Tragic Failures:

How Law and Science Fail to Protect Our Health

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THE ROMANELL LECTURES

TRAGIC FAILURES

How and Why We are Harmed by Toxic Chemicals

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Examples of Legal Failures

- Jeremy Darling—fell on crossbar of bicycle in DuPont C8 plant, hurt his groin, pain did not go a way; he was diagnosed with testicular cancer, associated with C8. Treatment cost $75,000, leading to bankruptcy.
- Co-worker Ken Wansley, a lab analyst, worked with C8 or PFOA, saw fine powder in the air, said it felt like soap. He contracted ulcerative coitis, known to be associated with C8 exposure, and ultimately rectal cancer.

Examples of Legal Failures

- Carla Bartlett, lived near a DuPont plant, drank tap water contaminated with C8, and later developed kidney cancer. Jury awarded her 1.6 million for her disease, known to be associated with C8 exposure.

- Sandy Guest, a hairdresser, used Brazilian Blowout, which was “loaded with formaldehyde,” became sick and eventually died of leukemia, a known outcome of formaldehyde exposure.

Overview

- *When* scientific studies are used to determine toxic effects is an important social (ethical) decision.
  - Premarket laws are far superior to postmarket laws
- *How much* and *what kinds* of data are required to remove substances from commerce are also important social (ethical) decisions.
  - We should not use “ideal” or “doubt free” science to protect the public.

Generic Legal Strategies for Protecting the Public' Health

Postmarket laws

Substances enter commerce with *no legally* required routine testing or approval (90-80% of industrial chemicals).

Endocrine disrupter Screening program

Premarket laws

Pre-mkt *notification law* (1976 TSCA) No routinely required toxicity data; only submission of what is known or what EPA requests.

Pre-mkt testing and approval laws *legally require routine* toxicity *testing & agency approval,* for drugs, pesticides, new food additives (~10-20%).

When Science Is Used to Determine Toxic Effects is An Important Social (Ethical) Decision

- Premarket laws: use the tools of science to try to identify toxic products before they enter commerce and they much better protect the public, and children in particular, from harm.

- Postmarket laws: legally call on science well after exposures, risks, and potential harms have occurred and poorly protect the public.

Developing Children Are of Special Concern

- Have greater exposures per body weight.
- Are more susceptible to toxicants.
- Have lesser defenses.
- Have a longer lifespan for diseases to develop.
- Several adverse effects appear irreversible.

(Cranor, *Legally Poisoned, 2011, 2013)*

When Science Is Used to Determine Toxic Effects is An Important Social (Ethical) Decision

- For forty years U.S. legal protections have been dominated by postmarket laws, especially the 1976 Toxic Substances Control Act and some subsidiary laws such the Safe Drinking Water Act, the Clean Air Act, the Clean Water Act and the Occupational Safety and Health Act.

Shortcomings of TSCA

- It legally created ignorance about chemical creations:
  - 62,000 substances were grandfathered as “safe”

Shortcomings of TSCA

- It created ignorance about chemical creations:
  - 22,000 new chemicals entered commerce without any required toxicity testing.
  - Companies must provide “all available data on chemical identity, production volume, by-products, use, environmental release, disposal practices, and human exposures.”
  - No requirements for toxicity data

Shortcomings of TSCA

- Considerable toxic ignorance resulted
  - 70-75% of all chemicals lack sufficient data to conduct adequate risk assessments. (NRC, 1984)
  - This was unchanged as of the early-1990s. (Bailar, Bingham, 2001)
  - About 85% of 84,000 lack health data. (CRS, 2007)

Shortcomings of TSCA

- TSCA invited even more ignorance:
  - If Company A tests a product but finds no toxic effects, it is free from legal requirements.
  - If its tests show the substance is toxic, the company is required to report that result to the EPA (If it complies with the law).
  - This only creates problems for itself; why test?

Shortcomings of TSCA

- TSCA invited even more ignorance for competitive reasons:
  - If Company A tests its products but Company B doesn't, then Company A's cost structure is higher than Company B's. Thus, both companies have competitive incentives not to test their products.
  - Many companies closed their quite good toxicology labs.

Shortcomings of TSCA in Implementation

- Since 1980 the EPA itself has required testing of only about 200 substances out of the 62,000 in commerce in 1979 (0.3 of 1%). Were the 61,800 remaining substances really “safe”? (GAO, 2009)
- The EPA has “rarely” imposed involuntary testing requirements on new substances; it is simply too burdensome. (CRS, 2007)

Shortcomings of TSCA in Implementation

- Because of ignorance consumers and businesses cannot choose between more toxic and less toxic alternatives
  - West Virginians were threatened by the spilling of 4-methylcyclohexane methanol, or MCHM. Was it risky, dangerous, or safe? No one knew or knows.

