STUDENT ESSAY COMPETITION WINNER

PIERCING THE VEIL OF TOXIC IGNORANCE: JUDICIAL CREATION OF SCIENTIFIC RESEARCH

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INTRODUCTION

We live in a world full of chemicals. The EPA currently has about 82,000 chemicals in its inventory of chemicals in commerce and adds over 700 new chemicals per year.[1] However, we know shockingly little about the safety of most of them. In a 1984 study, a National Research Council committee investigated a random sample of the country's most highly produced chemicals and found that "even minimal toxicity information" was not available in the public domain for 78% of them.[2] Over a decade later, the Environmental Defense Fund found that we still lacked "even the most basic toxicity testing results" for 75% of these common industrial chemicals.[3] Even the director of the Environmental

[1] *See* GOV'T ACCOUNTABILITY OFFICE, REPORT NO. GAO-05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 1–2 (2005), *available at* http://www.gao.gov/new.items/d05458.pdf [hereinafter GAO REPORT].

[2] The study randomly selected 259 chemicals produced in volumes of at least one million pounds per year. *See* NATIONAL RESEARCH COUNCIL, STEERING COMMITTEE ON IDENTIFICATION OF TOXIC AND POTENTIALLY TOXIC CHEMICALS FOR CONSIDERATION BY THE NATIONAL TOXICOLOGY PROGRAM, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 84 (1984), *available at* http://books.nap.edu/catalog.php?record_id=317#toc (noting that "additional information may be in the files of industries and government agencies").

[3] *See* ENVTL. DEF. FUND, TOXIC IGNORANCE: THE CONTINUING ABSENCE OF

Protection Agency's (EPA) Office of Pollution Prevention and Toxics has admitted that "EPA cannot reasonably assess the effects on health or the environment . . . of these chemicals because of insufficient data."[4] Consequently, this state of "toxic ignorance" has turned humans into guinea pigs in a vast, uncontrolled experiment.[5]

The American Cancer Society attributes six percent of cancer deaths each year to occupational and environmental exposure to pollutants.[6] These deaths correspond to 33,900 Americans per year.[7] However, cancer is "only one dimension" of the pollution problem.[8] Other potential health consequences of environmental exposure include birth defects, endocrine disruption, respiratory ailments, and cardiovascular disease.[9] Given that chemicals unquestionably can cause adverse reactions in humans, the lack of safety information on the vast majority of chemicals in commercial use is disturbing to say the least.

This Article will describe how the regulatory, tort, and market systems have created perverse incentives for companies to perpetuate this toxic ignorance. Consequently, plaintiffs in environmental exposure cases face a significant barrier to recovery. Several commentators have proposed reforms to strengthen government oversight or increase tort incentives for companies to perform safety testing. However, because these reforms would simply invert the inequities of the current system by financially devastating the chemical industry, or else fail to generate the missing research, they fall short of the mark.

This Article will therefore advocate an alternative approach—

BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE UNITED STATES 7 (1997), *available at* http://www.environmentaldefense.org/documents/243_toxicignorance.pdf.

[4] *High Production Volume Chemical Testing Program: Testimony Before the Subcomm. on Energy and Environment of the House Comm. on Science*, 106th Cong. (1999) (testimony of Dr. William Sanders, Director, Office of Pollution Prevention and Toxics, U.S. Envtl. Prot. Agency).

[5] *See* ENVTL. DEF. FUND, *supra* note 3, at 3; Holly E. Pettit, Comment, *Shifting the Experiment to the Lab: Does EPA Have a Mandatory Duty to Require Chemical Testing for Endocrine Disruption Effects Under the Toxic Substances Control Act?*, 30 ENVTL. L. 413, 414 (2000).

[6] *See* AM. CANCER SOC'Y, CANCER FACTS & FIGURES 22 (2006), *available at* http://www.cancer.org/downloads/STT/CAFF2006PWSecured.pdf.

[7] *See id.*

[8] *Id.*

[9] *See id.*; Pettit, *supra* note 5, at 415.

judicial creation of scientific research. Instead of watching plaintiffs founder for lack of research, courts can and should take active steps to generate the missing research within the context of class action litigation, whether by ordering studies for use at trial, providing research as a remedy, or approving research-based settlements. Although current research methods may render this approach too expensive and time consuming to be feasible, novel developments such as molecular epidemiology and toxicogenomics will clear the way for judicially created research in the not-too-distant future. Therefore, this proposal has the potential to end toxic ignorance while promoting fair litigation outcomes, as well as tort law's goals of compensation and deterrence.

I. PERVERSE INCENTIVES FOR TOXIC IGNORANCE

Although the companies that manufacture and use chemicals are generally in the best position to perform safety testing, they have many perverse incentives to remain ignorant.[10] The regulatory scheme for chemicals does not require any testing, and the market does not reward companies that perform voluntary testing. The tort system creates the strongest disincentive, since any negative information a company discovers about a chemical would invite potentially crushing liability. Other parties, including exposure victims and the scientific community, are also unlikely to perform tests due to a lack of resources or interest, as well as collective action problems. Consequently, as this Part will demonstrate, the current regulatory, market, and tort regimes foster a state of toxic ignorance, leaving victims unable to determine whether they will suffer injury from their exposure, let alone receive any compensation if they do.

A. *Regulatory Failure Under the Toxic Substances Control Act*

When Congress enacted the Toxic Substances Control Act (TSCA) thirty years ago, it declared its policy that "adequate data should be developed with respect to the effect of chemical

[10] *See generally* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773 (1997) [hereinafter Wagner, *Choosing Ignorance*]; Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619 (2004) [hereinafter Wagner, *Commons Ignorance*].

substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[11] Unfortunately, as this Part will demonstrate, TSCA has not come anywhere close to fulfilling this goal due to its self-defeating structure. TSCA does not mandate safety testing of chemicals; instead, EPA, the agency charged with administering TSCA, bears the burden of showing that a chemical presents a risk and must clear significant procedural hurdles before it can order a company to perform any testing. Although EPA has attempted to use voluntary testing programs to circumvent TSCA's onerous requirements, such efforts have failed dismally to fill the gaps in safety data.

1. *Premanufacture Notices*

TSCA authorizes EPA to review chemicals already in commerce at the time TSCA went into effect ("existing chemicals") as well as those that have entered into commerce since then ("new chemicals"). Ninety days prior to manufacturing or processing a new chemical, a company must submit a premanufacture notice (PMN) to EPA providing information about the chemical's identity, production process and volume, intended uses, potential release and exposure levels, disposal, byproducts, test data in the company's possession, and any other data about the chemical's health or environmental effects.[12] Since TSCA does not require companies to perform toxicity testing before submitting a PMN, companies typically do not perform such testing.[13] According to EPA, only 15% of PMNs contain any kind of health or safety test data.[14] In the absence of submitted data, EPA attempts to evaluate a new chemical's toxicity through use of structure-activity relationships analysis (SAR), which compares the chemical to those with similar molecular structures for which health and safety data exist.[15] However, this technique has not been validated and has been shown to produce inaccurate results.[16] Even if EPA determines that the chemical poses a risk to humans

[11] 15 U.S.C. § 2601(b) (2000).
[12] *Id.* §§ 2604(a)(1), (d)(1), 2607(a)(2).
[13] *See* GAO REPORT, *supra* note 1, at 10–11.
[14] *See id.* at 11.
[15] *See id.*
[16] *See id.* at 11–13.

or the environment, its options are limited to restricting or prohibiting use of the chemical, unless the agency can make the stringent findings required to justify promulgating a "test rule."[17]

2. *Test Rules*

Section 4 of TSCA[18] authorizes EPA to promulgate a test rule requiring a company to "develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience."[19] A test rule comprises identification of the substance, standards for development of the test data, and a reasonable time period to submit the test results to EPA.[20] Testing may include in vitro, animal, and epidemiological studies to determine the persistence and toxicity of the chemical.[21] Before EPA can promulgate a test rule, however, it must justify its decision by making three specific findings. First, it must show either that the chemical poses "an unreasonable risk of injury to health or the environment" (a "hazard finding"),[22] or that it "is or will be produced in substantial quantities" causing either "significant or substantial human exposure" or environmental exposure (an "exposure finding").[23] Second, EPA must demonstrate a lack of sufficient data or experience for determining or predicting the effect of the substance on human health or the environment.[24] Third, it must prove that testing is "necessary to develop such data."[25]

In addition to this high substantive threshold, TSCA test rules are subject to significant procedural requirements.[26] First, the Interagency Testing Committee (ITC), an independent advisory committee comprising sixteen government agencies, recommends

[17] 15 U.S.C. § 2604(e), (f) (2000).
[18] *See id.* § 2603.
[19] *Id.* § 2603(a).
[20] *Id.* § 2603(b)(1).
[21] *See id.* § 2603(b)(2)(A).
[22] *Id.* § 2603(a)(1)(A)(i).
[23] *Id.* § 2603(a)(1)(B)(i).
[24] *See id.* §§ 2603(a)(1)(A)(ii), (B)(ii).
[25] *Id.* §§ 2603(a)(1)(A)(iii), (B)(iii).
[26] *See* John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 315 (1991) ("TSCA test rules are rules in the Administrative Procedure Act sense and subject to elaborate procedures for development, promulgation, and judicial review.").

chemicals that should receive priority consideration for section 4 rulemaking.[27] The ITC must publish its recommendations in the Federal Register, along with its reasons for including each chemical in the list.[28] Any interested party can file written comments with the EPA Administrator, which EPA must make available to the public.[29] Within twelve months of the ITC's recommendations, EPA must either initiate a section 4 rulemaking, or else publish in the Federal Register its reasons for not initiating rulemaking.[30] EPA's test rules are subject to requirements above and beyond those mandated by the informal rulemaking provision of the Administrative Procedure Act (APA),[31] including written submissions, oral presentations, transcripts, and findings.[32]

Promulgating a test rule also imposes high practical costs on the agency. According to EPA, a test rule takes two to ten years and can cost up to a quarter of a million dollars.[33] Given section 4's substantial procedural hurdles, it is hardly surprising that EPA has promulgated only about 200 test rules for the 62,000 chemicals that were in commerce when it first began reviewing chemicals in 1979.[34]

3. *EPA's Voluntary Programs*

Because of the difficulties inherent in promulgating test rules, EPA invokes its rulemaking authority only as a "last resort."[35] Instead, EPA has shifted its focus to large-scale voluntary programs to encourage industry to "sponsor" targeted chemicals and pledge to perform tests. The most prominent of these programs is the High Production Volume Challenge Initiative. When EPA analyzed publicly available data on high production volume (HPV) chemicals (those produced in amounts over one million pounds per year), it found that 43% of them completely lack basic toxicity data, and 93% lack one or more basic tests.[36] To address this

[27] *See* 15 U.S.C. § 2603(e)(1)(A) (2000).
[28] *See id.* § 2603(e)(1)(B).
[29] *See id.*
[30] *See id.*
[31] *See* 5 U.S.C. § 553 (2000).
[32] *See* 15 U.S.C. § 2603(b)(5) (2000).
[33] *See* GAO REPORT, *supra* note 1, at 26.
[34] *See id.* at 4.
[35] *See* Pettit, *supra* note 5, at 431.
[36] *See* OFFICE OF POLLUTION PREVENTION AND TOXICS, ENVTL. PROT.

research deficiency, EPA launched the initiative to encourage industry to develop summaries of existing data and conduct testing to fill the gaps on 2800 HPV chemicals.[37] Sponsors' incentives to participate include "recognition as an industry leader on an issue of importance to the public" and avoidance of a test rule that would cover any unsponsored chemicals.[38]

In the eight years since the program's inception, all but about 300 of the 2,800 HPV chemicals have been sponsored; however, sponsors have submitted summaries of existing data and plans for further testing on only about 400 of the sponsored chemicals.[39] EPA has recently issued a test rule covering only 17 of the 300 "orphans"[40] and admits that it may not be able to make the findings necessary to justify a test rule for the remaining orphans.[41] Despite the laudable efforts by the agency to encourage testing, it is clear that a strictly voluntary program will make little inroads toward solving the toxic ignorance problem.

