

# Choosing Ignorance in the Manufacture of Toxic Products

Wendy E. Wagner

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Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 *Cornell L. Rev.* 773 (1997)  
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# CHOOSING IGNORANCE IN THE MANUFACTURE OF TOXIC PRODUCTS

*Wendy E. Wagner*†

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## INTRODUCTION

There is a widely held perception that scientific research on the long-term safety of products is produced spontaneously and in abundance, irrespective of the law. Some commentators even appear to believe that, to the extent the law matters, it encourages safety research.<sup>1</sup> For the vast majority of potentially toxic products,<sup>2</sup> however, these perceptions are wrong. No toxicity research is available for over eighty percent of the chemicals in commerce,<sup>3</sup> and the common-law rules are, in part, responsible for this dearth of information.

Indeed, rather than promoting safety testing for latent harms, the current common-law liability rules act to penalize it. Before a complaint can be filed against a manufacturer for latent harms, the common law requires *victims* to produce scientific research that demonstrates a cause-and-effect relationship between the manufacturer's product and the plaintiff's injuries. Unfortunately, it is the manufacturers that are better able, but disinclined, to produce this research due to pervasive failures in both the market and government regulatory programs.<sup>4</sup> Manufacturers can thus minimize their liability

<sup>1</sup> See *infra* note 63. Not all scholars, however, have made this mistake. See, e.g., John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 318-32 (1991) (proposing modifications to the Toxic Substances Control Act (TSCA) to enable the Environmental Protection Agency (EPA) to require industry to produce information); Heidi L. Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 41 (1995) (observing that the plaintiffs' burden of proof in toxic tort cases may create incentives for defendants to forego clarifying uncertainties in causation); Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 149-50 (1995) (arguing that "[t]he fact that a particular harm comes as a surprise when discovered may reflect the innovator's choices during innovation more than the inherent difficulties of discovering the side effect").

<sup>2</sup> For an excellent definition of what constitutes a "toxic" substance or waste, see Troyen A. Brennan, *Environmental Torts*, 46 VAND. L. REV. 1, 14-16 (1993).

<sup>3</sup> See *infra* Part I.B.2.

<sup>4</sup> See *infra* Part I.B.3.

through their research programs. A manufacturer that conducts no research can generally avoid liability because plaintiffs and government research programs are unlikely to conduct scientific research on their own.<sup>5</sup> Voluntary safety research, on the other hand, might reveal a long-term risk associated with a product, a revelation that could provide vital evidence for aggressive plaintiffs' attorneys and ultimately increase, rather than reduce, the manufacturer's exposure to lawsuits and potentially catastrophic liability.<sup>6</sup> The failure of the common-law courts to provide manufacturers with reliable immunity after the manufacturer has conducted an exemplary safety testing program exacerbates the self-incriminatory effect of voluntary safety research.<sup>7</sup>

Given this common-law treatment of safety research, it would be surprising if manufacturers ever conducted voluntary research on the long-term hazards of their products. H.L.A. Hart has likened the law to a "choosing system, in which the individuals can find out, in general terms at least, the costs they have to pay if they act in certain ways"<sup>8</sup> and make choices accordingly. If manufacturers face virtually no penalty for remaining ignorant about the latent health risks of potentially toxic products, but risk crushing liability if they learn of long-term hazards, it is only rational for manufacturers to choose ignorance. Studies documenting the paucity of testing available for most products confirm that manufacturers are making this rational choice.<sup>9</sup>

Tobacco, DES, the Dalkon Shield, and asbestos provide particularly vivid examples of the social calamities that attend inadequate legal accountability for ensuring the long-term safety of products before they are marketed.<sup>10</sup> Even for more common products, such as crayons,<sup>11</sup> hair dyes,<sup>12</sup> and gasoline,<sup>13</sup> which probably present at

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<sup>5</sup> This observation appears to be true for generic latent harms, *see infra* Part IV.B.1, but may not hold true for harms that manifest themselves immediately after exposure or for signature harms that are exceedingly rare and can be finger-printed to exposure to a particular substance, because in the latter cases causation is typically much easier to establish.

<sup>6</sup> *See infra* Part II.A.

<sup>7</sup> *See infra* Part II.B.

<sup>8</sup> H.L.A. HART, *Legal Responsibility and Excuses*, in PUNISHMENT AND RESPONSIBILITY 28, 44 (1968).

<sup>9</sup> *See infra* Parts I.B.2, IV.A.

<sup>10</sup> *See infra* notes 170-80 and accompanying text.

<sup>11</sup> *See, e.g.*, S.C. Rastogi & G. Pritzl, *Migration of Some Toxic Metals From Crayons and Water Colors*, 56 BULL. ENVTL. CONTAMINATION & TOXICOLOGY 527 (1996) (reporting the leaching of toxic metals from crayons and watercolors).

<sup>12</sup> *See* Michael J. Prival et al., *Mutagenicity of a New Hair Dye Ingredient: 4-Ethoxy-m-phenylenediamine*, 207 SCIENCE 907 (1980) (reporting on mutagenicity of new hair dye ingredient that replaces former hair dye ingredient, 4-methoxy-m-phenylenediamine, which was also mutagenic).

<sup>13</sup> *See, e.g.* Thomas M. Burbacher, *Neurotoxic Effects of Gasoline and Gasoline Constituents* 133 (Nat'l Inst. of Health Envtl. Health Persp. Supp. No. 6, Dec. 1993) (reporting that various components of gasoline are "neuroactive," at levels currently found in gasoline,

worst a low risk of latent harms, the existing liability system creates social costs that are undesirable and unnecessary.<sup>14</sup> But until some preliminary safety testing is done, it is virtually impossible to sort products into their appropriate risk categories and, ultimately, to make safer products legally superior and financially more competitive.

This Article investigates this failure of the common-law causation rule in toxic torts, explores the problems it creates, and discusses how this failure might be corrected without radically overhauling the tort system or imposing devastating costs on manufacturing firms.<sup>15</sup> The analysis proceeds in five sections. In Part I, two very distinct categories of scientific uncertainty are identified that courts and commentators tend to blur together when considering proof requirements for causation—information that cannot be known due to the limitations of scientific experimentation (“trans-scientific uncertainties”) and information that could be known, but is not, due to a lack of reasonable investment in scientific research (“preventable scientific uncertainties”). Part II discusses the common-law courts’ failure to separate these two very different types of uncertainty in adjudicating causation. Rather than assigning responsibility for basic testing to the manufacturer, the courts place the entire burden of developing both types of information on the plaintiff. Part III highlights the theoretical deficiencies of the common-law approach. Part IV considers the adverse social ramifications of the current causation rule, which include discouraging scientific research, underdetering manufacturers, undercompensating victims, and applying an otherwise clear causation rule inconsistently. Finally, Part V argues for a legal reform that better aligns the law with tort theory and public expectations.

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and that the neurotoxic effects of chronic, low-level exposure to gasoline have not been studied).

<sup>14</sup> See discussion *infra* Parts III, IV.

<sup>15</sup> Little theoretical attention has been focussed on the effect of liability rules on incentives to obtain optimal safety information. See, e.g., Jennifer H. Arlen, *Compensation Systems and Efficient Deterrence*, 52 MD. L. REV. 1093, 1122 (1993) (noting that not enough is known about how liability rules create incentives for obtaining information on risk to design an effective system); Steven Shavell, *Liability and the Incentive to Obtain Information about Risk*, 21 J. LEGAL STUD. 259, 259 n.1 (1992) (observing that incentives for obtaining information regarding risks created by liability rules “have not been studied systematically”). It appears that no effort has been made to determine the effect of liability rules on safety testing for latent harms, either empirically or through a systematic analysis of the case law. Yet this inquiry provides the foundation for both liability rules and regulations governing potentially toxic agents. An examination of these rules’ effects is thus essential.

I  
THE TYPES OF SCIENTIFIC UNCERTAINTIES IN TOXIC  
TORT CASES

Toxic tort cases typically involve claims against manufacturers for a variety of harms that result from occupational, environmental, or consumer exposures to toxic products or wastes.<sup>16</sup> In most toxic tort cases, a person is exposed to a toxic product and decades later becomes afflicted with cancer or another ailment that cannot always be traced to a single substance or cause.<sup>17</sup> The scientific uncertainties that plague proof of cause-and-effect in such cases fall roughly into two categories—(1) “trans-scientific uncertainties” that cannot be resolved by contemporary science due to the limitations of experimentation, and (2) “preventable scientific uncertainties” that result from incomplete testing.<sup>18</sup>

A. Trans-scientific Uncertainties in Toxic Tort Cases

Some of the information critical to determining cause-and-effect between a chemical and resulting latent harms is simply unknowable due to inherent limitations in scientific experimentation. Nuclear physicist Alvin Weinberg first identified these gaps in knowledge as trans-scientific—“questions which can be asked of science and yet *which cannot be answered by science.*”<sup>19</sup> In contrast to the uncertainty that is characteristic of all of science, in which “the answer” is accompa-

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<sup>16</sup> Included in the definition of “toxic tort” for the purposes of this analysis are worker compensation suits arising from a worker’s exposure to a toxic substance that allegedly causes latent harms such as cancer. For detailed definitions of toxic tort cases, see Daniel A. Farber, *Toxic Causation*, 71 MINN. L. REV. 1219, 1222-26 (1987) (providing an overview of toxic torts in a nutshell); David Rosenberg, *The Causal Connection in Mass Exposure Cases: A “Public Law” Vision of the Tort System*, 97 HARV. L. REV. 851, 851-55 (1984) (describing the characteristics and increased frequency of toxic tort litigation). For an extended discussion of specific mass and isolated toxic tort cases, 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, 274-351 (1993).

<sup>17</sup> See generally SHEILA JASANOFF, *SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA* 119-23 (1995) (discussing the imperfect state of scientific knowledge used to prove causation in toxic tort cases).

<sup>18</sup> For alternative frameworks for analyzing scientific issues at stake in toxic tort cases, see Boston, *supra* note 16, at 191 (arguing that “[t]he mistake of many commentators and courts is to assume that *all* cases should be decided by precisely the same standards of proof regardless of the mass or isolated nature of the exposures”); Troyen A. Brennan, *Helping Courts with Toxic Torts: Some Proposals Regarding Alternative Methods for Presenting and Assessing Scientific Evidence in Common Law Courts*, 51 U. PITT. L. REV. 1, 23-26 (1989) (categorizing cases based on types of toxicological uncertainties at issue in proving causation); Farber, *supra* note 16, at 1251-58 (chastising scholars for not recognizing the diversity of toxic tort cases and breaking causation questions into six subcategories of cases).

<sup>19</sup> Alvin M. Weinberg, *Science and Trans-Science*, 10 MINERVA 209, 209 (1972). As Dr. Weinberg pointed out, trans-scientific gaps typically result regardless of large investments in time, funding, and scientific effort. See *id.* at 213.

nied by some level of unpreventable statistical noise or uncertainty, the answers to trans-scientific questions are uncertain because scientists cannot even perform experiments to test relevant hypotheses. These limitations on testing arise from various ethical, informational, and technological constraints.<sup>20</sup>

In toxic tort cases, the greatest trans-scientific uncertainties relate to whether the results of studies on animals are applicable to humans, an extrapolation made unavoidable because ethical mores typically prohibit direct testing on humans.<sup>21</sup> Although researchers generally assume that animals can serve as surrogates for humans in research related to the carcinogenicity of a substance,<sup>22</sup> considerable uncer-

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<sup>20</sup> For example, some of the data that would provide critical information regarding the effects of a toxin are too expensive to obtain. Thomas O. McGarity notes that:

[In order] to demonstrate with ninety-five percent confidence that the carcinogenic response rate [in animals] is less than one in a million, an experimenter need only feed three million animals at the human exposure rate and compare the response with three million control animals that have been raised under identical conditions but with no exposure to the chemical.

Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 733-34 (1979) (footnote omitted). Obviously such "mega-mouse" experiments are never undertaken since "it would require feeding and caring for six million rodents for eighteen to twenty-four months." *Id.* at 734. Time constraints also limit the ability of science to answer a causation question. See Nicholas A. Ashford et al., *A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking*, 7 HARV. ENVTL. L. REV. 297, 313-14 (1983) ("Depending on the available data base, a study may take from two to forty years to complete. . . . In the many situations where a delay will be inappropriate, the agency will have to treat the question of carcinogenic risk as if it were a trans-scientific issue."). Finally, a bona fide split in the theories accepted by the scientific community on a particular point may cause certain questions to remain unresolvable. See *id.* at 314 ("Even when dealing with a scientific issue rather than a trans-scientific one, scientists may disagree on the proper scientific interpretation of the data. . . . For these issues, as for trans-scientific issues, science cannot now provide an answer.").

<sup>21</sup> See, e.g., COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 22 (1983) (describing limitations in toxicity testing due in part to the moral prohibition against releasing untested chemicals into environment); cf. McGarity, *supra* note 20, at 743 & n.67 (observing that while carcinogenicity testing on humans is morally unacceptable, some officials at EPA nevertheless proposed a study in which massive doses of cancer-causing fungicides were to be fed to Mexican citizens and to convicts who volunteered at the Tennessee state prison). Thus, for public health studies, scientists must be satisfied with extrapolations from studies on animals which cannot, in most cases, be based completely on scientific inferences. See *id.* at 743-45. For an excellent in-depth discussion of the specific limitations of science in establishing the causal relationship between toxic agents and latent harms, see Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 646-58 (1992).

<sup>22</sup> See, e.g., I. Bernard Weinstein, *Mitogenesis Is Only One Factor in Carcinogenesis*, 251 SCIENCE 387, 388 (1991) (reporting on how "virtually all of the specific chemicals known to be carcinogenic in humans are also positive in the rodent bioassays" and how additional chemicals known to cause cancer in animals may later be determined to be carcinogenic); see also COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NAT'L RESEARCH COUN-

tainty remains regarding the comparative sensitivity of animals and humans to potential toxins.<sup>23</sup> The relationship between the teratogenicity (propensity to cause birth defects) of a product on animals and on humans is even more tentative.<sup>24</sup>

The trans-scientific uncertainties associated with determining a cause-and-effect relationship are also problematic, even when some segment of the human population has been exposed to a potentially toxic substance.<sup>25</sup> The inability of epidemiologists to rule out many factors that can adversely affect an individual's health often preclude statistical conclusions regarding the effects of a particular substance on exposed populations. For example, persons who smoke compli-

CIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 58-59 (1994) [hereinafter SCIENCE AND JUDGMENT] (concluding that studies on animals can be used in risk assessments when epidemiological data is unavailable and listing their comparable advantages and disadvantages).

<sup>23</sup> The Committee on Risk Assessment of Hazardous Air Pollutants for the National Research Council has observed:

There are reasons based on both biologic principles and empirical observations to support the hypothesis that many forms of biologic responses, including toxic responses, can be extrapolated across mammalian species, including *Homo sapiens*, but the scientific basis of such extrapolation is not established with sufficient rigor to allow broad and definitive generalizations to be made.

SCIENCE AND JUDGMENT, *supra* note 22, at 59 (citation omitted). The committee identified "[o]ne of the most important reasons for species differences" as inter-species variation in "chemical metabolism." *Id.*

Other areas of scientific uncertainty include whether all tumors are indicative of chronic effects or whether only malignant tumors should be counted in determining carcinogenicity, whether the results of high-dose tests can demonstrate possible effects at low doses, and even whether the selection of the test animal was appropriate. *See, e.g., id.* at 85-86; Green, *supra* note 21, at 654-56.

<sup>24</sup> *See, e.g.,* OFFICE OF TECH. ASSESSMENT, REPRODUCTIVE HEALTH HAZARD IN THE WORKPLACE 168 (1985) [hereinafter OTA, REPRODUCTIVE HEALTH HAZARDS] (pointing out the many differences in reproductive processes between humans and animals). Nevertheless, animal studies have proven very enlightening in some cases. *See, e.g.,* DAVID BRUSICK, PRINCIPLES OF GENETIC TOXICOLOGY 109-10 (1980) (discussing the usefulness of rodent studies in determining the causes of some genetic mutations in humans that may express themselves as reproductive disorders).

<sup>25</sup> Epidemiology studies are often conducted in workplace settings when exposure rates are more consistent from individual to individual, although the limited pool of workers may make the sample size too small to detect statistically significant associations. *See, e.g.,* OTA, REPRODUCTIVE HEALTH HAZARDS, *supra* note 24, at 166-67. Epidemiology studies are also conducted on exposures occurring in other environments. Statistically significant results may be even more unlikely in these latter studies, however, since exposure rates are often more variable and difficult to measure *ex ante*. (Even in occupational settings, epidemiologists can encounter difficulties in determining exposure rates and separating out other causal factors. *See* JOSEPH H. HIGHLAND ET AL., MALIGNANT NEGLECT 48 (1979)). Even when results are significant, they typically are regarded as demonstrating only an association between a suspected carcinogen and various types of cancer that must be refined and clarified through laboratory studies. *See* Norton Nelson, *Environmental Cancer: Interplay Between Laboratory and Field Studies*, in PROCEEDINGS OF THE FIRST INTERNATIONAL CONGRESS ON TOXICOLOGY: TOXICOLOGY AS A PREDICTIVE SCIENCE 327, 327 (Gabriel L. Plaa & W.A.M. Duncan eds., 1978).



cate epidemiological analysis because smoking can act synergistically (as in the case of asbestos) to dramatically increase the risk of cancer.<sup>26</sup> In addition, scientists may be unable to draw definitive conclusions regarding cause and effect due to uncertainty regarding the causal mechanisms of many birth defects and cancers.<sup>27</sup> As a result, epidemiological studies often provide only limited assistance in determining the human toxicity of a substance.

## B. Preventable Scientific Uncertainties in Toxic Tort Cases

### 1. *Preventable Scientific Uncertainties Defined*

Although the "trans-scientific" limitations of science are significant, science can provide considerable information about the long-term risks a chemical poses to human health.<sup>28</sup> Over a decade ago, the National Research Council of the National Academy of Sciences ("NRC") recognized the need to conduct cost-effective toxicity tests. As a result, it identified a battery of thirty-three laboratory tests that scientists can use to reach some general conclusions regarding the potential of a chemical to cause cancer, neurological and reproductive hazards, and birth defects.<sup>29</sup> Such tests generally provide, within

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<sup>26</sup> See, e.g., OTA, REPRODUCTIVE HEALTH HAZARDS, *supra* note 24, at 167 (explaining the effects of confounding factors, which are variables that are "correlated with both exposure and outcome"). Other potentially devastating methodological constraints include (1) the need for large sample sizes (required to obtain statistically significant results); (2) large variations and uncertainties in measuring individual exposures; and (3) difficulties associated with identifying specific harms. See *id.* at 165-67. These methodological constraints are particularly significant when attempting to quantify risks just slightly above background levels. See, e.g., Green, *supra* note 21, at 653 (discussing the literature demonstrating that if a toxic "agent has only a small or modest effect, it will go undetected in a cohort study unless a massive number of subjects are included").

<sup>27</sup> See JUDITH S. MAUSNER & SHIRA KRAMER, EPIDEMIOLOGY: AN INTRODUCTORY TEXT 180-87 (2d ed. 1985) (describing role of interpretation in drawing inferences regarding cause and effect from epidemiology studies); see also BRIAN MACMAHON & THOMAS F. PUGH, EPIDEMIOLOGY: PRINCIPLES AND METHODS 18-20 (1970) (same).

<sup>28</sup> In answering the larger question regarding the human health effects of a substance, the subquestions that science can answer generally alternate with those that science cannot answer. See Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1622-27 (1995) (describing how science and trans-scientific questions alternate in risk assessment); see also Applegate, *supra* note 1, at 266 (noting that "not all uncertainty is 'intractable' [but] most uncertainty results from the difficulty of learning about toxic substances with limited resources"); John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277, 286 n.35 (1992) (noting that "given a lack of understanding of carcinogenic mechanisms, there may be a degree of refinement of estimates of toxicity which may ultimately resist quantification, but that level of refinement is well beyond the lack of basic data that presently plagues toxic substances regulation"). See generally Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL L. REV. 469, 502-09 (1988) (providing a thorough discussion of four types of studies that can be done to determine carcinogenicity).

<sup>29</sup> See STEERING COMM. ON IDENTIFICATION OF TOXIC AND POTENTIALLY TOXIC CHEMICALS FOR CONSIDERATION BY THE NAT'L TOXICOLOGY PROGRAM, NAT'L RESEARCH COUNCIL,

several orders of magnitude, a rough idea of the human health risks posed by a product.<sup>30</sup> For substances in commerce that are likely to have more limited paths for exposure to humans, the NRC recognized that as few as eleven of the thirty-three recommended toxicity tests could be sufficient for a health assessment,<sup>31</sup> while an initial basic screening of the health risks posed by a substance could be accomplished with one or two tests.<sup>32</sup>

To determine which scientific uncertainties regarding a chemical's toxicity are "preventable," safety testing can be split into a very basic or "minimal" level of research and a much higher or "comprehensive" level of research. Minimal safety research generally consists

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TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 60, 151-63 (1984) [hereinafter TOXICITY TESTING]. The NRC also listed basic criteria that should be followed in undertaking the studies, *id.* at 61-62, and preferred protocols for conducting the studies, *id.* at 62-64, 165-68. For a more recent and more detailed identification of the series of tests used to determine a range of health hazards covering a wide range of exposures and resulting harms, see 40 C.F.R. pt. 798 (1996) (providing detailed testing protocol for testing under authority of TSCA). For a more accessible overview of the five major categories of long-term tests frequently used in toxic tort cases (epidemiology, animal toxicology, in vitro testing, chemical structural analysis, and case reports), see Green, *supra* note 21, at 644-58.

<sup>30</sup> The NRC identifies five general categories of tests that provide general information on acute, subchronic and chronic effects, effects on reproductive or development biology, and mutagenicity. See TOXICITY TESTING, *supra* note 29, at 45-49. Although these tests cannot provide a substitute for more direct testing on humans, or for better understanding the "how" and "why" of toxic injury itself, the NRC determined that the tests provided a "basic measuring stick" for determining the hazardous propensities of a chemical. *Id.* at 82; see also SCIENCE AND JUDGMENT, *supra* note 22, at 57-67 (discussing types of studies that provide preliminary information about the toxic hazards of a chemical). When they are available, "[e]pidemiologic studies clearly provide the most relevant kind of information for hazard identification." *Id.* at 57. Unfortunately, however, the assistance provided by these studies is often very limited due to methodological and other constraints. See *supra* notes 26-27 and accompanying text.

<sup>31</sup> TOXICITY TESTING, *supra* note 29, at 161 app. G (listing the eleven tests). Ten additional tests may be appropriate depending on "available data and information." See *id.* at 163. For a list of tests deemed appropriate for the major categories of chemical products, see *id.* at 151-63 apps. B-G; *id.* at 114-16 tbl. 19 (listing tests in order of priority for seven major chemical categories). For the purposes of government testing, in fact, the need to devote scarce testing resources to the greatest risks led the NRC to conclude that the government could forgo all testing on low-risk substances, even though a modicum of testing would be optimal. *Id.* at 319-36 (noting that for some untested chemicals that are members of chemical groups not associated with cancer, limited exposure data may constitute all that is required in NRC's model prioritization of testing needs for government testing programs).

<sup>32</sup> See *id.* at 45-47 (identifying five basic tests as necessary to obtain "minimal toxicity information"). The NRC report is somewhat confusing with regard to which tests are necessary for basic screening. It recognizes that only one test is sufficient to constitute minimal toxicity information for unregulated chemicals in commerce, but it does not clarify which tests are sufficient for conducting a "partial health assessment." *Id.* at 12 (distinguishing minimal information from information sufficient for a partial or a full health assessment); *id.* at 119 (noting that for chemicals in commerce only one of five basic tests was sufficient to satisfy the "minimal toxicity information" requirement, but not defining what constitutes testing sufficient for a "partial health assessment").

of one or more short-term laboratory tests designed to determine if a product is likely to constitute a serious hazard.<sup>33</sup> The second level of testing, or the comprehensive level of research, consists of a series of studies sufficient to resolve most remaining, scientifically answerable questions regarding the extent of the hazard.<sup>34</sup> These studies constitute a full assessment. Depending on the concentration of the product and routes of exposure, this second level of testing might require a substantial investment of resources and time.<sup>35</sup>

## 2. *The Extent Of Preventable Scientific Uncertainty*

An examination of the research conducted on the long-term safety of chemicals reveals that considerable preventable scientific uncertainty exists, even at the minimal level of testing. In its comprehensive 1984 study, which still remains largely up-to-date,<sup>36</sup> the NRC found that for approximately eighty percent of the estimated 48,523 unregulated chemicals in commerce,<sup>37</sup> no toxicity information existed.<sup>38</sup> For the remaining chemicals in commerce, scientific uncer-

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<sup>33</sup> See, e.g., John H. Weisburger & Gary M. Williams, *Carcinogen Testing: Current Problems and New Approaches*, 214 Sci. 401, 404-06 (1981) (providing a decision-point approach to carcinogen testing, with chemical structure analysis and battery of short-term in vitro tests forming "the basis for preliminary decision-making" regarding carcinogenicity of a substance and advocating that short-term and long-term rodent studies be used more "selectively" or as a "last resort" due to their time and expense). For a substance that poses, in the worst case scenario, a de minimis opportunity for exposure (e.g., no more than fifty persons over the lifetime of the chemical) no testing could conceivably constitute a minimal level of research. Cf. Arlen, *supra* note 15, at 1121 n.93 (arguing that "[e]fficiency does not require that products be tested for every possible risk").

<sup>34</sup> See, e.g., 21 C.F.R. pt. 312 (1996) (listing testing requirements imposed for drugs under Food, Drug, and Cosmetic Act ("FDCA")); 40 C.F.R. pt. 158 (1996) (identifying testing requirements for registration imposed under Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")); *id.* pt. 798 (listing various preferred tests for assessing range of impacts of chemicals on human health under Toxic Substances Control Act ("TSCA")).

