

Reckless Nation, Contaminated Nation: Some Legal Strategies to Reduce Risks to Children

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Overview

- Describe the contamination of citizens and sketch some findings from developmental toxicology
- Review failures of reckless post-market laws
- Diagnose some of the failures
- Learn from the ethics of medical experimentation and pre-market laws
- Suggest more prudent legal structures

Summary of Science

- Citizens are contaminated by 250 manmade substances (will be more). (CDC Biomonitoring Program)
- Women's contamination is shared with developing children *in utero*--**placenta no significant barrier**--and by nursing.
- Children have **lesser defenses against toxicants**--reduced immunity, slow developing blood-brain barrier, etc.
- Children often have **greater exposures than mother per body weight** and increased childhood exposures for physiological and behavioral reasons.

Summary of Science

- Organ systems are **especially vulnerable during development**, e.g., brain, immune, lung, reproductive systems.
- Developing fetuses and neonates are generally **more vulnerable** than adults **at identical exposures**.
- The **timing of exposure** is quite important during development.
- Adverse effects can be latent until much later in life, e.g., toxicants can accelerate cancers or dementia.

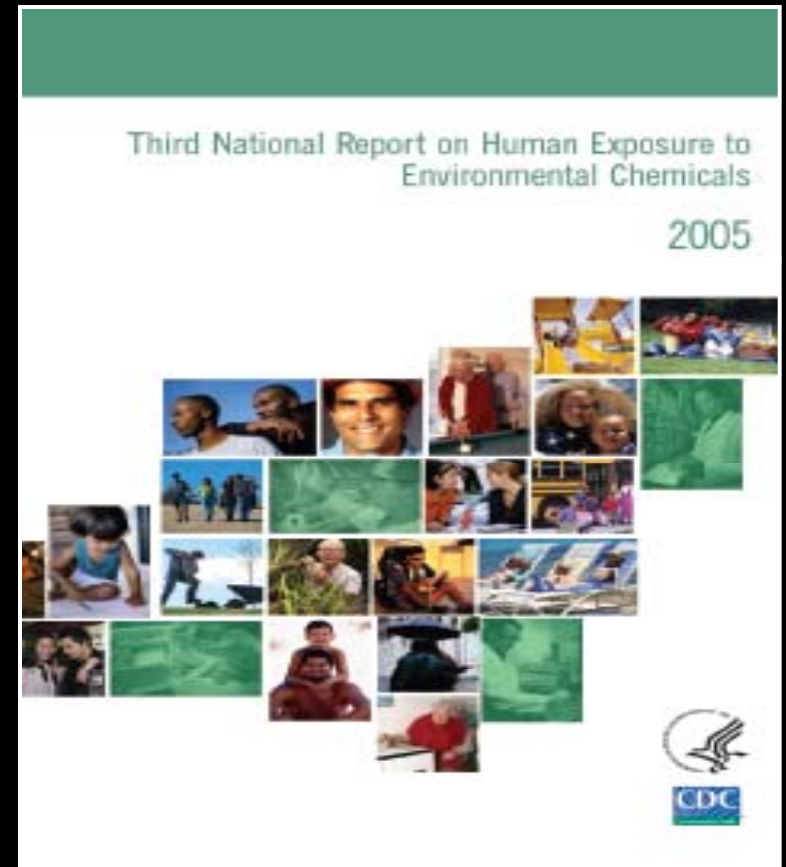
Contamination

Chemicals in 3rd Report

~148 chemicals

Exposure biomarkers for:

- Metals
- Polychlorinated biphenyls, dioxins and furans
- Organochlorine pesticides
- Carbamate pesticides
- Organophosphorous pesticides
- Pyrethroid pesticides
- Herbicides
- Polycyclic aromatic hydrocarbons
- Phthalates
- Phytoestrogens
- Pest repellants
- Cotinine
- VOCs



