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The interaction of science and law in protecting the public's health

Carl F. Cranor

Department of Philosophy, Graduate Program in Environmental Toxicology, University of California, Riverside, California, United States

Summary. As public health interventions largely eradicated infectious diseases, chronic diseases became the leading causes of morbidity and mortality in developed countries. Too many chronic diseases result from environmental exposures caused by the actions or products of others. My research has addressed how science-law interactions can reduce or prevent diseases caused by others. A recent work, *Tragic Failures: How and Why We Are Harmed by Toxic Substances*, explores the relations between science and the law 1) in administrative law, which aims to prevent or reduce environmentally triggered diseases, and 2) in the tort or personal injury law, a venue to compensate people who have been harmed by the actions or products of others. While laws guide both institutions, science assists in discovering, understanding, limiting, and mitigating risks. How it is utilized matters. This article first considers the law-science interaction under administrative laws to protect citizens from environmentally triggered diseases or dysfunctions: "*When* should science be used to identify potential risks to protect the public?" and, "*How much and what kinds of scientific evidence should used* to reduce or remove risks from products once they are commerce?" Next, the discussion addresses, "*How much and what kinds of evidence should the tort law require* for plaintiffs to be compensated for injuries caused by others? I suggest a unified approach to address the "how-much-evidence-is-needed-for institutional-responses" in the law. Recent scientific findings hold the promise for quicker identification of toxicants to protect the public health.

Key words: postmarket laws, premarket laws, science-law interaction, mechanistic evidence

Introduction

For most of our history humans have been afflicted, even ravaged, by infectious diseases, plagues, and pandemics. At the turn of the 20th century public health officials in the U.S. and other industrialized countries intervened to reduce infectious diseases as a source of morbidity and mortality.

They removed horse manure from streets and cleaned up sewage in rivers, a source of drinking water and a place for recreational swimming, both contributing to diseases. Public health officers and physicians also chlorinated drinking water, developed antibiotics, and discovered and used vaccines to prevent most infectious diseases.

Consequently, chronic diseases - cancers, neurological disorders, immune dysfunctions, lung disorders, diabetes, and cardiovascular diseases - became the leading causes of morbidity and mortality (1, 2, 3, 4). These diseases "last 1 year or more and require ongoing medical attention or limit activities of daily living or both" (5). They also "generally cannot be prevented by vaccines or cured by medication, nor do they just disappear" (6). This range of diseases can also cause greater or lesser interference with a person's normal biological functioning, which can burden or even un-

dermine a person's normal good health and flourishing during several life stages. In two different legal venues—administrative health law and tort law—companies tend to demand "doubt-free" or "ideal" evidence before either legal action is taken.

Chronic diseases may result from voluntary behavior, bad luck, unfortunate genes, or the *actions of others* (1, 7). Too many chronic diseases for children and adults alike are environmentally caused and my research has addressed how we could use science in the law to reduce or prevent diseases caused by the actions or products of others.

A recent work, *Tragic Failures: How and Why We Are Harmed by Toxic Substances*, (7) explores the relations between science and the law for two different areas: one, administrative or regulatory law, aims to prevent or reduce environmentally triggered diseases, and the other, the tort or personal injury law, provides a legal venue to compensate people who have been harmed by the actions of others.

The law provides the rules of the game for both institutions, but science importantly assists in discovering, understanding, limiting, and mitigating risks. It offers important evidence in different legal venues to help assess whether or not the laws have been carried out and how well they protect us. Administrative laws differ in specifying *when* science should be used to protect the public. U.S. pharmaceutical laws require scientific studies of products before the public is exposed, but many environmental health laws only require the use of science after exposures and even after harms have been triggered. Choices of how science is used in administrative institutions such as the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA) and how they are administered can either put us at risk or better protect us. These choices are important matters of justice and are the concerns of *Tragic Failures* (7).