<sup>35</sup> See, e.g., Veronica Henry, *Problems with Pharmaceutical Regulation in the United States: Drug Lag and Orphan Drugs*, 14 J. LEGAL MED. 617, 617 (1993) (reporting that the average cost of developing a new drug in U.S. is \$231 million and development takes 10-12 years).

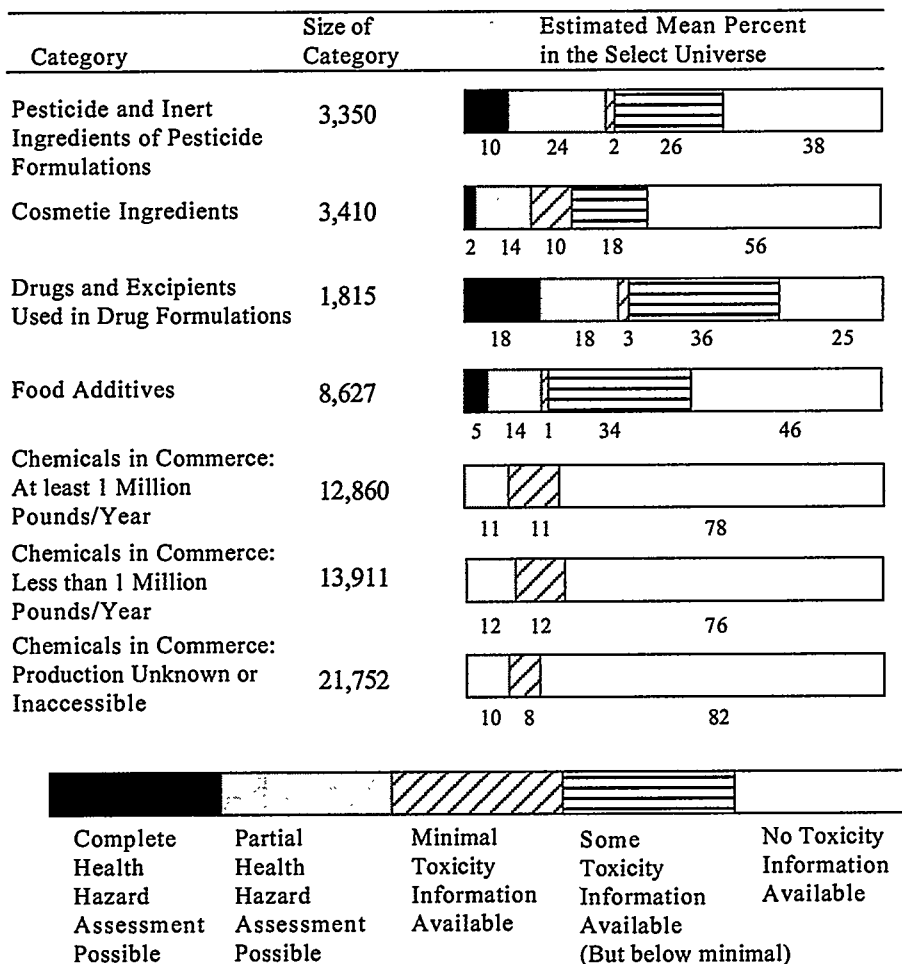
<sup>36</sup> See, e.g., Ellen K. Silbergeld, *The Risks of Comparing Risks*, 3 N.Y.U. ENVTL. L.J. 405, 413 (1995) (arguing that "[I]ttle has changed since the National Research Council (NRC) noted ten years ago that between seventy-three and eight-nine percent of chemicals in commerce have almost no toxicity data upon which even a qualitative identification of hazard can be made").

<sup>37</sup> See TOXICITY TESTING, *supra* note 29, at 12 fig.2 (documenting the number of chemicals in three categories of "chemicals in commerce").

<sup>38</sup> See *id.* at 84 tbl.7, 94 tbl.10, 117 tbl.20. The NRC also reported that the existence of toxicity information appeared to be independent from the extent of production: "Chemicals in commerce with indicated 1977 production of at least 1 million pounds have been tested no more often or more adequately than substances with 1977 production of less than 1 million pounds." *Id.* at 119. In contrast, the NRC found that considerably more testing was done on those categories of chemicals, like pesticides and drugs, that are generally required to undergo testing and regulatory approval before marketing. See *infra* note 51. For a description of the design of the NRC study, see *id.* at 81; see also Myra Karstadt & Renee Bobal, *Availability of Epidemiologic Data on Humans Exposed to Animal Carcinogens*, 2

tainty was also prevalent—a full health assessment could not be completed for *any* of these chemicals.<sup>39</sup> See Figure 1.

FIGURE 1  
TOXICITY TESTING INFORMATION AVAILABLE ON SEVEN  
CATEGORIES OF CHEMICALS



In addition, the NRC found that the quality of testing was inadequate for over thirty percent of the studies that had been conducted.<sup>40</sup>

TERATOGENESIS CARCINOGENESIS & MUTAGENESIS 151 (1982) (reporting that in 1982, only 13 of 75 animal carcinogens had been the subject of an epidemiologic study).

<sup>39</sup> See TOXICITY TESTING, *supra* note 29, at 118 fig.2, 119.

<sup>40</sup> See *id.* at 94 tbl.10 (reporting that 57 of 170 total tests done on chemicals in commerce were “inadequate” with retesting needed and that the adequacy of the testing on 29 of the remaining chemicals could not be judged).

### 3. *The Failure of Markets and Regulatory Programs to Resolve Preventable Scientific Uncertainties*

Market forces, internal management practices, and regulatory shortcomings combine to create an environment where preventable scientific uncertainty is prevalent. From a market perspective, comprehensive testing programs are not only costly and time-consuming,<sup>41</sup> but they do little to improve the marketability of a product.<sup>42</sup> Consumers appear to assume that most products are safe, regardless of the presence or absence of costly research programs.<sup>43</sup> The long delay from exposure to injury, the relatively low probability of harm, and the unlikelihood that customers will be able to link latent adverse effects with the manufacturer provide further assurance that the market will not discriminate between a tested and an untested product.<sup>44</sup>

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<sup>41</sup> Following TSCA protocols, the costs of conducting research on the possible carcinogenicity and teratogenicity of a chemical ranged in 1982 from \$300,000 to \$700,000 per chemical. See LYNDON B. JOHNSON SCH. OF PUB. AFF., POLICY RESEARCH PROJECT REPORT NO. 50, THE TOXIC SUBSTANCES CONTROL ACT: OVERVIEW AND EVALUATION 121 (1982); see also Paul R. Portney, *Toxic Substance Policy and the Protection of Human Health, in CURRENT ISSUES IN U.S. ENVIRONMENTAL POLICY* 105, 136 (Paul R. Portney ed., 1978) (reporting similar estimates). More recent reports identify the costs of carcinogenicity testing at \$2.4 million. See National Toxicology Program, Annual Plan for Fiscal Year 1996, at 2 (Nov. 1996). These estimates do not include the costs of conducting epidemiological studies, which are traditionally much more difficult to gauge due to the varying designs and test subjects.

<sup>42</sup> Scholars have observed market failures in the production of safety information on latent hazards. See, e.g., Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. PA. L. REV. 1027, 1038 (1990) (arguing that "[c]ommonly, producer firms simply won't have good information about risk (often because, as we shall see, they are not stimulated to have it) or, if they do, won't act on it or share it with typically underinformed consumers and employees"); Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1810-17 (1989) (describing market failure in safety testing of chemical products). See *infra* Parts IV.A-B.

In addition, safety research in its present form is a "free good": if a manufacturer conducts safety tests and determines that a product is safe, other manufacturers benefit from this research but pay nothing. See Applegate, *supra* note 1, at 298-99 (noting that safety information regarding chemicals "is a public good . . . which reduces to practically nil any return to these persons on investment in research"); see also *infra* note 272 (discussing how to solve free-rider problems).

<sup>43</sup> See, e.g., Arlen, *supra* note 15, at 1120-21 (arguing that market failure exists in the manufacture of toxic products because consumers do not know of risks, do not discover risks on their own, and often "do not expect the product to be risky in the first place"). The same assumptions are often made by employees who encounter latent risks in the workplace. See, e.g., W.L.F. Felstiner & Peter Siegelman, *Neoclassical Difficulties: Tort Deterrence for Latent Injuries*, 11 L. & POL'Y 309, 317-18 (1989) (arguing that for a number of reasons employees may not discover or understand the extent of latent risks at the workplace).

<sup>44</sup> See GEORGE EADS & PETER REUTER, DESIGNING SAFER PRODUCTS: CORPORATE RESPONSES TO PRODUCT LIABILITY LAW AND REGULATION 49-51 (1983) (recognizing that, despite the importance of reputation as an incentive, the decades of time that pass and the likelihood that hazards will remain undiscovered unless a product causes a signature disease may significantly mute this reputational incentive); Gillette & Krier, *supra* note 42, at 1039-40 (describing the latent, probabilistic, and diffuse nature of public risks as "dampen[ing] the incentives otherwise created by reputation and profit concerns," and

In contrast, if a manufacturer does invest in testing, and in doing so discovers that some risk of latent harm exists, marketing the product typically will be much more difficult.<sup>45</sup>

Internal management practices common to most firms also contribute to the failure of manufacturers to develop scientific information on the safety of their products. In their study of nine companies, Eads and Reuter observed that the fractionated nature of the design process and the individual incentives for staff and management to get a product to the market are likely to lead to an underestimation or undertesting of hazards, or to lead corporate officials to *mistakenly* assume that someone within the corporation has conducted safety testing.<sup>46</sup> The well-established short-term profit motivations of corporate officials, who tend to concentrate their efforts on "pursu[ing] tangible gains, rather than . . . avoid[ing] ethereal losses,"<sup>47</sup> further reinforce the bias against testing. Ethical codes are viewed as providing little

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that these "characteristics skew the incentives of presumably self-interested producers and consumers" to discount such risks); cf. James A. Henderson, Jr., *Product Liability and the Passage of Time: The Imprisonment of Corporate Rationality*, 58 N.Y.U. L. REV. 765, 776-77 (1983) (making a similar observation regarding the tendency of manufacturers to discount their potential liability based on the "possibility of escaping part or all of their responsibility in the long run as a result of government intervention").

<sup>45</sup> See, e.g., Lyndon, *supra* note 42, at 1813-14 (describing toxicity data as "negative features of chemical products" which potentially deter consumers); Shavell, *supra* note 15, at 266-67 (noting that obtaining information on the toxicity of a product may have a negative value).

<sup>46</sup> EADS & REUTER, *supra* note 44, at 56-57 (describing the fractionated divisions within companies typically involved in product-design and concluding that "unless a specific decision is made to incorporate [safety considerations] in the design reviews and associated design activities, there is likely to be no way of assuring that safety considerations are surfaced and resolved appropriately"). Corporate structure may insulate top management from information about safety issues because this information is dispersed among various "subordinate parts of the organization." *Id.* at 60-61. Eads and Reuter's review of the literature and their own case study research reveals that ultimately the commitment of management to safety exerts the greatest influence on the extent and quality of safety research. *Id.* at 64-65, 99-101. For a different view, see Albert Flores, *Engineering Ethics in Organizational Contexts: A Case Study*, in DESIGNING FOR SAFETY: ENGINEERING ETHICS IN ORGANIZATIONAL CONTEXTS 3, 7, 35 (Albert Flores ed., 1982) (concluding that Monsanto Co. dedicated careful attention to safety concerns in product development). But see EADS & REUTER, *supra* note 44, at 87-88 (raising questions about Flores's research). See generally discussion *infra* note 144 (discussing Monsanto's safety program).

<sup>47</sup> Gillette & Krier, *supra* note 42, at 1041. Tangible gains take the form of immediate liability and market pressures, rather than the threat of liability that will be delayed for decades. See *id.* at 1040 (observing that "[t]he lag between cause and effect shelters managers from the consequences of their decisions: evidence disappears, or the managers do").

In his review of the literature, James Henderson observed:

[M]anagers who defer taking necessary action may reasonably assume that they will be rewarded for the short-run benefits derived from their deferral tactics and that they will have been promoted to another position, possibly with another corporation, by the time the negative, long-run implications of their tactics have fully materialized.

Henderson, *supra* note 44, at 781; see also *infra* note 143.

counterbalance to the tendency of businesses to ignore long-term safety concerns in the manufacture of potentially toxic products.<sup>48</sup>

Governmental efforts to correct the underproduction of safety information only partially offset a manufacturer's tendency to remain ignorant regarding the latent effects of products. Several federal regulatory programs do require safety testing prior to, and in rare cases after, registration of the product,<sup>49</sup> but these testing requirements have been severely criticized for their less than perfect implementation.<sup>50</sup> Even giving these testing requirements

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<sup>48</sup> In their study of safety research, Eads and Reuter conclude that although ethical concerns might influence some design decisions, "there is little to suggest that the raised ethical consciousness of professional groups involved in product design is likely to have a major influence on the safety performance of U.S. manufacturers." EADS & REUTER, *supra* note 44, at 44. They base this conclusion on several professional realities that serve to supplant individual or societal ethical concerns. First, in contrast to doctors, engineers engaged in the design of products do not work independently; instead their concerns are supplanted by the larger interests of the firm. *See id.* Second, as a profession, engineers are fragmented and hence there is little opportunity for a unifying ethical code. *See id.* Third, professional associations do not appear to require many of the engineers to be licensed in order to practice. *See id.* at 44-45. Fourth, there appears to be little evidence of enforcement action taken against those engineers who are members of professional associations for ethical violations. *See id.* at 45. Fifth, many professional societies do not appear concerned with ethical codes in any case. *See id.* Sixth, a product goes through a complicated series of stages of innovation and review, making any particular individual or unit typically unable to control the outcome. *See id.* Seventh, and finally, ethics remains an under-emphasized concern in the education of design professionals. *See id.* at 46. Eads and Reuter also observe that likely:

the most fundamental problem is that the safety of a product is not a matter that can be readily determined by a single individual involved in the design process. The typical product goes through many stages of design review; each individual is responsible for only some component of that review.

*Id.* at 45.

<sup>49</sup> The primary statutes requiring such testing are the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), *see, e.g.*, 7 U.S.C. § 136a(a), (c)(5)(D) (requiring that for licensing under FIFRA the registrant has the initial burden of demonstrating "it will not generally cause unreasonable adverse effects on the environment"); the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2601-2692 (1994); *see, e.g., id.* § 2603(a) (requiring testing when there is an "unreasonable risk of injury" and insufficient data on a chemical substance or mixture, or when substantial quantities will enter the environment and "significant or substantial human exposure" will result); *id.* § 2604(a), (b)(1)(A) (1994) (requiring submission of test data at time of manufacture of new chemical or use); *id.* § 2604(e) (providing EPA with the powers to impose follow-up testing on chemicals of concern); and the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-395 (1994); *see, e.g., id.* § 348(b)(2) (requiring manufacturers of a food additive to file a petition detailing testing before additive can be used); *id.* § 355(b) (requiring same for new drugs); *id.* § 350a(b)(2)(B) (requiring same for infant formula); *id.* § 351(b) (same for drugs that vary in strength, quality, and purity than approved drngs); *id.* § 360b(b)(1) (same for new animal drugs).

<sup>50</sup> There is substantial evidence that the regulatory agencies have done a disappointing job overseeing safety testing for many products within their jurisdictions. *See, e.g.*, GEN. ACCOUNTING OFFICE, LAWN CARE PESTICIDES: RISKS REMAIN UNCERTAIN WHILE PROHIBITED SAFETY CLAIMS CONTINUE 12-14, 20 (1990) (criticizing EPA and Federal Trade Commission for inadequate testing and investigation of the long-term safety of 34 of the most widely used lawn care pesticides); GEN. ACCOUNTING OFFICE, TOXIC SUBSTANCES: EPA'S

the benefit of the doubt,<sup>51</sup> the vast majority of products remain largely unaffected—testing is simply not required for most chemicals.<sup>52</sup>

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CHEMICAL TESTING PROGRAM HAS MADE LITTLE PROGRESS 17-21 (1990) [hereinafter GAO, EPA'S CHEMICAL TESTING PROGRAM] (reporting alarming delays in EPA's issuance of test rules requiring manufacturers to generate additional safety data on their products, and noting that as of 1989 the "EPA had received complete test data for only six chemicals and had not finished assessing any of them for possible further action"); TOXICITY TESTING, *supra* note 29, at 8-9, 97 (reporting on the low quality of toxicity testing of drugs, pesticides, and other regulated products, although "[t]he major portion of testing need[s] [did ultimately] result[ ] from failure to do required tests, rather than from conducting tests in a manner inappropriate for the purpose of health-hazard assessment"); Applegate, *supra* note 1, at 313-14 (observing that for various reasons the EPA has not been aggressive in using its authority to force companies to generate safety information on existing chemicals or post-license information on new ones in the implementation of FIFRA).

Some problems appear to be procedural. Under TSCA, for example, manufacturers are required to keep records of allegations of "significant" harmful effects caused by their chemicals, *see* 15 U.S.C. § 2614(3) (1994), but there is no deadline for recording the allegation. *See, e.g.,* David J. Hayes & Ann Claassen, *TSCA Section 8: Key Issues, in HAZARDOUS WASTES, SUPERFUND, AND TOXIC SUBSTANCES* 191, 202 (ALI-ABA Course of Study, Oct. 28-30, 1993), available in WESTLAW, C864 ALI-ABA 191. Although the number of enforcement actions threatened or filed could not be determined, published rulings for violation of this requirement have been issued in only one case. *See* *ALM Corp. v. U.S. EPA, Region II*, 974 F.2d 380 (3d Cir. 1992). The EPA also has the statutory authority to require that companies produce health and safety information, but it has identified only a modest list of chemicals for which it demands this information. *See* 40 C.F.R. § 716.120 (1996) (listing a total of 346 chemicals requiring such study, only 45 (by June 1997 this number will drop to 15) of which have an unexpired sunset date). Even the "substantial risk" disclosure requirements set forth under Section 8(e) of TSCA, *see* 15 U.S.C. § 2607(e) (1994), appear to have been underutilized. Although the EPA obtained authority in 1977, the EPA still has not promulgated regulations clarifying its authority. *See* Hayes & Claassen, *supra*, at 208. Significant ambiguities thus still surround the point at which a manufacturer has acquired information that "reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment." *Id.*

<sup>51</sup> When the NRC compared the amount of toxicity information available for seven general product categories, it did see dramatically greater testing for those categories of chemicals, like pesticides and drugs, that are subject to more extensive safety regulation. *See, e.g.,* TOXICITY TESTING, *supra* note 29, at 118-21 fig.2 (concluding that categories of chemicals subject to testing requirements have more complete toxicity testing available and that it is possible to conduct "at least a partial health-hazard assessment" of 94% of pesticides, 92% of drugs, 62% of cosmetic ingredients, and 95% of food additives, but that this type of assessment is possible only for about 10% of the unregulated chemicals in commerce).

<sup>52</sup> *See* TOXICITY TESTING, *supra* note 29, at 48 tbl.4 (listing number of chemicals in various categories, 74% (over 48,000) of which are identified as largely unregulated chemicals in commerce). Only a subset of drugs, food additives, pesticide products, and a small universe of chemicals are actively regulated by agencies, although in theory existing statutory authorities would allow agencies to do far more with regard to their regulation. *See, e.g.,* Applegate, *supra* note 1, at 318-32 (proposing refinements to TSCA to better allow the EPA to obtain toxicity information on more chemicals). For example, although testing is not required, statutes or regulatory authorities often require manufacturers to disclose information suggesting that a product is hazardous. *See* 15 U.S.C. § 2607(c) (1994) (stating that the EPA may require industries to keep records of "significant adverse reactions . . . alleged to have been caused" by a regulated chemical); *see also* 7 U.S.C. § 136f(a) (1994) (same under FIFRA); 42 U.S.C. § 6924(a)(1) (1994) (same under RCRA); *id.* § 9603(d) (same under CERCLA).



In fact, in some circumstances existing regulatory programs may create additional incentives for manufacturers to remain ignorant rather than invest in developing information on the long-term safety of their products.<sup>53</sup> If a manufacturer voluntarily reports research demonstrating that its product might not be safe,<sup>54</sup> it is likely to be rewarded only with a demand by a regulatory agency either to conduct additional testing<sup>55</sup> or to undergo lengthy regulatory proceedings regarding possible market restrictions on its product.<sup>56</sup> In

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<sup>53</sup> See, e.g., Lyndon, *supra* note 42, at 1825-27.

<sup>54</sup> This reporting of adverse information in health or safety studies is typically required by statute. See 7 U.S.C. § 136d(a)(2) (1994); 15 U.S.C. § 2607(d) (1994) (requiring collection of toxicity research under TSCA); 42 U.S.C. § 6921(b)(3)(B)(i)(II) (1994) (similar requirements under RCRA); 40 C.F.R. § 152.125 (1996) (implementing similar requirements under FIFRA); see also 15 U.S.C. § 2607(e) (1994) (TSCA requirement that industry report information that "reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury"); 21 U.S.C. § 350a(e) (1994) (authorizing the FDCA requirement that manufacturers report any "knowledge which reasonably supports the conclusion" that its infant formula is adulterated); *id.* § 355(k) (stating the FDCA reporting requirements for approval on new drugs); *cf.* 29 C.F.R. § 1910.1200(b), (d)(2) (1996) (listing Occupational Safety and Health Act ("OSHA") requirement that employers report the possible health effects of hazardous chemicals to their employees if there is significant evidence of a hazard, which is demonstrated by one "statistically significant" study conducted in accordance with scientifically accepted methods). Perhaps the most comprehensive disclosure requirement arises under TSCA: chemical manufacturers must notify the EPA of their new products and submit Premanufacture Notices ("PMNs") that provide the results of all safety tests, as well as information regarding chemical composition and other chemical characteristics. Based on the PMN filings, the EPA determines whether further testing or regulation is necessary. See 15 U.S.C. § 2604 (1994). If no testing information is available, the EPA typically considers whether the chemical structure of a product or its components are sufficiently similar to other known toxins to necessitate further testing by the manufacturer. See 15 U.S.C. § 2603(c)(2)(A)-(B) (1994) (allowing exemption if equivalent to regulated substance and testing would be duplicative).

<sup>55</sup> See 15 U.S.C. § 2603(a) (1994). The EPA may require a manufacturer to conduct further testing on a product if it finds that product "may present an unreasonable risk of injury to health or the environment," § 2603(a)(1)(A)(i), or if there "may be significant or substantial human exposure to [the product]," § 2603(a)(1)(B)(i), and if there is insufficient data to reasonably determine its effects, § 2603(a)(1)(A)(ii). See also *id.* § 2607(d) (stating that for listed chemicals, manufacturers conducting safety tests voluntarily must notify the EPA of the results of safety tests); *id.* § 2604(h)(1)(A), (h)(2) (requiring testing for a new use of a chemical unless it will not present "an unreasonable risk of injury"). See generally Hayes & Claassen, *supra* note 50, at 205 (outlining the reporting procedures under the federal regulations).

<sup>56</sup> See 15 U.S.C. § 2605(a) (1994) (allowing the EPA to issue regulations regarding distribution or production of products under TSCA if the EPA finds that the chemical "will present an unreasonable risk of injury to health or the environment"); see also Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" about Consumer Product Hazards*, 11 YALE J. ON REG. 293, 298-361 (1994) (providing an overview of the "crazy quilt" of warning requirements governing products that research has revealed present some health hazard). Interestingly, only about 10% of substances for which manufacturers submit PMNs pursuant to TSCA undergo "some form of restriction." David J. Hayes & Robert M. Sussman, *EPA Activities Under the Toxic Substances Control Act*, in HAZARDOUS WASTES, SUPERFUND, TOXIC SUBSTANCES 299, 312 (ALI-ABA Course of Study, Oct. 31-Nov. 1, 1994), available in WESTLAW, C667 ALI-ABA 299. For most of this 10%, EPA imposes some type of "use restrictions, workplace practices, [or] labeling and environmental re-

contrast, a manufacturer who reports no knowledge of adverse effects of its product—precisely because it has avoided investigating possible harms—is likely to be successful in dodging regulatory oversight.<sup>57</sup> The low proportion of chemical products that are accompanied by long-term safety research suggests that, at the very least, disclosure requirements do not encourage toxicity research for a large percentage of potentially toxic products.<sup>58</sup>

Public testing programs, which are often created as part of a regulatory program, also fail to fill the information void. Although government testing provides vital information, resource constraints often limit testing to only a small number of chemicals annually, leaving the vast majority of products unstudied.<sup>59</sup> As of 1987, the government

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lease limitations." *Id.* In some cases, manufacturers enter into agreements with the EPA to conduct further safety testing. *See id.*

<sup>57</sup> Due in part to the TSCA's cumbersome process and the relatively serious findings the EPA must make before it can require manufacturers to undertake additional safety testing or otherwise restrict the production or distribution of a product, a manufacturer who chooses to avoid safety testing is unlikely to be caught by the regulators. *See, e.g.,* Applegate, *supra* note 1, at 319-30 (discussing procedural barriers in TSCA that explain, at least in part, the EPA's inaction in acquiring toxicity information); *see also* WILLIAM DRAYTON, AMERICA'S TOXIC PROTECTION GAP 69, 72 (1984) (noting that through 1983 the EPA "ha[d] required testing for only 4% of new chemicals" and had obtained voluntary agreements for testing on 84 chemicals); Milton C. Weinstein, *Decision Making for Toxic Substances Control: Cost-Effective Information Development for the Control of Environmental Carcinogens*, 27 PUB. POL'Y 333, 336 (1979) (concluding that by focusing on only a few chemicals, government testing programs "decrease the chances that others will be controlled"); *cf.* discussion *supra* note 50 and accompanying text (reviewing investigation by the General Accounting Office).

