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COLLISION COURSE? SCIENCE, LAW, AND REGULATION IN THE EMERGING SCIENCE OF LOW DOSE TOXICITY

JODY A. ROBERTS*

I. INTRODUCTION

Bisphenol-A (BPA) and phthalates are no longer words strictly contained in a chemist’s lexicon. In recent months, United States citizens have begun to use these words in correlation with the increased press coverage of these two synthetic chemicals. The attention surrounding BPA peaked earlier this year when Nalgene, a maker of polycarbonate water bottles, especially popular with outdoor outfitters, announced the removal of its line of bottles made with BPA with a plan to replace them with a BPA-free formulation.1 The news was particularly striking because portable, reusable water bottles have increasingly become the more “eco-friendly” choice in response to the recent revolt against bottled water and bottled water manufacturers.2 Nalgene’s announcement was not the only shake-up in the BPA market that week; it was the crescendo to a

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week filled with buzzing noise from Canadian and U.S. regulatory agencies concerning the chemical. Although none of the parties involved wanted to admit that BPA might cause problems, pressure from Non-Governmental Organizations (NGOs), the market and a committed group of international scientists have made change happen regardless of governmental assistance.

Phthalates have for the most part escaped the high-profile public scrutiny characterizing the recent attention on BPA. That is not to say, however, that phthalates have received a free pass. Indeed, while the BPA debate has lingered, phthalates have already been marked for replacement in children’s toys in the European Union (EU), an effect that is rippling across the oceans. These issues also followed on the heels of other high-profile events in recent months. For example, toys coming to the U.S. from China were found to contain intolerably high levels of lead. Overall, the past eighteen months have been tense for toys, chemicals and international trade.


4. See Mark Gunther, WalMart: The New FDA, FORTUNE, July 16, 2008, available at http://money.cnn.com/2008/07/15/magazines/fortune/gunther_bpa.fortune/index.htm (illustrating how products containing BPA were being forced out not by regulators, but by advocacy groups, including major retailers, such as WalMart).


7. See id. (discussing levels of toxicity in toys arriving from China).
Despite this recent attention, larger questions still loom, such as how did this situation come about in the first place? Lawmakers are currently revisiting the decades old Toxic Substances Control Act (TSCA) regulations with hopes of understanding how to breathe new life into this seemingly exhausted and ineffective law. Responses from individual consumers and consumer advocacy groups certainly helped pave the way for the recent hearings on Capitol Hill concerning the use of BPA and phthalates in consumer goods as well as the introduction of the Kid-Safe Chemical Act. The Act would initiate an overhaul of the system by bringing attention to the exposures of children and other vulnerable groups, which would require new pre-market testing protocols and the institution of ongoing biomonitoring studies for public health tracking.

Building on this recent momentum, this Article addresses issues concerning how to make law and regulation more accommodating to emerging science. This Article is intended to be part of a larger conversation that has also found a significant place in the pages of this Journal. This Article, more specifically, is a comment in response to an article published in the previous issue of this Journal by Carl F. Cranor. Finally, this Article will lay out the very brief history that links Cranor’s paper “Do You Want to Bet Your Children’s Health on Post-Market Harm Principles?”, this paper, and their similar roots.

Cranor’s article emerged from his talk at the Villanova University School of Law in the Fall of 2007. That Symposium grew out of a conference organized earlier that year at the Chemical Heritage Foundation in Philadelphia, Pennsylvania, which explored the in-
tersecting issues of human biomonitoring studies and research into endocrine-disrupting chemicals. The conference brought together practitioners of the various sciences involved in these issues, as well as historians, sociologists, public health professionals and legal scholars. The Symposium at the Villanova University School of Law refocused the discussion from the earlier conference by examining more intently the potential legal ramifications of low-dose toxicity issues. The Symposium organizers deserve much credit because these issues were not squarely on the radar when the Symposium was being planned. Their decision to go ahead with this topic demonstrated a great deal of foresight and courage; and the most tangible result is that we now have a legal forum, by way of this Journal, to have this discussion.

Cranor took the issue head-on by arguing that the current modes of regulating chemicals in the U.S. are woefully inadequate for protecting the health of the citizenry in his provocatively titled article “Do You Want to Bet Your Children’s Health on Post-Market Harm Principles?” Cranor points to the tremendous gap that exists among methods and assumptions in U.S. testing protocol and the current state of the toxicological sciences. He also outlines the inadequacies of a system that waits for harm to occur before action is taken. Cranor suggests two alternative approaches as potential remedies: one drawing on the Registration, Evaluation, Authorization, and Restriction of Chemical Substances (REACH) model currently being instituted in the EU, and, alternatively, an approach that rethinks the relationship between individuals and the chemicals that comprise our world. Additionally, he lays the groundwork for a form of trespass law that would not only make harm from chemical exposures a legal injury, but would also make