4. *Reporting Requirements and Confidentiality*

Section 8(e) of TSCA also imposes a reporting duty when companies obtain "information which reasonably supports the conclusion" that a chemical "presents a substantial risk of injury to health or the environment."[42] However, TSCA does not impose any affirmative duty to obtain such information. In fact, companies that perform testing face increased liability both in the way of EPA enforcement actions[43] and private litigation. It is

AGENCY, CHEMICAL HAZARD DATA AVAILABILITY STUDY: WHAT DO WE REALLY KNOW ABOUT THE SAFETY OF HIGH PRODUCTION VOLUME CHEMICALS? 2 (1998), *available at* http://www.epa.gov/hpv/pubs/general/hazchem.pdf. The six basic tests (as defined by the Organization for Economic Cooperation and Development) are acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate. *Id.* at 2.

[37] *See* OFFICE OF POLLUTION PREVENTION AND TOXICS, ENVTL. PROT. AGENCY, REPORT NO. 745-F-09-002(g), CHEMICAL RIGHT TO KNOW: HIGH PRODUCTION VOLUME CHEMICALS, FREQUENTLY ASKED QUESTIONS 2 (1999).

[38] *See id.* at 1.

[39] *See* U.S. Environmental Protection Agency, High Production Volume (HPV) Challenge Program: Robust Summaries and Test Plans, http://www.epa.gov/opptintr/chemrtk/pubs/summaries/viewsrch.htm (last visited May 9, 2007).

[40] *See* Testing of Certain High Production Volume Chemicals, 71 Fed. Reg. 13,707, 13,708 (Mar. 16, 2006) (to be codified at 40 C.F.R. pt. 9 & 799).

[41] *See* GAO REPORT, *supra* note 1, at 41.

[42] *See* 15 U.S.C. § 2607(e) (2000).

[43] *See* Wagner, *Choosing Ignorance*, *supra* note 10, at 788 (noting the

therefore not in a company's interest to perform tests that could trigger this reporting duty.

Even when companies report safety information to EPA, liberal confidentiality rules enable them to enshroud it in secrecy. Simply by marking the information confidential, companies can claim confidential business information (CBI) protection that renders it unavailable to the public via the Freedom of Information Act.[44] There are no substantiation requirements and no sanctions for improperly designated documents.[45] Furthermore, it is difficult and costly for EPA or the public to challenge improper CBI claims.[46] Consequently, companies routinely claim CBI protection even when unwarranted, resulting in denial of public access to important safety information.[47] For example, about 95% of PMNs purport to contain confidential information.[48]

Because TSCA provides no incentives for companies to perform safety tests and places a high burden on EPA before it can require testing, it does not adequately protect the public from potentially unsafe chemicals. EPA's voluntary measures have proven insufficient to make up for a fundamentally deficient regulatory scheme. As a result, the public cannot rely upon the government to screen chemicals for safety before they enter the environment—and their bodies.

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potential for a company's reporting of adverse results to result in "a demand by a regulatory agency either to conduct additional testing or to undergo lengthy regulatory proceedings regarding possible market restrictions on its product").

[44] *See* 15 U.S.C. § 2613(c)(1) (2000) (allowing a company to "designate the data [it] believes is entitled to confidential treatment"); *see also* Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 AM. J.L. & MED. 119, 129–35 (2004); Julie Yang, Note, *Confidential Business Information Reform Under the Toxic Substances Control Act*, 2 ENVTL. L. 219, 223 (1995).

[45] *See* Wagner, *Commons Ignorance*, *supra* note 10, at 1700–01.

[46] *See id.* at 1702–03 (noting that "the public is handicapped in its ability to challenge an EPA decision that information is appropriately classified as a protected trade secret").

[47] *See id.* at 1703–04.

[48] *See* GAO REPORT, *supra* note 1, at 5.

B. *Market Failure*

1. *Lack of Incentives for Companies to Perform Tests*

Although the "industries that produce and use chemicals ordinarily are in the best position to provide or obtain toxicity and exposure data most cheaply and accurately," the market provides little or no incentive for them to do so.[49] Cost and time concerns present formidable obstacles to testing.[50] Research can be very expensive, and it would not be economically feasible for a company to test every single chemical used or created in the manufacturing process. Moreover, the length of time it would take to conduct even basic testing of these chemicals may delay a product launch or implementation of a new manufacturing process, thus destroying a company's competitive advantage. In general, companies appear to be more focused on short-term profits rather than speculative long-term losses from potential safety problems.[51]

Even if testing reveals a chemical to be safe, testing may not translate into a market share advantage. In the case of consumer products, buyers already assume that products are safe[52] and may be suspicious of affirmative claims of safety. In the case of industrial chemicals, end-product consumers will not even be aware of their existence, and companies may not anticipate that the chemical will ever come into human contact such that testing would even be warranted.[53] Companies may also be reluctant to perform tests due to free rider problems.[54] After investing considerable time and money in performing safety tests, a company would not want the results to become a public good that would benefit its current or future competitors. However, safety testing would serve little use to a company unless it could publicize the fact that the chemical was proven to be safe.

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[49] *See* Applegate, *supra* note 26, at 299.

[50] *See* Wagner, *Choosing Ignorance*, *supra* note 10, at 784.

[51] *See* Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. PA. L. REV. 1027, 1036–42 (1990); Wagner, *Choosing Ignorance*, *supra* note 10, at 785.

[52] *See* Wagner, *Choosing Ignorance*, *supra* note 10, at 784.

[53] *See* Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181, 204–05 (1993) (noting the "unintended" nature of many toxic exposure cases).

[54] *See* Wagner, *Commons Ignorance*, *supra* note 10, at 1640.

2. *Lack of Incentives for Scientists to Perform Tests*

Another kind of "market" that might take an interest in testing a chemical is the scientific community. Unless a company specifically commissioned and funded a study to test its own chemical, however, it is unlikely that an independent scientist would take the time or effort to perform such a study. In many cases, scientists may not even be aware of the chemical's existence or the fact that humans are being exposed to it, and thus they will have little incentive for undertaking safety studies. Therefore, it is not surprising that scientists "may not be interested in researching the health effects of a product and may not be provided funding to do so until a critical mass of litigation is instituted or a public health outcry is raised."[55] For example, high-profile, nationwide cases such as Bendectin, silicone breast implants, asbestos, and Agent Orange have spurred the scientific community to conduct safety research.[56] However, in the run-of-the-mill environmental exposure case affecting only a few thousand residents near an industrial facility, the limited media attention may fail to catalyze the scientific community into action. Even assuming that the scientific community recognized the problem and added it to the research agenda, the first plaintiffs to file lawsuits would be unable to benefit from these studies and would therefore founder in their efforts to prove causation.

C. *Tort System Failure*

Although the tort system is often viewed as a safety net for regulatory failure, plaintiffs in environmental exposure cases cannot depend on any such protection. Exposure to tort liability is a powerful disincentive for companies to generate information about their products.[57] Since plaintiffs can obtain this information through liberal discovery tools, any company that did test its

[55] Margaret A. Berger, *Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court's Trilogy on Expert Testimony in Toxic Tort Litigation*, 64 LAW & CONTEMP. PROBS. 289, 303 (2001).

[56] *See* Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 370 (1999). For case studies showing how research can parallel the trajectory of litigation, *see* JOSEPH SANDERS, BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION 61–83 (1998); Rebecca S. Dresser et al., *Breast Implants Revisited: Beyond* Science on Trial, 1997 WIS. L. REV. 705, 743–45.

[57] *See* Applegate, *supra* note 26, at 299–300.

products, in spite of the powerful market pressures described above, would open itself up to potentially catastrophic liability if any negative results were found.[58]

Plaintiffs bear the burden of proof for causation and therefore must submit evidence demonstrating that the substance in question has the potential to cause injuries, yet they often lack the resources to create this research.[59] Because plaintiffs already must rely on contingency-fee arrangements to get a foot in the courthouse door, one could argue that their attorneys could also front the costs of testing along with their legal services. However, such a move would be very risky given the current judicial suspicion of litigation-driven research.[60]

In reviewing *Daubert v. Merrell Dow Pharmaceuticals, Inc.* on remand from the Supreme Court, the Ninth Circuit expressed skepticism of litigation-driven research as more likely to be biased and unreliable than research conducted completely independent of litigation.[61] Similarly, the Advisory Committee's Notes on Federal Rule of Evidence 702 lists as an indicium of reliability whether experts' testimony relates to "matters growing naturally and directly out of research they have conducted independent of the litigation."[62] Since defendants have little incentive to generate

[58] *See* Wagner, *Commons Ignorance*, *supra* note 10, at 1637.

[59] *See* Applegate, *supra* note 26, at 298–99 ("Toxicology information is too expensive for workers and consumers (or even unions and consumer organizations) to generate.").

[60] *See* William L. Anderson et al., Daubert*'s Backwash: Litigation-Generated Science*, 34 U. MICH. J.L. REFORM 619, 621 (2001). *But see* William G. Childs, *The Overlapping Magisteria of Law and Science: When Litigation and Science Collide*, 85 NEB. L. REV. 643, 646 (2007) (arguing that science and the law can both benefit from "cross-fertilization" in the form of litigation-driven research); *see also* Michael L. Martinez & Jay P. Kesan, *Debate Club: Judges in Lab Coats?*, LEGAL AFFAIRS (Apr. 3, 2006), http://legalaffairs.org/webexclusive/debateclub_daubert0406.msp (presenting both sides of the issue).

[61] Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) ("That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were 'derived by the scientific method.'"). This echoed the views the Court had expressed in the first litigation. *See* Daubert v. Merrill Dow Pharm., Inc., 951 F.2d 1128, 1131 n.3 (9th Cir. 1991) ("Scientific studies conducted in anticipation of litigation must be scrutinized much more carefully than studies conducted in the normal course of scientific inquiry.").