<sup>58</sup> Not surprisingly, only about 17% of the product disclosures required under TSCA contained any safety information on the long-term effects of the product. *See* OFFICE OF TECHNOLOGY ASSESSMENT, THE INFORMATION CONTENT OF PREMANUFACTURE NOTICES 50-51 (1983). For an insightful discussion of why TSCA appears to have failed in the production of safety research and suggestions for reform, see Applegate, *supra* note 1, at 319-32. Similarly, the NRC, in its 1984 study, observed that for "no substance in the . . . categories of chemicals in commerce . . . is information sufficient to permit a complete health-hazard assessment. Partial assessments could be made for 10-37% of the substances in the select universe." TOXICITY TESTING, *supra* note 29, at 125.

<sup>59</sup> *See* Applegate, *supra* note 1, at 306-07 (concluding after careful study that expense and breadth of the necessary toxicity research prevents the government research programs from "fill[ing] the existing data gaps on a chemical-by-chemical basis" and recommending that government instead focus resources on developing better risk assessment methodologies for using existing limited information). Under 42 U.S.C. § 9604(i), the Agency for Toxic Substances and Disease Registry ("ATSDR"), which is funded by responsible parties and registrants under TSCA and FIFRA, *see id.* § 9604(i)(5)(D), may provide "consultations . . . on health issues relating to exposure to" specific substances. *Id.* § 9604(i)(4). The ATSDR may also conduct health assessments at certain EPA Superfund Sites, which typically requires compiling information on potential exposures at contaminated sites and keeping records on exposed persons over time. *See id.* § 9604(i)(6). In litigation, this information may assist persons in proving exposure or increased health risks associated with living close to a contaminated site, but it does not address the preliminary issue of whether scientific research has been done on the potential long-term hazards of individual substances present at that site. For a list of the government research conducted on specific substances, see U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL TOXICOLOGY PROGRAM:

had conducted animal carcinogenicity bioassays on only 308 substances out of 594 that were nominated by various agencies for testing,<sup>60</sup> but since that time a gradually shrinking budget has led the government to test even fewer chemicals.<sup>61</sup>

## II

### THE COMMON-LAW COURTS' APPROACH TO SAFETY RESEARCH

Because common-law courts are charged with allocating responsibility between plaintiffs and defendants, one would hope that they would consider which party is better able to produce scientific information when assigning burdens of proof for causation. Yet, in adjudicating toxic tort and related cases,<sup>62</sup> the courts make no such distinction.<sup>63</sup>

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REVIEW OF CURRENT DHHS, DOE, AND EPA RESEARCH RELATED TO TOXICOLOGY (published annually).

<sup>60</sup> OFFICE OF TECH. ASSESSMENT, IDENTIFYING AND REGULATING CARCINOGENS 160, 174 (1987) [hereinafter REGULATING CARCINOGENS]. In addition, each study of a chemical takes from approximately six to eight years to complete. See *id.* at 167 ("Developing protocols, awarding contracts, and performing chemical disposition and prechronic and chronic tests takes at least 5 years; the evaluation of organs and microscopic sections adds at least an additional year; and preparation of the report, review, and publication add still more time.").

<sup>61</sup> See, e.g., *id.* at 161 (noting that "[t]he number of chemicals selected for testing is consistent with the NTP budget," which was adversely affected by cutbacks in 1986); Lyndon, *supra* note 42, at 1805-06 ("In fiscal year 1987, the federal government allocated \$210 million for toxicological research, but in real dollars, the budget for chemical testing was smaller than the 1980 budget."); cf. William J. Broad, *Science Research Would Be Hit Hard in Budget Cutting*, N.Y. TIMES, May 22, 1995, at A1 (reporting on Republican proposals to cut government funding of basic science by one-quarter to one-third).

<sup>62</sup> For an extended discussion of the types of claims available to plaintiffs in toxic tort cases, see Wendell B. Alcorn, Jr., *Liability Theories for Toxic Torts*, NAT. RESOURCES & ENV'T, Spring 1988, at 3; Robert F. Blomquist, *Emerging Themes and Dilemmas in American Toxic Tort Law, 1988-91: A Legal-Historical and Philosophical Exegesis*, 18 S. ILL. U. L.J. 1, 26-29 (1993).

<sup>63</sup> Many people writing in the toxic tort field take the existence of adequate scientific information for granted and thus tend to reinforce rather than correct the judiciary's failure to recognize the distinction between preventable scientific and trans-scientific uncertainties. See, e.g., Boston, *supra* note 16, at 366-67 (arguing without support that a rigorous scientific standard in mass exposure litigation will cause firms to "invest in safety research and precautionary measures commensurate with the risks potentially posed by the hazardous substances they generate"); Jean Macchiaroli Eggen, *Toxic Reproductive and Genetic Hazards in the Workplace: Challenging the Myths of the Tort and Workers' Compensation Systems*, 60 FORDHAM L. REV. 843, 900-04 (1992) (recognizing a lack of research on causation questions and recommending that plaintiffs' burden be reduced to proving only "general statistical causation," but assuming that enough scientific information exists to provide evidence for plaintiffs); Christopher H. Schroeder, *Corrective Justice and Liability for Increasing Risks*, 37 UCLA L. REV. 439, 443-51 (1990) (overlooking in analysis of corrective justice that some uncertainty regarding causation of toxic products is possibly due to negligent failure of manufacturers to conduct safety testing); Alan Schwartz, *Products Liability, Corporate Structure, and Bankruptcy: Toxic Substances and the Remote Risk Relationship*, 14 J. LEGAL STUD. 689, 695-705 (1985) (modelling incentives for long-term safety research, but overlooking the possibility that because no testing will be done for many chemicals by persons other than

### A. The Causation Rule: Immunity for Ignorance

At present, common-law courts place the entire burden of proving causation on plaintiffs, a burden that includes responsibility for resolving both "trans-scientific" and "preventable scientific uncertainties." Causation in tort requires that a plaintiff establish that her harm was more likely than not caused by a defendant's product.<sup>64</sup> Although

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the manufacturers, a lack of manufacturer accountability will cause widespread avoidance of safety testing); Shavell, *supra* note 15, at 262-63 (arguing that strict liability will lead defendant to obtain optimal level of information regarding risk based on the mistaken assumption that plaintiffs have other sources for obtaining information and prevailing on liability); Ellen Wertheimer, *Unknowable Dangers and the Death of Strict Products Liability: The Empire Strikes Back*, 60 U. CIN. L. REV. 1183, 1184-91 (1992) (arguing that strict liability is appropriate because it is fairer for the manufacturer rather than the victim to bear the risk from unknowable dangers, but overlooking the possibility that the current burden of proof on causation could, in theory, lead to less safety testing, less safety, and ultimately more injured victims); *cf.* Applegate, *supra* note 28, at 324 (recognizing numerous remedial data gaps regarding chemical safety, but suggesting that agencies focus regulation on those substances for which agencies can readily obtain the most information, even though this proposal would seem to reward scientific ignorance).

Proponents of proportional causation seem to assume both that adequate safety research exists, and that this research will allow for a rough probabilistic estimate of the contribution of a chemical to a resulting class of harms. *See, e.g.*, Farber, *supra* note 16, at 1220 (observing that "something of a scholarly consensus exists in favor of making recoveries proportional to the probability of causation"). *See generally* Richard Delgado, *Beyond Sindell: Relaxation of Cause-In-Fact Rules for Indeterminate Plaintiffs*, 70 CAL. L. REV. 881, 892 (1982) (arguing that tort law should allow "each member of the plaintiff class [to be] compensated in proportion to the damages sustained by the class as a whole"); Glen O. Robinson, *Multiple Causation in Tort Law: Reflections on the DES Cases*, 68 VA. L. REV. 713, 759-62 (1982) (contrasting various approaches to probabilistic apportionment of liability); Rosenberg, *supra* note 16, at 861-905 (advocating proportionality rule for mass exposure cases). While the latter assumption has been called under attack by several scholars, *see, e.g.*, Feldman, *supra* note 1, at 39-40 (noting that "strong uncertainty about general causation" causes market-share and proportional-liability schemes to be generally unhelpful); *cf.* Farber, *supra* note 16, at 1251 (arguing that scholars writing in area of proportional liability only consider one type of case that is not typical of all toxic tort cases), the doubtful availability of any toxicity testing on a particular carcinogenic substance is consistently overlooked. *See, e.g., id.* at 1241 (touting proportional recovery "as a means of compensating for actual harm given limited information about causation") (emphasis added). Although the ultimate effect of the proportional reform on firms that have conducted minimal safety testing will depend on courts' determinations of what constitutes sufficient evidence for proof of proportional causation, it is possible that the incentive not to test products is greater under proportional liability because firms with no testing are the only parties assured of avoiding liability.

<sup>64</sup> *See, e.g.*, W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 41, at 269-70 (5th ed. 1984) (discussing that when proving causation, "plaintiff must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a cause in fact of the result"); Bert Black & David E. Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 FORDHAM L. REV. 732, 749 (1984) (observing that in toxic tort cases courts generally "have explicitly adopted the preponderance test . . . in which the harmfulness of a substance was at issue"); Jean Macchiaroli Eggen, *Toxic Torts, Causation, and Scientific Evidence after Daubert*, 55 U. PITT. L. REV. 889, 895-909 (1994) (discussing causation requirements in toxic tort cases). Sometimes courts express this test as requiring the plaintiff to establish causation by a "preponderance of the evidence." *See* MICHAEL D. FINKELSTEIN, QUANTITATIVE METHODS IN LAW 66-67 (1978)

some courts seem content with expert testimony that expresses a probabilistic judgment that the cause-and-effect relationship between plaintiff and defendant was greater than fifty percent,<sup>65</sup> other courts require "particularistic" evidence that a particular plaintiff's harms were caused by a particular defendant's product or by-product.<sup>66</sup>

Despite variations between courts with regard to the sufficiency<sup>67</sup> and the admissibility of various types of scientific causation evidence,<sup>68</sup> all courts require a plaintiff to submit *some* scientific research demonstrating that a product is capable of causing latent injuries similar to her own.<sup>69</sup> As Joseph Sanders observed in his survey of Bendectin

(equating preponderance-of-the-evidence standard with requirement of more than fifty percent proof of causation); CHARLES T. MCCORMICK, HANDBOOK ON THE LAW OF DAMAGES § 31, at 118 (1935) (same). For a very insightful analysis of how this "more likely than not" test inappropriately collapses the burden of proof with the standard of persuasion, see Steve Gold, Note, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376, 380-86 (1986).

<sup>65</sup> See, e.g., Rosenberg, *supra* note 16, at 857-58 (describing a "weak" standard for causation which requires only statistical evidence of cause).

<sup>66</sup> See generally Renaud v. Martin Marietta Corp., 972 F.2d 304, 306 (10th Cir. 1992) (discussing medical causation); JASANOFF, *supra* note 17, at 124-25 (noting that, in cases with fewer plaintiffs, some courts appear to demand testimony from doctors who examined the plaintiff to prove causation and concluding that, when presented with such evidence, courts may be willing to overlook weaknesses in proof of general causation); Rosenberg, *supra* note 16, at 857 n.38 (citing courts that use "particularistic" requirement for causation); cf. Robinson, *supra* note 63, at 765 (attempting to explain some courts' hesitancy to accept probabilistic proof without additional, particularistic proof).

<sup>67</sup> See, e.g., Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH. L.J. 189, 211 (1992) (describing variation in how courts rely on statistical evidence of causation). For example, while some courts have held that epidemiological evidence of a statistically significant relationship between a substance and injuries is necessary to prevail on a defendant's motion for summary judgment or a directed verdict, see *infra* note 76 and accompanying text, other courts consider epidemiological evidence completely unhelpful in determining causation due to its purely statistical nature, see Brennan, *supra* note 28, at 492 & nn.114-15.

<sup>68</sup> See Poulter, *supra* note 67, at 223 (discussing varying rulings on admissibility of animal studies as proof of causation in toxic tort cases); Brian P. Voke, *Sources of Proof of Causation in Toxic Tort Cases*, 61 DEF. COUNS. J. 45, 45 (1994) (observing that "[d]efendants have had mixed success in excluding expert opinions based on animal and in vitro studies" and concluding that "[a]n examination of the cases shows that the courts have not established any uniform rules concerning the admissibility of animal and in vitro studies," although some rough factors can be identified). The most significant split in admissibility rulings concerns the probative value and relevance of animal studies to the long-term toxicity of a chemical on humans. Compare Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 830 (D.C. Cir. 1988) (excluding animal studies as not relevant to human causation when substantial epidemiological evidence is available), with Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1094 (D. Md. 1986) (admitting animal studies as relevant in resolving causation issue), *aff'd sub nom.* Wheelahan v. G.D. Searle & Co., 814 F.2d 655 (4th Cir. 1987). For an overview of admissibility questions arising in toxic tort cases, see generally Bert Black, *A Unified Theory of Scientific Evidence*, 56 FORDHAM L. REV. 595 (1988).

<sup>69</sup> See, e.g., KEETON ET AL., *supra* note 64, § 41, at 265-68 (describing generally accepted "but for" and "substantial factor" tests for cause-in-fact and citing cases that date back over 100 years); cf. Eggen, *supra* note 63, at 863 (describing imposition of somewhat similar burden of proof on plaintiff-workers required in worker compensation claims).

cases, "In mass tort cases, the importance of the science cannot be overemphasized. Without *in vitro* [tests on single cells], *in vivo* [tests on animals] and epidemiological findings, and experts prepared to present them, the plaintiff has no case."<sup>70</sup> Although this burden is not problematic in a handful of "hot" toxic tort cases in which a wealth of studies have been produced,<sup>71</sup> such cases are the exception rather than the rule.<sup>72</sup>

When assigning the burdens of proof for causation, then, the courts presume as a matter of policy that plaintiffs should not only bear the losses resulting from inherent limitations in scientific knowledge (trans-scientific uncertainties), but they should also be held responsible for conducting initial safety testing on products and byproducts when that information does not otherwise exist (preventable scientific uncertainties).<sup>73</sup> Given the resource<sup>74</sup> and time limitations<sup>75</sup> of plaintiffs and government testing facilities, chemicals for which inadequate safety research exists will likely fall outside of the litigation system due to this causation rule. The additional and more recent requirement some courts impose, that a plaintiff's burden of proof also includes the production of one or more epidemiology stud-

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This issue is likely to be resolved on a dispositive motion before trial. *See, e.g., id.* at 899 (concluding that worker-victims of reproductive injuries will likely lose because of insufficient proof of cause-in-fact).

<sup>70</sup> Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 331 (1992).

<sup>71</sup> *See, e.g.,* Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After Daubert*, 78 MINN. L. REV. 1387, 1415 (1994) (observing with disapproval that, in Bendectin cases, courts may exclude animal studies and insist on epidemiology studies for proof of causation "because of the rich epidemiological data available"); *id.* at 1434 (noting that "Bendectin cases are unique in a number of ways including the existence of an unusually rich body of epidemiological data"); *see also* Farber, *supra* note 16, at 1251-53 (discussing easy cases where the available research on latent toxicity of a chemical is extensive and the substance causes a "signature disease").

<sup>72</sup> *See infra* Part IV.A.

<sup>73</sup> *See, e.g.,* Blomquist, *supra* note 62, at 43 (noting as one of a toxic tort plaintiff's obstacles, "inadequate toxicological information . . . and the enormous expense of trying to gather whatever information or expertise is available"). Thus, not only must the plaintiff minimize the significance of other potential causes and re-create exposure measurements that occurred decades before, *see, e.g., id.* at 42-43 (describing the "serious obstacles" toxic-tort plaintiffs face in establishing causation); Lyndon, *supra* note 42, at 1801-02 (describing evidentiary handicaps plaintiffs face when proving causation), but there is often little scientific research available on most products, even though they may be identified as likely carcinogens, *see supra* Part I.B.3.

<sup>74</sup> *See supra* notes 59-61 and *infra* note 195 and accompanying text (discussing government resource allocation and the cost of toxic-tort litigation).

<sup>75</sup> Even the more permissive "discovery rule" in statutes of limitations, *see generally* Gerald A. McHugh, Jr., *The Statute of Limitations and the Discovery Rule: Variations on a Theme of Fairness*, 64 PA. B. ASS'N Q. 197, 197-98 (1993) (noting rule that the statute of limitations starts only when the plaintiff has knowledge of the injury and its cause), may not provide plaintiffs with sufficient time to conduct epidemiology studies in those jurisdictions where such studies are required for proof of causation.

ies,<sup>76</sup> further reduces the likelihood that a manufacturer will be held accountable for performing a basic level of safety testing. From a practical standpoint, then, victims are able to challenge the adequacy of a manufacturer's safety and design decisions only in the small percentage of cases where a substantial body of scientific studies exists, and in some jurisdictions, only once those studies reveal that a statistically significant number of human injuries or diseases resulted from exposure to the chemical.

## B. Penalty for Knowledge

In addition to offering manufacturers practical immunity for remaining ignorant about the latent hazards of their products and by-products, the courts provide, at best, unreliable rewards for manufacturers who institute comprehensive safety testing programs. Some (but not all) courts provide manufacturers who have conducted "state-of-the-art" research on the safety of their products with a complete defense to liability for hazards that were only later revealed through unexpected advances in scientific knowledge.<sup>77</sup> State-of-the-

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<sup>76</sup> See, e.g., JASANOFF, *supra* note 17, at 126-28 (discussing cases where courts appeared heavily influenced by existence and outcome of epidemiological studies); Black & Liliendorf, *supra* note 64, at 769-76 (observing with approval that courts generally accept and sometimes require toxic-tort plaintiffs to introduce epidemiological evidence that a particular hazardous substance causes harm); Brennan, *supra* note 18, at 23 n.107, 56 n.241 (1989) (stating that "[e]ven though animal data involves very different technical issues, there should be no doubt that they are probative regarding human disease," and arguing that rulings excluding animal studies "go against all principles of toxicological science"); Green, *supra* note 21, at 672-74 (observing that courts in both Agent Orange and Bendectin cases generally adopted "an epidemiologic threshold, or more restrictively, a statistically significant epidemiologic threshold for plaintiff's to establish in order to create a submissive case," but noting that not all Bendectin courts did so); see also *infra* text accompanying notes 161-66 (noting the relationship between available epidemiological studies and litigation).

This requirement is difficult if not impossible to meet in many cases. See Green, *supra* note 21, at 680 (noting the lack of epidemiological studies on most chemicals and concluding that given the time, expense, and experimental difficulties, "[f]or most potentially toxic substances, there will not be a solid body of epidemiologic evidence on which to rely"); *id.* (arguing that "plaintiffs should be required to prove causation by a preponderance of the *available evidence*"); Sanders, *supra* note 71, at 1415 (arguing that at least for a "first plaintiff" animal studies should be admissible).

<sup>77</sup> See, e.g., Anderson v. Owens-Corning Fiberglas Corp., 810 P.2d 549, 550 (Cal. 1991) (holding the state of art defense relevant in a product liability case); Fell v. Kewanee Farm Equip. Co., 457 N.W.2d 911, 920 (Iowa 1990) (adopting the state of the art as a complete defense); see also KEETON, ET AL., *supra* note 64, § 99, at 700 (observing that the "state of the art" defense is "often" asserted against strict liability claims); Wertheimer, *supra* note 63, at 1184, 1209-40, 1245-69 (lamenting that a majority of courts and legislatures permit some sort of state-of-the-art defense and citing cases and laws from various states). The state-of-the-art defense has been endorsed by the drafters of the Restatement. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) (providing that liability for failure to warn in products liability action is limited by "the present state of human knowledge"); *cf. id.* cmt. j (noting that seller's obligation to warn in products liability is limited to when the seller "has knowledge, or by the application of reasonable, developed human skill and foresight

art testing generally consists of "all of the available knowledge of a subject at a given time, and this includes scientific, medical, engineering, and any other knowledge that may be available."<sup>78</sup> Such immunities are not always reassuring to manufacturers, however, because plaintiffs typically control the venue and hence the availability of the defense. Even if a manufacturer is fortunate enough to land in a jurisdiction where a state-of-the-art defense is adopted, considerable uncertainties as to what the "should have known" standard actually entails reduces the benefits of a predictable immunity.<sup>79</sup> If a jury or judge determines, for example, that a manufacturer's long-term testing program fell slightly short of a jurisdiction's state-of-the-art stan-

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should have knowledge, of the presence of . . . the danger."); *id.* § 388 (providing that a manufacturer by definition, will not be held negligent for information that is beyond the reach of scientific testing); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (Tentative Draft No. 2, 1995) (providing that a "product is defective because of inadequate instructions or warnings when the *foreseeable* risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings . . . and [their] omission . . . renders the product not reasonably safe") (emphasis added). Some states have also adopted state-of-the-art defenses legislatively. *See, e.g.,* ARIZ. REV. STAT. ANN. § 12-683 (West 1992) (providing an affirmative defense to a claim of defect in design if the product "conformed with the state of the art at the time the product was first sold by the defendant"); COLO. REV. STAT. § 13-21-403(1) (a) (1987) (creating a rebuttable presumption of no defect if the product "conformed to the state of the art, as distinguished from industry standards"); KY. REV. STAT. ANN. § 411.310(2) (Banks-Baldwin 1991) (establishing rebuttable presumption for the defense that a product is not defective if designed consistent with the state of the art); NEB. REV. STAT. § 25-21, 182 (1995) (codifying state-of-art defense); TENN. CODE ANN. § 29-28-105(b) (1980) (requiring that the "state of scientific and technological knowledge available to manufacturer" is relevant to determining defect of product).

Not all jurisdictions, however, have adopted a state-of-the-art defense. *See, e.g.,* Roach v. Kononen, 525 P.2d 125, 129 (Or. 1974) (refusing to recognize a "state of the art" defense); Pegg v. General Motors Corp., 391 A.2d 1074, 1075, 1083 n.10 (Pa. Super. Ct. 1978) (holding seller responsible for warning buyer of risks associated with product "regardless of whether the seller knew or had reason to know of the risks and limitations") (citing Robbins v. Farmers Union Grain Terminal Ass'n, 552 F.2d 788, 794 n.15 (8th Cir. 1977)).

<sup>78</sup> Lohrmann v. Pittsburgh Corning Corp., 782 F.2d 1156, 1164 (4th Cir. 1986); *see also* Meisner v. Patton Elec. Co., 781 F. Supp. 1432, 1443-44 (D. Neb. 1990). The California Court of Appeals interpreted state-of-the-art testing to include "long-term animal studies" in the context of a medical device, *see* Hilliard v. A.H. Robins Co., 196 Cal. Rptr. 117, 133 (Cal. Ct. App. 1983), and follow-up studies as a result of consumer complaints for toxic shock syndrome from the use of tampons, *see* West v. Johnson & Johnson Prods., Inc., 220 Cal. Rptr. 437, 460 (Cal. Ct. App. 1985).

<sup>79</sup> *See, e.g.,* Michael A. Pope & Michael K. Bartosz, "State of the Art": Is There any Life Left in the Defense?, 316 PLI/Lit 187 (1986) (outlining the various approaches of courts in adopting the state-of-the-art defense in products liability action); John W. Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734, 756-60 (outlining variability in "state of the art" immunity with regard to types of knowledge over various time periods); Wertheimer, *supra* note 63, at 1213-39 (describing differences between states in adoption of the state-of-the-art defense). There are even variations within states. For example, the New Jersey Supreme Court refused to apply the state-of-the-art defense to an asbestos case in *Fischer v. Johns-Manville Corp.*, 512 A.2d 466, 471-72 (N.J. 1986), although the defense was allowed in a drug product liability action several years before, *see* Feldman v. Lederle Labs., 479 A.2d 374, 387-88 (N.J. 1984).



dards, the immunity is gone, and any adverse research performed by the manufacturer may be used against it.

Because a manufacturer that fails to test may be able to escape liability based on the plaintiff's inability to prove causation, the manufacturer may view any testing efforts that carry the dual possibility of falling short of state-of-the-art standards and producing adverse results as only encouraging, rather than discouraging, litigation.<sup>80</sup> On balance, therefore, manufacturers may benefit more from the practical immunity provided by scientific ignorance than from the state-of-the-art defense. When the costs and time of conducting a thorough testing program are added to this equation, choosing ignorance seems even more clearly to be a rational choice for manufacturers of potentially toxic products.<sup>81</sup>

### III

#### THE COMMON-LAW APPROACH IS WRONG IN THEORY

The common-law requirement that plaintiffs assume the entire burden of proving causation in toxic tort cases not only creates inappropriate incentives for long-term safety research, but also contradicts well-established theories of tort law and analogous precedents. Reference to economics, as well as to a variety of legal doctrines,<sup>82</sup> reveals

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<sup>80</sup> This is true as long as the manufacturer perceives that long-term safety research is unlikely to be performed by any party other than the manufacturer. *See, e.g.*, James A. Henderson, Jr., *Coping with the Time Dimension in Products Liability*, 69 CAL. L. REV. 919, 940-41 (1981) (observing that knowledge of hazards comes primarily from private enterprise and thus imposing strict liability on manufacturers may discourage them from safety testing "after distribution to discover whether products are causing harm"). Note that this liability picture is likely specific to toxic-tort cases for latent harms. More immediate or acute effects caused by products are likely to be proven by consumers with greater ease.

<sup>81</sup> *See, e.g., infra* Part IV.A.

<sup>82</sup> Currently, economic and moral theories provide the leading explanations for negligence and strict liability causes of action in the common law. *See, e.g.*, IZHAK ENGLAND, *THE PHILOSOPHY OF TORT LAW* 7 (1993) (describing the theories of moral responsibility and social utility as at the "foundation" of tort law analysis). Unfortunately, the current state of the leading moral theory of tort law—corrective justice—offers little insight into specific details of concern in this Article, such as what behavior is reasonable or when liability should be imposed for a defendant's actions that serve to increase risk. *See, e.g.*, Ernest J. Weinrib, *Toward a Moral Theory of Negligence Law*, 2 LAW & PHIL. 37, 39-40 (1983) (characterizing corrective justice as a matter of structure "not substance"); *see also* Jules L. Coleman, *The Practice of Corrective Justice*, 37 ARIZ. L. REV. 15, 19 (1995) (acknowledging and categorizing different views of corrective justice among leading scholars); Richard W. Wright, *Actual Causation vs. Probabilistic Linkage: The Bane of Economic Analysis*, 14 J. LEGAL STUD. 435, 435-36, 455-56 (1985) (noting the difficulties encountered when using corrective justice in defining principle elements of causation and rights). Consequently, a discussion of corrective justice has been omitted from the instant analysis of how the common-law approach comports with tort theory and doctrine.