14. See Cranor, supra note 11, at 251 (mentioning observations on low-dose toxicity).
15. See id. at 252 (observing U.S. allowance of products to enter commerce without testing).
16. See id. (describing how U.S. testing protocol allows citizens to be harmed prior to action to remove harmful product).
17. See id. at 252-53 (outlining Cranor’s two alternative models for handling low-dose toxicity issues).
the mere presence of an unwanted chemical a moral violation of an individual.18

While Cranor's article focuses on the problems relating to emerging science, David B. Fischer's article, published in the same issue of the Journal, addresses a subset of this broader problem. Fischer's article, "Nanotechnology – Scientific and Regulatory Challenges," looks at the introduction of a new class of materials and the pressures placed on the regulatory system.19 Fischer's choice of title is interesting. Instead of highlighting only scientific challenges to regulation or regulatory challenges to science, the title emphasizes how these new materials challenge both communities.

This is the crux of the problem and the idea behind the title of this Article. The challenges that emerging technosciences pose for their respective scientific and regulatory communities are intimately linked, but they are not the same. Do new nanomaterials, for example, place science, law and regulation on a collision course?

The following will provide a closer look at some of the issues of low-dose toxicity, its history, and the challenges that it poses in the context of a greater concern for emerging science; this case is clearly only one of many that have pushed the limits of the relationship between science and regulation in recent years. I am tempted here to use the term "regulatory science" to describe the place where the tension exists. Yet, while this phrase is not uncommon, it already implies a conclusion to the debate about whether or not science done for science and science done for regulation are different in kind.

Following this introduction, a more thorough exploration of the articles by Cranor and Fischer is offered. The thought experiment in which Cranor engages, and the conclusions he provides, will be emphasized. The discussion about Fischer's article will focus more on nanomaterials as a special subset of the more general problem that Cranor highlighted. Of particular interest here, however, is the question of whether nanomaterials, which present many of the same possible troubles that are dealt with under the low-dose category, can be accommodated within either of the systems that Cranor suggests, or whether they require all new regulations be-

18. See id. at 252 (noting trespass model).
19. See Fischer, supra note 11, at 315 (explaining new field of nanotechnology and resulting affects on regulatory system).
cause of their novel properties. The conclusion is a call to open up the conversation on the ways in which emerging science and its technoscientific products might be accommodated within the regulatory system. Whether this requires a retooling of existing regulations, as Fischer might suggest, or will necessitate overhauling philosophical foundations in such a way that entirely new methods will be necessary, remains uncertain and debatable. This Article is intended to add some momentum to that debate.

II. Low-Dose Toxicity and The Problem of Emerging Science

Current practices in the toxicological sciences, at least as applied to regulatory situations, operate within the paradigm best characterized by the centuries-old saying, “the dose makes the poison.” That is to say, toxicology generally operates under the assumption that everything is poisonous at some level; therefore, the job of toxicologists rests in uncovering what that dose is. This thinking provides the foundation for the LD_{50}, the lethal dose for 50% of the population tested, which results in the determination of safe limits of exposure. Maximum allowable exposures and doses, which differ depending upon whether discussing occupational standards or environmental standards, frequently change in response to

20. See Joachim Schummer, The Impact of Nanotechnologies on Developing Countries, in Nanoethics: The Ethical and Scientific Implications of Nanotechnology 261, 263 (Fritz Allhoff et al. eds., 2007) (discussing different approaches to defining technology and implications of each approach).

21. See Fischer, supra note 11, at 325-31 (discussing different regulatory challenges nanomaterials present and proposals for meeting those challenges by various groups).

22. Paracelsus, Four Treatises of Theophrastus von Hohenheim Called Paracelsus, 21-2 (Henry E. Sigerist ed., Johns Hopkins Univ. Press 1996) (1941). The original quote comes from Theophrastus Bombastus von Hoenheim, better known as Paracelsus, a fifteenth century iatrochemist. Id. The context, long since forgotten in the frequent reiterations of this quote is worth noting. Paracelsus, under attack from other apothecaries and medical practitioners for his use of supposed poisons for healing purposes defended his actions by explaining that everything was poisonous in some quantity. Id. at 21-4. It was therefore the duty of the practitioner to know the difference between the doses and intentions. Id. Much has changed in medicine since the fifteenth century, but listening to current exhortations on the toxicology of synthetic chemicals might lead some to believe that more is the same than we realize.

23. See John Doull, Toxicology Comes of Age, 41 ANN. REV. PHARMACOLOGY & TOXICOLOGY 1, 16 (2001) (discussing principle of “the dose makes the poison”). “Based on this principle [that “the dose makes the poison”], toxicologists conclude that there are no safe chemicals will be toxic under some conditions of exposure. Conversely, we also conclude that there is no chemical that cannot be used safely by simply reducing exposure.” Id.