In what follows I develop two ideas about these areas of the law. First, I consider administrative laws to protect citizens from environmentally triggered diseases or dysfunctions. How has science been used and how can it be used in this effort? That is, "*When* should the law require the use science to identify potential risks to better protect the public?" How this is answered is a major moral and justice issue. An additional concern is, "*How much and what kinds of evidence should the law require* administrative agencies to utilize in order to reduce risks from products once they are in commerce?" (7)

Second, I discuss the law-science interaction in toxic tort law, a legal venue for compensating people for harms caused by others. In the tort law for the most part no legal action may be authorized to compensate for harmful exposures until there is evidence someone is harmed and others caused it. This poses an analogue of the second science-law issue for administrative agencies: *How much and what kinds of evidence should courts require* for injured parties (the plaintiffs) to receive compensation for their injuries?"

There is some commonality in answering the science-law questions about products in commerce. The more scientifically or legally difficult it is to remove or reduce exposures under administrative law, or to compensate others in the tort law for injuries suffered, the greater the injustice (7).

There has been a strong temptation on the part of companies whose products are threatened in each legal venue to demand "doubt-free" or "ideal" evidence before either legal action is taken. They try to insist on certain necessary kinds of scientific evidence to be established before an administrative agency can act against their products or a tort law judge permits a scientific case to go a jury. This approach, on the one hand, unjustly fails to protect the public under administrative law and blocks just compensation for injured parties, and, on the other hand, is contrary to widely shared scientific approaches to evidence. Thus, *Tragic Failures* proposes something of a unified critique of a widespread practice and a unified approach to address the "how-much-evidence-is-needed-for institutional-responses" in the law (7). Recent scientific developments may help provide quicker scientific evidence of toxicity in both legal venues.

Administrative public health laws

Broadly speaking two different administrative strategies seek to "prevent" diseases caused by toxic substances. 1) In the U.S. Congress chose the laws for pharmaceuticals (1962) and pesticides (1968) that require *prudent routine testing* of products and scientific

review of the studies for potential risks before products are commercialized and people would be exposed. These are premarket testing and review laws. Thus, if studies fail to show a proposed pharmaceutical is safe and effective, it does not receive approval. Somewhat similar, but not identical requirements were placed on pesticides proposed for commercialization (7). Insufficient toxicity data, no market.

2) In sharp contrast to, and rejecting premarket testing laws, slightly later Congress chose *postmarket* laws to govern the vast majority of general chemical products under the Toxic Substances Control Act (TSCA) (1976). First, TSCA grandfathered as "safe" an inventory of about 62,000 *existing* "general" substances manufactured or imported into the United States (7).

Second, for "new" substances not on that inventory, Congress authorized their review without any blanket requirements for *prudent testing* and scientific review. It adopted the legal device of Premanufacture Notifications (PMN) for new products. This only required, "all available data on chemical identity, production volume, by-products, use, environmental release, disposal practices, and human exposures" (8). Routinely required toxicity testing of the product was missing from this provision, because Congress prohibited it (9). If the EPA could discern evidence of toxic effects from the minimal data submitted in a PMN, it could order needed toxicity tests, but even issuing the order could take up to three years with a rule-making procedure or court order. (7) The consequence was that about 22,000 products entered commerce with little to no understanding of their toxic properties. This brought the total inventory of chemical products to about 84,000. (7)

The multiple public health failures of postmarket laws

This law and some other postmarket laws issued about the same time fail to protect the public from harm, invite informational and scientific overkill to remove harmful products from commerce, and are unjust.

Failures in legal requirements: Apart from the inadequate protections of PMNs, a characteristic of TSCA and other postmarket laws is that the appropriate administrative agency in order to "protect" the public must already have evidence of serious risks or actual harms to some people before the EPA can act in conducting extensive risk assessments and prevent further harm (7). That is, those "first harmed" or "first at risk" became experimental subjects to trigger legal responses to prevent harms to others. However, when there are insufficient data under the law, there are no protections for the public.

In order to reduce risks from products already in commerce under the 1976 TSCA the EPA had to show that there were "unreasonable risk[s] of injury to health or the environment" (8). However, satisfying this informationally intensive and burdensome standard (10) was too difficult to meet for the deadly substance asbestos (9). The agency had to consider the probability and severity of risks and benefits to the public, the costs of regulation, impacts on small businesses, substitutes for the substance, and so on, and then choose the least burdensome means of reducing risks. Ten years after hearings and proceedings backed by 45,000 pages of scientific and legal documentation the U.S. Federal Court of Appeals for the Fifth Circuit struck down EPA's 1989 proposed ban of all uses of asbestos in the U.S. (11). If asbestos cannot be withdrawn from the market, observers argued, no substance could be; the court's view of legal requirements was simply too onerous.