www.cdc.gov/exposurereport

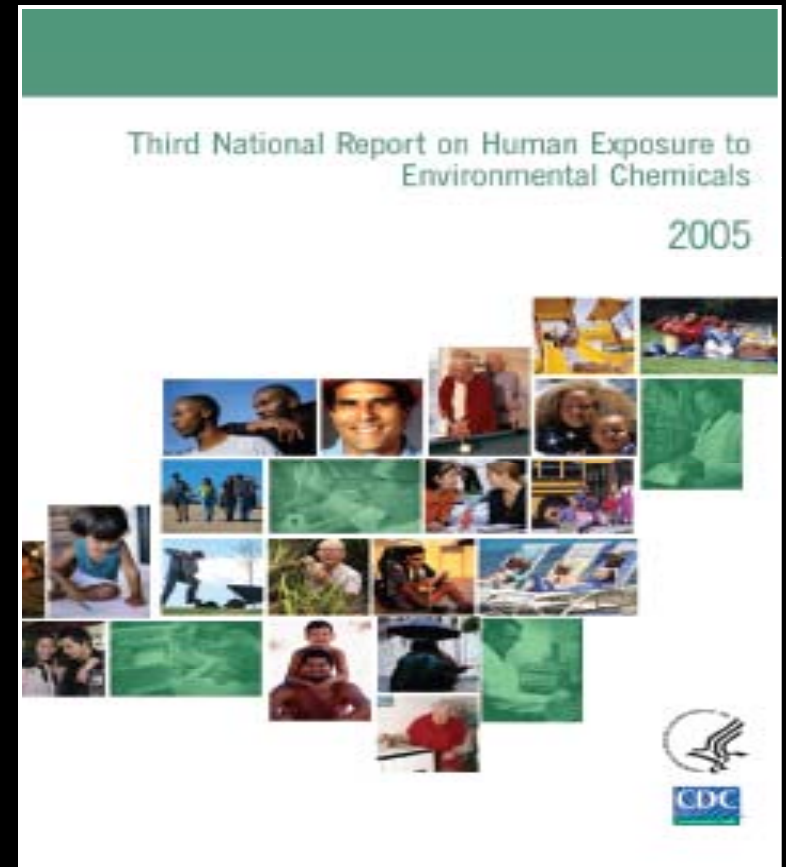
Courtesy Larry Needham

Chemicals in 4th Report

~250 chemicals

Exposure biomarkers for:

- Metals
- Polychlorinated biphenyls, dioxins and furans
- Organochlorine pesticides
- Carbamate pesticides
- Organophosphorous pesticides
- Pyrethroid pesticides
- Herbicides
- Polycyclic aromatic hydrocarbons
- Phthalates
- Phytoestrogens
- Pest repellants
- Cotinine
- Perfluorinated chemicals
- Brominated flame retardants
- VOCs
- Perchlorate
- Bisphenol A & Alkylated phenols
- Triclosan
- Sunscreen agent
- Speciated arsenic
- Acrylamide
- Parabens



www.cdc.gov/exposurereport

Courtesy Larry Needham

Centers for Disease Control Biomonitoring

- There are not more substances in citizens from the *Third Report* to the present.
- CDC has reliable protocols for identifying more chemicals.
- Most citizens are contaminated by most of these substances.
- More contaminants likely will be revealed in the future.

A Bit More Developmental Toxicology

Women's Contamination will Be Shared with Developing Fetuses and Newborns

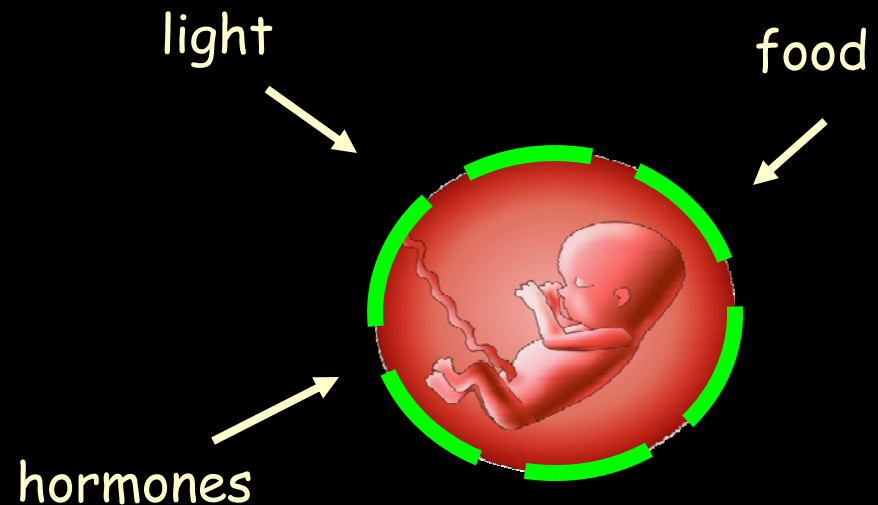
- 1965: The womb was seen as a time capsule, **relatively impermeable** to circulating drugs or toxicants. (Needleman & Bellinger)
- Contradicted early on by methylmercury and thalidomide followed by DES; now more evidence.
- There is “no placental barrier per se: the **vast majority of chemicals given the pregnant animal (or woman) reach the fetus** in significant concentrations soon after administration.” (Schardein, 2002)

