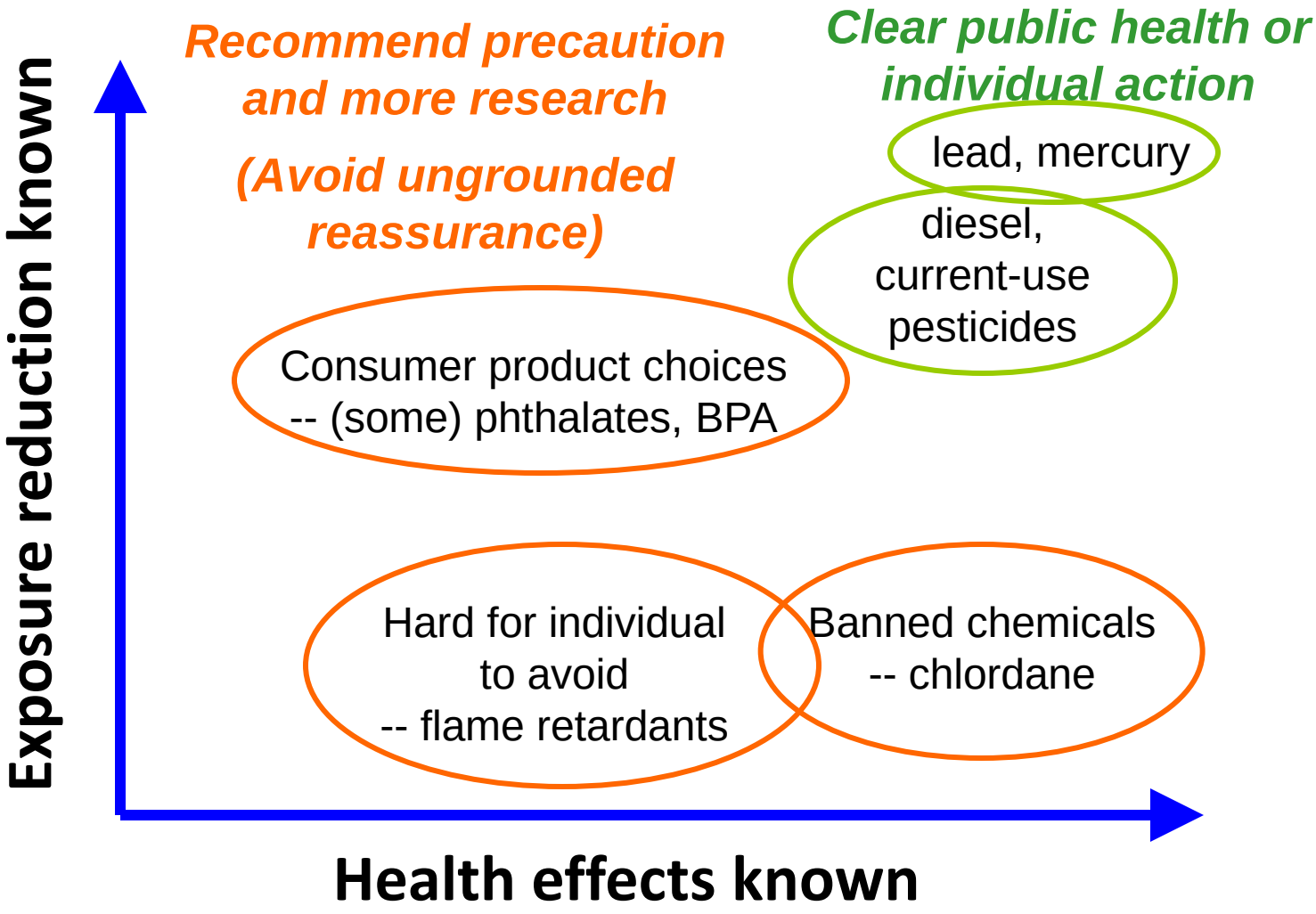
- Reference values are inconsistent, outdated, incomplete
- Many assumptions to derive equivalent bio-level from rodent intake amount
- Insufficient data on population variability in pharmacokinetics and dynamics
- Don’t consider combined effects
- Fail to communicate high level of uncertainty

Risk assessment-based “bright-line” approaches, while useful, can hide uncertainty and provide false reassurance



“We shall find a variety of devices which allow ignorance to masquerade as knowledge so that choices may be made . . .”