Similarly, laws governing the release of factory effluents into rivers or harbors under the Clean Water Act (CWA) only forbid this *if the effluent is already listed as toxic* under CWA (12). Contaminants in drinking water under the Safe Drinking Water Act (SDQA) can only be regulated if they are already on a list of identified toxicants (13). Finally, a similar listing law applies to toxic air pollutants under the Clean Air Act (CAA) (7). Thus, if there is insufficient data of toxicity for legal purposes, there will be no health protections from possible toxicants. No data, no protections.

The point: Health risks from commercial products under old TSCA or pollutants under the CWA, SDWA, or CAA can only be reduced or eliminated if they have *already been legally identified as toxic* (and under CWA, SDWA and CAA properly listed). Even worse, the last three laws have not been updated in a couple of decades (7, 14).

For another example, the perfluorinated compounds PFOA (perfluorooctanoic acid) or C8 in consumer products and pollutants that have entered the

water and air since the mid-1960s have been found to be toxic by researchers. Exposures to this particular substance at environmental concentrations have caused a variety of diseases, including kidney and testicular cancer, ulcerative colitis, high cholesterol, pregnancy- induced hypertension, and thyroid disease (7). Tort law settlements have awarded compensation for injuries from C8, but so far neither has been regulated under either CWA or SDWA (7). Other researchers are concerned C8 may contribute to a wider range of diseases, including ovarian cancer, prostate cancer, lymphoma, reduced fertility, arthritis, hyperactivity and altered immune responses in children, and hypotonia, or "floppiness in infants" (15).

Consequently, under postmarket laws any "protection" of the public typically occurs *only after and probably substantially after the public has been exposed to the substances and some people likely harmed*. Belated use of science offers poor and inadequate protections. The normative result? Postmarket laws are unjust because they a) permit harm to the public, b) undermine lifetime opportunities people would have with good health, and c) impose economic externalities that shift costs from the companies to those harmed, typically those less well-off in the community (7).

*Scientific hurdles in public health efforts to show harm***:** The post-exposure, post-risk feature of the science-law interaction under postmarket laws is only part of the story; further shortcomings are evident. Once a product is in commerce earning income, a company has powerful incentives to defend it, resist its removal, reformulate it, or reduce toxicants in a pollution stream because any of these actions will likely reduce its profit margins.

Features of science exacerbate the problems. Typically producing any science needed to reduce risks is likely slow. Studies march to their own drummers (sometimes funeral dirges) and the slower the studies document risks, if exposures are great enough, the more people will be harmed (7, 10). This poses a second major question, "How much and what kind of science must be shown to protect the public from products in commerce (discussed below)?"

Company behavior exacerbates answering these problems. There is a temptation for a company whose products are in commerce to insist and try to persuade administrative agencies that risks from their substance should only be reduced or removed by providing "doubt-free" or perhaps "ideal scientific evidence" of risks (16, 7). Most companies follow the tobacco industry in casting doubt on studies they find unfavorable to their products (16).

Some approaches come close to urging "ideal science" before taking action to reduce risks (this is more obvious in the tort law (below)). Arthur Furst, a well-known toxicologist (now deceased), provides a scientific example of this for identifying a substance as a carcinogen. (17) Roughly speaking, Furst required several well-designed human epidemiological studies supported by good and valid animal data at exposure levels similar to those found in human studies, further corroborated by short-term tests and biological mechanisms that function similarly on analogous organs in humans and animals. He also suggested that if any of these considerations was missing, there was not yet a scientifically proper case that the substance was a human carcinogen (7, 17). This proposal sets a very high scientific hurdle to clear before acting on toxicants, paralyzing health protections.

Companies strongly resist removing their products from commerce by approaching his view. They insist on high degrees of certainty about the science, "cast doubt" on others' evidence, and too often by engage in less scientifically honorable tactics. These include studies favoring company views when it paid for the research (18), hiring experts known to produce company-friendly outcomes (19), altering the outcome of study results (16), designing studies unlikely to find adverse effects worse than those already known (20), having lawyers "ghost-write" articles for scientific publication and then seeking scientists to sign on to the article (21), and sometimes engaging in outright fraud as found by a court (22).