There are of course other theories of tort law. *See, e.g.*, Fleming James, Jr., *Last Clear Chance: A Transitional Doctrine*, 47 YALE L.J. 704, 716 (1938) (arguing that tort law serves in part as a social insurance program); Jerry L. Mashaw, *A Comment on Causation, Law Reform, and Guerilla Warfare*, 73 GEO. L.J. 1393, 1395-96 (1985) (suggesting that tort law provides a

that society expects a manufacturer to resolve at least a few basic preventable scientific uncertainties regarding the long-term safety of its product before releasing the product or byproduct into commerce.

### A. Law and Economics

Utilitarian theory provides one of the primary theoretical justifications for tort law and is central to much of the economic analysis of torts.<sup>83</sup> If the potential harm to society is catastrophic and irreversible, as it is during the manufacture of toxic products that come into contact either directly or indirectly with humans,<sup>84</sup> then utilitarian theory tells us that some basic investment in determining the approximate probability of harm is socially optimal.<sup>85</sup> Not only is a basic

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forum for civilized battle between small and big, namely the individual versus the corporation); George L. Priest, *Modern Tort Law and Its Reform*, 22 VAL. U. L. REV. 1, 20-21 (1987) (arguing that at least a partial purpose of tort law is to deter harmful behavior). Although competing theories do not discuss a manufacturer's duty to test, their primary tenets reinforce the conclusion that a manufacturer should conduct some basic testing on its product if non-de minimis risks are possible.

<sup>83</sup> Utilitarian theory presupposes that the goal of tort law is to make society better off and that the optimal level of economic activity in society should reflect its social costs. An optimal level of economic activity or production is the level at which further accident prevention expenditures would exceed the social costs of the prevented accidents. See Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 32-33 (1972). See generally Dan W. Brock, *Utilitarianism*, in AND JUSTICE FOR ALL 217 (Tom Regan & Donald VanDeVeer eds., 1982) (discussing utilitarianism as a formal moral theory); Frank I. Michelman, *Pollution as a Tort: A Non-Accidental Perspective on Calabresi's Costs*, 80 YALE L.J. 647, 651 (1971) (describing Calabresi's position as characterizing optimal deterrence of inefficient risk-taking as the prime objective of an ideal tort system).

<sup>84</sup> See, e.g., Gillette & Krier, *supra* note 42, at 1040-41 (discussing the catastrophic and irreversible nature of chemical products and unique problems the management of these public risks present); Talbot Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 ECOLOGY L.Q. 207, 211-14 (1978) (same). Asbestos provides the most dramatic example of a product causing catastrophic and irreversible harm. Since the first recovery in *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973), an estimated 33,000-50,000 cases have been filed against asbestos producers. See THOMAS E. WILLGING, TRENDS IN ASBESTOS LITIGATION 12 (1987). The number of serious irreversible injuries resulting from the preventable latent hazards caused by the Dalkon Shield have been estimated in the tens of thousands. See *infra* note 191. The possibility that further mass catastrophes may lurk in products currently in use cannot be eliminated, particularly given the vast ignorance surrounding their safety. See *infra* Part IV.A.

<sup>85</sup> Information regarding safety is generally desirable as long as its social value exceeds the costs of its generation. See Shavell, *supra* note 15, at 260. The social value of the information includes not only the lives saved once the latent toxicity of a substance is determined, but also the socio-psychological benefits that attend greater security regarding the safety of products and workplaces. See Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 FLA. ST. U. L. REV. 653, 655 (1993) (arguing that "[i]f people are unaware of the consequences of their choices, they are, to that extent, less free"); Wagner, *supra* note 28, at 1653 n.138 (citing literature on the public's desire for freedom from toxic risks); see also Frank B. Cross, *The Public Role in Risk Control*, 24 ENVTL. L. 887, 894 n.28 (1994) (citing literature in which authors advocate the inclusion of lay public values in evaluating appropriate risk); *infra* Part III.B.3. Therefore, some basic testing must be done for all products that pose nonde-minimis risks of exposure because the research will prove consistently, and in some cases significantly, beneficial to society. Cf.

amount of safety testing required according to utilitarian theory, but manufacturers should conduct such testing because they are, in the words of Guido Calabresi, the "least cost avoiders."<sup>86</sup>

### 1. *Access to Information*

Manufacturers are best able to conduct research on preventable uncertainties regarding the long-term safety of their products and by-products because they generally have superior and often exclusive access to the information needed to conduct these tests. Most importantly, manufacturers frequently enjoy a legally protected right to information regarding the composition of their products<sup>87</sup>—information that is also essential in determining the toxicity of the products in a timely and cost-effective way.<sup>88</sup> The difficulty third parties face in

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Steven Shavell, *An Analysis of Causation and the Scope of Liability in the Law of Torts*, 9 J. LEGAL STUD. 463, 484-85 (1980) (arguing that the scope of liability should include activities when, "given the circumstances under which [a type of accident] occurs, there must be a sufficiently high potential for reducing losses by taking more care," even when the probability of the accident is low).

<sup>86</sup> GUIDO CALABRESI, *THE COSTS OF ACCIDENTS* 138-52 (1970) (discussing various approaches to finding the cheapest cost avoiders); see also Guido Calabresi, *Optimal Deterrence and Accidents*, 84 YALE L.J. 656, 666-67 (1975) (observing with approval a "strong trend" toward finding that enterprises engaged in the manufacture of products are in a better position than consumers to determine a product's social costs and benefits); Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L. J. 1055, 1070 (1972) ("It should come as no surprise that considerations of knowledge, alternatives, and category levels are implicit in the search for the cheapest cost avoider."); Jeffrey Trauberman, *Statutory Reform of "Toxic Torts": Relieving Legal, Scientific, and Economic Burdens on the Chemical Victim*, 7 HARV. ENVTL. L. REV. 177, 209 (1983) (arguing that "[e]nterprises dealing in hazardous chemicals can most easily determine whether the social costs of such activity exceed the potential benefits of that activity"). But see Steven Shavell, *Economic Analysis of Accident Law* 282 (1987) (suggesting that when information has public value, theoretically "a social authority may be in a superior position to obtain information").

<sup>87</sup> In a recent article, Mary Lyndon provides an excellent overview of the intersection of trade secrecy and health and safety demands for information on chemical composition, exposure, and health effects. Mary L. Lyndon, *Secrecy and Innovation in Tort Law and Regulation*, 23 N.M. L. REV. 1 (1993). After outlining the current prominence of trade secrecy claims under major regulatory statutes such as FTSA, OSHA, and EPCRA, see *id.* at 22-35, Lyndon makes the following observations:

Current rules thus effectively give firms a full trade secret exemption. The agency whose mandate is to foster health protection ends up in the anomalous position of "sanitizing" and protecting industry documents, editing chemical identities and health information out of disclosure systems, and thinking up ways of describing health effects so that no one will figure out what they are. Health regulators are put in the position of deciding matters about which they have little expertise—whether a chemical is a trade secret and what its commercial value is. A regressive circularity is injected into toxics regulation, because if it is not revealed, a chemical will not be studied and therefore will not be found toxic.

*Id.* at 35.

<sup>88</sup> See *id.* at 34-35 ("For a worker or neighbor seeking data from a company, trade secret information is, as a practical matter, simply unavailable. There is no incentive for an employer to disclose."); see also *id.* at 33 (reporting that "trade secret claimants persuaded the EPA [under EPCRA] that . . . disclosure of specific health effects data . . . [could]

gaining access to this information was highlighted by the NRC's attempt to determine the availability of toxicity testing results for hundreds of chemicals. The composition of a number of these chemicals proved to be "so undefined" or "so variable" that the NRC was unable to make even a preliminary assessment of the extent of safety research available on them.<sup>89</sup>

Manufacturers also tend to be in the best position to compile the underlying information needed to evaluate the long-term safety of a product.<sup>90</sup> Physicochemical properties of a chemical, the expected paths and extent of human exposure, and complaints of injuries caused by the chemical are relevant to the manufacturer's business.

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reveal trade secret identity" because in some cases "so little study has been done on the health effects of many chemicals that to reveal a known effect will identify the chemical"). In fact, under some statutes such as FIFRA, manufacturers have, at least temporarily, also enjoyed a property right in the confidentiality of their health and safety data. See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1010-11 (1984) (holding that FIFRA, for the six-year period before the 1978 amendments, provided manufacturers trade secret protection for registrations, including health and safety data). Lyndon has even suggested that manufacturers may actively seek trade secret protection in order to avoid accountability for conducting safety research. See Lyndon, *supra* note 87, at 36 ("Indeed, the expectation of a legal shield from health research may affirmatively guide investments in the direction of secrecy.").

Confidentiality is a legal construct, of course, but until trade secrecy is at least partially abandoned, publicly funded research institutions must overcome a number of time-consuming and resource-intensive hurdles before they can conduct meaningful safety tests on many chemical products. Cf. *id.* at 50 ("[Laws currently create a] technological commons . . . with legal protection for secrecy, which bars some uses of data which would help correct the negative effects of technologies . . . Access by those concerned with the impacts of technologies should be assured by establishing a basic rule of disclosure.") (footnote omitted). See *infra* note 89 and accompanying text.

<sup>89</sup> TOXICITY TESTING, *supra* note 29, at 61. NRC's efforts to learn more about the composition of these products proved generally futile. See *id.* at 194-95 (detailing the disappointing response of 600 companies to questionnaires and Federal Register notices requesting "otherwise unobtainable information on potential occupational exposures, manufacturing processes, waste disposal practices, and production"). They concluded based on this portion of their study that the "[r]eluctance or inability of industry to cooperate in studies like this was found to be only one factor inhibiting the collection of information on industrial practices and occupational exposure. It is very difficult—often impossible—to locate and contact all the current manufacturers of a given substance." *Id.* at 195. Ultimately, the NRC left these substances out of its sample and studied only the better-defined substances. See *id.*

<sup>90</sup> See Applegate, *supra* note 1, at 299 (concluding that "industries that produce and use chemicals ordinarily are in the best position to provide or obtain toxicity and exposure data most cheaply and accurately"); Trauberman, *supra* note 86, at 214 (arguing that the chemical manufacturers' position "makes them better informed, more likely to know of the potential effects of hazardous substances, and better able to identify those who might have been exposed to such substances"); *id.* at 209 & n.167 (concluding that chemical manufacturers have superior information regarding hazards and identifying, based on 1981 statistics, the billions of dollars spent by the chemical industry on research and development). Manufacturers are also often in the best position to keep centralized records (or contract with pharmacists) regarding the users of their products, or at least of the complaints from consumers. Cf. Robinson, *supra* note 63, at 734 (discussing the role of defendant drug manufacturers in keeping records of effects on users).

However, this information is also critical in determining the extent and types of needed toxicity tests.<sup>91</sup> The NRC again found this basic information missing for many chemicals<sup>92</sup> and was unable to identify a "comprehensive method of gathering the needed information."<sup>93</sup>

## 2. *Product Development*

Manufacturers are also in a better position than plaintiffs to research preventable uncertainties regarding the safety of their products because they can channel the results of safety testing back into product design before the product is finalized, thus avoiding the social costs of injuries and the production costs of recalls and product re-design.<sup>94</sup> Research on industrial innovation reveals that for chemical products, over seventy percent of the total development time (averaging from seventeen months to four to five years)<sup>95</sup> is dedicated to the *final* stages of product design—after the product is designed,

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<sup>91</sup> See TOXICITY TESTING, *supra* note 29, at 120 (noting that basic characteristics of a chemical such as "breadth of known exposure, expected trends in exposure, physicochemical properties and chemical fate of the substances, and strength of evidence of toxicity in humans" seem to be logically related to "quantity and quality of toxicity testing"). See also *id.* at 122-23 (describing the importance of this same basic information to determining the hazard posed by a chemical); *id.* app. L at 179-84 (listing the major components of an NRC dossier, including these same basic characteristics of a chemical).

<sup>92</sup> For 36% of the substances studied, the NRC reported that "no data were available from which the committees could determine the extent of exposure" and for 75% of the substances "no information was available from which trends in exposure could be estimated." TOXICITY TESTING, *supra* note 29, at 126; see also *id.* at 122 tbl.21 (listing the availability of specific basic information on various categories of chemicals). The Interagency Testing Committee ("ITC"), which is responsible for identifying chemicals in need of testing under TSCA, has been similarly impeded by the general unavailability of production and exposure data. In 1990, the GAO reported that, despite efforts to "call in" such information through regulations and other research channels over a ten-year period, the ITC "still did not have exposure information for more than 1,700 [out of 2,226 identified] chemicals." GAO, EPA'S CHEMICAL TESTING PROGRAM, *supra* note 50, at 15. The report noted that, "[a]ccording to the ITC chairman, the lack of current production and exposure data has prevented ITC from making more recommendations in recent years. He believes this continues to be a problem." *Id.*

<sup>93</sup> TOXICITY TESTING, *supra* note 29, at 120 ("[I]n the end, the principal basis for characterizing exposure information was the knowledge and expertise of the committee members.").

<sup>94</sup> See Lyndon, *supra* note 1, at 152-53 (discussing how the failure to require manufacturers to conduct safety testing as part of research and development postpones testing until after a technology is established and manufacturers can no longer adjust to defects, leading them to manipulate information regarding health and safety effects); see also Calabresi & Hirschhoff, *supra* note 86, at 1062-64 (describing circumstances where manufacturers are relatively better suited than consumers to making the cost-benefit analyses regarding product design); cf. Shavell, *supra* note 85, at 481 (arguing that liability should be imposed on a defendant when its increased care will lead to a "sufficiently pronounced" reduction in accident costs).

<sup>95</sup> See EADS & REUTER, *supra* note 44, at 53-54 & n.2.

but before the product is marketed.<sup>96</sup> Even after marketing, manufacturers continue to innovate by improving "equipment technology [and better exploiting] latent economies of scale."<sup>97</sup> This reality of innovation suggests that the most expedient time to conduct safety tests and, if necessary, decide not to market a product or make compositional modifications is during the early stages of product development.<sup>98</sup> In contrast, by the time public test results are prepared and disseminated,<sup>99</sup> it will likely

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<sup>96</sup> Edwin Mansfield has identified five stages of the design of a product, beginning with applied research and ending with manufacturing start-up. The final four stages consume most of the time of product design, but can begin only after the product itself has been determined. See EDWIN MANSFIELD ET AL., *RESEARCH AND INNOVATION IN THE MODERN CORPORATION* 116, 118 (1971). In addition, there appears to be a "neighborhood" concept of innovation where one new type of product is followed by a series of very similar new products. See RICHARD R. NELSON & SIDNEY G. WINTER, *AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE* 257 (1982).

<sup>97</sup> NELSON & WINTER, *supra* note 96, at 259-60; see also Nicholas A. Ashford & George R. Heaton, Jr., *Regulation and Technological Innovation in the Chemical Industry*, *LAW & CONTEMP. PROBS.*, Summer 1983, at 109, 113 (providing a model for the dynamics of product and process innovation in industry).

<sup>98</sup> See Lyndon, *supra* note 1, at 150 ("At least in the early stages of innovation, innovating firms are unquestionably in the best position to set the direction of the search for information. If nothing more, firms know what information they lack and can anticipate what data should be generated."). Interestingly, Eads and Reuter suggest that in practice "prime responsibility" for ensuring the safety of a product is with the division producing it, which means that safety concerns might not emerge until some midpoint in the several-year production process. EADS & REUTER, *supra* note 44, at 62.

Although basic safety testing does increase the costs of innovation, it is not clear whether the costs of basic testing will be substantial enough to adversely impact innovation in any significant way, particularly if the safety testing is conducted late in the first stage of product design. See *infra* note 277 and accompanying text; cf. Flores, *supra* note 46, at 16-19 (describing Monsanto's extensive safety review process that occurs early in the design process and presumably does not significantly deter innovation). Additionally, early safety testing will be far less costly than having to retrofit changes during later stages of product development or after the product has been marketed—a cost savings that will benefit innovation as well as other production sectors. In fact, those who have examined the effects of safety testing have focused primarily, if not exclusively, on the extensive regulatory requirements imposed on the drug and pharmaceutical industries in which the costs of research are estimated at over \$200 million per product and take approximately 10 to 12 years to conduct. See Henry, *supra* note 35, at 617.

<sup>99</sup> It takes the National Toxicology Program approximately six to eight years to study a single substance for toxicity and carcinogenicity. See, e.g., *REGULATING CARCINOGENS*, *supra* note 60, at 167 (explaining the time involved from nomination of a chemical to publication of the report); cf. NELSON & WINTER, *supra* note 96, at 394-95 (concluding that with regard to research and development, a "good share" of information "must be guided by information available in and criteria relevant to the firms who eventually use the technology," and that government control of technological advances will therefore lead "not to efficiency but to inefficiency"). In addition, the government's ability to identify the appropriate manufacturers and disseminate the testing information may also prove difficult, if not impossible. See, e.g., Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 *J. LEGAL STUD.* 357, 360 (1984) (arguing that in contrast to private parties, "[f]or a regulator to obtain comparable information would often require virtually continuous observation of parties' behavior, and thus would be a practical impossibility").

be too late or too expensive to make significant product changes.<sup>100</sup>

### 3. *Loss Spreading*

Manufacturers also tend to be in the best position to absorb the financial costs of safety testing and to pass the costs of product testing onto customers, thereby ensuring that product users pay the full cost of developing and manufacturing the product.<sup>101</sup> Some scholars have argued that this loss spreading objective provides at least a partial justification for holding manufacturers responsible for product safety.<sup>102</sup> Various courts have agreed with this reasoning.<sup>103</sup>

### 4. *The Hand Formula*

The Learned Hand Formula, which is used to gauge whether conduct is reasonable,<sup>104</sup> also suggests that when an activity threatens pos-

<sup>100</sup> See, e.g., Fred Hoerger et al., *The Cumulative Impact of Health, Environmental, and Safety Concerns on the Chemical Industry During the Seventies*, LAW & CONTEMP. PROBS., Summer 1983, at 59, 96 (identifying the extraordinary financial impact of product bans that resulted from delayed regulatory actions—from \$165 million for plastic beverage bottles to \$612 million for PCBs).

<sup>101</sup> John Applegate has argued convincingly that it is both more equitable and more efficient to require manufacturers and ultimately the users of chemicals to pay for the generation of safety information:

It is . . . equitable because the primary beneficiaries of the chemical pay for one of its externalities; efficient because, to the extent that the regulatory system internalizes costs (including the cost of detecting externalities), the price of the chemicals will more accurately reflect their true cost and consumption will adjust accordingly. Indeed, one justification given for data call-ins is that owners of marginally useful registrations will discontinue the product rather than pay for expensive research.

Applegate, *supra* note 1, at 317.

<sup>102</sup> See generally Calabresi & Hirschhoff, *supra* note 86, at 1074-85 (comparing strict liability and negligence). Most scholars presume that manufacturers are able to most cheaply ensure that a reasonable base of knowledge exists regarding the long-term product safety. See, e.g., CALABRESI, *supra* note 86, at 245-46 (arguing that “[a]n allocation [of accident costs through worker’s compensation] to nonfaulty employers could and did lead to cheaper cost avoidance because it resulted in adequate evaluation of the risk of injury and in its full retention as an economic factor internal to the employment contract”); cf. Trauberman, *supra* note 86, at 211 (arguing for the proposition that those who cause harm are generally best able to avoid the externalities which created harm).

<sup>103</sup> See, e.g., *Lartigue v. R.J. Reynolds Tobacco Co.*, 317 F.2d 19, 36 (5th Cir. 1963) (“The injuries from knowable risks are a cost of production for the industry to bear . . .”); *Bachner v. Pearson*, 479 P.2d 319, 328 (Alaska 1970) (discussing loss spreading as a tort objective); *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) (same); *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 547 (N.J. 1982) (same).

<sup>104</sup> The Learned Hand Formula instructs that a defendant’s conduct is “reasonable” only if he has taken precautions which are equal to or greater than the product of the magnitude of the harm his activity will cause times the probability that the harm will occur (B>PL). The Learned Hand formula made its algebraic debut in *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947). The Hand formula has been substantially refined in its details, see, e.g., ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 326-

sible catastrophic harm, the actor should make some effort to determine the probability that the harm will actually occur.<sup>105</sup> It follows that, to resolve preventable scientific uncertainties, a reasonable manufacturer should conduct safety testing as long as the social value of the testing exceeds its costs.<sup>106</sup>

## B. Public Laws and Values

For those who deny that existing economic theories offer satisfactory positive or normative explanations for tort law, common-law doctrines and statutory rules may provide the more reliable indication of what a manufacturer's responsibility for resolving preventable scientific uncertainties should be.<sup>107</sup> These doctrines paint the picture of a legal system that, despite its adherence to an outmoded and regressive causation rule, generally wishes to require manufacturers to test for latent hazards in their products. Indeed, the extraordinary legal complexity that surrounds the heavily regulated area of toxic products may obscure the damaging, yet largely invisible, counter-force the common-law causation rule exerts on incentives for adequate toxicity testing.<sup>108</sup>

### 1. *Direct Responsibility to Test under the Common Law*

The "duty-to-test" requirement is the most conspicuous tort rule that imposes a responsibility on manufacturers to resolve at least basic

476 (1988); WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF TORT LAW* 85-88 (1987), but its basic form remains largely unaltered, *see, e.g.*, NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* 155-56 (1994) (explaining the Hand formula's application to safety decisions). Despite its popularity as a conceptual tool, the Hand Formula has proven difficult to apply with quantitative precision. *See* *McCarty v. Pheasant Run, Inc.*, 826 F.2d 1554, 1557 (7th Cir. 1987) (admitting that the Hand formula is a conceptual tool that tends to defy reliable quantification); *see also* ENGLARD, *supra* note 82, at 38-42 (identifying a variety of weaknesses in the practical use of the Hand formula as a measure of negligence).

<sup>105</sup> More specifically, the manufacturer should invest in safety at roughly "the point at which the marginal costs of the investment equal the marginal costs of accidents thereby avoided." Henderson, *supra* note 44, at 768. Unfortunately, in their repeated use of the Hand formula, Landes and Posner give little insight into how to determine what level of research is reasonable in predicting the approximate values of the variables (such as the probability of injury). LANDES & POSNER, *supra* note 104, at 256-72 (analyzing negligence in the context of catastrophic injuries). Despite this omission, if the harm (L) is greater than zero and the probability (P) is unknown, the Hand formula instructs that the cost of care (B) is also likely to be greater than zero. How much greater seems impossible to gauge *ex ante* without the benefit of more refined ranges for the possible probabilities and magnitudes of harm. Only in situations where virtually no human exposure is possible would research be unnecessary. *See supra* note 85 and accompanying text.

<sup>106</sup> *See* Shavell, *supra* note 15, at 259-60.

<sup>107</sup> *Cf.* John Borgo, *Causal Paradigms in Tort Law*, 8 J. LEGAL STUD. 419, 419 (1979) (conceding that, although moral duties direct legal liability rules, at times "legal and moral judgments [must] diverge").

<sup>108</sup> *See infra* note 135.



preventable scientific uncertainties prior to marketing a product.<sup>109</sup> The Fifth Circuit has perhaps been the most emphatic with regard to the fundamental importance of this duty in holding asbestos manufacturers liable under a parallel "duty-to-warn" claim: "The manufacturer's status as expert means that at a minimum he must keep abreast of the scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby. But even more importantly, a manufacturer has a duty to test and inspect his product."<sup>110</sup>

Although the parameters of the duty-to-test requirement are not altogether clear,<sup>111</sup> this rule traditionally requires manufacturers to perform testing that is commensurate with the possible risks associated with their products.<sup>112</sup> Given the potentially catastrophic and irreversible risks associated with exposure to toxic products, it seems apparent that, at a minimum, manufacturers must perform a basic

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<sup>109</sup> See, e.g., RESTATEMENT (SECOND) OF TORTS § 395 cmt. e (1965). These responsibilities are doctrinally justified by the manufacturers' superior knowledge and the asymmetries of information that would result between seller and buyer if the manufacturers did not test the products and disclose the hazards. See, e.g., Bernard W. Bell, Note, *The Manufacturer's Duty to Notify of Subsequent Safety Improvements*, 33 STAN. L. REV. 1087, 1090 (1981) ("The duty to inform . . . rests on the assumption of an asymmetry of information . . . . The producer obtains information about technological advances in the ordinary course of doing business, but the customer . . . would have to expend extraordinary amounts of time to obtain and understand it.")

<sup>110</sup> *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089-90 (5th Cir. 1973).

<sup>111</sup> See, e.g., Eric B. Bruce, *Avoiding Product Liability Claims: How Much Testing Is Enough?*, 62 DEF. COUNS. J. 391, 392 (1995) (observing that "there remains a good deal of uncertainty" regarding parameters of the duty-to-test rule).

<sup>112</sup> See, e.g., *Borel*, 493 F.2d at 1090; see also *George v. Celotex Corp.*, 914 F.2d 26, 28 (2d Cir. 1990), *rev'd on other grounds*, 995 F.2d 343 (2d Cir. 1993). The Eighth Circuit in *Nicklaus v. Hughes Tool Co.*, 417 F.2d 983, 986-87 (8th Cir. 1969), provides possibly the most detailed description of manufacturers' testing obligations. One commentator has isolated five different ways a manufacturer might violate its duty to test under *Nicklaus*: (1) if the manufacturer fails to conduct any tests or conducts only de minimis testing; (2) if the manufacturer fails to conduct additional, alternative tests that are "reasonable" and that would have disclosed the defect; (3) if the manufacturer uses a sample testing frequency or other safety factor in its testing that is too permissive in light of the "circumstances" (e.g., the manufacturer samples only two percent of the products on its assembly line); (4) if the manufacturer fails to conduct the tests under "real life" conditions, such as "foreseeable misuse" by the consumer; and (5) if the manufacturer fails to conduct a reasonable amount of testing based on the risks posed by the product and the costs of testing. See Bruce, *supra* note 111, at 392-95.