Shortcomings of TSCA in Implementation

- No choices between more and less toxic alternatives
  - After British Petroleum's Deepwater Horizon explosion and oil spill, BP sought to use a known dispersant to break up large oil slicks. Was it safe?
  - Top EPA officials knew it had risks, but knew nothing about the risks of alternatives to it.

Shortcomings of TSCA in Implementation

- No choices between more and less toxic alternatives
  - Bisphenol A is a known endocrine disrupter, but is being discontinued because of public pressures and scientific concerns.
  - Companies opted for Bisphenol S or F. Are they safe? Both have the same order of estrogenic potency as BPS or estradiol. (Rochester, Bolden, 2015)

Postmarket Barriers to Health Protections

- Because little scientific data are produced simultaneously with commercialization, research likely starts from scratch to determine any toxicity.
- Compare with premarket testing and approval laws: Toxicity research has been done and there are public data about the product and adverse reactions reports.
    - Researchers can return to both sources to glean possible toxicity information.

Postmarket Barriers to Health Protections

- Under postmarket laws even if wise, conscientious, well-motivated scientists seeking to protect the public's health begin research as soon as toxicity is suspected, assembling cumulative results to support improved health standards can take substantial time (years).

Postmarket Barriers to Health Protections

- This and company intransigence slow EPA's Integrated Risk Information System risk assessments:
  - TCE—causes cancer, birth defects, and Parkinson's disease—has been under review for more than 20 years.
  - Dioxin—carcinogen, transgenerational toxicant and endocrine disruptor—has been considered for 17 years. (GAO, 2008)

Postmarket Barriers to Health Protections

- EPA's slow risk assessments:
  - Perchloroethylene—probable carcinogen, contributor to neurological diseases, and groundwater contaminant—has been in the queue for 13 years.
  - Formaldehyde —a human carcinogen that also damages the reparatory system—has been under review for 17 years. (GAO, 2008)

Postmarket Barriers to Health Protections

- It has been impossible for EPA to reduce or eliminate even the risks of asbestos, supported by 45,000 pages of legal and scientific justification.

  (Corrosion-Proof Fittings, 1991).

- Tort (personal injury) law actions have probably eliminated some asbestos products from commerce.

Postmarket Barriers to Health Protections

- C8 or PFOA, the main ingredient in Teflon, is toxic, but there are no safe drinking water standards for it. DuPont and 3M have ceased manufacturing it.

- A persistent substance, it will remain in the environment and drinking water for decades, with a substantial latency period before it even shows up in some drinking water. (Learrner,2015; Bartell, 2016)

Postmarket Barriers to Health Protections

- Because of IRIS's sluggishness Clean Air Act and Safe Drinking Water Act protections have stalled or been halted altogether.

Why are Health Protections So Slow?

- Health agencies have the burden of proof and must find or generate needed data (from scratch) and justifications for better protections.
- Multiple studies must funded and conducted, but these have their own pace. Because of latency, diseases must have time to appear.
- Likely little research interest in chemical creations until there is some suspicion of their toxicity.

Why are Health Protections So Slow?

- Companies need only play *defense* and they are good at it; they have various strategies:
  - They follow the tobacco industry: “Doubt is our product since it is the best means of competing with the ‘body of fact’ that exists in the minds of the general public. It is also the means of establishing a controversy.” (Brown and Williamson, 1969)
  - They generate a “fog of science” to cast doubt on impartial studies and may insist on “ideal” science.

How Much and *What Kinds* of Studies Are Used to Protect the Public Are Important Social Decisions

- An important social/ethical choice: How much and what kinds of studies should be used to improve public health protections?

- Two (related?) strategies harm the public:
  - Acceding to the “doubt” arguments. (Tobacco Industry)
  - Acceding to “ideal” science. (Furst, 1990)

“Ideal Science”

- Example of “ideal science” for carcinogens: “There should be a close agreement …
  - From well-designed epidemiological studies of exposed populations with …
  - Good, valid animal bioassays …
  - Corroboration from short-term tests will strengthen the association. …
  - [and] the mechanism of action of the agent . . . [must] not undergo a process or require an organ for which there is no human counterpart.” (Furst, 1990)

Shortcomings of Ideal Science

- Requiring epidemiological studies is problematic: They
  - Are Insensitive, can fail to detect risks when they are present.
  - Can face long latency problems, e.g., DES (20 years), asbestos (up to 40-45 years).
  - May have insufficient understanding of subtleties of a toxicant, e.g., lead.
  - May have to rely on crude exposure data.
  - People must be sick or have died to have data.