[62] FED. R. EVID. 702 advisory committee's note (citing Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995)).

potentially damaging research, and plaintiffs' efforts to do so would be met with judicial hostility, in most cases plaintiffs cannot meet their burden of proving causation.[63]

Even if courts were willing to consider plaintiff-produced research, *Daubert* sets a nearly insurmountable barrier for admissibility. Human epidemiological studies are the "gold standard" for proving causation in toxic tort cases,[64] and courts often refuse to consider animal toxicology studies.[65] Unfortunately, since human epidemiological studies are much more expensive and time consuming than animal toxicology studies, "[t]he vast majority of potentially hazardous substances have not been subjected to epidemiological study."[66] Furthermore, the epidemiology requirement may often be unreasonably stringent, given that animal toxicology data are also highly probative of causation.[67] Indeed, federal agencies such as the Food and Drug Administration, Consumer Safety Products Commission, Occupational Safety and Health Administration, and EPA regularly rely on animal studies for risk assessment purposes.[68] Since "toxicologic[al] studies are the only or best available evidence of toxicity" in most instances, courts' rigid insistence on epidemiological studies would bar recovery in most cases.[69] This

[63] *See* Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 41 (1995) ("[P]lacing the burden of proof on the plaintiff creates a perverse incentive for actors to foster strong uncertainty about general causation . . . .").

[64] *See In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985) (Weinstein, J.) (noting that epidemiological studies conducted were "the only useful studies having any bearing on causation").

[65] *Cf.* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 144–45 (1997) (refusing to decide "whether animal studies can ever be a proper foundation for an expert's opinion" on general causation, but finding that the animal "studies were so dissimilar to the facts presented in this litigation" that it was not improper for the trial court "to have rejected the experts' reliance on them").

[66] Mark Geistfeld, *Scientific Uncertainty and Causation in Tort Law*, 54 VAND. L. REV.1011, 1013 (2001).

[67] *See* Villari v. Terminix Int'l, Inc., 692 F. Supp. 568, 570 (E.D. Pa. 1988) (declaring that "the defendant cannot deny that animal studies are routinely relied upon by the scientific community in assessing the carcinogenic effects of chemicals on humans").

[68] Carl F. Cranor et al., *Judicial Boundary Drawing and the Need for Context-Sensitive Science in Toxic Torts After* Daubert v. Merrell Dow Pharmaceuticals, Inc., 16 VA. ENVTL. L.J. 1, 52 (1996).

[69] Michael D. Green at al., *Reference Guide on Epidemiology*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 346 (Fed. Judicial Ctr. ed., 2000); *see also* Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic*

standard therefore reinforces the perverse incentives defendants already have to forego testing their products.[70]

Toxic ignorance thwarts the compensatory, deterrent, and corrective justice functions of tort law.[71] If plaintiffs cannot prove causation because of a lack of scientific research, they will be unable to recover compensation for injuries caused by defendant's conduct. Hence, they will not obtain corrective justice from their injurer. Since defendants will not be found liable for their excessively risky conduct, they will have no economic incentive to reduce risks to prevent future harm.[72] Indeed, "repeatedly absolving defendants of liability in the face of strong uncertainty encourages defendants to market their products before they have extensive information about the causal powers of their goods."[73] Therefore, the current tort system perpetuates rather than alleviates the state of toxic ignorance.

The marketplace, scientific community, and tort system all stack the deck in favor of toxic ignorance. As a result, the link between exposure and injury remains uncertain for most chemicals currently in use, and plaintiffs with legitimate injuries cannot recover for them.

II. THE SHORTCOMINGS OF CURRENT PROPOSALS TO SOLVE THE IGNORANCE PROBLEM

This Part presents several suggested regulatory and tort-based reforms to solve the problem of toxic ignorance and facilitate recovery by plaintiffs. However, because these proposals would penalize industry without necessarily generating the missing

Substances Litigation: The Legacy of Agent Orange *and Bendectin Litigation*, 86 NW. U. L. REV. 643, 681 (1992) ("Imposing a burden of production that includes an epidemiologic threshold will screen out . . . cases, but at a cost of precluding more refined attempts, based on animal studies, structure analysis, available knowledge about biological mechanisms and related evidence, to make an assessment of whether there exists a causal relationship.").

[70] *See* Finley, *supra* note 56, at 370–71.

[71] *See* Feldman, *supra* note 63, at 34; Albert C. Lin, *Beyond Tort: Compensating Victims of Environmental Toxic Injury*, 78 S. CAL. L. REV. 1439, 1441–42 (2005) (describing "the systematic undercompensation of environmental tort victims and the systematic underdeterrence of polluters").

[72] *See* Troyen A. Brennan, *Environmental Torts*, 46 VAND. L. REV. 1, 6 (1993) ("Empirical evidence suggests that environmental tort suits currently send a weak deterrent signal.").

[73] Feldman, *supra* note 63, at 45.

research or ensuring rational litigation outcomes, they do not adequately address the problem.

A. *Regulatory Reform*

As Part I demonstrates, the current regulatory regime for chemicals fails to generate safety research. TSCA makes it well-nigh impossible for EPA to issue test rules, and EPA's informal agreements with industry to perform voluntary testing have met with little success. One potential solution to the toxic ignorance problem is to require companies to register and test their chemicals prior to commercial use, as is required for pesticides and drugs.[74] This proposal would thus shift the burden of testing toxicity from EPA to the manufacturer.[75]

Although a comprehensive approval and licensing scheme would minimize the risks of chemical production and use, it would also be extremely burdensome to industry given the time and money required for testing.[76] Furthermore, without stringent regulatory oversight, which EPA currently lacks the resources to provide, requiring industry to test its own products may lead to biased study design and reporting.[77] Given the vast numbers of existing chemicals with no toxicity information, EPA would either have to grandfather them and tolerate a continuing lack of data, or require retroactive licensing that would create a colossal backlog of chemicals for review.[78] EPA's current institutional limitations, coupled with the powerful industrial lobbies opposing a premarket approval scheme, make such a reform unlikely and impracticable.

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[74] The EPA requires premarket approval of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2000), while the FDA requires premarket approval of drugs under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2000).

[75] *See* GAO REPORT, *supra* note 1, at 52–53.

[76] *See* Applegate, *supra* note 26, at 310.

[77] *See id.* at 311.

[78] *See id.* at 312.

B. *Tort System Reform*

1. *Increasing Incentives to Perform Testing*

Several commentators have made proposals to reform the tort system in order to "skirt the difficulties that strong uncertainty about causation creates."[79] For example, Professor Berger suggests imposing liability on manufacturers for failing to provide consumers with "substantial information relating to risk."[80] By focusing on manufacturers' negligence in marketing an inadequately tested product or in failing to disclose risk information, her proposal aims to create an incentive for them to perform tests and disseminate the results to the public.[81] While this proposal would remove the burden of proving causation by changing the substantive law, others have sought a similar result through procedural reforms. Professor Wagner would grant plaintiffs a presumption that the product in question caused their harm if it did not undergo "minimal testing" prior to marketing.[82] Manufacturers who "have conducted a comprehensive battery of tests and found their product to be safe" would enjoy immunity from suit.[83] Similarly, Professor Feldman suggests shifting the burden of proof to defendants whenever there is strong uncertainty about general causation.[84]

Though these proposals would increase incentives for testing and disclosure, they have several serious drawbacks, as other commentators have noted. First, the Berger and Wagner proposals suffer from a definitional problem—what exactly constitutes "substantial information" or "minimal testing"?[85] A judge or jury may be incompetent to make such a finding, leading to

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[79] Feldman, *supra* note 63, at 45.

[80] Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2143 (1997).

[81] *See id.* at 2147.

[82] *See* Wagner, *Choosing Ignorance*, *supra* note 10, at 834.

[83] *Id.* at 833.

[84] *See* Feldman, *supra* note 63, at 45. *See generally* Ariel Porat & Alex Stein, *Liability for Uncertainty: Making Evidential Damage Actionable*, 18 CARDOZO L. REV. 1891 (1997) (proposing to shift the burden of proof to defendants who are responsible for creating evidential uncertainty).

[85] *See* Richard J. Pierce, Jr., *Causation in Government Regulation and Toxic Torts*, 76 WASH. U. L.Q. 1307, 1318 (1998).

inconsistent or unrealistic standards.[86] For example, the factfinder may well determine that a company must subject its chemicals to rigorous clinical trials akin to those required by the FDA to satisfy the testing requirement.[87] Aside from serious ethical concerns involved in testing products with no therapeutic benefit in humans, the process would take over a decade and cost a quarter of a million dollars.[88] Either consumers must pay a significant surcharge on every product they buy, or manufacturers will have to eliminate many useful chemicals from commerce.

Second, all three proposals would lead to ruinous liability even if the defendant's chemical is perfectly benign. Companies would be unable to test tens of thousands of chemicals in time to defend against a flood of litigation.[89] Plaintiffs who could prove exposure to a chemical that has not been tested would prevail without having to show any causal link to their injury. Without any safety data, it would be impossible for a jury to determine what injuries to recompense, leading to speculative damages awards for every ailment suffered after the exposure. Rather than balancing the inequities suffered by plaintiffs, these proposals would "simply invert the troublesome results produced by the current rules."[90] Hence, "overdeterrence might replace underdeterrence, and overcompensation might replace undercompensation."[91]

Third, despite the increased incentives for companies to test chemicals, these proposals may not actually lead to more research. Companies "may gamble that the future costs for compensation and litigation . . . will be less than the current cost of . . . paying for more research," thus choosing to forego testing.[92] Even if they do respond to these incentives, leaving defendants in charge of

[86] *See* Thomas O. McGarity, *Proposal for Linking Culpability and Causation to Ensure Corporate Accountability for Toxic Risks*, 26 WM. & MARY ENVTL. L. & POL'Y REV. 1, 45–46 (2001) (noting that "the jury would be in the position of determining the proper testing regime for toxic substances").

[87] *See* Pierce, *supra* note 85, at 1325.

[88] *See* Veronica Henry, *Problems with Pharmaceutical Regulation in the United States: Drug Lag and Orphan Drugs*, 14 J. LEGAL MED. 617, 617 (1993).

[89] *See* Pierce, *supra* note 85, at 1316 ("Berger and Wagner appear not to recognize the staggering scope of their proposals.").

[90] *See* Feldman, *supra* note 63, at 45.

[91] Lin, *supra* note 71, at 1515–16 (describing the consequences of shifting the burden of proving causation).

[92] *See* Berger, *supra* note 80, at 2139.

conducting safety testing without increased regulatory oversight could result in low-quality research due to poor study design, rushed testing, or worst of all, bias or fraud.[93] Plaintiffs would therefore be forced to challenge the tests and resulting risk information through expert witnesses, which would greatly add to their litigation burden.

The proposals of these various commentators do not directly rectify the toxic ignorance problem but instead create incentives on manufacturers to test their products. Because they would merely shift the inequities of the current system from plaintiffs to the manufacturers, they would more likely lead to bankruptcy than to increased safety testing.

2. *Waiting for Additional Research*

Because of the conflicting timelines of law and science, courts must inevitably deal with cases that are scientifically unripe.[94] For example, one toxic tort plaintiff asked in her opposition brief to a *Daubert* motion, "Given the dearth of research . . . , what is a plaintiff to do?"[95] The court's unsatisfactory answer: "Wait."[96] Unfortunately, "science's laggardly pace in researching a legitimate problem" often thwarts the toxic tort plaintiff's quest for current relief.[97] Furthermore, as the Court recognized in *Daubert*: "Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly."[98]

Several commentators have observed that litigation would benefit from extra time to allow the scientific record to develop.[99] Judge Jack Weinstein has noted that "[a]t times it will be

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[93] *Cf.* Wagner, *Choosing Ignorance*, *supra* note 10, at 845 ("A liability system that encourages manufacturers to undertake safety testing without adequately policing the accuracy of those tests could lead to more scientific cheating.").