Courts have also held that under some circumstances manufacturers have a continuing obligation to conduct research on their products. See, e.g., *Cover v. Cohen*, 461 N.E.2d 864, 871 (N.Y. 1984) ("A manufacturer or retailer may . . . incur liability for failing to warn concerning dangers in the use of a product which come to his attention after manufacture or sale, through advancements in the state of the art . . . or through being made aware of later accidents involving dangers in the product . . .") (citations omitted); *Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 836 (Utah 1984) (noting that a "drug manufacturer is responsible . . . for not only 'actual knowledge gained from research and adverse reaction reports' but also for 'constructive knowledge as measured by scientific literature and other available means of communication'") (quoting *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528-29 (Or. 1974)).

screening of possible hazards to satisfy the standard.<sup>113</sup> Manufacturers who have not conducted any safety testing are thus in violation of the common law duty-to-test requirement.<sup>114</sup>

Ironically, as the common-law courts have applied the rule, a manufacturer is still able to escape liability when the plaintiff cannot prove that the manufacturer's product caused plaintiff's harm, even though this proof problem is a direct result of the manufacturer's inadequate testing.<sup>115</sup> Despite this flawed circularity in its implementation, however, the well-accepted duty-to-test rule supports a conclusion that the common-law courts intend responsibility for testing to lie in the first instance with manufacturers.<sup>116</sup>

## 2. *Indirect Responsibilities to Test Under the Common Law*

A presumption that shifts the burden of proof to defendants when they are in superior control of information provides a second, albeit less direct, line of cases that reinforce the common-law responsibility of manufacturers to test the safety of their products.<sup>117</sup> Superior access considerations made their debut in negligence cases and sometimes influence courts' decisions with regard to whether to employ the *res ipsa loquitur* presumption—a presumption that the defendant was negligent<sup>118</sup>—when the defendant is in the best position to pro-

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<sup>113</sup> See *supra* Part III.A.4.

<sup>114</sup> See, e.g., *International Harvester Co. v. Sharoff*, 202 F.2d 52, 54 (10th Cir. 1953) (holding that because of potential for serious harm if a part should fail, a truck manufacturer had a duty to conduct available tests that would have revealed presence of latent flaw); *Putensen v. Clay Adams, Inc.*, 91 Cal. Rptr. 319, 329-30 (Cal. Ct. App. 1970) (holding that failure of manufacturer to conduct any tests on the uniformity, strength, and thickness of the walls of tubing used in heart catheterization was unreasonable and violated the duty to test).

<sup>115</sup> See ALLAN KANNER, *ENVIRONMENTAL AND TOXIC TORT TRIALS* § 6.07, at 119 (1991) ("In cases where a company has marketed a product without adequately pre-testing for safety, it may currently be able to escape responsibility because plaintiff cannot prove causation.").

<sup>116</sup> Other duty-to-test rules, while less directly relevant, further suggest that the common-law courts believe that responsibility for safety testing should be placed, in the first instance, on manufacturers. See, e.g., M. Stuart Madden, *The Duty to Warn in Products Liability: Contours and Criticism*, 89 W. VA. L. REV. 221, 236 (1987) (noting that a manufacturer is presumed in duty-to-warn claims to have "superior knowledge" regarding safety of its products); Dix W. Noel, *Manufacturer's Negligence of Design or Directions for Use of a Product*, 71 YALE L.J. 816, 853-55 (1962) (noting that manufacturers' responsibility in duty to warn claims includes adequate testing).

<sup>117</sup> See generally Fleming James, Jr., *Burdens of Proof*, 47 VA. L. REV. 51, 66 (1961) (arguing that "[a]ccess to evidence is often the basis for creating such [a] presumption" on grounds of convenience, fairness, and public policy); Robinson, *supra* note 63, at 733-35 (discussing superior access justification for shifting burden of proof).

<sup>118</sup> Under the *res ipsa loquitur* doctrine, the burden of proving negligence shifts to the defendant once the plaintiff establishes an inference, either direct or circumstantial, that a defendant's act was likely to have been negligent. See, e.g., KEETON ET AL., *supra* note 64, § 39, at 244. This burden shifting is justified implicitly, and in some courts explicitly, by the fact that the plaintiff might otherwise be unjustly denied compensation simply because

duce exculpatory information.<sup>119</sup> Although this presumption is used primarily in limited situations in which other conditions also support shifting the burden of proof to the defendant,<sup>120</sup> a defendant's superior access to critical information regarding its exercise of due care nonetheless appears to be an important consideration for some courts in allocating burdens of proof.<sup>121</sup>

Courts have also shifted the burden of proving causation in cases involving multiple defendants when the defendants appeared to have superior access to information regarding the causal link between their

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she could not produce evidence that was in the defendant's exclusive possession. *See id.* (citing Chief Justice Erle in *Scott v. London & St. Katherine Docks Co.*, 159 Eng. Rep. 665 (1865)). When the defendant is better able to determine the reasonableness of its acts, then it should be up to the defendant to establish that it was behaving in a socially acceptable way. *See id.* (observing that in application of *res ipsa*, "[s]ome courts have at least suggested . . . [as a] condition, that evidence as to the true explanation of the event must be more readily accessible to the defendant than to the plaintiff"); *see also id.* at 254-55 (discussing caselaw regarding superior access factor).

<sup>119</sup> Prosser and Wigmore both question the importance of defendants' superior access to information in applying the *res ipsa loquitur* presumption. *See, e.g.,* KEETON ET AL., *supra* note 64, § 39, at 254-55 (agreeing that defendant's superior access to critical information could be considered, but arguing that based on analysis of caselaw it is not an indispensable requirement); 9 JOHN HENRY WIGMORE, EVIDENCE IN TRIALS AT COMMON LAW § 2509, at 507 (James H. Chadbourn ed., rev. ed. 1981) (same); William L. Prosser, *Res Ipsa Loquitur in California*, 37 CAL. L. REV. 183, 204 (1949) (same). A more recent analysis of *res ipsa* cases, however, reveals that "[t]he defendant's presumably superior access to relevant information . . . serves as the foundation for the policy-driven version of *res ipsa loquitur*" which the author characterizes as a subset of "enhanced *res ipsa loquitur*" cases. Stephen A. Spitz, *From Res Ipsa Loquitur to Diethylstilbestrol: The Unidentifiable Tortfeasor in California*, 65 IND. L.J. 591, 599 (1990). These enhanced *res ipsa loquitur* cases occur in two situations; the first occurs when a special relationship exists between plaintiff and defendant that justifies the imposition of any uncertainty on defendant; the second is comprised of cases in which the "doctrine is primarily used to sanction the defendant for the nonavailability of evidence." *Id.* In these cases, courts seem to be unconcerned about "whether the defendant actually had relevant information that could have been produced at trial." *Id.* at 604; *see also* Louis L. Jaffe, *Res Ipsa Loquitur Vindicated*, 1 BUFF. L. REV. 1, 6 (1951) ("[T]ypically . . . the defendant has greater access to the facts than the plaintiff . . . . *Res ipsa* rests on the notion that it is fair to treat the probability as the fact if the defendant has the power to rebut the inference."). *See generally* Spitz, *supra*, at 599-606 (discussing the development and application of enhanced *res ipsa loquitur* doctrine).

<sup>120</sup> *See* Robinson, *supra* note 63, at 735 (arguing that "[t]he law does not routinely allocate burdens merely according to who is the best (cheapest) information-producer," and that to shift the burden the plaintiff should show additional justification, including probability and public policy).

<sup>121</sup> *See, e.g.,* Kitto v. Gilbert, 570 P.2d 544, 549 (Colo. Ct. App. 1977) (holding that in medical malpractice action in which patient was injured while unconscious during surgery, the "absence of voluntary disclosure by the participants [doctors] as to the precise cause . . . [and the resulting] evidentiary disadvantage [to plaintiffs]" justified the application of *res ipsa loquitur*). *See generally* KEETON ET AL., *supra* note 64, § 39, at 254 n.31 (citing cases where courts "have said, and on rare occasions have held, that *res ipsa loquitur* cannot be applied unless evidence of the true explanation of the accident is more accessible to the defendant than to the plaintiff").

activities and the resulting injury.<sup>122</sup> Although "superior access to information" may not be the pivotal factor, both the courts and the Restatement pay at least lip service to its import in determining when to shift the burden of proof to defendants to disprove causation.<sup>123</sup> In fact, in several multiple-defendant cases in which the courts refused to shift the burden of causation to defendants, the courts found that defendants were no more prepared than plaintiffs to establish causation.<sup>124</sup>

Finally, some courts shift the burden of proof of both causation and negligence when a defendant has negligently or intentionally destroyed medical records or other evidence that is central to plaintiff's case.<sup>125</sup> This "spoilage of evidence" doctrine provides yet another example of the common law's intolerance of defendants who attempt to profit from missing evidence that is within their superior control.

### 3. *Statutes*

Federal and state statutes also indicate a trend towards imposing responsibility on manufacturers to keep the public abreast of the long-term safety of their products. The most compelling evidence of this trend is the growing popularity of "right-to-know" laws at both the na-

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<sup>122</sup> See, e.g., *Summers v. Tice*, 199 P.2d 1, 4 (Cal. 1948) (shifting burden of proof for gunshot injuries to two defendant hunters and stating that "[o]rdinarily defendants are in a far better position to offer evidence to determine which one caused the injury") (citing *Ybarra v. Spangard*, 154 P.2d 687 (Cal. 1944)).

<sup>123</sup> See, e.g., RESTATEMENT (SECOND) OF TORTS § 433B cmt. d (1965) ("As between the proved tortfeasor who has clearly caused some harm, and the entirely innocent plaintiff, any hardship due to lack of evidence as to the extent of the harm caused should fall upon the former."). In situations in which recordkeeping makes good policy sense and can be done in a cost-effective manner, the presumption of burden-shifting encourages this practice by manufacturers. See *Robinson*, *supra* note 63, at 734 (discussing how the presumption encourages recordkeeping). However, courts do not always find that manufacturers are in the best position to maintain the records needed in litigation. See, e.g., *Sindell v. Abbott Labs.*, 607 P.2d 924, 929-30 (Cal. 1980).

<sup>124</sup> See, e.g., *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069, 1074 (N.Y. 1989) (refusing to shift the burden of proof on causation to defendant DES manufacturers partly because the "DES defendants are not in any better position than are plaintiffs to identify the manufacturer of the DES ingested in any given case"); see also *KEETON ET AL.*, *supra* note 64, § 41, at 271 (observing that with regard to shifting the burden of proof for causation to multiple defendants, "where there is no evidence even as to where culpability lies, the hardship may be equally great upon an innocent defendant; and except in very special cases the courts have refused to shift the burden of proof.") (citations omitted).

<sup>125</sup> See, e.g., *Sweet v. Sisters of Providence*, 895 P.2d 484, 491-92 (Alaska 1995) (holding that missing medical records that result from negligence or intentional acts of defendant and that impair the ability of plaintiff to prove a prima facie case create a rebuttable presumption shifting the burden of proof for negligence and cause to defendant); see also *id.* at 491 (citing cases creating similar presumptions).

tional<sup>126</sup> and state level.<sup>127</sup> These statutes generally compel industry to monitor and disclose the hazardous properties or releases of their products and by-products.<sup>128</sup> Although right-to-know statutes do not require manufacturers to conduct safety research, they are logically premised on an assumption that existing safety testing is prevalent, or at least widespread enough to ensure that the worst hazards have been identified.<sup>129</sup> Otherwise, the public would have a right-to-know, but there would be no information to obtain and evaluate. The very existence of these statutes, then, evinces a public belief that comprehensive safety testing is occurring. As discussed in Part I.B.2, however, this appears not to be the case.<sup>130</sup> The legislative history undergirding at

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<sup>126</sup> See, e.g., 29 U.S.C. § 655(b)(7) (1994) (requiring under OSHA that employees be "apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure"); 42 U.S.C. § 11023 (1995) (mandating under Emergency Planning and Community-Right-to-Know Act ("EPCRA") that a large number of industries submit "toxic chemical release forms" disclosing the movement of listed chemicals). Right-to-know laws provide the most comprehensive attempt to force manufacturers to disclose toxic hazards in their products and by-products. For an argument that a series of other statutes and regulations at both the federal and state level produce too many warnings, see Noah, *supra* note 56, at 298-344. Noah's concern further supports the observation that the public wishes to have the opportunity to avoid toxic hazards, a desire that can only be fulfilled after some initial testing has been done.

<sup>127</sup> In California, for example, the voters approved Proposition 65, which required industries to disclose listed chemicals (those chemicals suspected of being carcinogens or reproductive toxins) if present in products. See Proposition 65, *reprinted in* CAL. HEALTH & SAFETY CODE § 25249.6 (1992). As of 1994, several other states had considered similar legislation, although none of them had passed the legislation. See Noah, *supra* note 56, at 343.

<sup>128</sup> The right-to-know provision of EPCRA, for example, requires covered industries to annually report the quantity of their releases, off-site transport, on-site treatment, and recycling of hundreds of listed chemicals. See 42 U.S.C. § 13106 (1994). California's Proposition 65 requires covered persons to provide warnings for over 600 listed chemicals to individuals likely to be exposed to the chemical. CAL. CODE REGS. tit. 26, § 22-12201(d) (1995).

<sup>129</sup> Specifically, the statutes seem to erroneously presume either that the worst hazards have been scientifically identified, see *supra* Part I.B.3 (discussing NRC's toxicity testing study), or that the testing will occur without added legal direction. See *supra* Part II (discussing the inability of market factors, regulation, and current law to encourage safety testing). Right-to-know provisions may actually discourage testing because a manufacturer will find itself forced to monitor and disclose hazards associated with a potentially toxic product that, if it remained untested, would go unnoticed under the right-to-know law.

<sup>130</sup> In fact, the explicit purpose of Proposition 65 was to fill the gap in toxics control left by regulatory failure.

[One] tradition in American politics is that the burden of proof rests with the public. . . . The recent performance by regulatory agencies indicates that public institutions simply cannot stay apace with industry's production of chemicals with unknown effects.

Proposition 65 has provided an indication that the American electorate may no longer be willing to adhere to [these] time-honored political traditions.

least some of the right-to-know laws also supports an inference that the public expects manufacturers to bear responsibility for generating and providing basic information on potentially toxic products and by-products.<sup>131</sup>

Several statutes that provide regulatory agencies with authority to require manufacturers to conduct safety testing before or even after a product has been marketed<sup>132</sup> and to require manufacturers to finance public testing programs are also instructive with regard to the public's expectations for safety testing.<sup>133</sup> Although regulatory failures and statutory drafting decrease their effectiveness,<sup>134</sup> the express purpose of the most comprehensive regulatory statute, TSCA, is clear: the public expects "adequate [safety] data [to be] . . . developed . . . and that the development of such data should be the responsibility of

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The chemical industry itself has noticed this missing link in the right-to-know laws. In an article published in the early 1980's, several officials from Dow Chemical lamented that "so much has been said recently about the 'right-to-know' issue that one is on the verge of losing sight of how much information is available." Hoerger et al., *supra* note 100, at 73.

<sup>131</sup> As the sponsor of EPCRA stated, the statute represents the "heartfelt belief that people in communities have an absolute, fundamental right to know what goes into the air their kids breathe, the water they drink and the ground they play on." Keith Schneider, *For Communities, Knowledge of Polluters is Power*, N.Y. TIMES, March 24, 1991, § 4, at 5 (quoting U.S. Rep. Gerry Sikorski). For repeated expressions of a public desire to "know" the risks confronting them, see *Superfund Provisions: Community Right-to-Know and Cleanup of Abandoned Hazardous Wastesites Located at Federal Facilities: Hearing Before the Subcomm. on Commerce, Transp., and Tourism of the House Comm. on Energy and Commerce*, 99th Cong. 2-4 (1985) (statement of Rep. Sikorski); see generally Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 318-20 (1996) (providing an overview of the purpose of Proposition 65 and noting that the "statute is clearly intended to promote informed individual choice"); cf. *infra* Part IV.C (hypothesizing that where manufacturers have been negligent in conducting safety tests, juries may excuse weak or, by some accounts, non-existent evidence of cause-in-fact); *supra* note 85 (concluding that information about safety is desirable if its social value exceeds its cost).

<sup>132</sup> See, e.g., 7 U.S.C. § 136a(c)(2)(B)(i) (1994) (providing the EPA with authority under FIFRA to "call-in" additional safety information on previously approved pesticides); 15 U.S.C. § 2605(a), (c) (1994) (providing the EPA with authority under TSCA to impose follow-up testing controls on chemicals of concern). See generally *supra* note 49 and accompanying text (listing statutes requiring testing). TSCA, however, is seldom used because it is narrowly drawn, agency resources are limited, and the authority necessitates elaborate procedures and agency findings that tend to discourage regulatory activity. See, e.g., Applegate, *supra* note 1, at 313-16; see also *Shell Chemical Co. v. EPA*, 826 F.2d 295 (5th Cir. 1987) (remanding EPA test requirement on chemical under Section 4 of TSCA because of limited evidence of potential human exposure to the chemical). In contrast, much more extensive safety testing is a pre-condition to marketing a subset of products such as drugs, food additives, and pesticides that pose the greatest likelihood of significant exposure. See *supra* note 34 and accompanying text.

<sup>133</sup> See, e.g., 42 U.S.C. § 9604(i)(2)-(5) (1994) (providing EPA with authority to promulgate regulations to provide for payment of costs for research on 100 priority toxins found at hazardous waste sites conducted by the Agency for Toxic Substances Disease Registry).

<sup>134</sup> See *supra* note 50 and accompanying text.

those who manufacture and those who process such chemical substances and mixtures."<sup>135</sup>

#### IV

##### THE COMMON-LAW APPROACH IS WRONG IN PRACTICE

The common-law approach to establishing liability in toxic tort cases is not only inconsistent with the key theories and doctrines running through tort law, but it also can have serious adverse consequences. These adverse effects include an inadequate understanding of product safety, a lack of deterrence in the development of toxic products, undercompensation for victims who have been harmed by such products, and even the tendency of juries and some judges to nullify the causation rule when a defendant has been negligent in testing.

##### A. Inadequate Understanding of Product Safety

Although a manufacturer's decision to choose ignorance may be attributed in part to market or regulatory failures,<sup>136</sup> the existing liability system does little to counteract this choice. Indeed, as we have seen, the existing liability system makes choosing ignorance a rational choice for manufacturers of most chemical products.<sup>137</sup> As a result,

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<sup>135</sup> 15 U.S.C. § 2601(b)(1) (1994). The counter-argument is that the public has perfect knowledge of the content of the statutes and their implementation problems and has intentionally limited testing requirements to only the most egregious, known hazards. Rather than supporting an inference that the public generally expects manufacturers to remain accountable, then, these statutes might suggest exactly the opposite. This counter-explanation seems unlikely to be the better interpretation of the public's will for a number of reasons. The most persuasive reason is that this explanation not only requires the public to understand the subtleties of legislative drafting, *cf.* Applegate, *supra* note 1, at 319-30 (detailing problems with statutory wording of TSCA that explains why it fails to ensure adequate safety testing), and the prevalence of regulatory failure in the area of toxics control, *see* Wagner, *supra* note 28, at 1677-85 (outlining extended failure of agencies in science-based regulations), but it also requires that the public appreciate the prevalence of parallel failures in the market and the common law to promote safety testing. The latter understanding (of the common-law failure) is particularly counter-intuitive in light of the well-established duty to test rule. Thus, the possibility that the failure of TSCA to encourage testing is a result of careful public design seems to expect more of the public than even the most savvy lawyers, versed in the complexities of toxic product regulation, have achieved. *Cf.* Peter H. Schuck, *Legal Complexity: Some Causes, Consequences, and Cures*, 42 DUKE L.J. 1, 26-31 (describing how legal complexity reduces public understanding or can even be used to escape public accountability).

<sup>136</sup> *See supra* Part I.B.3.

<sup>137</sup> "Indeed, what would be surprising would be to discover that, notwithstanding these factors, [scientific ignorance was] . . . other than commonplace." Henderson, *supra* note 44, at 782; *see also* Victor E. Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U. L. REV. 892, 899 (1983) (hypothesizing that, in wake of recent case law, manufacturers may be deterred from making safety improvements rather than encouraged to do so). Interestingly, although Henderson insightfully identifies and analyzes the effect of liability rules in decreasing a firm's incentives to make a

socially optimal "managerial behavior [may in fact be] . . . constrained by the law, rather than the other way around."<sup>138</sup>

Steven Shavell has concluded that a negligence rule similar to the current causation rule that bases the determination of reasonable conduct on the level of safety information a defendant actually possesses (rather than the level of information a defendant *should* possess) will produce, at best, suboptimal levels of information.<sup>139</sup> In some cases, such a rule may lead a party to "decide not to obtain [any] information no matter how cheaply it can be done" since the "private value of information may be negative."<sup>140</sup> Alan Schwartz's economic model similarly predicts that a firm will sell a product without safety research if it perceives the possible benefits of research to be small<sup>141</sup> or the costs of research to be high.<sup>142</sup> Choosing ignorance, Schwartz argues, becomes even more sensible when years are likely to pass before the harm materializes.<sup>143</sup>

That manufacturers have a strong incentive to choose to be ignorant about even the most basic preventable scientific uncertainties regarding the safety of their products is supported by empirical evidence—the present knowledge of latent chemical toxicity is

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product design safer over time—below what might be socially desirable—he overlooks the parallel phenomenon occurring in safety research. This error leads him to understate the importance of his observations, suggesting that the cases affected are only "at the margin." Henderson, *supra* note 44, at 774.

<sup>138</sup> Henderson, *supra* note 44, at 783.

<sup>139</sup> Shavell, *supra* note 15, at 266-68.

<sup>140</sup> *Id.* at 266.

<sup>141</sup> Consumers are unlikely to discriminate between most chemical products based on the extent of safety research performed because consumers are not generally aware of such risks in the first place. See *supra* notes 42-44 and accompanying text.

<sup>142</sup> Schwartz states that his economic model shows that:

the amount of research a profit-maximizing firm will do to discover how dangerous a product is depends on three variables: the mean of the profit distribution if the firm were to sell without doing further research; the variance of this distribution—the amount of uncertainty about dangerousness; and research costs.

Schwartz, *supra* note 63, at 700-01.

<sup>143</sup> See *id.* at 710 (predicting that a firm will not insure against accidents if accident costs are not likely to be incurred for six or more years because the "entrepreneur . . . would operate if he could earn enough in the accident-free period to recover start-up costs and make a profit"); see also EADS & REUTER, *supra* note 44, at 22 (suggesting that to the extent injuries (and claims) occur "only far in the future, and to the extent that these costs can be reduced by firm actions other than increased design efforts related to safety, the incentive to design safer products is undercut"); Felsstiner & Siegelman, *supra* note 43, at 310 (discussing considerable body of literature documenting the short-term focus of American corporations); Henderson, *supra* note 44, at 775-76 (noting that without pre-judgment interest and in light of discount rates, "to have deferred a liability for six or seven years beyond the time when it otherwise would have incurred was to avoid a substantial part of that liability"); Glen O. Robinson, *Probabilistic Causation and Compensation for Tortious Risk*, 14 J. LEGAL STUD. 779, 784 (1985) (discussing how "[l]ong-lagged effects also [tend to] escape deterrence").



poor.<sup>144</sup> As discussed earlier, the National Research Council found an alarming scarcity of information regarding the toxicity of most chemical products.<sup>145</sup> In addition, the NRC reported that the availability of toxicity information was unrelated to the potential hazard a substance posed. A chemical that potentially posed a significant risk of harm was often subjected to less toxicity testing than a chemical that was more likely to be benign.<sup>146</sup> Not surprisingly, when some testing was done, the completed tests were typically the least expensive and least time-consuming and, as a result, provided the least amount of information about the long-term hazards the chemical posed—a plethora of preventable scientific uncertainties were thus left unresolved.<sup>147</sup>

A recent investigation into the extent of safety research and innovation activity<sup>148</sup> on forty-three of the least-studied chemicals consid-

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<sup>144</sup> See Rosenberg, *supra* note 16, at 854 n.19 (listing reports of considerable scientific ignorance regarding latent chemical toxicity); *infra* notes 170-181 and accompanying text (providing examples); but see *infra* note 154 (discussing possibility that some manufacturers are conducting safety tests but not releasing the data). Two separate reports published in the 1980's suggest that the Monsanto Corporation may provide an exception to this apparent trend toward choosing ignorance. Albert Flores's in-depth investigation of Monsanto in 1982 and an extensive interview of Monsanto officials in 1981 both indicate that Monsanto is very concerned about ensuring the long-term safety of its products and processes. Although Monsanto does screen for long-term product and process safety by reviewing the scientific literature, it is not clear whether Monsanto also conducts in-house testing on potential chemical hazards that appear understudied in the literature. See Flores, *supra* note 46, at 16-20; see also David W. Ewing & Millicent R. Kindle, *Monsanto's 'Early Warning' System*, HARV. BUS. REV., Nov.-Dec. 1981, at 107, 108-10 (interviewing John W. Hanley, CEO, Monsanto). Monsanto's recent objection to EPA regulations requiring it to conduct two screening tests on several chemicals that it produces or discharges (tests which the EPA estimated will cost from \$200,000 to \$328,000 per chemical), however, suggests that it may not be conducting even these more basic safety tests in the absence of regulatory requirements. Compare Office of Water Chemicals; Final Test Rule, 58 Fed. Reg. 59,667, 59,675 (1993) (reporting that both Monsanto and the Chemical Manufacturers Association estimated the costs of basic screening tests for four chemicals would be "burdensome" on the industry), with Ewing & Kindle, *supra*, at 115 (quoting the Chairman and CEO of Monsanto as saying that Monsanto "take[s] the lead in testing," and that "federal and state regulatory agencies have no relevance at all to the need for our testing programs"). If this is the case, then the benefits of Monsanto's safety program could be quite limited; the company may simply be replacing products with known adverse effects with products that are not necessarily known to be safe, but instead are simply unstudied.