Development is a genetic program



Mother is the fetal incubator

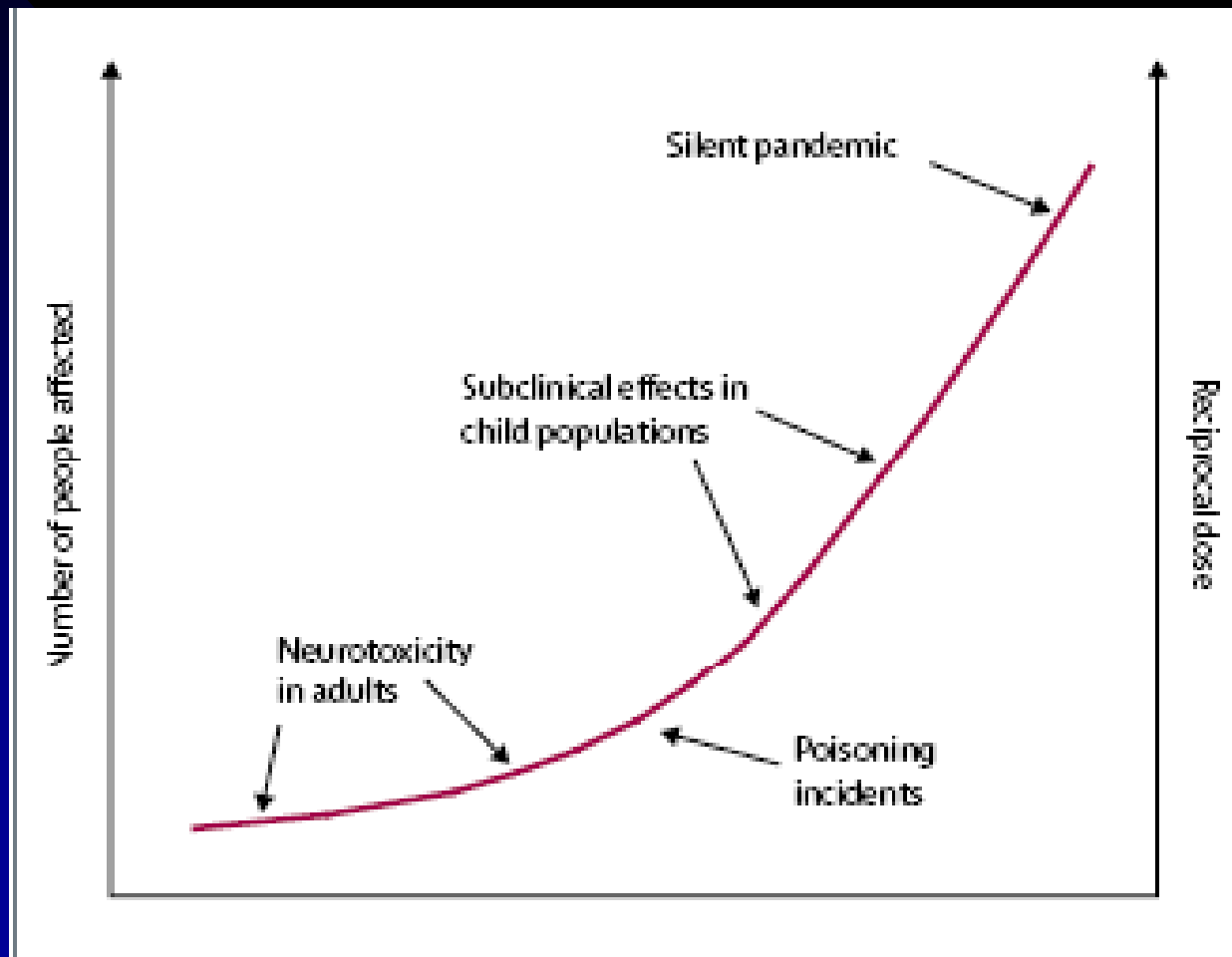
Development is an open system (developmental plasticity, ECO-DEVO)



Mother is the fetal environment

Courtesy
Ana Soto

Neuro-toxicity Conjecture



Tiny doses;
large populations;
sub-clinical effects
for developmental
neurotoxicity

Figure 1: The effects of a neurotoxic chemical on a population over time

Landrigan &
Grandjean, 2006

Evidentiary Picture

The evidentiary picture may be something like a pointillist painting with parts of the picture filled in with some data points, other parts blank, but the general background reasonably solid.