The public health failure of postmarket laws: Even though agencies must act within their governing laws, they should resist as best they can corporate pressures to slow health protections. To do this they will often have to sort through misleading, sometimes fraudulently submitted evidence urging inaction. In addition, there are some recent scientific findings that facilitate

the quicker production of science (7). Moreover, the International Agency for Research on Cancer (23, 24), the National Toxicology Program (25), the National Academy of Sciences (26) and individual researchers (27, 28) have identified scientific approaches that could expedite identification of harm, often by utilizing mechanistic data with combinations of other evidence. Unfortunately, agencies are also further handicapped because of some concerted congressional efforts and presidential actions to reduce funding for agencies and undermine their efforts in the name of "easing regulatory burdens" on businesses.

The effects of toxicants on children

While such laws poorly protect adults, children are at even greater risk. As children develop biologically from fetuses, through childhood and teenage years to adulthood, research shows they are especially vulnerable to toxic exposures (29).

Children's biology during development is more easily damaged by toxicants. They have greater exposures per body weight *in utero* and after birth. They have lesser defenses than adults against toxic invasions, and they have a longer lifespan for diseases to materialize if they are triggered early in life (29). Moreover, some of the adverse effects affecting the brain, immune system, and probably the reproductive system are irreversible. Individual genetic variability exacerbates these risks (7, 30).

The Biomonitoring Program at the Centers for Disease Control and Prevention has found that adults and children alike are contaminated by about 300 manmade toxicants (31). Pregnant women can harbor up to 43 toxicants that would be shared with developing children *in utero* (32, 33, 34). And, babies have been born with toxicants in their bodies (35, 36).

No magic cloak prevents human permeability or developmental vulnerability to toxicants. 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" (37). New technologies are joining the invasions: plastic nanoparticles can move from mom to baby through the placenta (36).

A quite important point about lifetime exposures follows from these observations. Given environmental exposures to toxicants and the tendency for nearly all of them to enter our bodies and to remain there for shorter or longer times, we will be susceptible during many life stages: entering a contaminated environment at conception, *in utero*, in early childhood, during puberty, during pregnancy (for women), and then in older age (38). Each of us is not merely exposed prenatally and then home free from disease. We are potentially at risk from early life exposures that may be augmented over a lifetime. Thus, it is important to test for such effects to understand when this occurs in order to protect the public (39). Postmarket laws have permitted toxic products into the public sphere, while substantially burdening and frustrating their removal. Our mammalian biology makes us vulnerable as a result. Thus, it is quite important to reduce toxic exposures to avoid triggering diseases during life's different susceptibility periods.

Moreover, children are not merely vulnerable and exposed; they are harmed. The estimated *annual* costs of pediatric diseases of environmental origin include the following: lead ($50.9 billion), methylmercury ($5.1 billion), asthma ($2.2 billion), intellectual disability ($5.4 billion), autism ($7.9 billion), attention deficit hyperactivity disorder ($5.0 billion), and childhood cancer ($95 million), with a best total estimate of these diseases of $76.6 billion (40).

While the 1976 TSCA has well served the interests of chemical manufacturers and its panoply of experts, it inflicts unjust risk burdens on many others, harming some. However, there are better approaches.

Using science to prevent risk burdens: Premarket testing and review laws

A more just and morally defensible approach is to use science with good premarket testing and review laws to prevent risk burdens to the public before potentially toxic substances enter commerce. If premarket toxicity testing and approval laws are conscientiously administered and follow required toxicity testing protocols with good scientific studies, they offer superior protections. Companies proposing new pharmaceuticals have both legal and scientific burdens of proof to show they are safe and effective for their medical pur-

poses (7). The public is not at any risk until products enter commerce following safety reviews. Also, if there is insufficient data for a safety determination, a product may not enter the market - "no data, no market."

Premarket testing laws, however, are not perfect (a much too high a standard), because some products approved under them may not be free of risks. Sometimes even conscientiously administered laws with well-conducted studies miss adverse side effects. In this they should be improved.

In addition, pharmaceutical companies just like those subject to postmarket laws can be tempted to cut scientific corners. Some may conceal potentially toxic effects from the FDA as Merrell-Dow did by withholding the reproductive risks of Bendectin (41).