24. See id. (explaining that determining threshold for chemical’s adverse effects is required to define safe and dangerous toxic levels).
new information, new instrumentation (that allows analytical chemists to see ever smaller concentrations) and public health crises. The most obvious example, perhaps, is the changing conceptions of harmful blood lead levels. Despite its widespread use in the U.S. for the better part of the twentieth century, lead has been a known toxicant for centuries. Over time, a combination of activism, politics and information from public health advocates, pediatricians and parents, succeeded in lowering the allowable limits, thus producing one of the few regulatory success stories for U.S. public health.

Converging sciences and technologies are making the case for a new approach to be taken in regulatory toxicology. The first, as outlined above, relates to the ways in which scientific advances in other fields, such as endocrinology, have found their way into discussions of toxicology. Adopting endocrinology data, however, involves more than the assimilation of facts; the conceptual basis for thinking through mechanisms of action is entirely different in endocrinology versus toxicology. Traditional toxicology works off of the idea that the relationship between dose and response is linear (which is why we can test a small range of doses and extrapolate in each direction), whereas endocrinology views the body as a system responding to signals from various chemicals, including hormones, or chemicals that can mimic the function of hormones. The view


26. See id. (reiterating that although the dangers of lead have been known for sometime, U.S. has continued widespread use of lead).

27. See id. (discussing efforts made and challenges faced by activists attempting to reduce all allowable exposure limits for lead).

28. See Doull supra note 23, at 17-18 (discussing flawed assumptions in early regulatory efforts to estimate exposure limits and subsequent theories for estimating limits); see also Frederick S. vom Saal & Claude Hughes, An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment, 113 ENVTL. HEALTH PERSP. 926, 931 (2005) (urging for new risk assessment on BPA exposure levels and urging reexamination of assumption justifying linear-threshold model used in risk assessments).

29. See Andrea C. Gore et al., Endocrine Disruption for Endocrinologists (and Others), ENDOCRINOLOGY, June 2006, at S1, S1 (mentioning scientists, physicians, clinical scientists, and epidemiologists at conference discussing endocrine disruption); see also David Crews & John A. McLachlan, Epigenetics, Evolution, Endocrine Disruption, Health, and Disease, ENDOCRINOLOGY, June 2006, S4, S4-S9 (discussing approach to examining whether endocrine disruptors can participate in evolutionary process).

30. See John A. McLachlan, Environmental Signaling: What Embryos and Evolution Tell Us About Endocrine Disrupting Chemicals, 22 ENDOCRINE REV.S. 319, 320 (2001) (describing endocrine system). The endocrine system has been described as "an integrated network of chemical signals." Id.
of the body as a system in constant communication with its environment disrupts the traditional view of linear dose-response, making extrapolation not only impossible, but potentially misleading.

Practically none of these advances would have been possible without the tremendous advances that have taken place in analytical and instrumental technologies and experimental methods in recent years.31 These new methods and machines have aided scientists in seeing more of these chemicals in new places, namely within humans.32 One result has been the increasing number of human biomonitoring studies now available.33 While the U.S. government has been engaged in these activities for several decades, state health organizations, NGOs and other countries are exploring ways of utilizing this data for monitoring and tracking public health.34 Just what information can be gleaned from these studies, beyond the obvious fact of exposure, remains to be determined. Unfortunately, due to limited information linking specific chemicals with either chronic exposure or life-long storage of synthetic chemicals, there is little direct health information that can be extrapolated from these studies.35

Despite new evidence, new science, new machines, and new information which together indicate that we have all become repositories of our modern world, little has been done to incorporate these findings into U.S. regulatory practice. There have been several obstacles, but two of them are most noteworthy. The U.S. Environmental Protection Agency (EPA)'s Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), formed in

31. See e.g., COMMONWEAL BIOMONITORING RES. CTR., TAKING IT ALL IN: DOCUMENTING CHEMICAL POLLUTION IN CALIFORNIANS THROUGH BIOMONITORING 6 (2005) (observing advances not possible without technology).
32. See id. (noting impact of new methods).
34. See generally Ken Sexton et al., Human Biomonitoring of Environmental Chemicals, 92 AM. SCIENTIST 98 (2004) (discussing history and potential in biomonitoring).
35. See generally Richard Jackson et al., Will Biomonitoring Change how we Regulate Toxic Chemicals?, 30 J.L. MED. & ETHICS 177, 182 (Supp. 2002) (urging that biomonitoring can help regulatory decision-making through assessing exposure levels).
1996, was charged with developing a chemical screening program to test manufactured chemicals for possible endocrine-disrupting activity.EDSTAC was given two years to complete the set-up phase at which point the EPA would implement these new procedures. Despite this initial surge of activity, it took the EPA a decade to release its first draft list of chemicals of concern. The methods for screening these chemicals are still under development.