[94] Edward K. Cheng, *Changing Scientific Evidence*, 88 MINN. L. REV. 315, 329 (2003).

[95] Sanderson v. Int'l Flavors & Fragrances, Inc., 950 F. Supp. 981, 1003 (C.D. Cal. 1996).

[96] *Id.*

[97] *Id.*

[98] Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579, 597 (1993); *see also* Cranor et al., *supra* note 68, at 73 ("A court . . . must decide the issue one way or another; it does not have the luxury of postponing judgment as a scientist might.").

[99] *See, e.g.*, Cheng, *supra* note 94, at 332; Jack B. Weinstein, *Ethical Dilemmas in Mass Tort Litigation*, 88 NW. U. L. REV. 469, 563 (1994).

appropriate to delay decision or provide for intermediate relief while studies go forward."[100] Consequently, Professor Cheng has proposed the use of stays in judicial proceedings "until the body of scientific evidence became more substantial and stable."[101] In his proposal, "either party could move for a stay for scientific maturity."[102] If a court deemed the evidence scientifically immature, it would grant a stay of a fixed period "to stimulate scientific research."[103] The fixed stay would provide an incentive for the parties or independent scientists to conduct additional research that would allow the record to develop and mature.[104]

Unlike the other proposals outlined above, the use of stays would address the time lag problem inherent in scientific research. Moreover, Professor Cheng's proposal would not unfairly penalize defendants who have not had time to conduct studies before litigation. Nevertheless, it fails to ensure that research will actually occur. Defendants lack the incentive to perform any testing, even if the product is benign, since plaintiffs bear the burden of proof at trial. As discussed previously in Part I.C., plaintiffs simply lack the resources and credibility to perform studies for the purpose of litigation. Stays are also unlikely to generate independent research in most cases, since scientists would have no incentive to study the problem without sufficient media outcry or public attention.[105] Waiting therefore would confer no advantage to plaintiffs unless a mechanism exists to generate more research.

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[100] Weinstein, *supra* note 99, at 563; *see also In re* Breast Implant Cases, 942 F. Supp. 958, 961 (E.D.N.Y. & S.D.N.Y. 1996) (declining to grant defendants summary judgment until the National Science Panel reports its results, noting that "[a] grant of summary judgment and dismissal of plaintiffs' cases now would be unfair since scientists are still developing relevant information").

[101] Cheng, *supra* note 94, at 340.

[102] *Id.*

[103] *Id.*

[104] *See id.* at 341.

[105] *See supra* Part I.C.

III. A NEW PROPOSAL TO USE THE COURTS TO CREATE SCIENTIFIC RESEARCH

When failure of the regulatory, market, and tort systems have engendered scientific uncertainty about general causation, plaintiffs should not be denied a forum for recovery simply because they are not in a position to resolve that uncertainty. However, neither should defendants be held liable for mere exposure without any evidence of toxicity. As Judge Weinstein recognized in the Agent Orange settlement, both outcomes in toxic torts litigation are grossly inequitable, resulting in "either a tortious defendant being relieved of all liability or overcompensation to many plaintiffs and a crushing liability on the defendant."[106]

Rather than allow injustice to flow from scientific uncertainty, judges should take active steps to reduce that uncertainty. Instead of merely identifying gaps in scientific research, judges should strive to fill them. Professors Walker and Monahan have argued persuasively for an increased judicial role in conducting "independent investigations" of social science research rather than relying upon studies proffered by the parties.[107] Although they contemplate a literature review of existing studies rather than original research,[108] there is good reason to extend their logic beyond research location toward research creation.[109] Indeed, Judge Weinstein has endorsed such an activist role for judges in mass tort cases: "The court . . . has an obligation to go beyond the experts proffered by the parties. Where adequate science is not yet available it should encourage research and analysis by independent national groups."[110]

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[106] *In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 836 (E.D.N.Y. 1984).

[107] *See* John Monahan & Laurens Walker, *Social Authority: Obtaining, Evaluating, and Establishing Social Science in Law*, 134 U. PA. L. REV. 477, 497 (1986).

[108] *See* John Monahan & Laurens Walker, *Judicial Use of Social Science Research*, 15 LAW & HUM. BEHAV. 571, 575 (1991) (proposing that judges may "locate social science research by searching for it themselves").

[109] *But see* Monn v. State, 811 P.2d 1004, 1008 (Wyo. 1991) (Cardine, J., concurring) ("A major risk when the trial judge resorts to outside sources to verify facts is that he may choose to decide the whole dispute on the basis of his own independent research.") (quoting Nuspl v. Nuspl, 717 P.2d 341, 344 (Wyo. 1986)).

[110] Weinstein, *supra* note 99, at 563.

This Part proposes a multi-phase procedure by which the judiciary can encourage or even generate independent, high-quality research. First, if plaintiffs can meet the requirements for class certification, the court would certify a class action on the issue of general causation. The court would then have the option of appointing neutral experts to commission causation studies for use at trial. Given the timeline of litigation, this proposal contemplates that animal toxicology studies would be most appropriate for this phase; however, in exchange for lowering the evidentiary hurdle on causation, plaintiffs would only be allowed an equitable medical monitoring remedy rather than money damages. If plaintiffs can prove liability based on the commissioned studies, the court would award further scientific research in the form of long-term medical monitoring coupled with an epidemiological study component. This phase would allow latent injuries time to develop, as well as generate epidemiological data that could serve as the basis for individual damages claims for plaintiffs who manifest injuries linked to their exposure. Alternatively, if the defendant decides to settle, courts could approve settlements in which the defendant agrees to provide medical monitoring and fund independent causation studies.

A. *Research at Trial*

1. *Overview*

As I elaborate below, an equitable medical monitoring class action would provide an efficient vehicle to resolve uncertainty about general causation in latent-injury environmental exposure cases. Furthermore, class certification would create a manageable threshold for applicability of this proposal. After certifying a class action, the court would appoint a panel of neutral experts to direct causation studies. The parties would have some input into the study design and analysis of the results, but ultimately the expert panel would have control over the studies and would author an independent report with its conclusions on general causation. The panel's conclusions would not be binding on the court and would still be subject to scrutiny by the parties' own experts; however, given that the panel's research would not suffer from any taint of partisan bias, its conclusions would carry great weight and may resolve the causation issue.

Because of the long timeline required for epidemiological

studies, the proposal would allow plaintiffs to rely on animal toxicology studies but would limit remedies to equitable relief in the form of medical monitoring; however, the equitable remedy would generate epidemiological research that could form the basis for future compensatory relief. Furthermore, Part V will describe advances in technology that will allow for alternative forms of causation research that are much less expensive and time consuming than animal experiments or human observational studies, potentially making this proposal even more attractive and viable in the future.

2. *Class Certification*

Since environmental exposure cases often affect hundreds if not thousands of people, certification as a class action would render litigation more efficient for the parties and the courts alike. Moreover, class certification provides a convenient threshold for applicability of this proposal. Under Rule 23(a), certification requires a showing of numerosity, commonality of law or fact, typicality of the representative's claims, and adequacy of representation.[111] These requirements would limit court-approved studies to cases involving large-scale exposures of similarly situated plaintiffs, which would be the most compelling case for further research. Furthermore, Rule 23(g) imposes stringent standards for appointment of class counsel that would curb the potential for abusive litigation.[112] If the class certification requirement proves too low a threshold for costly studies, the proposal could instead be limited to cases transferred for multidistrict litigation. The Judicial Panel on Multidistrict Litigation determines whether cases with "one or more common questions of fact" pending in different districts should be transferred to a single district for "coordinated or consolidated pretrial proceedings."[113] The Panel already has extensive experience with complex mass exposure cases such as the Agent

[111] FED. R. CIV. P. 23(a).

[112] FED. R. CIV. P. 23(g). When appointing counsel, Rule 23(g) requires that the court consider "the work counsel has done in identifying or investigating potential claims in the action, counsel's experience in handling class actions, other complex litigation, and claims of the type asserted in the action, counsel's knowledge of the applicable law, and the resources counsel will commit to representing the class," as well as "any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class." *Id.*

[113] 28 U.S.C. § 1407 (2000).

Orange litigation[114] and would be well equipped to manage neutral experts.

Certification as a Rule 23(b)(2) medical monitoring class action would also curb potential abuse where plaintiffs have latent injuries. "A claim for medical monitoring seeks to recover the anticipated costs of long-term diagnostic testing necessary to detect latent diseases that may develop as a result of tortious exposure to toxic substances."[115] Courts have generally refused to certify medical monitoring classes for damages under Rule 23(b)(3), finding that common issues do not predominate over individual issues as required under that subpart.[116] However, many courts have recognized the establishment of a court-supervised medical monitoring fund or program as a form of equitable relief appropriate for a Rule 23(b)(2) class action.[117] As one court pointed out, "because of the group nature of the harm alleged and the broad character of the relief sought, the (b)(2) class is, by its very nature, assumed to be a homogeneous and cohesive group with few conflicting interests among its members."[118] Furthermore, equitable relief ensures that plaintiffs "would be

[114] *See* In re "Agent Orange" Prod. Liab. Litig., MDL No. 381, 100 F.R.D. 718 (E.D.N.Y. 1983) (certifying nationwide class of veterans exposed to Agent Orange), *aff'd*, 818 F.2d 145 (2d Cir. 1987).

[115] Bower v. Westinghouse Elec. Corp., 522 S.E.2d 424, 429 (W. Va. 1999). The current law of medical monitoring is fractured, with some states treating it as a cause of action, others as a remedy, and still others refusing to recognize it in any form. *See* Pankaj Venugopal, Note, *The Class Certification of Medical Monitoring Claims*, 102 COLUM. L. REV. 1659, 1659–60 (2002). States that currently recognize medical monitoring in some form include Alaska, Arizona, California, District of Columbia, Florida, Louisiana, Missouri, New York, New Jersey, Pennsylvania, Utah, Virginia, Washington, and West Virginia; states that do not allow medical monitoring in any form include Alabama, Kentucky, Michigan, and Nevada; and over twenty states have yet to rule on the availability of medical monitoring. *See* Steven J. Boranian & Kevin M. Hara, *Medical Monitoring: Innovative New Remedy or Money for Nothing?* 6–9 (Wash. Legal Found., Critical Legal Issues: Working Paper Series No. 136, 2006).

[116] *See, e.g.*, Perez v. Metabolife Int'l, Inc., 218 F.R.D. 262, 273 (S.D. Fla. 2003).

[117] *See, e.g.*, Barnes v. Am. Tobacco Co., 989 F. Supp. 661, 665 (E.D. Pa. 1997) (3d Cir. 1998) (finding that "the establishment of a court-supervised medical monitoring program through which the class members will receive periodic examinations . . . can be properly characterized as claim [sic] seeking injunctive relief"), *rev'd on other grounds*, 161 F.3d 127; Venugopal, *supra* note 115, at 1670 ("Because the very nature of medical monitoring rests on the prevention of greater future harm, a specific remedy such as a fund is appropriately characterized as equitable relief.").