However, once pharmaceuticals are in commerce the FDA has the legal and scientific burden of proof to show that they are no longer legally "safe." In this premarket laws resemble postmarket laws. For the most part carrying these burdens of proof can be almost as difficult as those the EPA faces under several of its postmarket laws. However, there are at least two major differences.

First, physicians and other medical professionals along with the companies have legal duties to report any adverse effects of pharmaceuticals. Thus, the FDA may receive early warnings about a drug's adverse effects and can begin protective actions earlier. A pattern of adverse effects can reveal serious problems. Consider the example of the breast milk suppression product, Parlodel, approved for commercialization in 1980 (42). By 1983 the FDA began receiving adverse reaction reports that Parlodel caused dizziness, fainting spells, strokes, some heart attacks, and eventually a number of deaths. The FDA first requested that the company warn doctors to advise and protect higher risk patients. The company refused, which was legally permitted. The FDA next requested the company to modify product labels to warn consumers of various risks. The company refused, but eventually relented. However, by then the FDA's concerns moved it to request that the company voluntarily withdraw Parlodel. The company refused. Finally, the FDA invested several years and considerable effort to issue a proposed rule to remove Parlodel from commerce.

Thirteen years after initial approval of Parlodel, ten years after modest to quite serious adverse event reports, and ultimately with more than a hundred adverse event reports, the company voluntarily withdrew the product under threat of FDA regulatory action (42). In the meantime many women had suffered strokes or heart attacks and some died. Thus, even premarket laws for drugs need improvements, and some modest ones have been made (43).

Second, when the FDA needs to remove a product from commerce, unlike under a postmarket law, it does not start in scientific ignorance. Data from the approval process plus subsequent adverse reaction reports potentially provide evidence and perhaps overlooked clues to toxic effects, perhaps assisting a shorter and more targeted research inquiry to reduce or remove risks.

However, even at this point a company may still choose to hide the results of studies, as did Merck Pharmaceutical with the pain and anti-inflammatory medication VIOXX. It argued that a competitor, Aleve, *lowered the risk of heart attacks* compared with VIOXX instead of correctly reporting that VIOXX increased the rate of heart attacks four-fold after only nine months of use (7, 16). Merck mislead physicians about the VIOXX's risks, attacked detractors, and "threatened the careers of academic physicians who questioned Merck's position on the safety of its drug" (16). Dishonorable tactics are not peculiar to postmarket law, but tend to appear whenever companies' products are threatened.

Addressing the question - "when should science be used to protect the public?" - the answer is clear: Using science to determine a product's toxicity *before* it enters commerce and puts people at risk is more just, better protects the public from harm, and causes less disruption of people's lives than utilizing science well after products have already been commercialized.

Amending TSCA with some better provisions

In 2016 Congress finally recognized the shortcomings of "old" TSCA, amending it with the Frank R. Lautenberg Chemical Safety for the 21st Century Act (44). This contains several provisions that, if administered well in the spirit of the law, can provide better protections from industrial chemical substances in products. Consider a few (7).

1) Theoretically, it authorized using scientific studies before public exposures, requiring the EPA to "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" (44). It 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 of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation'" (44).

2) To obtain missing evidence the EPA can more easily demand it by an *administrative order* rather than by using a time-consuming notice and rule-making procedure, (44) which could take up to three years (7). Because no specific toxicity tests appear to be required for identifying toxic effects (these could be developed under new EPA rules), EPA seems to have flexibility to decide what kinds and amounts of data it needs for particular substances. It may also open the door for EPA backtracking or for companies to pressure the agency not to require some data.

3) The amendments mandate safety reviews for all chemicals currently in "active commerce," namely those a company has manufactured in the last ten years. Within the first six months after the date of enactment the EPA must have 10 ongoing risk evaluations and must have "20 ongoing risk evaluations within 3.5 years." (44). The number of "active" substances is unknown, but may be as high as 30,000 (7, 45). The EPA must still show that a product poses "unreasonable risk of injury to health or the environment" (44). The scope of this changed requirement may not drag along all the burdensome, informationally intensive requirements of the earlier TSCA, but this has not yet been fully clarified.

4) EPA must give priority to chemicals that are persistent, bioaccumulative, and are known human carcinogens or otherwise have high toxicity. This is an important addition (7, 44).