Shortcomings of Ideal Science

- Using animal data is much better, but even this should not be “required” because on occasion these have not revealed the toxicity of products, e.g., arsenic, benzene.

Shortcomings of Ideal Science

- Distinguished scientific committees, i.e., IARC, do not require human data to identify known human carcinogens, e.g., the anti-caner drug CCNU; MOCA, an ingredient in the plastics industry; neutron radiation; some benzidine dyes. (IARC; NTP)

Contrasts with Ideal Science

- IARC lists 64 substances as *probable human carcinogens* but 35 lack human data—they were identified on the basis on animal studies, plus various kinds of mechanistic data.
- IARC regards both known and probable carcinogens as "*equally compelling cancer hazard[s]*," … it merely distinguishes between them based on strong human data (emphasis added). (Cogliano, 2008)

Contrasts with Ideal Science

- Mechanistic data has become especially important:
  - "data on preneoplastic lesions, tumor pathology, genetic and related effects, structure–activity relationships, metabolism and toxicokinetics, physicochemical parameters and analogous biological agents." (IARC, 2006)

- It can substitute "for conventional epidemiological studies when there is less than sufficient evidence in humans,[and] for conventional [animal] bioassays when there is less than sufficient evidence in experimental animals." (Cogliano, et. al., 2008)

Contrasts with Ideal Science

- IARC upgraded 6 agents to “known” and 38 agents to “probable” carcinogens based on mechanistic data.(Cogliano, et. al., 2008)

- Thus, 38 more substances that can cause cancer will be “live” candidates for instituting health protections. (California immediately listed glyphosate (Roundup) under Proposition 65 and France took some health-protective actions).

An Alternative to "Ideal" Evidence

- There should be no hierarchy of evidence for toxicity and no necessarily required kinds of evidence (Carbone, 2004).
- "It seems impossible and undesirable to build a scientifically defensible framework in which evidence is integrated in a completely explicit, fixed, and predefined recipe or algorithm." (NRC, 2014)

An Alternative to “Ideal” Evidence

- Sometimes there will be good human studies, sometimes not. Sometimes there will be good animal data and few or no human data. Sometimes good mechanistic data is available that can serve instead of animal or human data, and so on.

- Researchers and agencies should consider the *total body of scientifically relevant evidence* that is readily available to determine how it does or does not “fit together” to credibly assess the toxicity of a chemical creation. If missing data are needed to complete the scientific picture, they should seek it out or develop it.
(Cranor, 2017)

Shortcomings of Requiring Ideal or “Doubt-Free” Evidence

- Requiring “ideal science” will protect the public from few toxicants.
  - The public will not be quickly protected from a substance under review, because it will take a long time.
  - Other substances that should be addressed will also be delayed.

The “New” TSCA Improves Aspects of the “Old” TSCA

- The Frank R. Lautenberg Chemical Safety for the 21st Century Act amends the 1976 TSCA has
  - Premarket assurances that products pose no “unreasonable risks to human health.” (EPA, 2016)
  - Mandated schedules and procedures to review commercially “active” products in the market.
  - Must give priority to chemicals that are persistent, bioaccumulative, and are known human carcinogens or otherwise have high toxicity.

The Lautenberg Act

- Premarket assurances: EPA “must make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace.” (EPA, 2016)

The Lautenberg Act

- Susceptible subpopulations: EPA must “consider risks to susceptible and highly exposed populations [these may include infants, pregnant women, children and workers] and ensure a substance does not pose an “unreasonable risk.” (EPA, 2016)

The Lautenberg Act

- Mandated schedules: for addressing existing products in commerce. (EDF, EPA, 2016)

- However, the history of EPA actions (IRIS) and of industry intransigence raise concerns about the success of these requirements.

The “New” TSCA Improves Aspects of the “Old” TSCA

- Under the Lautenberg Act :
  - Even if it could conduct risk assessments and improve health protections for 20 per year, an unheard of rate, it would take 1,500 years to review the likely commercially “active” substances.
  - At the mandated 6-7 years per 20 substances the legacy chemicals from the “old TSCA” will exist for centuries.

Some Conclusions

- *When* and *how* we use science under public health laws (and personal injury law) are important social/ethical decisions.
- Premarket toxicity testing and review laws are vastly superior to postmarket laws. The U.S. has finally moved to this with the Lautenberg Act.
- Researchers, public health agencies and judges in personal injury cases should not accede to "ideal" or "doubt free" science in order to better protect the public.

Thank you