What should I do?



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Your house was selected for retesting because we detected high levels of PCBs

The levels of PCBs in your blood were . . . among the highest of 4,000 people tested in a national survey by the US Centers for Disease Control.

This suggests that the PCBs in your house are an important source of your overall PCB exposure. . . . We can't tell from these tests what the sources are in your house.

PCBs were used in electrical equipment, such as transformers, some fluorescent lights, and other products listed on the back of this page.

At high exposures, PCBs affect thyroid hormones and brain development. Scientists have found that eating fatty fish – for example, sea bass, blue fish, and lobster tamale – is usually a significant source of exposure.

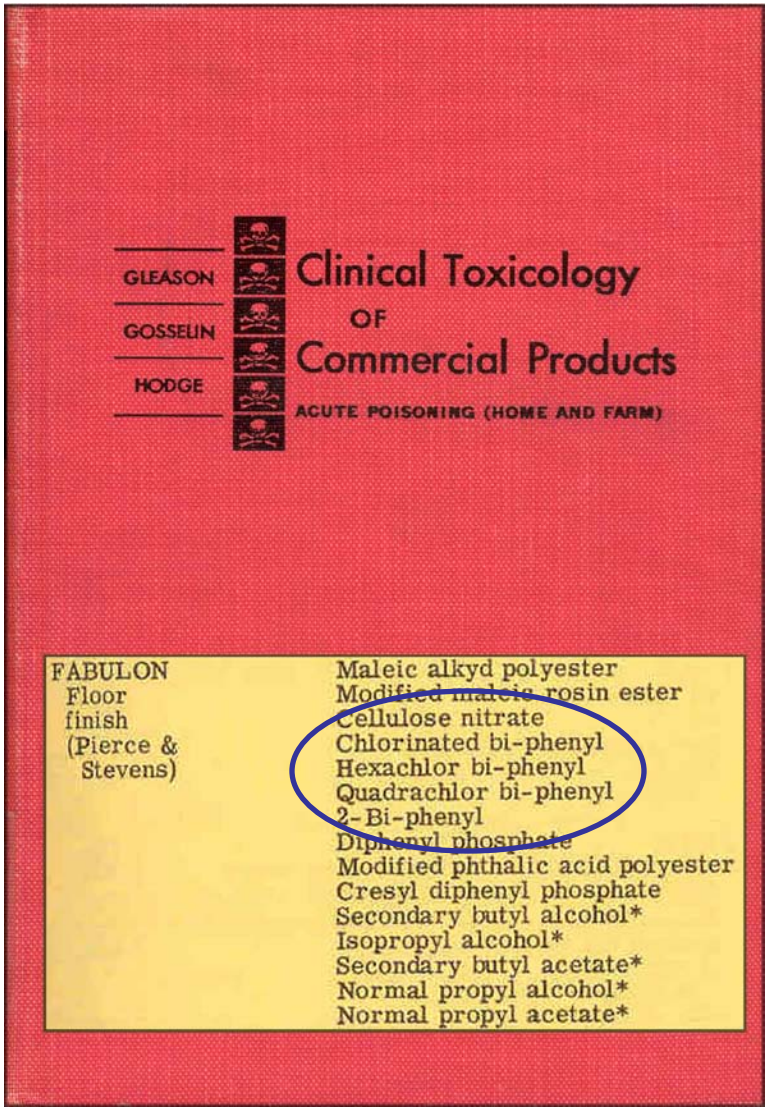
Let's follow up with a phone conversation about this.

Cape Cod homes with high levels of PCBs:

5 years later

- Air concentrations still high
  - 3-10x higher than EPA guideline (3 ng/m3)
- Dust also
  - 100-1000x higher than EPA guideline (0.22 μg/g)
- Blood levels above 95% level in national survey
- What is the source?

Entry from 1957 edition lists PCBs as ingredients of Fabulon wood floor finish



Previously unidentified source of PCBs

Rudel, Seryak, and Brody. 2008. *Environmental Health*

Follow up of high exposed individuals

- Responsive to individual expectations
- Consistent with a surveillance program
- Can produce important new information
  - ID high exposed populations
  - discover undocumented sources
  - describe population exposure variability
  - highlight where public health intervention and study could be most fruitful

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All the cited papers are available on our web site

www.silentspring.org