[118] Allison v. Citgo Petroleum Corp., 151 F.3d 402, 413 (5th Cir. 1998).

unable to cash out their share" and "reduces the incentives for plaintiffs to falsely claim relief not owed to them."[119]

Part III.B will describe the mechanics of how a medical monitoring remedy can both provide diagnostic testing for exposed plaintiffs as well as generate additional research in the form of an epidemiological study.

3. *Neutral Experts*

In an environmental exposure case for which causation research is in its state of infancy, neutral experts can conduct studies to develop the scientific record. First, the court would use its discretion to determine whether to appoint a neutral expert or panel under Rule 706.[120] Appointed experts would evaluate the current research and determine whether further studies are appropriate. They would then design, oversee, and evaluate the studies with input from the parties, but the experts would have ultimate authority for study design and analysis. Based on the results of the studies, the experts would author a report in the form of a scientific manuscript of publishable quality, and the parties would be free to use the report at trial.

Although appointing a neutral expert may appear unorthodox, the Supreme Court has repeatedly recommended the use of neutral experts. For example, in *Daubert*, the Supreme Court specifically noted that Rule 706 permits the appointment of experts as a tool to help judges in making their admissibility determination.[121] Moreover, in his concurrence in *General Electric Co. v. Joiner*, Justice Breyer endorsed the judicial use of Rule 706 to help resolve scientifically complex causation issues in toxic tort cases.[122] Judges have invoked Rule 706 to appoint neutral experts in mass tort cases to evaluate scientific studies and make findings about general causation.[123] For example, in breast implant cases

[119] Venugopal, *supra* note 115, at 1693.

[120] FED. R. EVID. 706.

[121] *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 595 (1993).

[122] *See* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 147–50 (1997) (Breyer, J., concurring).

[123] *See, e.g.*, Laurens Walker & John Monahan, *Scientific Authority: The Breast Implant Litigation and Beyond*, 86 VA. L. REV. 801, 808–09 (2000). *See generally* Karen Butler Reisinger, Note, *Court-Appointed Expert Panels: A Comparison of Two Models*, 32 IND. L. REV. 225 (1998) (discussing history of court-appointed experts and comparing panel models used in breast implant litigation).

consolidated by the Judicial Panel on Multidistrict Litigation for pretrial proceedings, Judge Samuel Pointer appointed a multidisciplinary National Science Panel to "review, critique, and evaluate existing scientific literature, research, and publications" but specifically stated that the panelists "will not be asked to conduct any independent research."[124] Nevertheless, judges should be receptive to using neutral experts to conduct independent research where such research is lacking.[125]

Although judges have not yet used neutral experts to conduct general causation studies, they have employed experts to perform other types of independent research. For example, in environmental litigation, courts have used experts to take samples and measure them for contamination.[126] In patent cases, courts have appointed experts to conduct experiments to evaluate infringement claims.[127] In asbestos litigation, Judge Weinstein appointed a Rule 706 panel to conduct a "court-sponsored independent study to predict the flow of future claims."[128] The panel issued a draft report based on the study, and the parties were provided ample opportunity to study, evaluate, and comment on the report.[129] In response to comments and questions, the panel issued a supplemental draft containing additional information and "further analyses suggested by the parties."[130] This framework, which allows the parties to participate in the independent expert's work, provides a useful model for the causation research context.

Despite the myriad benefits of appointing neutral experts, several concerns may give courts pause. First, courts might fear that the neutral expert's participation would undermine the

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[124] *In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL 926, CV 92-P-10000-S, at 4 (N.D. Ala. May 30, 1996) (Order No. 31).

[125] *See* Young K. Lee, Note, *Beyond Gatekeeping: Class Certification, Judicial Oversight, and the Promotion of Scientific Research in "Immature" Pharmaceutical Torts*, 105 COLUM. L. REV. 1905, 1930 (2005).

[126] *See, e.g.*, Anderson v. Beatrice Foods Co., 129 F.R.D. 394, 396, 404–05 (D. Mass. 1989) (discussing previous appointment of an independent expert to test groundwater for contamination), *aff'd* 900 F.2d 388 (1st Cir. 1990) .

[127] *See, e.g.*, Kaehni v. Diffraction Co., 342 F. Supp. 523, 527 (D. Md. 1972) (discussing previous appointment of a neutral expert to conduct experiments on the allegedly infringing device during the course of the trial).

[128] *In re* Joint E. & S. Dists. Asbestos Litig., 151 F.R.D. 540, 542 (E.D.N.Y. & S.D.N.Y. 1993).

[129] *See id.*

[130] *Id.* at 542–43.

adversarial system.[131] Indeed, studies have shown judges to be reluctant to appoint neutral experts for this reason, though those who appointed experts were ultimately very satisfied with the experience.[132] Rule 706 includes several important safeguards that should alleviate such concerns. It specifically provides that the parties must be advised of the neutral expert's findings and can depose, call to testify, and cross-examine the expert.[133] The parties also retain their right to call their own expert witnesses.[134] Consequently, this proposal would not jeopardize the adversarial process, though by allowing the parties to participate in study design and analysis, it might reduce the number of issues in dispute.

Second, a neutral expert may enjoy an "aura of infallibility" that would effectively usurp the fact-finding role.[135] Although critics primarily focus on the jurors' perceptions of the expert,[136] judges sitting in bench trials "may be just as susceptible to the 'aura of infallibility' as any lay juror."[137] Nevertheless, at least one study has shown that jurors do not give any more weight to a neutral expert's testimony than to a party expert's testimony,[138] and other studies show a high level of agreement among judges and juries on issues of liability.[139] Therefore, concerns that judges and juries unduly defer to neutral experts may be exaggerated.

Third, a neutral expert's *ex parte* communications with the judge or parties have the potential to create prejudice that would

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[131] *See* Joe S. Cecil & Thomas E. Willging, *Court-Appointed Experts*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 540 (Fed. Judicial Ctr. ed., 1994).

[132] *See* Joe S. Cecil & Thomas E. Willging, *Accepting* Daubert*'s Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 1008, 1018 (1994).

[133] *See* FED. R. EVID. 706(a).

[134] *See* FED. R. EVID. 706(d).

[135] FED. R. EVID. 706 advisory committee's note.

[136] *See, e.g.*, Ellen Relkin, *Some Implications of* Daubert *and Its Potential for Misuse: Misapplication to Environmental Tort Cases and Abuse of Rule 706(a) Court-Appointed Experts*, 15 CARDOZO L. REV. 2255, 2263–64 (1994).

[137] Thomas M. Crowley, *Help Me Mr. Wizard! Can We Really Have "Neutral" Rule 706 Experts?*, 1998 DETROIT C.L. REV. 927, 970 (1998) n.223.

[138] *See* Nancy J. Brekke et al., *Of Juries and Court-Appointed Experts: The Impact of Nonadversarial Versus Adversarial Expert Testimony*, 15 LAW & HUM. BEHAV. 451, 468 (1991).

[139] *See* Neil Vidmar & Shari Seidman Diamond, *Juries and Expert Evidence*, 66 BROOK. L. REV. 1121, 1176–77 (2001).

violate due process.[140] Although Rule 706 does not address the issue of ex parte communications, "[c]ase law and canons of judicial ethics discourage off-the-record contacts between a judge and an expert witness."[141] Indeed, judges have been sanctioned for meeting privately with their appointed experts.[142] Therefore, if a court appoints a neutral expert, it should not only refrain from its own ex parte communications,[143] but it should also ban ex parte communications with the parties in order to prevent any erosion of the expert's impartiality.[144]

Finally, a "neutral" expert may not be truly neutral due to personal or professional interest in the outcome of the litigation.[145] Furthermore, if a judge picks the expert based on personal connections, a common practice, "there is little assurance that such acquaintances bring an unbiased, or even a well-informed, perspective."[146] By letting both parties participate in selection of the panel, such as by making a joint recommendation, the court could guard against bias while enhancing the legitimacy of the appointment process.[147] If the parties cannot come to a consensus,

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[140] *See* Adam J. Siegel, Note, *Setting Limits on Judicial Scientific, Technical, and Other Specialized Fact-Finding in the New Millennium*, 86 CORNELL L. REV. 167, 207–08 (2000) ("The potential for abuse under Rule 706 is great, and private communications between judges and technical advisors may have a devastating effect on the adversarial system."); *cf.* George D. Marlow, *From Black Robes to White Lab Coats: The Ethical Implications of a Judge's* Sua Sponte, Ex Parte *Acquisition of Social and Other Scientific Evidence During the Decision-Making Process*, 72 ST. JOHN'S L. REV. 291, 308 (1998) (noting the potential for ex parte information to mislead the court and create bias in judges who conduct independent research relating to litigation).

[141] Cecil & Willging, *supra* note 132, at 1029.

[142] *See, e.g.*, Edgar v. K.L., 93 F.3d 256, 259–60 (7th Cir. 1996) (issuing a writ of mandamus to remove a district judge after he met privately with the appointed experts, creating "an unacceptable potential for compromising impartiality").

[143] However, "incidental communications" between the judge and expert about logistical matters would not require the presence of all parties. *See* Cecil & Willging, *supra* note 132, at 1065.

[144] *See* Sophia Cope, Comment, *Ripe for Revision: A Critique of Federal Rule of Evidence 706 and the Use of Court-Appointed Experts*, 39 GONZ. L. REV. 163, 192 (2003–2004).

[145] *See* Ellen E. Deason, *Court-Appointed Expert Witnesses: Scientific Positivism Meets Bias and Deference*, 77 OR. L. REV. 59, 100–21 (1998) (describing three sources of bias in expert testimony: partisanship, cultural and personal context, and scientific disagreements).

[146] *See* Cecil & Willging, *supra* note 132, at 1023.

[147] *See* Si-Hung Choy, Comment, *Judicial Education after* Markman v. Westview Instruments, Inc.*: The Use of Court-Appointed Experts*, 47 UCLA L.

the court could resort to a professional association's recommendation.[148] To further protect against bias, the court could use questionnaires to weed out candidates with prior contacts with the parties or any financial or professional interest in the outcome of the litigation.[149]

4. *Funding*

Perhaps the most serious concern raised by this proposal is how it will be funded. Rule 706 already provides a mechanism for funding neutral experts. It provides that "compensation shall be paid by the parties in such proportion and at such time as the court directs."[150] The court could therefore require the parties to split the cost of the expert's time or else charge the losing party.

Since Rule 706 does not address the issue of funding studies conducted by the neutral expert, a separate funding mechanism would be required. The simplest option is for the government to provide grant money through the National Institutes of Health, National Science Foundation, and other agencies, as it already does for much of the scientific research conducted in this country.[151] The expert could write a proposal and apply for grant money just as it would for non-litigation-related research, and peer reviewers would decide whether to provide a grant based on the scientific merits of the proposal. The public funding option would have the lowest costs because it would use a pre-existing infrastructure with which a neutral expert would already be familiar. The public funding option is also reasonable given that scientific inquiry benefits the public at large.[152] This option could

REV. 1423, 1448–49 (2000).