Despite the good intentions in establishing EDSTAC and the attempt to find a way to screen and test for endocrine-disrupting effects, researchers and regulators ran into the same set of problems. First, because the science behind low-dose toxicity was still developing, there was little agreement on how best to reliably and efficiently test for endocrine-disrupting effects. While screening individual chemicals seemed difficult, the real goal has been to find a way to screen the synergistic effects of chemicals, a more accurate reflection of the way individuals and populations actually experience the world. However, with recent Center for Disease Control and Prevention (CDC) data providing evidence of hundreds of synthetic chemicals in each of us, the challenge of screening and testing has become virtually impossible.

It was within this situation that the Data Quality Act (DQA) entered the legal record buried deep in the budget bill passed in December 2000. The DQA has a slightly sinister, if not uncom-


37. See Food Quality Protection Act of 1996, §§ 408 (p)(1)-(2), 21 U.S.C. § 346a(p)(1)-(2) (2006) (requiring Administrator to develop screening program to determine whether certain substances have any hormonal or endocrine effecting within two years, and implement plan within three years).

38. See Endocrine Disruptor Screening Program; Chemical Selection Approach for Initial Round of Screening, 70 Fed. Reg. 56,449 (Sept. 27, 2005) (describing approach EPA will use for selecting first round of chemicals to be screened in Endocrine Disruptor Screening Program).


40. See McLachlan, supra note 30, at 320 (discussing how interdisciplinary nature and relative youth of endocrine disruption created much debate and controversy in field).


42. See Data Quality Act, Pub. L. No. 106-554, §551, 114 Stat. 2763 (2000) (directing Office of Management and Budget to issue guidelines to ensure and maximize "quality, objectivity, utility, and integrity" of information federal agen-
mon, history. The DQA passed through Congress in section 515 of the 712-page appropriations bill in December of 2000. Congress passed the law without hearings, and thus it lacks an official legislative history. It was inserted by Rep. Jo Ann Emerson at the prompting of Jim Tozzi, a former Office of Management and Budget (OMB) official who was then running the Center for Regulatory Effectiveness. 43

The language in the bill requires the OMB to service complaints made by any organization that feels it is being unfairly regulated due to faulty science. 44 The DQA is only one piece of what is perceived as a “war on science.” 45 It certainly fits well within the larger language game of “sound science” and “junk science” rhetoric that has characterized much of the politics-science nexus for the past decade or so. 46 Whatever the specific politics of the DQA, it plays two important roles in framing this discussion. First, it has played a direct role in the regulatory debates that might have let endocrine-disruptor and low-dose science into the EPA’s fold. 47 Second, it operates off of the very tension that has perpetuated these issues more broadly; namely, that science can be certain and easily translated into the supposedly concrete world of law and regulation.

With this background in mind, I will now provide a closer look at the challenges posed to us by Cranor and Fischer by way of the topics of low-dose toxicity and nanomaterials.

III. EMERGING CHALLENGES: LOW DOSE TOXICITY AND NANOMATERIALS

Cranor’s article provides a creative and provocative approach to thinking about the challenges posed by emerging sciences and the ways in which these challenges might be incorporated into a new, or significantly overhauled, regulatory system. 48 He is con-

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44. See id. (explaining legislative language).
45. See generally, Chris Mooney, The Republican War on Science (2005) (demonstrating example of war on science).
46. See Michaels, supra note 43, at 178-79 (providing author’s opinion).
47. See Weiss, supra note 42, at A01 (noting effect on debate).
cerned with how new science can be accommodated within existing science-based regulatory structures. Drawing on the work of Thomas Kuhn, Cranor points out that paradigm shifts in science do not affect science alone; rather, shifts in science require concomitant shifts in society. Cranor argues that the emerging science behind low dose toxicity, disease endpoints and human biomonitoring studies have created just such a moment. Finding a place for these new facts, however, has been difficult within the current system.

Despite years of an evolving regulatory infrastructure, Cranor convincingly argues that our current system fails to provide the basic protections that it is designed, or at least presumed, to offer U.S. citizens. For Cranor, the evidence clearly establishes that while specialty synthetic chemicals have continued to be found in human samples, and studies have shown that timing of exposure, more so than dose, can be a better predictor for serious outcomes that put fetuses and young children at greatest risk, the U.S. regulatory system continues to rely upon a fundamentally flawed harm-based system. This is primarily because current harm-based regulations rely heavily, if not exclusively, on three approaches: (1) pre-market screening; (2) pre-market testing; and (3) post-market actions.