<sup>145</sup> See *supra* Part I.B.2.

<sup>146</sup> See TOXICITY TESTING, *supra* note 29, at 121 (reporting that "[t]he amount of testing that had been performed was not related to the committee's judgment that the chemicals warranted additional concern on the basis of physicochemical information").

<sup>147</sup> See TOXICITY TESTING, *supra* note 29, at 95 (observing that toxicity "[t]ests that were more complex . . . were frequently absent" for most chemicals in the study).

<sup>148</sup> The databases used to gather this information were as follows: (1) Patents and Patent Abstracts—Search of U.S. Patent Text File, U.S. Patent & Trademark Office (July-August 1995) (search of all patents and/or abstracts with chemical name in text); (2) Chemical Releases—U.S. ENVIRONMENTAL PROTECTION AGENCY, 1994 TOXICS RELEASE INVENTORY: PUBLIC DATA RELEASE 78-89 tbl.1-45 (1996) (organized by chemical name); (3) Short-term and long-term studies conducted in laboratories (primarily on animals)—Search of the Registry of Toxic Effects of Chemical Substances ("RTECS"), Nat'l Inst. of

ered for the right-to-know provisions of the Emergency Planning and Community Right-to-Know Act ("EPCRA")<sup>149</sup> underscores the NRC's 1984 findings. Safety research on these forty-three chemicals is inadequate: a number of preventable scientific uncertainties, such as reproductive effects, have not been assessed satisfactorily, or, in some cases, at all.<sup>150</sup> Yet investments in innovation on these same chemicals, evi-

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Occupational Safety and Health ("NIOSH") (July-August 1995) (search using chemical name; long term and short term studies were sorted manually using NIOSH's general categories (i.e., mutagenicity as the basis for delineation) (for most chemicals, estimates of the numbers of employees exposed to the chemical in 1974 and 1983 were also available from RTECS—these numbers are reported *infra* Appendix A)); (4) Human studies—Search of MEDLINE, National Library of Medicine (July 1996) (search of abstracts of published studies in biomedical journals (English only) using chemical name and "adverse effect" sub-heading to narrow the search; results were screened manually for "epidemiology studies" (defined as involving more than 100 subjects) and "clinical studies" (defined as involving less than 100 subjects)); (5) "Active" litigation—Search of WESTLAW, All Cases File (May-June 1996) (using common chemical name as the only search term; results were screened manually and include each case that involves a claim of harm resulting from exposure to the named chemical; occupational cases are those brought against employers and toxic tort cases are the remainder). For raw data, see Appendix A.

<sup>149</sup> Chemicals listed under EPCRA were selected because some safety information was available (an implicit prerequisite to listing), but in some cases this information was not extensive. EPCRA chemicals were also attractive because information is readily available for recent discharge quantities. See *supra* note 128. Initially, a subset of 109 EPCRA chemicals was chosen based on the apparent scarcity of information for all 109 chemicals sufficient to permit the EPA to conduct an estimate of toxicological potency for various human health and ecological effects. See 2 U.S. EPA, TOXIC CHEMICAL RELEASE INVENTORY RISK INVENTORY SCREENING GUIDE (VERSION 1.0) app.A at A-9 to A-37 (1989) (listing chemicals and toxicology potency for five categories of adverse effects; the 109 selected chemicals were those that had no potency identifications for any of the 5 categories of adverse effects). Through the process of the study, the list was ultimately pared down to 43 chemicals for reasons having nothing to do with the extent of study or innovation. Specifically, a chemical was eliminated from the study either because: (1) There was substantial variability in the common names used to refer to a single chemical. Although dozens of synonyms typically exist for a single chemical, in this study, chemicals were excluded only when the chemical name used in the EPCRA database (compiled by the EPA) differed from the name used for the identical chemical in the RTECS database (compiled by NIOSH). See *supra* note 148. Although the chemical identification number ("CAS") would have ensured a common chemical identity, several of the databases (MEDLINE, WESTLAW, PATENT DATABASE) do not use CAS numbers consistently or at all; (2) Primitive search techniques required for some of the databases prevented a common ingredient of a chemical (e.g., ethylene) from being identified separate from its more notorious derivatives (e.g., diethylene dibromide; ethylene glycol). While search difficulties could have been remedied with manual screening, this would have added several hundred hours to this study with limited benefits. Even after paring the list to the 43 chemicals with very dependable chemical names, some minor variability in chemical names and chemical derivatives remained, although it is possible that these false negatives and false positives in database "hits" largely canceled each other out.

<sup>150</sup> See *infra* note 151. In fact, the testing that has been conducted on these chemicals appears to have been conducted predominantly by third parties in academic institutions, rather than by manufacturers. The affiliation of the authors conducting long-term studies were not available on the computer databases, and manual searches were not possible due to resource constraints. However, author addresses were available for epidemiology and clinical studies dating back to the mid 1980s, and a tally of these addresses reveals that the authors for 95% of the 195 studies were affiliated with universities or research institutions.

denced by the number of times the chemical is referenced in a patent, is generally quite high. Although the data is highly variable depending on the chemical, the number of times a chemical is cited in a patent typically exceeds by ten to one-thousand times the number of reported toxicity studies done on that chemical.<sup>151</sup> Moreover, the extent of innovation (e.g., patent activity) bears no relationship to the extent of long-term safety testing on animals:<sup>152</sup> for some chemicals patent activity is high and safety testing is low, while for other chemicals safety testing is high and patent activity is low.<sup>153</sup> This preliminary data suggests that manufacturers are making significant investments in product innovations that use these forty-three chemicals and far less in needed safety research.<sup>154</sup>

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Search of MEDLINE, *supra* note 148. (Studies meeting the criteria described *supra* note 148 were then manually screened and tallied for author affiliation.) This does not preclude the possibility that manufacturers are financing a portion or all of this third-party research. It does suggest, however, that manufacturers are not doing much of the published safety research in-house.

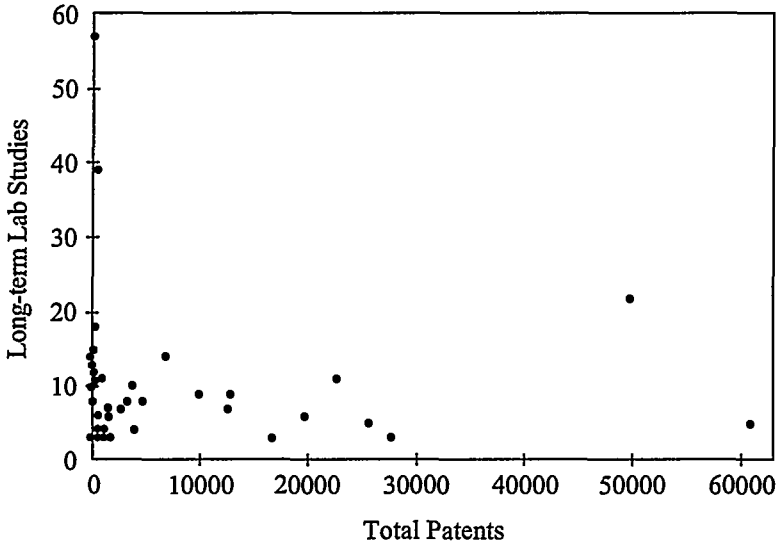
<sup>151</sup> Of course, at some point the number of long-term studies that are needed to assess the risks a chemical posed are "capped." Additional safety research has diminishing returns after sufficient data exists to conduct a full health assessment. Based on the NRC criteria, however, existing research appeared to be sufficient, at best, for only a few of these 43 chemicals to conduct such an assessment. For example, reproductive effects were rarely investigated in the sample of 43 chemicals, even though these effects constitute one-fifth of the basic hazards the NRC recommends for testing. *See supra* note 30.

<sup>152</sup> Although caution must be exercised in applying statistical tests in a group of chemicals that does not represent a "random" population, correlation coefficients may provide the reader with at least a sense of the weakness of the correlation (a strong positive correlation is +1, no correlation is 0, and a strong negative correlation is -1). The correlation between long-term animal studies on a chemical and the frequency the chemical was referenced in the abstract or text of a patent was essentially nonexistent (.09).

<sup>153</sup> *See* Figure 2. Discharge quantities also appeared to bear no relationship to either patent activity or the number of long-term safety studies. (The correlation coefficients ranged from -.24 to -.07 in comparing discharge quantities with various types or totals of safety studies). However, a moderate correlation may exist between innovation and human studies that might warrant further study with an expanded random data set. (The correlation between patent activities and the number of epidemiological studies was .6 and for total patents versus all studies (clinical, epidemiological, long-term laboratory and short-term animal combined) the correlation coefficient was .48.) In addition to investigating a correlation between these variables, it would be interesting to learn more about their interaction over time. For example, do human studies tend to *follow* rather than precede bursts in innovation activity? Does greater innovation mean greater exposure, which in turn means more opportunities for studying the effects on humans?

<sup>154</sup> It is also possible that manufacturers and their consultant laboratories are conducting a good deal of long-term safety testing, but are not reporting the results of this testing. In such a case, manufacturers may decide privately whether, based on the results of the toxicity testing, a product should be modified or discontinued. *Cf. TOXICITY TESTING, supra* note 29, at 194 (observing that "[m]anufacturers and trade associations are repositories of otherwise unobtainable information" on various chemical characteristics). Although this possibility certainly cannot be eliminated, the lessons learned from the devastating liability imposed on firms caught with in-house research that suggested their product was hazardous, *see infra* notes 176-86 and accompanying text, makes the presence of widespread secret safety research unlikely. *See also supra* notes 46-48 and accompanying text (discussing characteristics of manufacturing process that tend to minimize the role of

FIGURE 2  
 NUMBER OF TOTAL PATENTS VS. NUMBER OF  
 LONG-TERM LABORATORY STUDIES ON EACH OF  
 43 EPCRA CHEMICALS



## B. Underdeterrence and Undercompensation

A causation rule that provides a negligent manufacturer who deliberately fails to conduct toxicity tests higher odds of escaping liability than a manufacturer who does conduct safety testing underdeters harmful activity and likely undercompensates victims.<sup>155</sup> Considerable evidence suggests that both are occurring in the manufacture of potentially toxic products.

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safety research in product development). In any case, if testing is not disclosed to the government or public, it is essentially the same as not having testing information at all—absent an in-house “whistleblower,” the manufacturer completely escapes accountability for its internal cost-benefit decision regarding the optimal safety of the product. Short record retention policies implemented in at least some manufacturing firms may further ensure that companies succeed in escaping accountability for their decisions. Cf. John M. Fedders & Lauryn H. Guttenplan, *Document Retention and Destruction: Practical, Legal and Ethical Considerations*, 56 NOTRE DAME LAW. 5 (1980) (surveying federal and state law and ethical codes governing the retention and destruction of corporate documents); Michael Allen, *Cleaning House: U.S. Companies Pay Increasing Attention to Destroying Files*, WALL ST. J., Sept. 2, 1987, at 1 (reporting that “[a]s important as teaching companies which documents to destroy . . . is teaching them which ones never to create in the first place”).

<sup>155</sup> Several scholars have argued that the liability rules underdeter and undercompensate because of the great scientific uncertainty that plaintiffs face. See, e.g., Trauberman, *supra* note 86, at 187-88 n.48 (citing literature). Although the undercompensation and underdeterrence caused by inadequate safety testing is somewhat different than that addressed by the majority of scholars, see sources cited *supra* note 63, it is a *preventable* handicap that plaintiffs are currently forced to bear.

### 1. *Underdeterrence*

The traditional common-law approach to assigning responsibility for proving causation in toxic tort cases creates, at least in theory, a "recurring miss";<sup>156</sup> manufacturers can act negligently, but avoid liability precisely because of that misconduct.<sup>157</sup> Debate currently surrounds the question of whether and how much tort rules actually

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<sup>156</sup> See Saul Levmore, *Probabilistic Recoveries, Restitution, and Recurring Wrongs*, 19 J. LEGAL STUD. 691, 692 (1990) (defining a "recurring miss" as the class of cases that "involves wrongful conduct that is not likely to be linked under a preponderance-of-the-evidence rule with the injury that it sometimes causes"). In his analysis of "recurring miss," Levmore focuses on the related, but still different, set of cases where adequate scientific research exists, but the resulting probabilistic causation cannot reach the "substantial cause" or "more likely than not" sufficiency threshold. See, e.g., *id.* at 706 ("The identifying feature of these [recurring miss] cases is, once again, that there is a wrongful party who is more than 0 percent but possibly never more than 50 percent likely to have caused an injury.").

<sup>157</sup> James Henderson similarly observes that prevailing tort rules may actively discourage manufacturers from making safety improvements after their products are marketed. See Henderson, *supra* note 44, at 774 (arguing that "[t]o the extent that increases in exposure to liability are likely to flow from reasonable efforts by manufacturers to make their products safer, they discourage manufacturers from engaging at the margin in precisely the sorts of activities that tort law purports to encourage"); see also Arlen, *supra* note 15, at 1121 (arguing that "imposing [additional] liability on manufacturers may be necessary to provide them with the requisite incentives to test products properly and to reveal to consumers information about the risks of products currently on the market as that information becomes available"); Eggen, *supra* note 63, at 896-97 (observing that in the workers' compensation context, employers are not held fully accountable for reproductive injuries caused by exposure to toxic substances because of workers' inability to prove causation); Feldman, *supra* note 1, at 41 (arguing that underdeterrence will occur under current toxic tort liability rules because placing the burden on plaintiff "creates a perverse incentive for actors to foster strong uncertainty about general causation").

In jurisdictions where medical monitoring claims are allowed and causation burdens are slightly lower, some manufacturers may face an increased likelihood of liability for at least medical surveillance costs deemed necessary as a result of plaintiffs' exposure to defendants' hazard. These claims are allowed in some jurisdictions even when the research on long-term product safety is incomplete. See, e.g., Leslie S. Gara, *Medical Surveillance Damages: Using Common Sense and the Common Law to Mitigate the Dangers Posed by Environmental Hazards*, 12 HARV. ENVTL. L. REV. 265, 265-67 (1988) (providing overview of nature of medical monitoring claims). However, these claims do not begin to offset the problems with proving general causation for latent harms because: (1) the proof of causation required in most jurisdictions for a medical monitoring claim cannot be provided when basic safety research has not been conducted, see, e.g., *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 826 (D.C. Cir. 1984) (granting medical monitoring claim, but still requiring the plaintiff to introduce "competent medical testimony" or other evidence of need for diagnostic testing); (2) medical monitoring claims are filed less often due to the availability of primary insurance for most victims, see, e.g., Gara, *supra*, at 269 (observing that "[t]hose financially able to afford medical care will heed scientific and medical advice and undergo precautionary testing regardless of a judicial remedy"); (3) some courts may require present physical harm associated with exposure before allowing a monitoring claim, a requirement that substantially limits its availability to plaintiffs, see, e.g., *Potter v. Firestone Tire & Rubber Co.*, 274 Cal. Rptr. 885, 896 (Cal. Ct. App. 1990) (requiring present physical injury for medical surveillance claim), *rev'd*, 863 P.2d 795, 800 (Cal. 1993) (holding that physical harm is not required for medical surveillance claim).

affect behavior.<sup>158</sup> Although there is presently no way to prove that the tort rules cause manufacturers to avoid learning of their products' latent hazards,<sup>159</sup> the striking absence of even a weak correlation between patent activity and long-term safety testing suggests that the tort system is at least not encouraging safety testing.<sup>160</sup>

A direct relationship between epidemiological research on a product's latent effects and litigation provides even more compelling evidence that liability rules currently penalize rather than reward safety testing. In case studies of Bendectin<sup>161</sup> and benzene,<sup>162</sup> a single

<sup>158</sup> Compare Howard A. Latin, *Problem-Solving Behavior and Theories of Tort Liability*, 73 CAL. L. REV. 677, 682-93 (1985) (noting absence of proof regarding deterrent effect of liability rules); Mashaw, *supra* note 82, at 1394 (same); and Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 UCLA L. REV. 377, 381-87, 405-13 (1994) (providing overview of debate concerning whether tort doctrines deter and more focused discussion of literature on deterrence in products liability), with Neil K. Komisar, *Injuries and Institutions: Tort Reform, Tort Theory, and Beyond*, 65 N.Y.U. L. REV. 23, 51 (1990) (using institutional analysis to argue against assertions about the lack of deterrence in tort system); Richard A. Posner, *Can Lawyers Solve the Problems of the Tort System?*, 73 CAL. L. REV. 747, 749-50 (1985) (arguing that liability insurance premiums affect decisions to drive); and Rosenherg, *supra* note 16, at 862-63 (suggesting that firms with potential for mass exposure torts should be increasingly sensitive to liability rules). Some commentators have gone so far as to argue that toxic tort rules overdeter manufacturers, see, e.g., Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 291-93, 314-16 (1985), although these analyses seem to focus exclusively on a small subset of heavily regulated products, such as new drugs and vaccines, for which safety testing is extensive, see TOXICITY TESTING, *supra* note 29, at 12 (noting that, in 1984, unregulated chemical products in commerce included over 40,000 chemicals in contrast to less than 2000 drug products).

Interestingly, inadequacies in existing liability rules may impair empirical efforts to determine whether existing tort doctrines actually deter manufacturers. For example, a survey of 250 companies with regard to how the product liability system affects their manufacturing decisions revealed that only nineteen percent had "[i]mproved safety of products" and only thirteen percent had "[r]edesigned product[s]" in anticipation of liability. E. PATRICK MCGUIRE, *THE IMPACT OF PRODUCT LIABILITY* 20 (1988). This may suggest that the effect of product liability on manufacturers' decisions is slight or it might suggest that gaps in tort rules provide many manufacturers with relatively reliable ways to avoid liability.

<sup>159</sup> One can argue, in the abstract, that many of the factors that tend to mute tort law's signals are absent or less significant in litigation involving latent toxic harms. For over a century, courts in every state have imposed the burden of proof for producing *some* scientific information supporting a cause-and-effect relationship on plaintiffs. See *supra* note 69 and accompanying text. Thus, the temporal and jurisdictional variations that are often blamed for suppressing tort law's messages to manufacturers are not present with the causation rule. Cf. JERRY L. MASHAW & DAVID L. HARFST, *THE STRUGGLE FOR AUTO SAFETY* 241 (1990) (concluding that products liability law does not significantly influence automobile design because its messages are "weak and full of static").

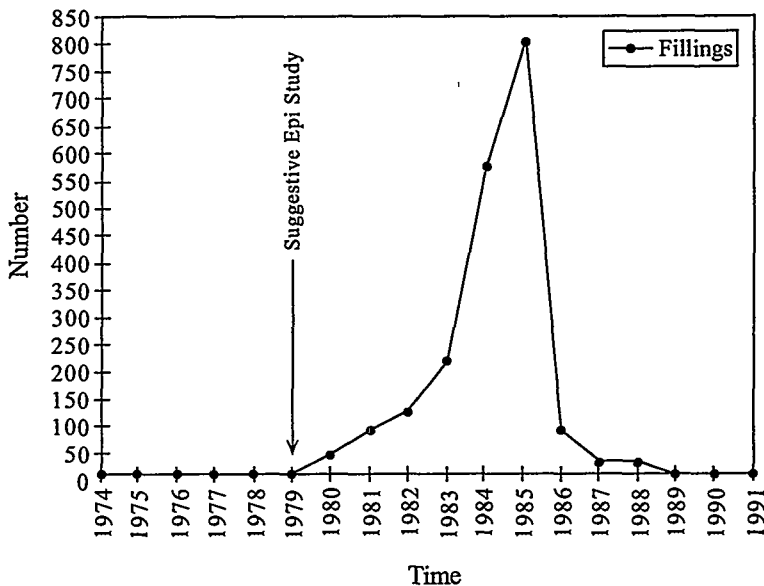
<sup>160</sup> See Figure 2; see also *supra* notes 151-54 and accompanying text.

<sup>161</sup> The filing information was based on data published by Sanders, *supra* note 70, at 396 tbl.5 (including state and federal filings). For a "suggestive epidemiology" study that provided a scientific turning point in the Bendectin litigation, see Kenneth J. Rothman et al., *Exogenous Hormones and Other Drug Exposures of Children with Congenital Heart Disease*, 109 AM. J. EPIDEMIOLOGY 433 (1979), described in Sanders, *supra* note 70, at 342.

<sup>162</sup> The benzene "case hits" were collected from a search of WESTLAW, Allcases file (June 1996) ("henzene" as the search term), see *supra* note 148 (describing WESTLAW search in greater detail), and include opinions from both toxic tort and workers' compen-

positive or inconclusive epidemiology study appeared to lead to plaintiffs' verdicts and increased filings.<sup>163</sup>

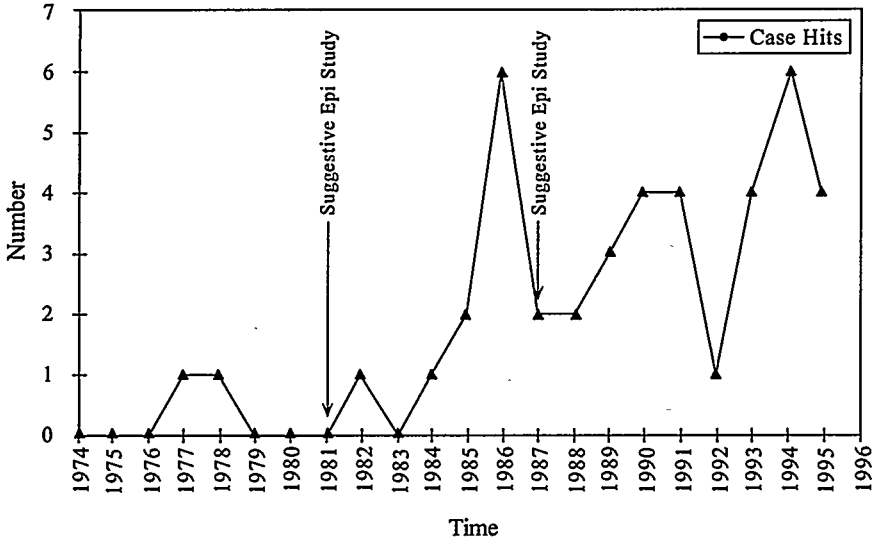
FIGURE 3  
BENDICTIN FILINGS OVER TIME IN RELATION TO SUGGESTIVE  
EPIDEMIOLOGICAL STUDY



sation suits that involve claims for harms resulting from benzene exposure. The suggestive epidemiology studies of benzene are Robert A. Rinsky et al., *Benzene and Leukemia*, 316 NEW ENG. J. MED. 1044 (1987); Robert A. Rinsky et al., *Leukemia in Benzene Workers*, 2 AM. J. INDUS. MED. 217 (1981). These studies are discussed in Brennan, *supra* note 18, at 33, as "large and complete epidemiological studies" that demonstrate higher incidences of leukemia after exposure to benzene, as well as dose-response effects.

<sup>163</sup> See FIGURES 3 & 4; see also Sanders, *supra* note 70, at 342 (discussing scientific and legal watershed resulting from highly regarded 1979 epidemiological study that suggested an association between Bendectin and birth defects); *cf. id.* at 321 ("Science is . . . a leading indicator of what was to happen in the Bendectin trials. To know the science was, to some extent, to be able to predict what would come."). Sanders also observed that mass filings generated, in turn, greater scientific research, because questions regarding latent effects of the chemical became "hot." *Id.* at 346. Media attention tends to stimulate the interest of prestigious journals and funding sources, which in turn encourage scientists to propose research in the particular area. See *id.* Research on Bendectin dropped only after scientists began to reach a consensus that Bendectin was at best a weak teratogen, the number of exposed persons declined because Bendectin was removed from the market in 1983, and other "hot" topics began to take funding priority. See *id.* at 347.

FIGURE 4  
 BENZENE "CASE HITS" OVER TIME IN RELATION TO  
 SUGGESTIVE EPIDEMIOLOGICAL STUDIES



This case-specific trend is repeated in the broader study of forty-three EPCRA chemicals.<sup>164</sup> The number of "case hits" for a chemical is strongly correlated with the number of epidemiological studies publicly available on that chemical:<sup>165</sup> the number of epidemiology studies increases at the same rate as the litigation (using published opinions as a measure). This relationship is not repeated for any other data pairs.<sup>166</sup>

<sup>164</sup> Recall also that the target chemicals used in this study are regulated under the right-to-know provisions of EPCRA, *see supra* note 149 and accompanying text, and, hence, will have considerably more safety information than the average unregulated chemical. Three or four long-term studies is a low number for chemicals listed under EPCRA; it is a good deal for an average unregulated chemical. *See supra* Part I.B.2.

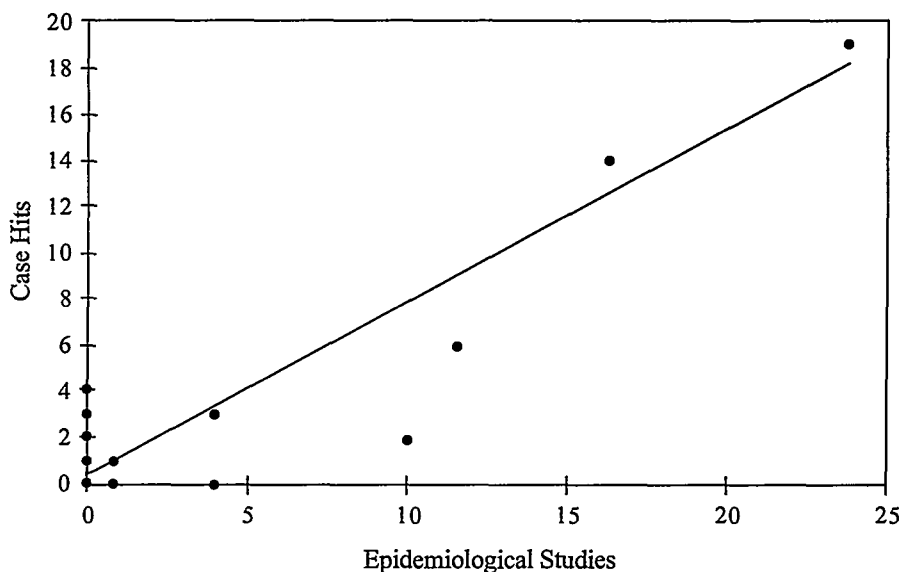
<sup>165</sup> Despite the coarse nature of the case-hit data collected from WESTLAW computer database, which does not provide the total number of case filings, case settlements, or settlements prior to filing on a chemical-by-chemical basis, and despite other sources of error stemming from the study more generally, *see supra* note 149, the correlation between case-hits and epidemiology studies was a surprising 0.94 (with a perfect correlation being 1 and no correlation being 0).