[148] For example, the American Association for the Advancement of Science operates the Court Appointed Scientific Experts (CASE) service that recommends neutral experts "on a case-by-base basis, tailoring the search to the specific request for assistance." Am. Ass'n for the Advancement of Sci., *Court Appointed Scientific Experts: A Demonstration Project of the AAAS*, http://www.aaas.org/spp/case/case.htm (last visited Apr. 2, 2007). Justice Breyer implicitly recommended the AAAS service in his *Joiner* concurrence. *See* Gen. Elec. v. Joiner, 522 U.S. 136, 149–50 (1997) (Breyer, J., concurring).

[149] *Cf.* Choy, *supra* note 147, at 1451–52 (arguing that experts should sign affidavits stating that they are neutral with regard to ideological, financial, professional, and personal interests in the litigation).

[150] FED. R. EVID. 706(b).

[151] *See* Deason, *supra* note 145, at 108 (explaining that federal agencies have "traditionally supplied the bulk of the money for basic research").

[152] For example, in the silicone breast implant litigation, the National Science

require reimbursement from defendants who are ultimately found liable.

A second option would be to draw upon funds from industry rather than the general tax base. Several possibilities include an industry-wide tax or a fee that would accompany TSCA PMNs. The industry fund could operate in conjunction with existing grant-approving bodies such as the National Science Foundation or the National Institutes of Health or else with its own, separate grant-approving mechanism overseen by an independent expert panel. The major benefit of industry funding would be that it would force industry to internalize the costs of its harmful activities rather than distribute the cost among taxpayers. The major drawback is that it would require legislation to become operative; however, legislation may not be a significant obstacle, given that the government has successfully imposed industry user fees in the past.[153]

B. *Research as a Remedy*

Courts have broad equitable discretion to shape appropriate remedies.[154] That discretion should include requiring defendants to fund research when they have negligently exposed plaintiffs to chemicals shown to be toxic at trial. For example, if the court awarded the plaintiffs medical monitoring pursuant to the proposal in Part III.A., it could engraft an epidemiological research component to generate more scientific data. Since epidemiological studies take too long to be feasible during trial, they would be better suited to the post-litigation phase.

A trust overseen by special masters with appropriate expertise would administer the monitoring program and design an epidemiological cohort study of the medical monitoring class. If the results showed a significant incidence of cancer or other illness within the exposed population, then the plaintiffs would be able to

Panel's work was partially funded by federal grants. *See* Peter J. Goss et al., *Clearing Away the Junk: Court-Appointed Experts, Scientifically Marginal Evidence, and the Silicone Gel Breast Implant Litigation*, 56 FOOD & DRUG L.J. 227, 238 (2001).

[153] For example, the Prescription Drug User Fee Act has allowed the Food and Drug Administration to defray the costs of reviewing drug safety and advertising. *See* 21 U.S.C. §§ 379g–379h (2000).

[154] *See* Bower v. Westinghouse Elec. Corp., 522 S.E.2d 424, 434 (W. Va. 1999) (noting the court's equitable power to "fashion appropriate remedies" in medical monitoring cases).

bring individual damages suits.[155] In addition to epidemiological research, the court could empower the trust to fund basic research of the chemical on issues other than causation. As described below, the fluid recovery doctrine provides precedent for remedies that accrue to class members indirectly.

1. *Epidemiological Studies*

Medical monitoring could provide a promising framework for courts to facilitate scientific research. The American Law Institute has proposed that medical monitoring be reconceptualized as "some form of scientific epidemiological investigation of where and when the disease actually manifests itself among the exposed group."[156] Since medical monitoring already provides for testing and surveillance of an exposed population, a logical extension of monitoring would be to incorporate the data into an epidemiology study.[157]

Plaintiffs would form a convenient population for an epidemiological cohort study, which determines disease incidence by prospectively comparing a group of exposed individuals to a group of similarly situated individuals who were not exposed.[158] Cohort studies are "regarded as the most powerful" type of epidemiological study because they lack the recall-bias problem of retrospective case studies.[159] Using the plaintiffs themselves in the epidemiological study rather than an unrelated subject population would eliminate concerns over differences in exposure levels and characteristics between the plaintiffs and subject population.[160] Consequently, both the plaintiffs and defendants could rely upon the study results in related future litigation arising out of actual

[155] *See infra* Part III.B.4.

[156] AMERICAN LAW INSTITUTE REPORTER'S STUDY, 2 ENTERPRISE LIABILITY FOR PERSONAL INJURY 378 (1991). The ALI adds that "a socially beneficial role for medical monitoring is to finance serious scientific study for the potential impact of health hazards on exposed groups. . . ." *Id.* at 379.

[157] *See generally* Ann Taylor, *Public Health Funds: The Next Step in the Evolution of Tort Law*, 21 B.C. ENVTL. AFF. L. REV. 753, 789 (1994) (proposing that courts "adapt medical monitoring funds to include a formalized public health fund component").

[158] *See* McGarity, *supra* note 86, at 15 (describing "cohort" studies).

[159] *See* Boston, *supra* note 53, at 234.

[160] *See id.* at 313 (noting that because Agent Orange plaintiffs had personally participated in the epidemiological studies showing lack of causation, they could not credibly contest the results on grounds of differences in comparison to the study populations).

injuries.

Several courts have already approved of using medical monitoring data for population-based studies. For example, in *Day v. NLO, Inc.*, the court anticipated that medical monitoring would generate medical data to be utilized for group studies.[161] Similarly, in *Cook v. Rockwell Int'l Corp.*, the court recognized that "[p]ooling the [medical monitoring] examination results is a reasonable complement to normal diagnostic testing that furthers the objective behind the tort—to assure the early diagnosis of a latent disease."[162]

Courts seeking to implement such a remedy would create a trust fund with special masters as trustees to administer medical monitoring and the epidemiological study. The special masters would be akin to neutral experts and would have appropriate backgrounds in medicine and public health. They would design the study, collect the data, and perform the analysis, culminating in a written report that would be submitted for peer-reviewed publication. If the results identify an illness with an appropriately high relative risk, then the plaintiffs suffering from that illness could institute individual damages suits. As explained below in Part III.B.4., the single controversy rule will not necessarily bar a second suit. If the results do not implicate the chemical in causing any illness, then the medical monitoring program would terminate, and the defendant would likely face no further liability unless future studies showed otherwise.

2. *Basic Research*

Although courts have allowed pooling of medical monitoring results for further study, they have been less receptive to funding more generalized research. For example, the court in *Cook v. Rockwell Int'l Corp.* was careful to limit any scientific studies to the exposed plaintiffs, finding "no authority for their common law claims to recover the costs of generalized scientific studies."[163] However, the fluid recovery doctrine, coupled with appropriate due process safeguards, could provide a doctrinal framework for funding research that is not strictly related to the plaintiffs or the

[161] 144 F.R.D. 330, 336 (S.D. Ohio 1992), *vacated on other grounds sub nom. In re* NLO, Inc., 5 F.3d 154 (6th Cir. 1993).

[162] 778 F. Supp. 512, 515 (D. Colo. 1991).

[163] *Id.* at 514.

causation issue.

Fluid recovery (or "cy pres")[164] is an equitable remedy that originates in trust law. As one court explained the concept, "[w]here compliance with the literal terms of a charitable trust became impossible, the funds would be put to 'the next best use,' in accord with the dominant charitable purposes of the donor."[165] Courts have applied fluid recovery in class actions where identifying victims or distributing individual relief would be impracticable.[166] For example, courts have invoked fluid recovery to order defendants to lower their rates[167] or to distribute unclaimed funds to educational, charitable, or other public interest groups.[168] These courts have recognized that distributing funds to the identifiable plaintiffs would create a windfall and returning the unclaimed funds to defendants would unjustly enrich them.[169] Although the funds could escheat to the state, the government would not be obligated to use the funds to benefit those harmed by the defendant's conduct. Consequently, fluid recovery provides greater assurance that victims will receive some sort of benefit, even if only indirectly.

Courts have cautioned that fluid recovery "runs the risk of being a vehicle to punish defendants in the name of social policy, without conferring any particular benefit upon any particular wronged person."[170] If fluid recovery "benefits a group far too remote from the plaintiff class," it may infringe upon a defendant's due process rights.[171] To allay due process concerns and ensure at

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[164] From the French, meaning "as near as." BLACK'S LAW DICTIONARY 392 (7th ed. 1999).

[165] State v. Levi Strauss & Co., 715 P.2d 564, 570 (Cal. 1986).

[166] *See* Stan Karas, Case Note, *The Role of Fluid Recovery in Consumer Protection Litigation:* Kraus v. Trinity Management Services, 90 CAL. L. REV. 959, 961 (2002).

[167] *See* Colson v. Hilton Hotels Corp., 59 F.R.D. 324, 326 (N.D. Ill. 1972) (ordering defendant hotel chain to reduce its room rates for a defined period because of the difficulty of identifying some victims of overcharging).

[168] *See* Superior Beverage Co. v. Owens-Illinois, Inc., 827 F. Supp. 477, 479–87 (N.D. Ill. 1993) (awarding unclaimed antitrust settlement funds to a variety of educational, charitable, and other public service organizations, including clinics at several Chicago-area law schools).

[169] *See* Susan Beth Farmer, *More Lessons from the Laboratories:* Cy Pres *Distributions in* Parens Patriae *Antitrust Actions Brought by State Attorneys General*, 68 FORDHAM L. REV. 361, 393–94 (1999).

[170] Six Mexican Workers v. Arizona Citrus Growers, 904 F.2d 1301, 1312 (9th Cir. 1990) (Fernandez, J., concurring).

[171] *Id.* at 1308.

least indirect benefits to victims and their communities, courts should ensure that the research has a sufficient nexus to the harm caused by the defendant's conduct.[172] For example, a court could use the fluid recovery doctrine to distribute any unclaimed trust funds to basic research on the defendant's chemical unrelated to causation, such as studies on degradation pathways, byproducts, and environmental persistence. Although this research would arguably provide no direct benefit to exposure victims, it would shed light on how the chemical enters the environment and how it behaves once it gets there. Such research would help communities prepare for future exposure events and would assist industry in determining what protective measures to take to prevent or mitigate such events.

3. *Trusts*

A trust would serve as an ideal mechanism for managing future studies.[173] Trusts and similar devices have been used effectively to distribute payments in class action litigation. For example, in the Agent Orange litigation, the court ordered the creation of a tax-exempt charitable organization overseen by court-appointed special masters to manage payments to class members.[174] Courts have also employed trusts to supervise medical monitoring of plaintiffs. In *Ayers v. Township of Jackson*, the court deemed such a trust "a highly appropriate exercise of the

[172] For guidance, a court could consider the nexus requirement of Supplemental Environmental Projects (SEPs), which are environmentally beneficial projects that violators of environmental statutes agree to undertake in exchange for EPA's reduction of their civil penalties. *See* Edward Lloyd, *Supplemental Environmental Projects Have Been Effectively Used in Citizen Suits to Deter Future Violations as Well as to Achieve Significant Additional Environmental Benefits*, 10 WIDENER L. REV. 413, 413 (2004). SEPs must have an "adequate nexus" or "relationship between the violation and the proposed project." Final EPA Supplemental Environmental Projects Policy Issued, 63 Fed. Reg. 24,796, 24,798 (May 5, 1998). Accordingly, EPA will not approve SEPs that fund academic environmental research programs, since there would not be any nexus to the violation. *See id.* at 24,801. However, it will approve SEPs that fund studies of the chemical contaminant itself. *See, e.g.*, *In re* E.I. du Pont de Nemours & Co., Docket No. TSCA-HQ-2004-0016 (EPA Dec. 14, 2005) (consent agreement and final order) (requiring the defendant to study biodegradation of the contaminant).