Pre-market screening, as Cranor correctly points out, is inconsistent at best, and non-existent at worst. Current laws also cover only a small fraction of the chemicals actually produced for market use. Producers are required to submit information outlining possible toxicological effects to the government before these chemicals reach the market. Yet, because there is no legal limit to the amount of information that must be produced and turned over to the regulatory agency, most chemicals lack data of any significance.

49. See id. at 252 (stating concerns of balancing competing scientific methods).
50. See id. at 251 (commenting on finding of Kuhn's work).
51. See id. (explaining emerging science).
52. See id. at 276 (commenting on impact of emerging science).
53. See Cranor, supra note 11, at 252 (noting failures in current legal system).
54. See id. at 269 (discussing Cranor's belief that timing is more important than dosage).
55. See id. at 276-88 (explaining flaws in legal system).
56. See id. at 277-84 (providing three possible legislative approaches).
57. See id. at 277-78 (stating worst of three possible approaches).
58. See Cranor supra note 11, at 276-88 (providing commentary on current state of law).
59. See id. at 252 (noting requirements for producers).
60. See id. at 286-90 (noting insufficient data on chemicals).
majority of these chemicals were grandfathered into the U.S. regulatory system, which yields virtually no health data now or in the future.

The second approach, pre-market testing, is also woefully out of date. Testing priorities were set years, if not decades, ago, when current knowledge linking low-level exposures to developmental abnormalities was still an emerging research area. Screening and testing efforts, therefore, emphasized only priority issues, such as lethality, and in some cases carcinogenicity.

The final approach, post-market laws, represents the retrospective possibilities for dealing with problems that arise once a chemical has cleared the pre-market hurdles, but has nonetheless demonstrated "harm" of one kind or another. The approach also aids in overcoming the problem of chemicals that were grandfathered in under current regulatory policies. Recourse for those "injured" in these instances falls under the auspices of tort law. Here, the burden is on the injured person or persons to demonstrate the direct link between exposure and injury.

The problem with this entire system, Cranor argues, is that the emphasis is always on proof of harm, which has been scientifically validated and vetted. Nevertheless, Cranor rightly asks, why do we allow harm to happen at all? That is, why is our system designed to address problems only post hoc, rather than devoting its attention to preventing harm in the first place? As a basis for this critique, Cranor offers two thoughts based on the flaws of this system and recent scientific advances. First, the logic of pre- and post-market testing in the U.S. system is backwards, and greater emphasis on the former will obviate the need for the latter. It also makes the system more timely, since building a tort case can take years; years in which the substance in question continues to be on the market and to work its way through the ecosystem, carrying it to new bodies through new exposure routes. Second, according to Cranor, the presence of a compound (as validated by biomonitoring studies) already represents a harm. Thus, waiting for the health effect to manifest is unnecessary since the mere presence of a molecular invader is evidence of a violation.

61. See id. at 277-78 (stating inadequacy of second approach).
62. See id. (providing historical timeline of testing priorities).
63. See Cranor, supra note 11, at 277-78 (explaining shortcomings of pre-market testing approach).
64. See id. at 278-80 (discussing framework of post-market regulation).
65. See id. at 279-81 (highlighting difficulties in establishing proof of harm under current post-market model).
To overcome the inherent weaknesses of current U.S. regulatory approaches, Cranor puts forth two alternative models. They are dealt with here in reverse order from the way Cranor addresses them because the permission model, based on the EU REACH model, is perhaps more familiar and certainly less provocative than his trespass model; though the REACH model is not without its detractors and skeptics.

The EU REACH program stands as a mirror image to the U.S. TSCA program for controlling the production and distribution of potential hazardous chemicals. Attempting to overcome decades of evaluative neglect, REACH applies retroactively to all chemicals being produced in the EU or for use and sale in the EU. It attempts to overcome the limitations of problems faced by TSCA in recent decades and to accommodate more recent scientific developments by implementing a three tiered system. First, all chemicals must be registered with the EU. From there, chemicals (based on known hazards and quantities to be produced) enter into a system where they are subjected to increasingly rigorous standards for testing. Most notable is the use of new developmental data related to toxicology and the emphasis placed on a chemical's potential effects on those most vulnerable. Authorization by the EU is the final step.