<sup>166</sup> *See* Figure 5. The strongest "second" correlation was between the combined total of epidemiological and clinical studies and case-hits. Surprisingly, there appears to be no correlation between long-term laboratory studies and case-hits, and only a weak to moderate correlation between innovation activity and case-hits.

The absence of a similar correlation between case-hits and long-term animal studies is puzzling. Absent more detailed information (such as filing information) these results can be interpreted in several very different ways. The first interpretation is that most heavily litigated toxic tort claims are going to be those supported by relatively well-developed scientific proof due to selection factors. *See infra* notes 292-95 and accompanying text. A second interpretation is that the data in this study are too rough and, therefore, the absence of a correlation is inconclusive rather than meaningful.



FIGURE 5  
 NUMBER OF EPIDEMIOLOGY STUDIES VS. NUMBER OF "CASE  
 HITS" ON EACH OF 43 EPCRA CHEMICALS



Perhaps even more importantly, the manufacturing community appears to believe that safety research regarding latent harms invites, rather than wards off, litigation.<sup>167</sup> Defense lawyers tout the effectiveness of ignorance of long-term product effects as a defense to litigation,<sup>168</sup> and this advice appears to be followed, in some cases

<sup>167</sup> Cf. Deborah R. Hensler & Mark A. Peterson, *Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis*, 59 BROOK. L. REV. 961, 1017 (1993) ("The history of mass torts has shown that manufacturers may doubt or at times even suppress information about potential product-related dangers, allowing products to remain on the market until their dangers are obvious and many people have been placed at risk.")

<sup>168</sup> See, e.g., Voke, *supra* note 68, at 48 (identifying as successful defense strategy in toxic tort cases "[e]licit[ing] a concession [from an expert witness] that a positive response from either an epidemiological, in vitro or in vivo study is generally required in the scientific community before an expert can offer an opinion that the product in question caused the plaintiff's disease"); see also Blomquist, *supra* note 62, at 30 (observing based on a survey of caselaw that defendants in toxic tort disputes rely on "causation-based arguments" and that inadequate evidence exists on causation for their defense); cf. Henderson, *supra* note 44, at 779 (observing that in terms of making safety improvements in an existing product, frequently "the safest course in the short run . . . is to admit nothing, alter course as little as possible, and offer to settle with no one"); Allan Kanner, *Continuity and Change in Toxic Tort Litigation*, in 2 ENVTL. LITIG. 539, 564-65, 594-95 (ALI-ABA Course of Study, June 20-24, 1994), available in WESTLAW, C921 ALI-ABA 539 (observing strategic litigation tactics manufacturer-defendants use "to keep incriminating information out of the public marketplace of ideas," which include staying discovery until all dispositive motions have been ruled on, entering into confidential settlements to keep information from other victims, and attacking plaintiffs' causation experts and evidence).

successfully.<sup>169</sup> Case studies show that a manufacturer's decision to refrain from conducting even the most basic tests to resolve preventable scientific uncertainties regarding the safety of their product is often made even after the company becomes aware of a potential problem. For example, in the manufacture of the Dalkon Shield,<sup>170</sup> Ultra-Absorbent Tampons,<sup>171</sup> Ben-

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<sup>169</sup> In a case brought by parents for the death of their child from aplastic anemia allegedly resulting from exposure to Pratt 505K, which was sprayed in the city for mosquito control purposes, defense attorneys "persistently demanded [from plaintiffs] studies showing an increased risk of aplastic anemia in humans from exposure to Pratt 505K, evidence which the plaintiffs in this case, or any similar case, could not realistically present." Brennan, *supra* note 18, at 44, 46-47 (citing testimony in trial record of Vann v. City of Woodhaven, No. 84425 092 NI (Wayne County Cir. Ct. Mich., June 12, 1988) and noting the paucity of epidemiological studies available on most chemicals) (footnotes omitted). Defendants won a jury verdict in the case. See *id.* at 47.

<sup>170</sup> The A.H. Robins Company manufactured the Dalkon Shield, an intrauterine birth control device ("IUD"). Dr. Robert Murphy, the director of scientific development and international research for the company, stated in a memorandum "we possess[ed] inadequate support data from animal studies as to long-term safety of the current Dalkon Shield." MORTON MINTZ, AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALCON SHIELD 123 (1985) (quoting memo) see also *id.* at 133 (quoting memo of Dr. Oscar Klioze, Director of Pharmaceutical Research and Analytical Services, warning that the string on Dalkon Shield "has not been subjected to any formal stability testing"); *id.* at 134 (quoting memo by Kenneth Moore, Dalkon Shield Project Coordinator, warning that "[c]onsidering that we have been marketing the device for going on three years, . . . it is about time that data are collected on the effect of the uterine environment"). See generally SHELDON ENGLMAYER & ROBERT WAGMAN, LORD'S JUSTICE: ONE JUDGE'S BATTLE TO EXPOSE THE DEADLY DALCON SHIELD 28, 36-38 (1985) (describing inadequate safety testing of Dalkon Shield); MINTZ, *supra*, at 132-47 (describing the considerable amount of information that Robins ignored when it delayed and avoided safety testing of the string on the Dalkon Shield). Robins also apparently failed to disclose that the shield contained copper and copper sulfate in order to avoid having the FDA classify and ultimately regulate the Shield as a drug. See MINTZ, *supra*, at 123-27; see also Hilliard v. A.H. Robins Co., 196 Cal. Rptr. 117, 132 n.21 (Cal. Ct. App. 1983) (observing that "plaintiff presented substantial evidence of a conscious decision by defendant Robins not to test the IUD device prior to or during marketing").

<sup>171</sup> In 1980, when the Center for Disease Control ("CDC") became aware of a virtual epidemic of Toxic Shock Syndrome ("TSS") among women, it conducted an epidemiology study that correlated the disease with the recent use of tampons. See West v. Johnson & Johnson Prods., Inc., 220 Cal. Rptr. 437, 442-43 (Cal. Ct. App. 1985). The CDC then requested safety research from tampon manufacturers but received almost no information. See *id.* at 443. As a result of the considerable scientific uncertainty, CDC conducted a second study and within three to four weeks had isolated the cause of TSS as a bacteria present in a small percentage of women that thrived as a result of tampon use. See *id.* Estimates in 1980 reported that approximately ten percent of the women suffering from TSS died. See *id.* at 442 (quoting an expert witness)

Evidence later adduced by plaintiffs revealed that between 1975 and 1980 one of the tampon manufacturers (Johnson & Johnson) had received 150 complaints "of a more serious nature" resulting from tampon use. *Id.* at 445. When the complainant would cooperate, Johnson & Johnson would test remaining tampons in the box owned by the complainant to ensure that they met manufacturing specifications, but did no additional testing. See *id.* In fact, the court found that "[u]p to the time of trial, [Johnson & Johnson] had conducted no studies to ascertain whether use of a tampon was in any way related to vaginal infection." *Id.* Plaintiffs told a similar story against Playtex, another manufacturer of ultra-absorbent tampons. See O'Gilvie v. International Playtex, Inc., 821 F.2d 1438, 1446

dectin,<sup>172</sup> D.E.S.,<sup>173</sup> and breast implants,<sup>174</sup> well-established corporations repeatedly resisted conducting relatively straightforward studies on the long-term safety of their products. Not surprisingly, some of these companies defended their products in litigation by arguing that the existing scientific research was insufficient to prove that the products actually caused harm.<sup>175</sup>

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(10th Cir. 1987) (finding that Playtex disregarded studies demonstrating a connection between highly absorbent tampons and TSS).

<sup>172</sup> See *infra* note 203 and accompanying text.

<sup>173</sup> See, e.g., *Bichler v. Eli Lilly & Co.*, 436 N.E.2d 182, 185 (N.Y. 1982) (reporting that "[t]he jury determined that Lilly and other DES manufacturers wrongfully marketed the drug for use in preventing miscarriage without first performing laboratory tests upon pregnant mice," and that these tests would have alerted the companies that "DES was capable of causing cancer"); *id.* at 189 (discussing Lilly's partial admissions regarding foreseeability of cancer resulting from DES).

<sup>174</sup> Breast implants were not subject to FDA regulation until 1988, 24 years after they had been on the market (a delay attributed in part to successful lobbying by breast implant manufacturers and surgeons). See Zöe Panarites, Note, *Breast Implants: Choices Women Thought They Made*, 11 N.Y.L. SCH. J. HUM. RTS. 163, 192-93 (1993). The research finally filed with the FDA in 1991 was sorely inadequate. The Leader of the FDA's Breast Implant Task Force reported that Dow's clinical studies were:

"so weak that they cannot provide a reasonable assurance of the safety and effectiveness of these devices[,] because they provide "no assurance that the full range of complications are included, no dependable measure of the incidence of complications, no reliable measure of the revision rate and no quantitative measure of patient benefit."

STAFF OF SUBCOMM. ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS OF THE HOUSE COMM. ON GOVERNMENT OPERATIONS, 102d CONG., REPORT ON THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS 22 (Comm. Print 1993). Because of remaining scientific and trans-scientific uncertainties regarding the safety of breast implants, the FDA has substantially restricted their availability. See, e.g., *id.* at 43-45 (observing FDA's 1992 moratorium on implants, but criticizing FDA for inadequate monitoring of "urgent need" exception).

<sup>175</sup> Michael Ciresi, a plaintiffs' lawyer in the Dalkon Shield litigation, reported that "[t]he defense strategy has been to insulate Robins's officials from the information gathered by the defense [legal] team, so as to enable them to testify that they have no medical or technical evidence that the Dalkon Shield causes injury to a degree different [from that caused by] other IUDs.'" MINTZ, *supra* note 170, at 203 (alteration in the original); see also *id.* at 17-19, 203-06 (reporting on scientific ignorance as defense in the Dalkon Shield litigation). Defending claims that their untested o.b. tampons caused TSS, Johnson & Johnson's experts consistently maintained that "no study had proved a cause-and-effect relationship between the use of tampons and the occurrence of TSS. They also maintained . . . that tampons by themselves did not cause TSS . . ." West, 220 Cal. Rptr. at 446. Despite its extensive in-house knowledge of the health hazards of cigarettes, see *infra* note 180, even the tobacco industry has attempted to claim that existing research does not establish a scientifically established cause-and-effect link between tobacco and cancer. See, e.g., PHILIP J. HILTS, *SMOKESCREEN: THE TRUTH BEHIND THE TOBACCO INDUSTRY COVER-UP* 18 (1996) (reporting the tobacco industry's argument that existing research did not prove tobacco causes cancer and that for sufficient proof, the victim would need to scientifically establish "every individual biochemical step as a disease is created" and then establish that each of these steps led to her particular cancer); *id.* at 41 ("The position of the tobacco companies . . . is dominated by legal considerations. . . . It has retreated behind impossible, perhaps ridiculous, demands for what in PR terms is called scientific proof . . . usually the first reaction of the guilty.") (quoting former British American Tobacco Company vice president for research, Sidney James Green) (alterations in original).

More attenuated, but also more disturbing, are isolated examples of corporate decisions to continue marketing products after confidential in-house research revealed latent hazards, but publicly available studies demonstrating adverse effects were scarce or non-existent.<sup>176</sup> Corporate concealment of adverse testing results occurred in the marketing of asbestos,<sup>177</sup> the Dalkon Shield,<sup>178</sup> and breast implants,<sup>179</sup> and may be occurring in the marketing of tobac-

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<sup>176</sup> See generally Kanner, *supra* note 168, at 587-88 & n.220 (charging that manufacturer defendants engage in deliberate efforts to suppress damaging scientific data).

<sup>177</sup> The record of asbestos manufacturers' attempt to conceal or downplay the hazards of asbestos is well-documented. See generally PAUL BRODEUR, *OUTRAGEOUS MISCONDUCT: THE ASBESTOS INDUSTRY ON TRIAL* (1985) (chronicling asbestos litigation throughout the industry). More dramatic examples include: animal studies on asbestosis in the 1930's, the findings of which, by agreement, belonged to the investors until they agreed to disclose it to the public, see *id.* at 118-19; notes detailing Johns-Manville Co.'s health review committee meeting during which executives "developed a corporate policy of not informing sick employees of the precise nature of their health problems for fear of workmen's-compensation claims and lawsuits," see *id.* at 145; and successful company efforts to persuade the editor of a trade magazine that growing scientific studies on "asbestos . . . [should] receive the minimum of publicity." *Id.* at 116-17.

<sup>178</sup> For example, A.H. Robins's primary strategy was to avoid safety research on the Dalkon Shield, but it selectively disclosed the limited safety testing it did conduct when the results were positive. See *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1240 (Kan. 1987) (awarding punitive damages based on corporate misconduct, including evidence that A.H. Robins "commissioned studies on the Dalkon Shield which it dropped or concealed when the results were unfavorable" and "consigned hundreds of documents to the furnace"). Cf. MINTZ, *supra* note 170, at 122 (referencing memo by Kenneth Moore, Project Coordinator of Robins's Dalkon Shield, reporting that Robins's main purpose in engaging in studies was "'to make available for publication extremely good Dalkon Shield results'"). Robins initiated a two-year study on the effects of the Dalkon Shield on baboons eight months after it started selling the Dalkon Shield that was never made available to the medical profession. "Among eight [of the baboons tested], one 'perished,' and among ten, three suffered perforation of the uterus . . ." *Id.* at 123 (quoting testimony of Dr. John W. Ward, director of toxicology and assistant director of scientific development). Following an escalation of concern by company employees over the potential of the string of the Dalkon Shield to carry bacteria from the vagina to the uterus, Robins retrieved 303 used strings for examination by a staff scientist, Thomas C. Yu. Dr. Yu found defects in all but 35 of the strings. Yu's boss swore that Robins maintained "no written records of the exams or the results." *Id.* at 134-35. There is also some suggestion that Robins destroyed sensitive Dalkon Shield documents in order to better defend against litigation. See Francine Schwadel, *Robins and Plaintiffs Face Uncertain Future*, WALL ST. J., Aug. 23, 1985, at A1.

<sup>179</sup> See *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1127-28 (9th Cir. 1994) (affirming punitive damage award based in part on evidence that company concealed adverse results of clinical studies and knew that long-term studies were needed). In *Hopkins*, the court stated:

Dow obtained results of a study in which four dogs received silicone gel implants that resembled the implants that Dow was then marketing. The results demonstrated that after six months, the implants appeared to be functioning properly, but that after two years, inflammation surrounding the implants demonstrated the existence of an immune reaction. Dow did not publicly release the results of this research for several years, and when it did ultimately release the results, Dow omitted the negative findings and implied that the implants were safe.

*Id.* at 1119. See also Rebecca Weisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 GOLDEN GATE U. L. REV. 973, 987 n.122 (1993)

co products as well.<sup>180</sup> Although limited, these examples provide dramatic evidence that at least some corporations perceive liability for certain types of latent harms as either unlikely or a risk that should be significantly discounted as long as their own in-house research is concealed.<sup>181</sup>

The well-publicized demise of these same corporations who engaged in in-house research and were later "caught" with their adverse results may also have the untoward effect of deterring firms from conducting such research in the future, particularly for products already on the market.<sup>182</sup> Experience in other mass tort cases has revealed that in-house research is helpful only if it is used to determine when to remove or recall a product from the market so that the manufacturer can "deplete" the pool of future plaintiffs<sup>183</sup> and reduce liability judgments to a payable size.<sup>184</sup> Beyond this function, additional in-house safety research has been relatively ineffective in supporting a firm's defense, because a manufacturer's research conducted after litigation

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(quoting Dow Corning discovery documents and summary of scientific studies). Dow Corning also conducted a study in 1974 that revealed that silicone could "trigger strong reactions of the immune system," but Dow Corning denied such a reaction at an FDA hearing in 1991. *Id.* at 988 n.123 (citing Boyce Rensberger, *Reaction to Silicones was Denied; Despite 1974 Study, Dow Scientist Told FDA No Risk Seen*, WASH. POST, Jan. 18, 1992, at A1). Finally, in 1987 Dow Corning was aware that some of its employees had falsified documents regarding silicone breast implants, but Dow Corning did not alert the FDA to these misstatements until 1992. *See* Weisman, *supra*, at 988 n.123 (citing Thomas M. Burton, *Dow Corning Employees Falsified Data on Breast Implants, Counsel Concludes*, WALL ST. J., Nov. 3, 1992, at A3).

<sup>180</sup> *See* HILTS, *supra* note 175, at 6-7 ("[The tobacco industry's] plan was to spend large amounts of money every year indefinitely into the future to prevent, not sworn adversaries, but *scientists and public health officers*, from warning people of a potential hazard . . . There is no case like it in the annals of business or health."); *see also id.* at 10-11, 20-22, 23-41, 129 (describing concealment of adverse health studies conducted by tobacco industry).

<sup>181</sup> Gross negligence by manufacturers in marketing products is of course not limited to safety testing. In his article on tort deterrence, Gary Schwartz highlights several other disturbing examples of manufacturers who marketed drugs and medical devices with the knowledge that they were defective and could cause serious injuries or death. Schwartz, *supra* note 158, at 406-07.

<sup>182</sup> Henderson has similarly observed the tendency of liability rules to deter safety improvements for marketed products "at the margin." Henderson, *supra* note 44, at 774; *see also id.* at 772 (discussing "'confession by implication'" occurring when manufacturer introduces safety changes in product which later comes back as evidence against safety of original design).

<sup>183</sup> *See* Sanders, *supra* note 70, at 347 (noting that Merrell, a manufacturer of Bendectin, produced a "case depletion effect" and an "epidemiological depletion effect" by removing product from market).

<sup>184</sup> According to plaintiff's attorneys, if A.H. Robins had recalled the Dalkon Shield in 1974, when it became aware of the dangers, it "would have cost about \$50 million" as opposed to the nearly \$500 million it expended in settling cases and legal bills because of its "decision to defend the product." *See* Schwadel, *supra* note 178, at A1. Clearly, Robins failed to properly estimate either the potential hazard of its product or the number of victims who would ultimately file claims.

has commenced is generally viewed as biased.<sup>185</sup> By contrast, additional in-house research that demonstrates some latent product risks can reinforce a conclusion that the product is harmful. In fact, a manufacturer's adverse research may provide a basis for a punitive damage claim—a plaintiff is virtually certain to argue that the manufacturer behaved recklessly when it continued to market a product that its own research revealed was hazardous.<sup>186</sup>

## 2. Undercompensation

Underdeterrence leads to undercompensation; the relationship is logical. If manufacturers are not adequately deterred from wrongful conduct, they must be underpaying their collective debt to the victims of these undetected wrongs.<sup>187</sup> Unfortunately, whether and to what extent the current causation rule may undercompensate victims is impossible to determine precisely because the long-term toxicity of most chemical products is unknown and unstudied. Those who have

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<sup>185</sup> See, e.g., Sanders, *supra* note 70, at 337 (describing Merrell's research conducted after litigation began as a "lose-lose proposition" because "[i]f they showed an effect, the studies would be used against the company" and if they did not "[a]ny slight technical flaw in the design or execution of the experiment would be exploited by plaintiffs to undermine Merrell's findings"). In at least the Bendectin litigation, this appeared to happen with some studies Merrell conducted or funded. See *id.* at 337-38 nn.169-70 & 172. In fact, one letter between a Merrell employee and Professor Richard Smithells, who conducted research for Merrell, suggested that the researcher hoped for greater financial generosity from Merrell if his findings supported Merrell's case. See *id.* at 337 n.170 (quoting letter from Richard W. Smithells, Professor of Pediatrics, to Mark T. Hoekenga, M.D. (Jan. 26, 1977)). Sanders notes that in the only trial in which the court excluded this letter, the Multi-District Litigation ("MDL"), the jury verdict was entered for defendant Merrell Dow. Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 54 (1993) [hereinafter Sanders, *Bendectin Cases*] (discussing *In re Richardson-Merrell, Inc. "Bendectin" Prods. Liab. Litig.*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988)).

<sup>186</sup> Punitive damages have been awarded when a manufacturer had internal information indicating that their product posed latent harms, but they failed to act on that information. See, e.g., Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 39-46 (1995) (providing survey of punitive damage awards in Dalkon Shield, Copper-7 Intrauterine Device, super-absorbent tampons, and silicone and saline breast implants, based in part on the fact that manufacturers concealed adverse information or avoided testing product in face of mounting evidence of hazard).

<sup>187</sup> One response to this argument is that undercompensation is insignificant in comparison with the number of undeserving plaintiff verdicts, even in mass toxic tort cases. Cf. MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 193-99 (1996) (suggesting that based on existing scientific evidence the number of claims filed against bankrupt breast implant manufacturer exceeded the number of actual harms); PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 4 (1991) (commenting on the unprecedented and rapid rise in "junk science verdicts" for plaintiffs). Absent better toxic tort data, however, no method exists to determine whether, in general, the tort system is overcompensating or undercompensating plaintiffs. The argument presented here is not meant to deal with the aggregate impact of the tort system, but to address whether undercompensation may occur for specific victims in specific circumstances.

examined the question closely, however, argue that victims are probably undercompensated in most toxic tort cases.<sup>188</sup>

Even for those products that have been causally linked to specific types of harms, undercompensation of victims is evident. In the cases of asbestos,<sup>189</sup> DES,<sup>190</sup> and the Dalkon Shield,<sup>191</sup> for example, thousands of serious injuries (including death) are estimated to be linked causally to each of the inadequately tested products. Some of these victims nevertheless remain uncompensated or undercompensated because of the limited financial viability of various manufacturers;<sup>192</sup> because of the inherent evidentiary handicaps toxic tort

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<sup>188</sup> See SENATE COMM. ON ENV'T AND PUB. WORKS, 97th CONG., SIX CASE STUDIES OF COMPENSATION FOR TOXIC SUBSTANCES POLLUTION: Alabama, California, Michigan, Missouri, New Jersey, and Texas 520-21 (Comm. Print 1980) (concluding that legal mechanisms for compensating harms caused by toxic substances are generally inadequate); 2 AM. LAW INST., APPROACHES TO LEGAL AND INSTITUTIONAL CHANGE 355-56 (1991) (reporting that, despite estimates that 10,000 environmentally-related cancer deaths occur annually, surprisingly little litigation occurs and few plaintiffs obtain awards (\$50 million from 1983 to 1986)); Troyen A. Brennan & Robert F. Carter, *Legal and Scientific Probability of Causation of Cancer and Other Environmental Disease in Individuals*, 10 J. HEALTH POL. POL'Y & L. 33, 59 (1985) (arguing that workers' compensation for occupational diseases such as cancer is "appallingly inadequate" because "[o]nly a tiny percentage of victims" file claims and even if successful, workers are often rewarded with compensation that is "astonishingly low"); Eggen, *supra* note 63, at 897-98 (concluding that undercompensation for reproductive injuries is likely due to difficulties workers confront in proving cause-in-fact); Rosenberg, *supra* note 16, at 858 (arguing that the "more probable than not" rule for liability is not a "just means of resolving the systematic causal indeterminacy presented by mass exposure cases involving defendants whose tortious conduct has caused or will cause a statistically ascertainable increase in the incidence of a particular disease").

<sup>189</sup> Brodeur reports that the number of persons exposed to asbestos included "[m]illions of unsuspecting workers—four and a half million men and women in the wartime shipyards alone—[who] were left to undergo exposure to dangerously high levels of asbestos dust as they applied insulation products." BRODEUR, *supra* note 177, at 120. In 1992, over 200,000 personal injury claims had been filed or were pending against asbestos manufacturers. See Hensler & Peterson, *supra* note 167, at 1004.

<sup>190</sup> See, e.g., Hensler & Peterson, *supra* note 167, at 981-83 (reporting that from 4 to 6 million women were exposed to DES and identifying over 6000 named plaintiffs in 600 DES suits by 1985 and 1000 cases pending against DES manufacturers in 1991).

<sup>191</sup> Tens of thousands of women fitted with Dalkon Shields had suffered serious injuries and that nearly all had suffered pelvic inflammatory disease (PID) that adversely affected their ability to bear children. See MINTZ, *supra* note 170, at 3. The Shield was also an ineffective birth control device (5% of the wearers became pregnant). See *id.* Of these pregnancies, there was a high incidence of "spontaneous abortions" during the first or second trimester and a rare form of "septic spontaneous abortions" during the fourth to sixth months. *Id.* at 4. "By the count of the Food and Drug Administration, 248 women just in this country endured this dangerous, Shield-related complication; for 15 of them, these septic abortions were fatal." *Id.*

<sup>192</sup> See, e.g., Frank J. Macchiarola, *The Manville Personal Injury Settlement Trust: Lessons for the Future*, 17 CARDOZO L. REV. 583, 584 (1996) (describing Manville Trust (established as a result of Johns-Manville Corporation's bankruptcy, which was caused by asbestos liability) and observing that early plaintiffs recover a far greater percentage of their loss than later plaintiffs); Schwadel, *supra* note 178, at A1 (reporting that Robins filed for Chapter 11 bankruptcy because of plaintiffs' claims). For an insightful discussion of the intersection of

plaintiffs generally confront in trying their cases;<sup>193</sup> and because some plaintiffs may not have availed themselves of the court system despite the fact that they had meritorious claims for compensation.<sup>194</sup> Even those victims who do "win" their cases through favorable verdicts or settlements typically remain undercompensated due to the costs of legal counsel.<sup>195</sup>

### C. Jury Nullification

More recently, commentators have expressed concern over jury verdicts for toxic tort plaintiffs that appear to contradict the weight of the scientific evidence.<sup>196</sup> These "mistaken" jury verdicts have led at least a few authors to conclude that lay juries may not be competent to handle trials involving complex scientific evidence without further changes to the legal system.<sup>197</sup>

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mass torts and bankruptcy, see Mark J. Roe, *Bankruptcy and Mass Tort*, 84 COLUM. L. REV. 846 (1984).