The end result is of considerable concern.

Failures of the Legal System

Failures of the Legal System

Post-market laws will not prevent sub-clinical toxicity; they are **reckless toward children's health** and **permit companies** to be reckless as well.

The U.S. and countries with similar laws need to develop more prudent approaches to preventing sub-clinical effects in children that have potential long-term adverse effects.

Failures of the Legal System

Generic legal strategies

Post-market laws

No required testing

Technology-based

Ambient exposure laws
Time-consuming,
science-intensive, &
burden of proof favors
contaminator

Endocrine disrupter
Screening program

Pre-market laws

Pre-mkt *notification* laws (1979)

No required testing; only
submission of what is known

Pre-mkt *testing and
approval* laws:

require testing &

agency approval for

drugs, pesticides, new
food additives (~10-20%).

Failures of the Legal System

The U.S. legal system regulates the **vast majority** (80-90%) of chemical substances with **post-market** laws:

- products are permitted into commerce without any **legally required pre-market testing**, and
- remain in commerce until a regulatory agency
 - bears a legal and scientific burden of proof sufficiently strong to change the status quo to reduce exposures or remove them.
- Typically an agency must show that they pose **risks of harm** (can come close to requiring **harm**).

Failures of the Legal System

Technology-based laws require a governmental agency to find that a substance causes a risk and then to employ some *appropriate* technology to reduce it. (Try as hard as technology permits to protect the public.)

Ambient Exposure laws require a governmental agency to find that a substance causes a risk, determine the potency of the substance, the amount of exposure that would produce adverse effects, and then indicate some overall risk characterization for setting ambient exposure levels to it. (Very science-intensive, costly and time-consuming).

Failures of the Legal System

To show risks of harm has become increasingly difficult:

- *In theory* most post-market laws regulate **risks** and use surrogates, e.g., **animal studies**, other **non-human evidence**, to identify the risks before they cause actual human *harm*.
- Agencies are under increasing pressure to to substantiate claims with **multiple sources of data** and **multiple studies** as well as greater documentation (takes time, great expense).

Failures of the Legal System

- No science, no legal protections.
 - Do not produce data that will harm your product.
 - Cast doubt on other's science.
 - Advocate high standards of proof with multiple and duplicative studies.
 - Less honorable tactics: mislead agencies, salt literature with misleading studies, have lawyers ghost-write scientific papers, and so on. (Michaels, *Doubt is Their Product*, 2008)

Failures of the Legal System

Proposed health protections under post-market laws become mired in a swamp of **procrastination**, **obfuscation**, and **endless disputes** about the **science** and legal procedures.

Not an accident: **“Doubt is our product!”** (from a tobacco industry memo followed by many others). (Michaels, *Doubt is Their Product*, 2008; Cranor, *Science*, 2008)

Scientific Ignorance of Toxicity

NRC Details:

- 12,860 substances produced in excess of one million lbs/yr (78% no toxicity data). Post market
- 13,911 chemicals < 1 million lbs/yr produced (76% no data). Post market
- 8,627 food additives (46% no data). Some post market
- 1,815 drugs (25 % no data).
- 3,410 cosmetics (56% no data). Post market
- 3,350 pesticides (36% no data). (NRC, 1984)

Scientific Ignorance of Toxicity

- Early 1990s: insufficient change in the data to justify updating the 1984 findings. (J.C.Bailar, E. Bingham, 2002)
- About 2000-3000 new substances are added each year **without legally required testing** under TSCA's pre-market **notification** provision. (Goldman, 1998, 1999; IOM/NRC 2006)

Failures of the Existing Legal System

Generic legal strategies

Post-market laws No required testing

Technology-based

Ambient exposure laws
Time-consuming,
science-intensive, &
burden of proof favors
polluter

Endocrine disrupter
Screening program

Pre-market laws

Pre-mkt notification laws (1979)
No required testing only
submission of what is known

Pre-mkt **testing and
licensing** laws:
*require testing &
agency approval* for
*drugs, pesticides, new
food additives.*

Failures of the Legal System

Pre-Market Laws: Pre-market Notification Provision of TSCA

- All chemicals submitted for manufacturing must undergo a **pre-market notification**--a company must submit to EPA what it knows about a substance; EPA has 90-180 days to permit manufacturing or not. (It may request further testing.)
- **No** legally required testing of such products; if companies have test data, they must submit it. If not, they need only provide what they know.
- It probably has some deterrent effect.
- This law **invites scientific ignorance** about products.