The important difference between the REACH program and the U.S. system is the REACH program's precautionary approach to authorization. If a chemical might be a problem, it is not authorized until data exists which can exonerate it. If, in fact, further research does provide this counter-evidence, it is released into commerce. The EU does not wait for a future harm to be proven; future harm is avoided whenever possible. While critics in the U.S. argue that the use of a precautionary approach proves illogical, since one can never prove that a substance will not be harmful in all future instances, this logic is supplemented with a desire to protect the public health, even if it means restricting the use of a chemical that is perhaps “safe” for use.66

A permission-based, pre-market regulatory system, akin to the REACH program in the EU, has two important effects. First, it shifts the burden of proof from the plaintiff, arguing that there is a harm in the post-market environment, and instead requires the demonstration of safety, within the bounds of current scientific un-

derstandings, of the chemicals being produced. Second, it poses a
direct challenge to the assumed right to produce chemicals; a right
that, Cranor argues, has proven more salient in recent years than
rights individuals and communities have for protecting themselves.
Indeed, though Cranor does not take his argument this far, there
seems to be a natural connection between the development of
these new sciences and the information they are producing, and
the U.S.-based Right to Know Act. The question is: what do citi-
zens, communities and the public have a right to know? Under the
current administration of this law, we have the right to know very
little. If we judge recent efforts by states to extend the scope of this
doctrine to include, for example, chemicals known to have carcino-
genic, mutagenic, or developmental effects, then perhaps the ex-
tension of this right will prove increasingly difficult. We might,
however, be able to glean the information produced, procured, and
made available from our European counterparts.67

The permission model, while contentious in its own right, is
not nearly as radical as Cranor’s suggestion for the use of a trespass
model as a means of achieving chemical regulation.68 Cranor care-
fully lays the groundwork in detail in the context of his article. The
basic tenants, and how those might translate into a framework for
regulating chemicals, deserve attention.

Cranor’s argument, as I understand it, is based on three points:
(1) the unwanted violation of a person’s body by unwanted sub-
stances is a personal wrong, like trespass; (2) trespass does not have
to cause damage to be a wrong; and (3) because we know for sure
that we do have chemicals within us (as exemplified in CDC data)
that entered without our permission, we have been wronged; we
have been trespassed upon or violated.69 In this case, as indicated
by Cranor, mere presence is already a wrong: a moral wrong.70 Beyond
the philosophical argument that Cranor lays out in support of this
position, he notes that in many contexts, this approach is already
the norm.71 In cases of medical testing where seemingly harmless
acts take place, the law protects the violated patient.72

67. See Schapiro, supra note 5, at 1-19 (advocating adoption of EU methods).
68. See Cranor, supra note 11, at 298-307 (describing trespass model).
69. See id. (detailing theory behind trespass model).
70. See id. at 255 (explaining that in trespass model, presence of chemicals in
body is wrong).
71. See id. at 298-302 (analogizing invasion of chemicals in body with trespass
in other contexts).
72. See id. at 294 (explaining multiple causes of action for patient).
Cranor offers a compelling argument. The most potent feature, however, is not the logic of insufficiency that characterizes our current modes of safeguarding health, but the introduction of a moral basis for regulation. As it stands, regulation and violation of those safeguards exemplified by the perpetration of a harm, are based solely in terms of a strict cause-effect mechanism that links specific exposure with a specific, quantifiable health outcome. Nevertheless, as Cranor argues, this approach ignores several other important features of our lives that are incorporated into the law in other areas.

In his moral argument, Cranor argues that the autonomy of the individual, within whom we can now undoubtedly locate the presence of synthetic chemicals, must be respected. Drawing on examples from private property and trespass cases, as well as the rights of an individual in medical situations, Cranor attempts to build a bridge between these areas of the law and current tort law; the place where individuals currently must plead their cases.

Extending the private property-trespass model becomes difficult, however, when we consider two basic, but only recently developed, facts: the inevitability of what Cranor terms “chemical invasion,” and the technologies required for mediating and monitoring that invasion. Whereas a typical trespass case has some element of control or involves some decision-making process that may result in trespass, our intimate chemical interaction with the world virtually guarantees that we will all have some molecular trace of a chemical that is mass produced at some point. Although this step may be inevitable, we face the additional challenge posed by the technoscientific infrastructure necessary to make this violation visible. Needless to say, access to these resources is not readily available to the vast majority.

Cranor’s suggestions go a long way in shaping alternative legal and regulatory frameworks for handling the emerging sciences related to low-dose toxicity. These suggestions also highlight at least two places where the intersection between science, law and regulation continue to cause friction. First, the implementation of either of Cranor’s suggested frameworks assumes we know more than we currently do about the possible harm that exposure to these chemicals may cause. This is not to suggest that there is no evidence that low-dose chemical exposures do indeed cause harm because the

73. See Cranor, supra note 11, at 302-06 (discussing policy proposals).
74. See id. at 298-302 (comparing invasion of chemicals in body to invasion of person on another’s personal property).
literature is impossible to ignore in that respect. Rather, Cranor’s assertion that pre-market tests must be conducted assumes that such pre-market tests exist. As the EDSTAC program of the EPA demonstrates, however, developing these tests proves a Herculean task, one that stretches the very limits of our current scientific knowledge. The challenge, then, is how to act on the partial information that we already have while working to develop a clearer understanding of the possible harms these chemicals pose.