5) In implementing these reviews, there are aggressive and judicially enforceable deadlines for EPA actions that many commentators applaud (45). The above are not the only modifications, merely some notable ones.

Importantly, how will this law be implemented? With a current strongly anti-regulatory administration in charge, committed to "reducing regulatory burdens on companies," what will the agency do? Will proposed new chemical creations have to be supported by good toxicity testing and receive in-depth review before commercialization or will they be quickly approved with little testing and only cursory review by EPA? (7) Early reports suggest that the second course of action is being followed. About January 2017 the EPA approved at least 600 new products to enter commerce (46). It seems doubtful they received careful review to prevent risks to developing children or adults.

How quickly will EPA act under "aggressive and judicially enforceable" deadlines for removing unreasonably toxic substances in commerce? A considerable distortion of the new law would be for the EPA to assert new products as "safe" and permit them into the market with little or no toxicity testing required and then to insist on quite detailed and certain evidence before removing health risks, an approach resembling old TSCA's. Neither protects the public well. Will the agency continue to be plagued by delays and extensive industry lobbying in removing health risks, will it collaborate in delaying health protections, or will it commit to enforcing legally mandated deadlines? If one does the arithmetic of a timeline for adequately reviewing existing substances of unknown toxicity, at best it will take decades, but probably more than a century (7, 47).

The tort law

In the tort law in order for an injured party to receive redress for harms caused by a defendant a plaintiff must show that a) the defendant violated the law, b) plaintiff suffered a legally recognized compensable injury, c) defendant's product can cause the kind of harm plaintiff suffered, and d) defendant's product did cause plaintiff's harm. Scientific findings are particularly important to address c) and d) in a legal case involving potentially toxic substances. How well are judges utilizing science in the tort law? (7, 48)

Unsurprising patterns for scientific requirements developed in the tort toxic law that continue to the present, likely because that same companies are affected as under administrative laws. 1) Some commenta-

tors and a few courts demanded "ideal" science - multiple lines of the "best" evidence, somewhat analogous to those recommended by Furst (above). This siren call, which leads to a shoal on which plaintiffs' cases can perish, serves two constituencies. For judges, uncomfortable with addressing scientific issues, requiring highly certain or near ideal evidence may protect them from some scientific mistakes, but incur others, namely leaving wrongfully injured plaintiffs without compensation (7, 48, 49). However, such requirements protect companies from tort losses, bad publicity, and having to compensate plaintiffs. While plaintiffs might have sufficiently good evidence of harm from toxic exposures, they might not have all the lines of the best and fullest evidence, bringing an end to their cases. Demands for ideal evidence would preclude redress for nearly all plaintiffs (7, 48, 49).

2) Even if many courts do not require ideal data, early on some required human statistical data, because according to one influential court epidemiological studies are "the only [ones] having [a] bearing on causation." (50). This ruling led to epidemiological studies becoming a legally necessary condition for receiving a jury trial and potentially a favorable verdict. Human statistical studies clearly can be good evidence, yet when they become necessary conditions for bringing a tort case, this is contrary to the approach taken by distinguished international and national scientific committees that review the toxicity data of substances and the Federal Judicial Centers' Reference Manual on Scientific Evidence (23-25, 49, 51) and constitutes a mistaken view of science for identifying human harm, barring many plaintiffs from receiving redress for harms suffered. (More on other scientific shortcomings below.) In addition, quite frequently, such studies are too insensitive to identify adverse effects in people even if they are present (7, 49). Restrictive though it is, some courts continue the requirement, influencing other courts (52). However, by now some courts understand the error of their restrictive views, but it is not clear how many of them act on them (52).

The U.S. Supreme Court's transformation of the tort law: The U.S. Supreme Court transformed how science is used in tort litigation with three cases - Daubert *v. Merrell-Dow Pharmaceutical, Inc.* (1993) (53), General Electric v. Joiner (1997) (54), and Kumho Tire v. Carmichael (1999) (55). Without dwelling on many details, these cases substantially modified how courts review science in order for a legal claim to go to a jury. First, the *Daubert* decision endorsed a much more intrusive role for judges in assessing the scientific data and reviewing expert testimony before permitting a jury to hear a case.