Failures of the Legal System

Generic legal strategies

Post-market laws

No required testing

Technology-based

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Time-consuming,
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Endocrine disrupter
Screening program
(instituted 1996)

Pre-market laws

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Failures of the Existing System

Endocrine disrupter Screening Program 1996 Food Quality Protection Act (FQPA) and the 1996 Amendments to the Safe Drinking Water Act (SDWA)

- As of 2005, EPA still **had not**
 - Elected the 50-100 chemicals with high potential for human exposure to be screened.
 - Identified the administrative procedures to be followed,
 - Identified the validated tests or the the battery of tests to be included.
 - Identified the time frame for testing or receiving the data.
- **No substances** addressed to **reduce exposure**.

Proposition 65

Proposition 65 is a post-market law that has some features that assist public health protections.

The governor must publish a **list of chemicals** known to cause **cancer** or **reproductive toxicity** based on the judgment of qualified experts.

Proposition 65

Burden shifting: Once substances are listed, then those who expose the public have a burden to

Issue clear and reasonable warnings about exposures,

generate more information

to show there is *no significant risk*,

to show there is **no exposure**, or

phase out the product, or

reduce exposure so there is no significant risk, or

pay a fine.

Proposition 65

- Uses **available data** from other agencies **better and more quickly** than other statutes--about 309 carcinogens and 225 reproductive toxicants have been listed.
- Utilizes **expedited potency assessments** to create “safe harbors” for businesses and to provide some (esoteric) protection information to the general public--appx. 150 potency values generated by this method--potentially usable by other agencies.
 - Greatly accelerates an important step in risk assessment: **1 chemical per day** v. **1 chemical every 1/2 to 5 person-years** (1 chemical every 180-1725 days). (Hoover, *et. al.*, 1995; Cranor, 1995)

Proposition 65

- It remains a post-market statute:
 - exposure continues until the science is developed, and
 - the legal effects of listing occur, and possibly beyond that.
- Whether or not it reduces exposures likely varies with different substances. It warns the public, but how much this results in altered exposure may not be clear.
- It assigns responsibility to companies that expose the public to toxicants.

Diagnosing the Failures

Diagnosing the Failures

Existing Laws are Misaligned with Science

- There is an **endemic delay** of *any* scientific investigation.
 - Explanation and understanding presuppose the existence or truth of something to be explained or understood.
 - Understanding, thus, logically and temporally follows the phenomena one seeks to understand.

Diagnosing the Failures

Existing Laws are Misaligned with Science

- Ordinarily, there is little or no urgency to understand or explain some phenomena, e.g., the orbit of the moon or DNA replication.
- In public health there is greater urgency to understand adverse effects to prevent or minimize any harm.

Diagnosing the Failures

Existing Laws are Misaligned with Science

- Under post-market laws, research likely begins after exposure reveals toxic effects, and lags the phenomena even longer than the “endemic delay” in scientific understanding.
- Understanding will be even slower when there are
 - **subtle effects** (v. normal variations),
 - diseases with **long induction and latency periods**, and
 - **developmental harms**, e.g., cancers, pesticide-caused Parkinson’s disease, any neurological effects from PBDEs.

Diagnosing the Failures

Existing Laws are Misaligned with Science

- **Research tools** and scientific and legal **standards of proof demanded** likely further delay coming to a satisfactory legal and scientific conclusion, e.g.,
 - Compare human epidemiological studies vs. other combinations of evidence;
 - Greater or lesser standards of proof to justify citizen protection.

Deeper Issues

- Cops and Robbers Laws
 - Most policing laws utilize publicly available violations to assist in enforcement.
 - Molecules are silent, invisible, typically odorless invaders
 - Not publicly detectable; citizens' senses cannot publicly assist detection.
 - No immediate injury or cause-effect feedback.