Second, we must ask, what are the consequences of viewing bodies, our bodies, as personal property? Cranor makes a strong argument based on the literature extending out of personal property law and medical rights law. This argument, however, might leave us wondering what this says about the definitional problems related to bodies and property. Perhaps, more importantly, we might wonder what this focus on the body does to community-based contexts upon which so much of current environmental justice is based. Would a focus on the individual body expand or impede our progress in addressing chemical contamination as an environmental justice issue?

While Cranor is concerned with the big picture—the failures of current U.S. regulatory frameworks to accommodate new scientific knowledge—Fischer focuses on one particularly prescient predicament: the potential toxicological effects of increased nanotechnology development. His concern, shared with others working and worrying in this field, is this: how do we reap potential benefits while, to the extent possible, minimizing the risk? Fischer’s article focuses on three key elements crucial to the further development of nanotechnologies: (1) exposure concerns, (2) regulatory frameworks; and (3) filling in the current knowledge gaps related to novel technologies.

When we speak of exposures to nanomaterials, we can think about three different cases. The first, is exposure in the workplace; i.e., exposure during the manufacturing process. The second, is exposure during use of the product. The third, is exposure during use of the product.

75. See e.g., Story, supra note 5, at C1; Lipton, supra note 5, at C1 (referencing literature acknowledging effect of low-dose toxicity).
76. See Cranor, supra note 11, at 277-78 (explaining pre-market laws).
77. See id. at 298-302 (discussing trespass model in relation to historical background of tort law).
78. See Fischer, supra note 11, at 317 (mentioning properties of nanomaterials that may be hazardous to humans).
79. See id. (summarizing focus of Article).
80. See id. at 315-18 (identifying elements crucial to development of nanotechnologies).
through the release of the material into the environment. The route of exposure is important to understand because in each case we have the potential involvement of different regulatory bodies. Additionally, there are different control measures and approaches in each instance. Finally, as we saw with Cranor's concerns above, there is the potential for exposures to different segments of the population.

The latter concerns, those of incidental exposures, have already caused much trepidation along the lines that this Article has outlined. The EPA, and to a lesser extent the FDA, have already laid out what it believes its role is or ought to be.81 Data is still coming in, and much of it is of great concern. Some toxicologists have attempted to sketch out what a general approach to nanomaterials in the environment might look like, but serious and concerted efforts only just now seem to be gaining traction.82

The more obvious and yet invisible concern of nanomaterials in a manufacturing facility seems to have far less appeal at the moment. Nevertheless, in the wake of recent studies that have attempted to liken nanomaterials to asbestos as a possible exposure model, concerns are growing.83 Invoking asbestos is a strategic move for those who want to raise concerns about the unknown potentials behind mass-produced nanomaterials. In both the public and the workforce, asbestos recalls memories of massive exposure problems that continue to linger. From a corporate and legal perspective, asbestos screams liability and the potential for litigation. Perhaps more importantly, however, from a technical standpoint, invoking asbestos attempts to relate what we know about one thing to something we still do not quite understand. This argument by analogy is potentially dangerous, yet is important in trying to gain an understanding of this new area.

In any exposure case, the bigger point is the inevitability of human and broader ecosystem exposure. We will find nanomaterial-

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82. See e.g., Gunter Oberdörster et al., Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles, 113 Envtl. Health Persp. 823, 823 (2005) (discussing emerging field of nanotoxicology).

83. See generally Craig A. Poland et al., Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study, 3 Nature Nanotechnology 423 (discussing study involving nanotechnology which likens effects to that of asbestos).
als in human samples in the years to come. The question, then, is how best to protect the population and the environments within which we live?

IV. OLD REGULATIONS REBORN OR REGULATION BORN ANEW?
HOW BEST TO ACCOMMODATE EMERGING SCIENCE?

In light of the challenges that emerging technosciences pose in the form of new understandings of old materials (e.g., plastics) and new ones like nanomaterials, we face the question of how best to protect ourselves and our ecosystems.

Cranor and Fischer, in their own ways, offer some ideas about the directions that we might take. Fischer, in highlighting the possible problems presented by a specific class of emerging technologies, demonstrates both the inadequacies of current regulatory frameworks, but also a way to make them work in the present and future without much restructuring. By addressing definitional, classificatory and knowledge gaps that nanomaterials present, he hopes to fit these technologies into current systems, however broken they may be. His attempts to do so are not new; indeed, some of the earliest legal wrangling and head scratching over the possible problems associated with nanomaterials were exactly along these lines.