Second, the Court augmented this with detailed guidelines by which a judge should assess expert testimony and its foundation. These first two issues can lead to decisions preventing a jury trial and dismissal of a case. Judges may so decide if they find that expert testimony is unreliable or does not 'fit' the facts of the case, if there is an insufficient relation between the scientific testimony and the underlying evidence, or if in the judge's view scientific data is inadequate (7, 48).

Third, in *General Electric v. Joiner* the Court permitted a judge to review an expert's testimony by *individually assessing each study* on which the expert relies in isolation from other evidence in the case. For some time lower courts followed this model of review. However, this "atomistic" evaluation of data is quite contrary to how scientists themselves assess a body of evidence to determine what it shows (7, 25, 50, 56).

Judges' greater involvement in reviewing scientific testimony together with some of the Supreme Court decisions has led lower courts to adopt comparatively simplified rules for reviewing scientific testimony and evidence (7, 48, 52). (We have seen two such errors above - requiring ideal evidence and requiring epidemiological evidence.) Because judges lack familiarity with scientific issues, some of them adopt such rules and sometimes other misleading scientific requirements. Corporate defendants welcome these guides, because a judge can stop a trial at the pretrial stage if he/she thinks testimony or the science is inadequate.

Numerous courts go further, requiring quite specific, but conventional ideas for statistical significance—it must not be higher that 0.05 (57, 58). As a necessary condition for a scientific study, this is at odds with recommendations by the American Statistical Association and leading epidemiologists (59, 60). Such requirements may also lead to studies that are too insensitive to detect adverse effects even if they are present (7, 48, 49).

Still others forbid testimony based largely on animal studies (7, 49). However, distinguished national and international committees recognize the importance of data from mammals other than humans (23, 24, 25, 56). Thus, when courts legally exclude reliance on such data this is contrary to settled scientific practice and a scientific mistake (7, 48).

Some courts have required that human studies supporting a legal case must rest on studies that reveal a relative risk greater than two in exposed populations compared with controls (49). While this can be legally helpful, diseases may not be sufficiently potent for human studies to detect such high rates, and, again, distinguished international scientific committees identify hazards with less restrictive evidence (7, 61, 62).

A few courts have required mechanistic evidence supporting a claim of harm from a toxicant--"[t]he underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur" (63, 64). Mechanistic data can be especially helpful and powerful evidence and is becoming more so, as scientists better understand the toxicology of substances (7, 23, 24, 25, 56). However, as a necessary condition for evaluating a substance as toxic, this also is too demanding and not supported by what is currently known. Too often such evidence is absent (65). Thus, holding litigants' science to such standards precludes them from court. Even when some major mechanisms of toxicity are understood and scientifically helpful, every mechanistic step from exposure to disease is not (7, 47, 65).

Common scientific issues plague both the administrative and tort law for products already in commerce. Overly stringent scientific norms may dominate legal and health protection values. Such arguments under either set of laws can became a deliberate strategy because they favor companies whose products are in commerce and threatened in both venues. As a consequence I have argued,

> 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, [tort law experts], 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 [for the particular legal venue]. If missing data are needed to complete the scientific picture, they should seek it out or develop it. [Scientists in legal venues] should free themselves from a priori and necessary kinds of evidence in order to better and more quickly assess toxicants to protect the public. Indeed, these are current policies at research agencies such as the IARC and the NTP, along with regulatory agencies such as the US and the California Environmental Protection Agencies (EPAs) (7).

In addition, developments in science hold the promise of more rapidly identifying the causes of adverse effects under both administrative and tort law (23-28). Like public health officials of an earlier period, scientists' work may more quickly protect the public than amendments to laws.

Conclusion

The themes in *Tragic Failures* address the science-law interaction to protect the public health in two major legal institutions: How can we better use science in administrative law to protect the public from harm? How can we better use science in the tort law to better ensure compensation for those wrongfully injured by toxic substances? The preceding discussion reviews some major answers to these questions, but it is important that we better implement preventive laws with recent scientific findings to more quickly identify toxicants already in commerce to protect the public's health.

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Correspondence:
Carl F. Cranor
Distinguished Professor of Philosophy
University of California
Riverside, CA USA
Fax: 951-827-5298
E-mail: carl.cranor@ucr.edu