[173] *See* Laurens Walker, *A Model Plan to Resolve Federal Class Action Cases by Jury Trial*, 88 VA. L. REV. 405, 422–25 (2002).

[174] *See* Ryan v. Dow Chem. Co. (*In re* "Agent Orange" Prod. Liab. Litig.), 611 F. Supp. 1396, 1434 (E.D.N.Y. 1985).

Court's equitable powers."[175] It noted that a trust would ensure that plaintiffs used the funds solely "to compensate for medical examinations and tests actually administered," while limiting defendants' liability to amounts actually expended.[176] Because "[d]istribution by trust adds a desirable element of precision to the remedy stage," it would ensure fairness to both parties.[177]

4. *Damages Phase*

If a plaintiff manifests injuries from exposure, and the epidemiological study confirms that the chemical doubled the plaintiff's relative risk of injury, the plaintiff should be allowed to institute a traditional suit for money damages in light of the new research. Preserving the potential for damages would provide plaintiffs with an incentive to participate in medical monitoring and epidemiological research as well as require defendants to internalize the costs of plaintiffs' injuries.

Unfortunately, the rule against claim splitting may serve as a barrier to recovery. Under traditional *res judicata* principles, a plaintiff "may bring only one claim for a given cause of action."[178] Consequently, some courts have balked at the prospect of post-medical-monitoring damages suits.[179] However, it is reasonable to characterize a medical monitoring claim as a separate cause of action from a personal injury claim, since the former addresses a risk of injury while the latter addresses an actual, present injury. Under that reasoning, "'monitoring' for diseases cannot logically be deemed to preclude class members from bringing future actions for diseases which class members may subsequently suffer from their exposure."[180] Several courts have thus endorsed claim splitting in toxic tort cases as an equitable principle.[181] Thus,

[175] Ayers v. Twp. of Jackson, 525 A.2d 287, 314 (N.J. 1987).

[176] *Id.*

[177] *See* Walker, *supra* note 173, at 425.

[178] Wood v. Wyeth-Ayerst Labs., 82 S.W.3d 849, 858 (Ky. 2002) (refusing to recognize a medical monitoring cause of action because of the "impasse" created by res judicata).

[179] *See id.* at 859.

[180] Arch v. Am. Tobacco Co., 175 F.R.D. 469, 480 (E.D. Pa. 1997).

[181] *See* Ayers v. Twp. of Jackson, 525 A.2d 287, 300 (N.J. 1987) (rejecting the notion that "the single controversy rule should bar timely causes of action in toxic-tort cases instituted after discovery of a disease or injury related to tortious conduct"); Eagle-Picher Indus. v. Cox, 481 So. 2d 517, 521 (Fla. Dist. Ct. App. 1985) (finding that "the procedural rule against splitting causes of action must be

plaintiffs who participate in medical monitoring and epidemiological research should be entitled to benefit from the results.

C. *Research at Settlement*

Since most class actions settle,[182] research-based settlements could go a long way toward solving the toxic ignorance problem. Indeed, settlements involving trusts for scientific research are not unprecedented. For example, the Three Mile Island class action settlement created a $5 million "Public Health Fund" to finance studies on the long-term health effects of radiation exposure.[183] The fund convened a Scientific Advisory Board to oversee the research, including workplace exposure studies and epidemiological studies of area residents.[184] In the Hawaii heptachlor class action,[185] the court approved a settlement to create a non-profit corporation to sponsor epidemiological studies, basic scientific research, and public education programs.[186] Another toxic exposure class action, *In re Fernald Litigation*, culminated in a settlement with a research component.[187] The court created a settlement fund and appointed three special masters as trustees to develop and administer a medical monitoring program and epidemiological studies.[188]

In addition to providing for additional studies, settlements could explicitly include a mechanism allowing the results of the studies to have a binding effect in future litigation. In the class action settlement involving a chemical used to process Teflon®, DuPont committed to conducting a "community study" to

relaxed when equitable considerations demand it").

[182] *See* Walker, *supra* note 173, at 410.

[183] *In re* Three Mile Island Litig., 557 F. Supp. 96, 97 (M.D. Pa. 1982).

[184] *See* Maureen C. Hatch et al., *Cancer Near the Three Mile Island Nuclear Plant: Radiation Emissions*, 132 AM. J. EPIDEMIOLOGY 397, 398–400 (1990); Maureen C. Hatch et al., *Cancer Rates After the Three Mile Island Nuclear Accident and Proximity of Residence to the Plant*, 81 AM. J. PUBLIC HEALTH 719 (1991).

[185] Memorandum in Support of Motion for Approval of Disbursements, *In re* Heptachlor Litig., Civ. Nos. 76335, 76338 (Haw. 1st Cir. Ct. Mar. 31, 1988).

[186] *See* Hawaii Heptachlor Health Effects Research Program, http://www.heptachlor.org/site/foundation/research.htm (providing a search engine for current and completed projects) (last visited Sept. 14, 2007).

[187] *In re* Fernald Litig., No. C-1-85-0149, 1989 WL 267038 (S.D. Ohio 1989) (order awarding attorneys' fees and costs).

[188] *Id.* at 4.

determine the health effects on the exposed community.[189] An independent scientific panel will evaluate the data generated from the study, and if it finds a "probable link" between the chemical and human disease, DuPont will provide medical monitoring for the 80,000 affected plaintiffs, and it will concede the issue of general causation in any personal injury lawsuit arising out of their exposure.[190] However, if no such link is found, then the plaintiffs must release any claims for personal injury or punitive damages.[191] Consequently, the research-based settlement will efficiently resolve future claims.

Since class action settlements often raise suspicion about "sweetheart deals" for the plaintiffs' attorneys, and "blackmail" for the defendants, courts must be vigilant of the interests of the parties in approving a settlement.[192] In *Amchem Products, Inc. v. Windsor*, the Supreme Court emphasized that Rule 23's requirements "demand undiluted, even heightened, attention in the settlement context."[193] Rule 23(e) also requires judicial approval of class action settlements and procedural protections for plaintiffs such as notice, fairness hearings, opportunities for objection, and even a discretionary second opt-out right for Rule 23(b)(3) class members.[194] Given these safeguards, research-based settlements could provide a promising solution for plaintiffs in environmental exposure litigation.

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[189] *See* Joint Motion for Preliminary Approval of Settlement, Leach v. E.I. DuPont de Nemours & Co., No. 01-C608, at 5 (Cir. Ct. Wood Cty. W. Va. Nov. 22, 2004).

[190] *See id.*

[191] *See id.*

[192] *See generally* Bruce Hay & David Rosenberg, *"Sweetheart" and "Blackmail" Settlements in Class Actions: Reality and Remedy*, 75 NOTRE DAME L. REV. 1377, 1377–78 (2000) (describing "sweetheart" and "blackmail" settlements).

[193] 521 U.S. 591, 620 (1997).

[194] *See* FED. R. CIV. P. 23(e).

IV. THE PROS AND CONS OF JUDICIAL CREATION OF RESEARCH

Research conducted by neutral experts in the context of litigation would generate badly needed answers to causation questions. Instead of having the courthouse gates slammed in their faces for lack of research, plaintiffs would now be able to enter—and stand or fall on the merits.

A. *Pros*

Plaintiffs would benefit from judicially directed causation studies because they would no longer have to fear the worst. Environmental toxins "provoke a special dread . . . because they can become absorbed into the very tissues of the body and crouch there for years, even generations, before doing their deadly work."[195] Toxicological and epidemiological data would give plaintiffs a more realistic sense of what the future holds in store. If their exposure is unlikely to result in any adverse health effects, plaintiffs would benefit from peace of mind; if their exposure places them at increased risk of illness, then they can monitor their health more closely and benefit from early detection and treatment, and the defendant would have to pay for these measures. Most importantly, if they do suffer from an injury as a result of their exposure, they can recover for that injury without facing an insurmountable causation barrier.

This proposal would also increase the fairness and efficiency of judicial proceedings. Use of neutral experts to design the studies would bolster their legitimacy, not only in the current proceeding but in future litigation as well. With both parties able to give input about the study design and analysis, they are more likely to accept the validity of the results regardless of which side they favor.[196] Moreover, judicial involvement in the research process would help ensure that studies met the appropriate admissibility standard. As a result, courts could avoid many contentious and confusing admissibility debates. Given the

[195] Kai Erikson, *Toxic Reckoning: Business Faces a New Kind of Fear*, HARV. BUS. REV., Jan.–Feb. 1990, at 118, 122; *see also* Lisa Heinzerling & Cameron Powers Hoffman, *Tortious Toxics*, 26 WM. & MARY ENVTL. L. & POL'Y REV. 67, 88–89 (2001) (describing the "special anxieties associated with toxic substances").

[196] *See* Lee, *supra* note 125, at 1931.

deference that courts would pay to judicially created research, plaintiffs would be more selective about filing suit if a court-initiated study vindicated a chemical, and defendants would be more apt to settle if the study inculpated it.

Finally, the scientific community and indeed the public as a whole would benefit from toxicity and public health research on a chemical in widespread production and use.[197] Research results could spur further inquiry and lead to a riper body of scientific knowledge about a chemical or class of chemicals. This information could lead to corrective action by regulatory agencies and market forces, reducing the risks experienced by the general public.

B. *Cons*

One inevitable argument against judicial involvement in research is the concern that courts lack the institutional competence to direct scientific endeavors.[198] However, this proposal does not demand any more from judges than *Daubert*. In making admissibility decisions, judges already immerse themselves in complex scientific issues and scrutinize studies proffered by the parties. Using neutral experts would only alleviate the burden on judges, since they would have less to worry about with respect to bias and other forms of scientific misconduct.

Another concern is the potential for duplicative research in collateral litigation. For example, in the silicone breast implant litigation, one judge "repeated much of the [National Science] Panel's work" by convening his own technical advisors to evaluate causation research.[199] Professors Walker and Monahan have recognized that such redundancy can "jeopardize the utility of the Panel findings and . . . discourage the future appointment of similar panels."[200] Consequently, treating a court-appointed panel's general causation findings as "scientific authority" akin to legal authority would "permit[] the use of doctrines of precedence to reduce redundancy and encourage courts to decide similar cases similarly."[201]

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197 *See* Taylor, *supra* note 157, at 794.

198 *See* Lee, *supra* note 125, at 1934.

199 Walker & Monahan, *supra* note 123, at 813–14.

200 *Id.* at 817.

201 *Id.* at 830.