Yet, this may not be a good sign. In the decade since those earlier musings, how far have we come? Why are we still struggling with these same sets of questions? To be sure, Fischer is not alone in arguing that the best way forward is through a modification of existing frameworks, if only to provide consistency and to protect us more immediately while the specifics are negotiated. Nonetheless, this reasoning seems to be resting on the logic of the treadmill: research in these areas is already taking place; such research will not stop, and, therefore, we must use whatever protections are available while we still can. While this may be the simplest and most immediately plausible way of framing protections from emerging nanomaterials, the potentially flawed logic is left squarely in place.

84. See Fischer, supra note 11, at 325-30 (explaining how regulatory challenges can be met).
Cranor’s work questions precisely this logic. Why are we on a treadmill at all? Why can we not get off, or at least slow it down until we can figure out the proper safeguards? Indeed, if we use the recent examples of BPA and phthalates as any kind of guide, then we might want to proceed into the future at a much slower pace. This is how I interpret Cranor’s methods: question the logic of progress by replacing assumptions. While we assume a right to produce new goods, maybe we should assume permission to produce new goods. When we lack data on safety, we assume everything is just fine or safe until we learn otherwise. Perhaps we should take a more precautionary stance on behalf of ourselves, our communities and our ecosystems.

Yet, we should note the politics now embedded in the word “precaution,” and its manifestation in the Precautionary Principle. The most recent incarnation of the principle emerged from the Wingspread Conference in Racine, WI in 1998 (which Cranor participated in) as a general principle for dealing with emerging science related to health and the environment. The principle reads: “[w]here an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”

Cranor, in his paper, argues for ways in which this principle can become a reality. It involves taking steps ahead of time (pre-market testing), and a reliance on what we do know rather than what we do not. Cranor, echoing advocates of REACH, goes further in arguing that the responsibility for filling in these gaps ought to be placed on the producers.

Nevertheless, whether we are talking about new technologies such as nanomaterials, or simply new information about old materials, as in the case of BPA and phthalates, the challenge is the same: how do we accommodate emerging knowledge into our regulatory frameworks? Right now, the system of linkages among science, law and regulation does not readily allow this to happen. A case can be made, however, for working within existing structures or rebuilding them anew as Cranor suggests, and as the EU has recently done by way of its REACH program.

Working within the current structure provides consistency in application and an immediate response. This is perhaps one reason why this approach has been advocated by those working in, or

formerly associated with, regulatory bodies. Yet, there are also many weaknesses with this approach. The regulatory system has been slow to react, whether due to the long delays in incorporating endocrine-disrupting data or failing to articulate a clear stance on nanomaterials. Perhaps this latter event is one reason why some groups have taken it upon themselves to create their own quasi-regulatory research frameworks, which itself is an interesting development in the regulatory world. Most importantly, working within the current structures fails to open the debate to important discussions involving the underlying philosophical assumptions of regulation. How can we move beyond strict scientific reasoning to incorporate a more traditional moral aspect to regulation? How do we balance the rights of the corporation with the rights of the individual that will inevitably be subject to the presence of corporate goods within each of us? How do we balance the right to produce (if it is indeed a right) with the right to protect oneself or to not subject oneself to certain molecular exposures? I cannot be sure that simply tinkering with TSCA, as many are advocating, will allow for these sorts of questions to be asked, let alone answered.

In the end, what we are looking for is a way to exist in the world that Ulrich Beck describes as a "risk society." Within the world that we currently inhabit, characterized by risk, we can no longer identify the sources of our risk. Legal and regulatory systems that attempt to tease out direct connections between polluter, emissions, exposure and health consequences, are operating in a world that no longer exists. Each day all of us are bombarded with the effluence of our affluence. Our chemical bodies mix and mingle with the molecules of the world, now including scores of thousands that did not previously exist just a few years or decades ago. Our bodies are now distinctively chemically different than pre-World War II generations. The result is that our sciences, which gave birth to these many miraculous molecules, can no longer keep


90. See Luoma, supra note 89 (arguing that TSCA should be made to accommodate emerging technologies such as nanomaterials).

pace with understanding the world that they have created. Con-
comitantly, neither can legal nor regulatory frameworks that seek to
apply this old logic to our new circumstances. What is needed is a
framework that understands that the environment is now different
and our bodies are now different, and that as a consequence, we do
not yet fully understand what these bodies in these environments
are becoming. We need a framework that will accommodate new
knowledge as it emerges out of new sciences, such as genetic toxi-
cology, endocrine-disrupter science, bioinformatics and, perhaps
broadly, sustainability science. In this world, knowledge is contin-
gent and still evolving, yet this should not prevent us from taking
action through our democratic tools of law and regulation. Indeed,
we must make these institutions as flexible as the current science.
We need a space where science, law and regulation can work to-
gether, without colliding.