Deeper Issues

- Environmental health laws owe some **inspiration to nuisance laws** (Rodgers, 1994): immediate vibrations, blasting, unpleasant odors (e.g. pigs), smoke or dust or gas, loud noises, presence or noise of a bawdy house. (Prosser, 1984)
- Environmental health threats are quite different.
 - Toxic molecules differ from ordinary nuisances.
 - Nuisances announce their presence; with immediate feedback legal action can be taken.
 - Toxic molecules do not; legal action will be long-delayed.

Learning from Other Laws and Medical Testing

Learning from Pharmaceutical Laws

- Human volunteers *may not even be exposed* during experimental clinical trials of a drug without its having been previously *tested for safety in animals* in accordance with FDA protocols. (FDA, CDER)
- The **possibility of risks** to volunteers is sufficient to justify testing.

Learning from Pesticide Laws

The pesticide laws recognize the possibility of risks to citizens and require pre-exposure testing.

- A single chemical can contaminate citizens by multiple pathways.
- Several substances may act by a similar toxic mechanism.
- Pesticide laws increase protections for infants and children “whose developing bodies may be especially sensitive to pesticide exposure.” (U.S EPA)

Other chemicals are not significantly different.

Learning from Medical Experiments

I. Participation/informed Consent:

- The subjects must be “[Informed] volunteers . . .”, legally capable of consenting. (HD.20; NC.1) and at liberty to end the experiment at any time. (NC.9)
- Children “**should not be included in research** unless [it] is necessary to promote the health of the population represented and cannot be otherwise be performed. . . .” (HD.24)
- Experiment must be overseen and approved by an ethical review committee. (HD.13)

Learning from Medical Experiments

II. Preparations and Assurances of Safety

- There should be **prior research** on the safety and risks of the experiment. (NC.3, HD.11)
- Researchers should abstain from the research “unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed.” (HD.17)

Learning from Medical Experiments

II. Preparations and Assurances of Safety

- Proper preparations should be made to protect the experimental subjects against even *remote possibilities* of *injury, disability* or death (NC.7)
- In medical research on human subjects, considerations related to the *well-being of the human subject* should take precedence over the interests of science and society. (HD.4)
- *Concern for the participant is central.*

Learning from Medical Experiments

III. Scientific Oversight and Management

- There should be independent review of the experiment to ensure compliance with safety, aims and informed participation.

Learning from Medical Experiments

Ethical Constraints on medical testing: reveal shortcomings of post-market laws that permit contamination of citizens:

- No prior preparations and reasonable assurances of safety. *
- No careful assessment of acceptable doses. *
- No special concern for children; concern for contaminated person is not central. *
- No independent scientific or ethical oversight. *

Learning from Medical Experiments

Ethical Constraints on medical testing suggest revisions in the law to address existing problems:

- **Societal authorization** of laws permitting products into market and citizen contamination **only if** there is
 - Prior testing and reasonable assurances of safety with scientific oversight.
 - Better assessment of doses that may contaminate persons so that they pose no significant risks.
 - Special concern for children and greater concern for those who might be contaminated.

Toward More Prudent Legal Strategies

Toward More Prudent Legal Strategies

- It is biologically plausible (and highly probable) that industrial chemicals enter citizens' bodies and penetrate their tissues and fluids. Virtually all will; a few very large ones will not. (Larry Needham, CDC, 2005)
- Most substances enter our bodies in the same ways pesticides do and can have additive or synergistic effects similar to pesticides.

Toward More Prudent Legal Strategies

- It is biologically plausible that “The vast majority of chemicals given the pregnant animal (or woman) **reach the fetus** in significant concentrations **soon after administration.**” (Schardein, 2000)
 - Should we know this before substances enter the market and expose citizens and their developing children?

Toward More Prudent Legal Strategies

- Biological plausibility: developing fetuses and newborns can be **at live risk from toxicants** in their bodies. Human studies reveal this for some substances; animal studies document a wider range of chemical toxicity from *in utero* exposures.
 - Should we know which substances will and which will not pose risks pre-natally or neo-natally before exposures occur?
 - Or, should we permit exposures without testing, and wait for problems to be identified?
 - Is there some intermediate strategy between these possibilities?

Toward More Prudent Legal Strategies

- A “possibility of risks” model like those for drugs and pesticides, or
- A **battery/trespass** model, or
- A **permission** model such as REACH from the European Union.