Even if this scientific authority model were not implemented, courts could reduce redundancy through coordination efforts of varying levels of formality, ranging from cooperation among courts to share results[202] to consolidation of cases (at least on the causation issue) via the Judicial Panel on Multidistrict Litigation.[203] To facilitate cooperation, the funding source could operate a centralized database of all past and ongoing studies, which judges could consult before deciding whether to approve a new study. However, there is also definite value to repeating experiments as a way to "increas[e] the generalizability of experimental findings."[204] Courts should therefore consider appointing an expert to determine whether it would be worthwhile to duplicate another court's study.

From the plaintiffs' perspective, the major drawback to studies conducted during the course of litigation is delay. First, evidence of exposure and specific causation may degrade over time, and witnesses may move away or die while the studies are ongoing.[205] However, parties anticipating a delay would no doubt protect themselves by carefully preserving physical evidence and using depositions and other methods to record witness' accounts.[206] Second, delay would postpone relief for the plaintiffs, perhaps permanently if the defendant becomes insolvent in the interim.[207] Nevertheless, the risk of delay is preferable to dismissal or summary judgment due to lack of causation evidence; in other words, getting their foot into the courthouse door is better than having it slammed in their faces.[208] Finally, the case may stagnate as the judge and attorneys allocate their time and

[202] For example, Judge Pointer videotaped depositions of the National Science Panel experts for use by future courts. *See* Reisinger, *supra* note 123, at 248–49.

[203] *See* 28 U.S.C. § 1407 (2000) (allowing for consolidation of cases for convenience and efficiency).

[204] Walker & Monahan, *supra* note 123, at 819–20 (citing ROYCE SINGLETON ET AL., APPROACHES TO SOCIAL RESEARCH 177 (1988)); *see also* DAVID L. FAIGMAN ET AL., 1 MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 2-5.0 (1999) ("The more different circumstances a phenomenon can be replicated in, the greater its generality, and the more confidence researchers as well as consumers of research should have in the phenomenon.").

[205] *See* Cheng, *supra* note 94, at 333, 344.

[206] *See id.* at 344. However, "the benefits of live witnesses" may still be lost, even if their testimony is saved. *Id.*

[207] *See id.*

[208] *See id.* at 341.

resources elsewhere while waiting for results. Of course, delay might also give the parties time to build a better case, and ultimately they may choose to settle rather than wait and face uncertainty. At any rate, research-related delays would not necessarily differ from the delays already attendant to complex litigation. For example, the Agent Orange litigation took six years to reach settlement, without having fully explored the causation issue.[209] Furthermore, as Part V will describe, advances in technology promise alternative forms of causation research that are much less expensive and time consuming than animal experiments or human observational studies, making this proposal even more attractive and viable in the future.

Defendants would naturally worry that this research would be expensive and would increase their tort liability compared to the status quo. However, this proposal would merely require companies to internalize the costs of the toxic ignorance they themselves have perpetuated. They could always allocate these costs among consumers who benefit from their products or adjust their activity levels to avoid liability.[210] The judicially directed safety studies would also lead to more rational litigation outcomes, creating optimal deterrence rather than the lopsided underdeterrence of the current system. Another concern for defendants is the potential for abusive litigation, such as plaintiffs flooding the courts with nuisance suits to test tens of thousands of chemicals. This proposal aims to filter frivolous lawsuits by restricting studies to federal class actions and allowing only equitable remedies until plaintiffs can prove causation via the "gold standard" of human epidemiological research.

V. SOLUTIONS AT THE FRONTIER OF CAUSATION RESEARCH

Since the time and expense required by causation studies present the primary practical obstacle to judicial creation of research during litigation, technological advances in causation research may provide the solution. Toxicological and epidemiological research "traditionally has focused on exposure

[209] *See* PETER H. SCHUCK, AGENT ORANGE ON TRIAL: MASS TOXIC DISASTERS IN THE COURTS 5 (1987).

[210] *See* Leslie S. Gara, Note, *Medical Surveillance Damages: Using Common Sense and the Common Law to Mitigate the Dangers Posed by Environmental Hazards*, 12 HARV. ENVTL. L. REV. 265, 279 (1988).

and disease, with everything between remaining a black box."[211] However, the emerging fields of toxicogenomics and molecular epidemiology may revolutionize causation studies by linking substances to diseases mechanistically rather than probabilistically. In essence, they will enable scientists to peer into the "metaphorical 'black box' that hobbled earlier scientific investigations" of causation.[212] Moreover, since they can provide results rapidly and inexpensively, they will make it feasible for courts to order causation studies during trial.

A. *The Technology*

Toxicogenomics and molecular epidemiology will adapt traditional causation research to the biotechnology era. Toxicogenomics is the study of how environmental agents affect an organism's genome, while molecular epidemiology focuses on molecular-level effects. Both provide an internal window to pathology, establishing a mechanistic link between exposure and disease.[213] By elucidating a direct causal chain rather than relying on statistical correlations and inferences, these new fields "would be more valuable to toxic tort litigants than standard epidemiological studies."[214]

Molecular epidemiology brings the traditionally observational science of epidemiology into the laboratory using the tools of molecular biology.[215] Researchers can gain insights into a chemical's effects on the body through biological indicators called biomarkers, which flag "various stages and interactions on the pathway from exposure to disease."[216] For example, a chemical may bind itself to human DNA, creating a unique chemical-DNA

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[211] Gary E. Marchant, *Genetic Susceptibility and Biomarkers in Toxic Injury Litigation*, 41 JURIMETRICS J. 67 (2000).

[212] Jamie A. Grodsky, *Genetics and Environmental Law: Redefining Public Health*, 93 CAL. L. REV. 171, 175 (2005); *see also* Frederica P. Perera, *Uncovering New Clues to Cancer Risk*, SCI. AM., May 1996, at 54–55 (noting that molecular epidemiology "looks into the black box to uncover important steps leading from carcinogenic exposures to disease").

[213] *See* Lin, *supra* note 71, at 1470–73.

[214] Jon R. Pierce & Terrence Sexton, *Toxicogenomics: Toward the Future of Toxic Tort Causation*, 5 N.C. J.L. & TECH. 33, 54 (2003).

[215] *See* Christiana P. Callahan, Note, *Molecular Epidemiology: Future Proof of Toxic Tort Causation*, 8 ENVTL. LAW. 147, 147 (2001).

[216] Grodsky, *supra* note 212, at 183.

adduct.[217] Formation of these adducts is believed to be the first step in carcinogenesis, since they can lead to mutations in genes implicated in cancer development.[218] Consequently, biomarkers "provide a direct molecular-level link between toxic exposure and genetic effects."[219] Biomarkers can also be measured to determine the "biologically effective dose of a carcinogen" in humans,[220] a method superior to current environmental modeling techniques, which require "significant guesswork as to actual human exposure levels."[221]

Unlike traditional toxicology, which is "insufficiently sensitive to detect low-level toxicity or early pre-clinical stages of disease," toxicogenomics allows researchers to evaluate how molecules of a chemical can induce changes in gene expression that presage cancer and other diseases.[222] This early detection creates a significant advantage over traditional toxicology and epidemiology studies, since many adverse health effects have long latency periods.[223] Moreover, the use of human DNA means that there are no interspecies variations to worry about as with animal studies.[224] Another advantage is that toxicogenomic research can be performed quickly and cheaply using "high-speed, high-volume" tools such as DNA microarrays, which allow scientists to monitor the interaction between a chemical and thousands of genes simultaneously on a single silicon chip.[225] Toxicogenomics

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[217] *See id.* at 186–87; Frederica Perera, *Validation of DNA Adducts as Biological Markers of Carcinogen Exposure and Effects*, *in* BIOMARKERS AND OCCUPATIONAL HEALTH: PROGRESS AND PERSPECTIVES 105, 105–06 (Mortimer L. Mendelsohn et al. eds., 1995) (discussing a study which found chemical-DNA adducts significantly related to exposure to ambient air pollution).

[218] *See* Frederica P. Perera, *Environment and Cancer: Who Are Susceptible?*, SCI., Nov. 7, 1997, at 1068, 1069 fig.1.

[219] David E. Adelman, *The False Promise of the Genomics Revolution for Environmental Law*, 29 HARV. ENVTL. L. REV. 117, 130 (2005).

[220] *See* BD. ON HEALTH SCIENCES POLICY, INST. OF MED., CANCER AND THE ENVIRONMENT: GENE-ENVIRONMENT INTERACTION 34 (Samuel Wilson et al. eds., 2002), *available at* http://www.nap.edu/catalog/10464.html.

[221] Grodsky, *supra* note 212, at 185.

[222] *See* NAT'L CTR. FOR TOXICOGENOMICS, NAT'L INST. OF HEALTH, USING GLOBAL GENOMIC EXPRESSION TECHNOLOGY TO CREATE A KNOWLEDGE BASE FOR PROTECTING HUMAN HEALTH 2–4, http://www.niehs.nih.gov/nct/pdf/nctpub.pdf (last visited May 3, 2007).

[223] *See* Gary E. Marchant, *Genomics and Toxic Substances: Part I—Toxicogenomics*, 33 ENVTL. L. REP. 10071, 10079 (2003).

[224] *See* Lin, *supra* note 71, at 1473 n.187.

[225] Grodsky, *supra* note 212, at 190.

therefore presents an attractive alternative to traditional general causation studies.

B. *Use in Litigation*

Both molecular epidemiology and toxicogenomics are still in their infancy and therefore may not pass muster under *Daubert*. Although *Daubert* has replaced the *Frye* general acceptance test, the *Daubert* Court did list general acceptance as one criterion courts should consider in the reliability inquiry.[226] One concern is that this type of evidence has not achieved general acceptance as proof of causation, though some judges may simply regard molecular epidemiology as "just another type of epidemiology evidence."[227] Another stumbling block is the lack of a known error rate in these fields.[228] Many biomarkers have not been validated for reliability, since "the discovery of putative new biomarkers has far outpaced the validation process."[229] The same holds true for DNA microarray technology used in toxicogenomic studies, given that "[n]ew chips can be developed faster than chips can be validated."[230] In the future, as technology catches up to the *Daubert* standard, these alternative types of causation studies will become a staple of environmental exposure litigation and can help plaintiffs overcome the practical objections to judicially created research.

CONCLUSION

Toxic ignorance is the unfortunate byproduct of the perverse incentives created by the regulatory, market, and tort systems. Although the toxic ignorance problem has raised widespread concern among commentators, their proposals do not go far enough to fill the void in safety research. Consequently, it is time for courts to take a more active role in creating research by using the tools they already have at their disposal—most significantly, the authority to appoint neutral experts and the broad equitable power to craft innovative remedies. Developments at the frontier

[226] Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 594 (1993).

[227] *See* Pierce & Sexton, *supra* note 214, at 54.

[228] *See id.*

[229] Grodsky, *supra* note 212, at 188.

[230] Bernard A. Schwetz, *Toxicology at the Food and Drug Administration: New Century, New Challenges*, 20 INT'L J. TOXICOLOGY 3, 6 (2001).

of science will enable courts to implement this research-based solution efficiently. By legitimating "litigation-driven research," courts can ensure fair outcomes while helping to reduce toxic ignorance.