Analogy with Pesticide and Drug Laws

- Because industrial chemicals enter citizens' bodies with many crossing the placenta, and there is the **live potential for risks** to children, before exposures occur they should be tested to identify risks, so that protective steps can be taken, if need be.
 - Utilize some analogies with drug and pesticide laws.
 - Begin the toxicity studies prior to a product's commercialization--**laws should better align the needed science and health protections.**

Analogy with Pesticide and Drug Laws

- It is wrong to commercialize industrial chemicals **knowing** they will enter people's bodies without understanding risks that might result. For pesticides there must be a "**reasonable certainty of no harm.**" (U.S. EPA) Specify this quantitatively.
 - *Nonthreshold toxicants:* aggregate exposure should not pose "**more than a 1 in 1,000,000 risk** of adverse effects in the population of concern,"
 - *Threshold toxicants:* ensure "an **additional tenfold** margin of safety to take into account . . . in-utero, infant, or childhood exposure to all sources of the chemical substance." (U.S. Senate Bill S.3040, 110th Congress, 2009)

Battery and Trespass-based Regulatory Laws

- An analogy with battery:
 - The integrity of a person should not be violated by **contact with an agent or a foreign substance** in a manner the recipient would **reasonably regard as offensive** without his or her permission [battery]. (*Prosser and Keeton on Torts*, 1984)
 - One could bring an action in battery in the tort law (*Mink v. U. of Chicago*, 1978) or use the idea of battery as justification for a regulatory law.

Trespass-based Regulatory Laws

- Since an unauthorized invasion is a wrong, we should have a **social contract** to require firms to test their products to determine **whether they will invade** and, further, whether they will cross the placenta or be carried in breast milk.
- If there are likely to be invasions, firms should test the products to provide reasonable assurance that there is a **reasonable certainty of no harm** to developing fetuses, newborns, developing children or adults.

A More Prudent Legal Strategy

- Those who create, manufacture, import and distribute industrial chemicals that invariably invade humans should be required
 - To conduct business in a manner to *reduce risks* and *avoid chemical battery* to developing children and adults (A major rationale of *licenses* is to reduce risks from an activity).
 - They should begin the science earlier and conduct tests before exposures occur to provide a reasonable certainty of no harm.
 - Test results should be reviewed by independent scientists before companies are *licensed* sell their products.

A More Prudent Legal Strategy

- NATIONAL RESEARCH COUNCIL: “All new and existing environmental agents should be evaluated; [but], the intensity and depth of testing should be based on practical needs, [e.g.,] the use of the chemical, likelihood of human exposure, and . . . science-policy [issues at stake].” (NRC, 2006)
- “[I]t is neither practical nor desirable to attempt to test every chemical (or mixture) against every end point during a wide range of life stages. . . .
 - [Test] every agent for which there is a strong potential for human exposure. . . .
 - [Design a test strategy] that would trigger more in-depth testing for various end points or in various life stages.” (NRC, 2006)

REACH: License Model

“No safety data, no market”

Registration, Evaluation, Authorization and Restriction of Chemicals

- Requires the testing of 30,000 new and existing chemicals under REACH. This holds some promise as a model.
- REACH is a *license-based* law: manufacturers and distributors **have no permission** to enter EU's market without **safety data** on their products.
- They must conduct tests and provide safety assurances; these vary with production volume.
- Whether or not this will work for sub-clinical developmental effects depends upon the tests that are authorized.

REACH: License Model

“No safety data, no market”

- Concerns about costs are likely exaggerated:
 - Independent researchers estimate that testing 30,000 new and existing chemicals under REACH to be 2.3 to 3.5 billion euros over 11 years (1 euro per citizen per year for 11 years).
 - Required testing may increase costs of chemical products 1/16 to 1/5 of one percent. (Ackerman, 2006)
 - Even if the costs were several times higher, they would not seem unreasonable.

Conclusion

- Without more prudent legal strategies, we will have to rely upon
 - **time-consuming** science bogged down in obfuscation, procrastination, and delay
 - well **after the fact** of exposure and contamination
 - to confirm on a **case-by-case** basis
 - against **powerful political groups** and difficult **scientific and legal burdens and standards of proof**
 - that there are risks or **actual harms** resulting from early exposures.
- Any harms will be perpetrated through decades of annual cohorts before they are identified, and prevented for others.
- This will not protect our or our children's health.



Thank you