<sup>193</sup> See, e.g., Poulter, *supra* note 67, at 199-200

<sup>194</sup> See, e.g., DEBORAH R. HENSLER ET AL., COMPENSATION FOR ACCIDENTAL INJURY IN THE UNITED STATES 122 (1991) (reporting from empirical study that 19% of victims actually considered the possibility of obtaining compensation for accidental injuries, but only 10% made any effort to do so, and 2% of the total number of victims actually filed a lawsuit); Hensler & Peterson, *supra* note 167, at 1019-26 (discussing factors that affect victim awareness and access to legal system); cf. Michael J. Saks, *Do We Really Know Anything about the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1183-89 (1992) (reporting low filing rates (10% or less) by victims in a variety of other types of legal disputes). There is also growing evidence that manufacturers sometimes include an agreement that the plaintiff's attorney will not bring further suits against the manufacturer or assist others in doing so as a condition for settlement. See, e.g., Felstiner & Siegelman, *supra* note 43, at 315 (citing literature). Although it is difficult to imagine that the demand for lawyers can outstrip supply, it is possible that the removal of the more successful plaintiff attorneys in certain types of cases could further exacerbate the failure of many victims to pursue meritorious claims.

<sup>195</sup> See, e.g., JAMES S. KAKALIK ET AL., VARIATION IN ASBESTOS LITIGATION COMPENSATION AND EXPENSES xii-xix (1984) (noting that litigation expenses in asbestos cases constitute approximately 63% of recovery, leaving only 37% for victim compensation).

<sup>196</sup> See Poulter, *supra* note 67, at 193 (arguing that "[s]ubmission of a case to the jury may result in a plaintiff's verdict where even the most cursory examination of the evidence reveals its deficiencies"); Sanders, *Bendectin Cases*, *supra* note 185, at 85 ("[I]n such mass exposure cases, our current litigation practices inevitably lead to situations in which juries are unable to appropriately weigh the complex scientific evidence they are presented at trial. As a result, trial verdicts and damage awards bear little relation to the weight of scientific opinion.")

<sup>197</sup> See, e.g., ANGELL, *supra* note 187, at 204 (discussing "problematic" nature of juries in cases involving complex scientific evidence and suggesting that some consideration should be given to eliminating juries for civil trials); HUBER, *supra* note 187, at 4 (arguing that juries are not capable of sorting good science from bad and that "[j]unk science verdicts, once rare, are now common"); Michael Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 HARV. ENVTL. L. REV. 429, 437-38 (1983) (questioning whether juries are able to comprehend and accurately consider epidemiological evidence); Sanders, *Bendectin Cases*, *supra* note 185, at 84 ("[I]n mass exposure cases, judges are superior to juries in legal competence and decisionmaking accuracy and sometimes in factfinding competence as well."); *id.* at 60-67 (outlining differences between jurors and



Although misplaced jury sympathies that go unchecked when the bulk of the critical evidence lies beyond a jury's comprehension can explain a plaintiff-bias,<sup>198</sup> juries may also excuse weak evidence of causation, "commingle" elements of liability,<sup>199</sup> or even "nullify"<sup>200</sup> the causation rule in a pro-plaintiff direction when manufacturers fail to conduct basic safety testing and this failure disadvantages the plaintiff.<sup>201</sup> It would seem more than coincidental that in those cases in

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experts in evaluating how different types of scientific studies demonstrate causation and identifying refinements to the trial process that might improve jury competence.); cf. Kenneth S. Bordens & Irwin A. Horowitz, *Mass Tort Civil Litigation: The Impact of Procedural Changes on Jury Decisions*, 73 JUDICATURE 22, 27 (1989) (reporting results of empirical research that demonstrate that juries are very inconsistent and tentatively observing that juries have "a great deal of difficulty comprehending complex trial evidence").

<sup>198</sup> See, e.g., Jane Goodman et al., *What Confuses Jurors in Complex Cases*, TRIAL, Nov. 1985, at 65-74 (outlining factors affecting jurors' decisions); James K. Hammit et al., *Tort Standards and Jury Decisions*, 14 J. LEGAL STUD. 751, 753-56 (1985) (analyzing effect of "deep pockets" theory on juries' verdicts); cf. Horowitz & Bordens, *supra* note 197, at 24 (reporting on empirical study that revealed strong positive correlation between presence of plaintiff with severe injuries and higher damage awards).

<sup>199</sup> Joseph Sanders and Michael Green have both suggested that juries in Bendectin cases may have "commingled" the evidence of causation (which was weak) with evidence of negligence (which was strong) in order to find Merrell Dow liable. See MICHAEL D. GREEN, *BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION* 263, 289 (1996); Sanders, *Bendectin Cases*, *supra* note 185, at 53-54; see also *infra* notes 203-08 and accompanying text (discussing Bendectin verdicts in greater detail).

<sup>200</sup> Although "jury nullification" is associated most frequently with criminal trials, particularly those involving race, nullification also occurs in civil trials. See, e.g., Noel Fidel, *Preeminently a Political Institution: The Right of Arizona Juries to Nullify the Law of Contributory Negligence*, 23 ARIZ. ST. L.J. 1 (1991). See generally MORTIMER R. KADISH & SANFORD H. KADISH, *DISCRETION TO DISOBEY: A STUDY OF LAWFUL DEPARTURES FROM LEGAL RULES* 45-66 (1973) (discussing prevalence of juries that disobey applicable legal doctrine); Alan W. Schefflin, *Jury Nullification: The Right to Say No*, 45 S. CAL. L. REV. 168 (1972) (providing historical perspective on jury nullification). For a discussion of the possibility that jury nullification might lead to the "correct" result in some cases, see VALERIE P. HANS & NEIL VIDMAR, *JUDGING THE JURY* 156-60 (1986).

<sup>201</sup> Elliott has similarly suggested that verdicts in toxic tort cases may reflect "our society's prevailing sense of justice in cases where innocent people have been involuntarily exposed to substances that are potentially dangerous to their health," rather than a jury's misunderstanding of the scientific mechanisms of underlying cause-in-fact. E. Donald Elliott, *The Future of Toxic Torts: Of Chemophobia, Risk as a Compensable Injury and Hybrid Compensation Systems*, 25 HOUSTON L. REV. 781, 787 (1988). Elliott, however, does not discuss the potentially pivotal role that a manufacturer's negligence or even recklessness may play in this dispensation of public morality. For more general suggestions that some of the "scientific errors" in jury and judicial opinions "are not all scientific," see Poulter, *supra* note 67, at 266 ("policy concerns, sometimes unspoken but often implied, seem to underlie courts' willingness to entertain unfounded and poorly reasoned evidence"). Thus some of the more dismal views of jury decisionmaking may be overstated, although the chaos that appears to result from jury nullification might not be. Professor Masbaw's characterization is perhaps the most dramatic:

I am tempted to suggest that in the toxic torts context we should describe the tort system as primarily a system of guerrilla warfare. . . . [with] a lot of potential revolutionaries (plaintiffs and jurors) who are throwing bombs (litigation) and who aren't too interested in what shape the rubble (the civil liability system) takes after the litigation is over.

which juries have awarded damages in spite of weak causation evidence, the defendant manufacturers' negligence in testing often rose to the level of gross negligence or recklessness sufficient to support the simultaneous award of punitive damages.<sup>202</sup>

In the Bendectin litigation, for example, the plaintiffs highlighted Merrell Dow's failure to test the drug's long-term safety in a prompt or adequate way<sup>203</sup> and its prior failures to test effectively the

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Mashaw, *supra* note 82, at 1395.

<sup>202</sup> See, e.g., *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1127 (9th Cir. 1994) (affirming jury award of punitive damages in case alleging harms resulting from silicone breast implants where evidence of causation was generally weak but evidence of manufacturer's egregious conduct was strong). General empirical research on jury decisionmaking also lends support to a jury nullification hypothesis. Research suggests that in bifurcated trials during which juries hear causation evidence without evidence of a manufacturer's negligence, they are less likely to find for the plaintiff than when negligence and causation are tried in a unitary trial or when evidence of negligence is presented first in a trial separate from a subsequent trial on causation. See Bordens & Horowitz, *supra* note 197, at 25-27. The authors attribute these results in part to juries' ability to decide cases based on stories, an ability that is thwarted to some extent by separate trials. *Id.* at 27; see also Irwin A. Horowitz & Kenneth S. Bordens, *An Experimental Investigation of Procedural Issues in Complex Tort Trials*, 14 LAW & HUM. BEHAV. 269, 277-78 (1990) (providing more detailed account of study); Nancy Pennington & Reid Hastie, *Evidence Evaluation in Complex Decision Making*, 51 J. PERSONALITY & SOC. PSYCHOL. 242, 242-43 (1986) (examining how cognitive representation of evidence influences juror decisionmaking process and concluding that jurors tend to use the story model, incorporating evidence presented at trial with individual experience). When a defendant's fault (or a plaintiff's damages) assists in understanding causal uncertainties, they may be able to formulate a more coherent story than when causation is tried first, in isolation from the rest of the case. See Bordens & Horowitz, *supra* note 197, at 27 (explaining empirical results and noting that the juries in their study used "[less sophisticated] heuristics" such as "corporate-capitalist versus the little guy" to decide cases when causation was tried first and separately).

<sup>203</sup> Although Merrell Dow did not appear to violate laws in its marketing of Bendectin, its actions to ensure the safety of Bendectin were far from exemplary. Merrell conducted only a minimal amount of safety studies on Bendectin, all of which were done after marketing the product. See Sanders, *supra* note 70, at 321 (citing Record at 20-21, *Mekdeci v. Merrell Nat'l Lab.*, 711 F.2d 1510 (11th Cir. 1983)). Even the minimal safety research Merrell conducted appeared biased to demonstrate Bendectin's safety. Sanders notes that in 1967-68 Merrell conducted the first research on the teratogenicity of Bendectin in response to the Thalidomide disaster, but it was "inherently suspect." *Id.* at 334. First, "the [Merrell] authors interpreted the results as indicating no effect, although there does appear to be both a higher incidence" of adverse affects in animals receiving higher doses of Bendectin. *Id.* at 334 n.158. Second, Merrell did not present any statistical analysis of the studies. See *id.* Thus, both the quantity and the quality of Merrell's long-term safety tests appeared to be quite low.

At trial, plaintiffs' attorneys used Merrell's apparent negligent safety testing as an offensive strategy to prove causation by attempting to "commingle elements, thereby bolstering weak evidence on causation with stronger proof of breach of duty and damages." Sanders, *Bendectin Cases*, *supra* note 185, at 53. In presenting the results of animal studies, for example, plaintiffs' counsel concentrated much of one of their expert's time and attention in pointing out the numerous errors in scientific research done by Merrell, while simultaneously highlighting that other animal studies revealed the long-term hazards of Bendectin. See *id.* at 53 (discussing testimony of Dr. Adrian Gross, the plaintiffs' primary animal studies expert in various Bendectin cases).

safety of Thalidomide and MER/29.<sup>204</sup> This evidence went largely un rebutted by defendants.<sup>205</sup> A subsequent survey of several Bendectin jurors in the *Havner* case<sup>206</sup> (a case in which the plaintiff enjoyed large compensatory and punitive damage awards despite weak causation evidence)<sup>207</sup> in fact revealed that the "jury deliberations did commingle the issues of negligence and causation."<sup>208</sup> The jurors spent more time on evidence of Merrell's scientific misconduct than on any other evidence.<sup>209</sup> This same jury nullification dynamic may also explain more recent jury verdicts entered for plaintiffs in breast implant cases, in which the causation evidence is again limited due, in part, to the manufacturers' failure to conduct adequate pre- and post-market testing.<sup>210</sup> In fact, the manufacturers' conduct with regard to ignoring

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<sup>204</sup> See Sanders, *supra* note 70, at 313-15. Merrell, the manufacturer of Bendectin, was already associated with the manufacture of two notorious drugs, Thalidomide and MER/29. In its manufacture of both of these drugs, allegations of corporate misconduct in safety research had strong support. See, e.g., *id.* at 313-15 (discussing Merrell's history with Thalidomide and noting that Merrell "did not come away with completely clean hands"); *id.* at 315-16 (discussing Merrell's history with MER/29, including fact that Merrell, its parent company, and three Merrell scientists "were indicted under the federal False Writing Statute for withholding data from the FDA") (footnote omitted).

<sup>205</sup> Sanders reports that defendants did not attempt to counter this "story" of negligence, but instead focused much of their case on the argument that existing scientific evidence did not support a finding of general causation. See Sanders, *Bendectin Cases*, *supra* note 185, at 55 (observing that Merrell "increasingly based its entire case on general causation, despite the fact that its most direct and complete counterpart to the plaintiffs' story—that Merrell was careful in the testing and marketing of Bendectin . . . makes due care a central issue").

<sup>206</sup> *Havner v. Merrell Dow Pharm., Inc.*, No. 88-3915-F (D. Tex. 1991) (decided without opinion), reported in 19 PROD. SAFETY & LAB. REP. (BNA) 1134 (Oct. 11, 1991).

<sup>207</sup> The *Havner* jury awarded \$3.75 million in compensatory damages and \$30 million in punitive damages. See Joseph Sanders, *Jury Deliberation in a Complex Case: Havner v. Merrell Dow Pharmaceuticals*, JUST. SYS. J., 1993 (Special Issue), at 45, 55-56 (citing unpublished district court opinion). Sanders goes on to report that "[b]ecause punitive damages are limited to four times compensatory damages in Texas, the judge later reduced the punitive award to \$15 million." *Id.* at 56 n.27.

<sup>208</sup> *Id.* at 58. Sanders suggests that this commingling may be in part a result of the jury instructions. *Id.*

<sup>209</sup> See *id.*

<sup>210</sup> Many of the hazards of breast implants were not investigated prior to or even after marketing. See Lois Ember, *Breast Implants: Silicone Effects in Body to Be Probed*, CHEM. & ENG'G NEWS, Mar. 2, 1992, at 4 ("After 30 years of silicone gel breast implant use, the biological, physiological, physical, and chemical reactions of silicones in the human body are likely, finally, to be systematically studied."); see also *supra* notes 174, 179 and accompanying text (providing additional background on breast implant litigation). It appears that manufacturers' failure to test implants has influenced the jury. See, e.g., *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1127 (9th Cir. 1994) (affirming jury award of \$840,000 compensatory and \$6.5 million punitive damages to silicone breast implant recipient based in part on evidence that Dow Corning rushed development of the implants, failed to adequately test them, and ignored knowledge of adverse health consequences associated with the implants). For a lively analysis of the breast implant litigation and how the legal system misinterpreted the science, see ANGELL, *supra* note 187, at 69-89, 111-32. Although Angell does discuss the breast implant manufacturers' negligence in some detail, *id.* at 38-44, 58-60, she does not consider how this conduct might explain resultant jury awards.

potential hazards and avoiding safety testing was so egregious that two-thirds of the verdicts for breast-implant plaintiffs also included punitive damages awards,<sup>211</sup> and the "median punitive damages award in [these cases] . . . is the largest in the history of mass torts."<sup>212</sup>

Some of the more hotly criticized toxic tort bench opinions may also reflect "judge nullification" or efforts by the judiciary to deter a defendant's choice of ignorance when it simultaneously deprives a plaintiff of evidence on causation.<sup>213</sup> Although these cases are often used as prime examples of the judiciary's inadequate understanding of scientific information, they may actually represent the judges' sophisticated ability to distinguish between trans-scientific and preventable scientific uncertainties<sup>214</sup> and to consider whether the plaintiff or the defendant should be responsible for conducting some preliminary

<sup>211</sup> See Koenig & Rustad, *supra* note 186, at 44. This is a much higher rate than the punitive damages awarded in Dalkon Shield, *see id.*; *see also supra* note 178 and accompanying text, for which the company's negligence easily "shocks the conscience."

<sup>212</sup> See Koenig & Rustad, *supra* note 186, at 44.

<sup>213</sup> See, e.g., Gillette & Krier, *supra* note 42, at 1044 n.52 (hypothesizing that public risk cases criticized for being pro-plaintiff instead "might simply reflect an awareness that traditional doctrine (regarding the burden of proof in particular) demands too much of the victims of many technological risks, and that correctives are therefore necessary"); Poulter, *supra* note 67, at 257-60 (speculating that the court in *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1535-36 (D.C. Cir. 1984), made admissibility and sufficiency decisions that were driven in part by an effort to "correct the imbalance [in tort rules] that disfavors toxic torts plaintiffs").

Judge nullification may also explain other decisions where, for other reasons, the scientific grounding of a judge's decision is questionable but the result may comport with a larger sense of justice. The most obvious example is Judge Weinstein's impatience with veterans who opted out of the large class settlement in the Agent Orange case. *See In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1255-56, 1263 (E.D.N.Y. 1985). His controversial ruling on causation was based on a highly questionable exclusion of all toxicology evidence. *See supra* note 76 (discussing trend by courts to impose epidemiological threshold on plaintiffs in causation and associated evidentiary rulings and resulting problems such a threshold creates). Some observers use this case as an example of the general inability of common-law courts to competently handle scientific evidence. *See, e.g.*, Brennan, *supra* note 18, at 56, 71 (using mistaken rulings in the Agent Orange litigation as partial support for concluding that "the traditional common-law approach is not functioning well" in dealing with complex scientific evidence on causation). It is more likely, however, that Weinstein's controversial ruling was result-oriented. *Cf.* PETER H. SCHUCK, *AGENT ORANGE ON TRIAL: MASS TOXIC DISASTERS IN THE COURTS* 111-12 (1986) (observing creativity and high natural intelligence of Judge Weinstein). As Michael Green observes: "[O]ne is left with the nagging feeling that Judge Weinstein's treatment of plaintiffs' experts and causation evidence was driven more by concerns about upholding the fairness of a settlement that was essential to making the *Agent Orange* class action manageable than a detached assessment of the causation record." Green, *supra* note 21, at 677. Sanders has also suggested that these scientifically wrong admissibility rulings are the result of result-oriented objectives. Sanders, *supra* note 71, at 1430-31. He argues that admissibility rulings in Bendectin cases provided judges with "one of the few devices available to achieve the goal of non-suiting these plaintiffs" because judges "became increasingly certain that plaintiffs did not have valid claims and sought to prevent separate trials." *Id.* at 1431. They thus served the purpose of "an ad hoc method of jury control." *Id.* at 1433.

<sup>214</sup> See *supra* Part I.A.-B.

safety testing. For example, commentators have criticized *Elam v. Alcolac, Inc.*,<sup>215</sup> a Missouri Court of Appeals' opinion, for "abjur[ing] any rational analysis"<sup>216</sup> because it excused the absence of critical information on causation between the plaintiffs' various injuries and the defendant manufacturing plant's releases of toxic chemicals into the environment over an eight-year period.<sup>217</sup> Yet, in this case, the defendant's flagrant disregard of applicable environmental regulations requiring monitoring and reporting of toxic releases<sup>218</sup> prevented the plaintiffs from learning the nature and extent of their exposures—information critical to proving causation.<sup>219</sup> By ruling in favor of plaintiffs, despite significant deficiencies in the proof of causation, the court repeatedly justified its decision on the grounds that "the but for proof [defendant] insists upon the toxic tort plaintiffs . . . was made impossible by the very conduct of the defendant."<sup>220</sup> This judge nullification dynamic may also explain other problematic judicial decisions in scientifically complex cases.<sup>221</sup>

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<sup>215</sup> 765 S.W.2d 42 (Mo. Ct. App. 1988).

<sup>216</sup> Bert Black & David H. Hollander, Jr., *Unravelling Causation: Back to the Basics*, 3 U. BALT. J. ENVTL. L. 1, 9 (1993).

<sup>217</sup> *Elam*, 765 S.W.2d at 179 (causation consisted of circumstantial proof of some hazardous chemicals at the plant and the fact that some of the chemicals were occasionally discharged or emitted).

<sup>218</sup> The misconduct by defendant was reiterated by the court at several points in the lengthy opinion and was indeed shocking:

[Defendant's negligence which prevented plaintiffs from learning of their exposure consisted of] evidence of a state of the art system of toxic waste control and disposal mismanaged by untrained personnel and by operating procedures left undefined. It was evidence of recurrent toxic spills vented into the atmosphere, but unrecorded so that the quantity, identity and dates of those exposures cannot be known. It was evidence of toxic waste from the monomer process diverted from the decontamination procedure and expelled, still toxic, into the bioponds for evaporation into the air—without record or other note of these recurrent events. It was evidence of a liquid incinerator, designed to consume particulate toxic wastes, but which so malfunctioned as to be declared a "hundred percent failure" by the Alcolac [defendant] management—but continued in use for more than two years so that countless, unidentified, unmeasured and unrecorded emissions of toxic compounds were released into the atmosphere. It was evidence of an agreement by Alcolac with DNR [May 30, 1980], but never honored, to install monitors on the monomer stacks to identify and measure the emissions for each product—so that the record intended by the regulatory agency never took form.

*Id.* at 176.

<sup>219</sup> The court noted that because of defendant's misconduct there was no information on the identity of "the particular chemical at a particular exposure, the particular concentration of the chemical, the particular dosage of the chemical taken in bodily, or the particular duration of the exposures." *Id.* at 178.

<sup>220</sup> *Id.* at 177; see also *id.* at 178-80, 182 (same).

<sup>221</sup> For example, in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535-38 (D.C. Cir. 1984), the court did not discuss directly the defendant's failure to test long-term hazards of paraquat (a herbicide distributed in the United States solely by the defendant). However, the court was intolerant of the defendant's defense of scientific ignorance and concluded

V  
REFORM

Requiring plaintiffs to prove causation in toxic tort cases clearly has a significant adverse effect on both the legal system and on safety research. The extent to which these adverse consequences are also unnecessary, however, depends on whether alternative approaches are available that, on balance, represent an improvement over the status quo. This final section proposes a reform of the common-law causation rule that reduces the incentives for manufacturers to remain ignorant about the long-term safety of their products and does so realistically, without imposing unreasonable requirements on industry or on the common-law courts.

A. The Essential Features of the Reform

The proposed reform seeks to accomplish two things. First, it penalizes manufacturers who fail to conduct minimal safety testing on their products.<sup>222</sup> Second, it provides immunity from suit for manufacturers who have conducted a comprehensive battery of tests and found their product to be safe. Common-law courts could adopt this reform incrementally, or legislatures could do so unilaterally.<sup>223</sup> To

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that, based on other incidents, the defendant "should have known" of possible latent hazards of paraquat. *See id.* at 1538. This discussion provides at least a partial explanation for why the court affirmed the jury finding on causation despite limited scientific proof. *See id.*; *see also* Brennan, *supra* note 28, at 497 (hypothesizing that liberal attitude by the court in *Ferebee* may have been in part the result of the "unfairness of penalizing the earliest victims of any bazardous substance"). Although not involving latent hazards, *Haft v. Lone Palm Hotel*, 478 P.2d 465 (Cal. 1970), may best represent this category of cases. The defendant-hotel violated safety codes by failing to have a lifeguard at their pool after being notified of their violations on three occasions by the county inspector. *See id.* at 468 & n.5. Despite the absence of any evidence of why father and son drowned in the pool, the court found for plaintiffs. *See id.* at 467, 472. The judge's inclination to find liability in spite of the plaintiffs' inability to prove causation was likely based on the defendant's flagrant violation of the statute, which prevented the cause from being known. *See* Daniel A. Farber, *Recurring Misses*, 19 J. LEGAL STUD. 727, 731 (1990) (proposing that the presence of a "flagrantly negligent defendant who could not be deterred through the application of the normal evidentiary rules" influenced the court's judgment for plaintiff); *cf.* Rosenberg, *supra* note 16, at 863-64 (suggesting that in "sporadic accident cases," courts abandon the causal connection requirement when defendants do not take optimal care).

<sup>222</sup> The jurisdictional reach of the proposed reform is flexible. At one end of the spectrum, it could apply to all products, wastes, and workplace hazards occurring through the manufacturing process. At the other end of the spectrum, it could apply only to products coming under the jurisdictional reach of the TSCA. *See* 15 U.S.C. § 2602(2) (1994) (defining "chemical substance[s]" that are subject to TSCA jurisdiction). Because of the additional financial burden the reform places on industry, it may be most prudent to begin with only a piece of the testing problem and work in stages toward a more comprehensive solution.

<sup>223</sup> Although there are several possible impediments to adoption of the reform through the common law, *see infra* note 252 and Part V.B.1, these may be modest in comparison to the obstacles inherent in a legislative reform. Even if the public, or at least the legislators, appreciated the current error in the common-law approach to causation, the

protect manufacturers from potentially catastrophic liability, ideally, the reform should include a five-to-ten year grace period,<sup>224</sup> during which manufacturers would be put on notice that they must comply with the new rules.<sup>225</sup>

The mechanics of the reform are simple. In toxic tort cases, rather than requiring plaintiffs to resolve both trans-scientific and preventable scientific uncertainties, a revised causation rule would place the initial burden for resolving basic, preventable scientific uncertainties on manufacturers. If, prior to marketing its product or prior to the grace period a manufacturer is not able to publicize the "minimal" safety research on its product where some potential for exposure exists ("minimal testing"),<sup>226</sup> the plaintiff is entitled to a presumption that the insufficiently tested product caused her harm. The plaintiff thus establishes a prima facie case with proof of the following: (1) inadequate minimal testing on a product,<sup>227</sup> (2) normal or foresee-

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public may simply have insufficient political resources to prevail against the well-organized manufacturers at a legislative level. *See, e.g.*, KOMESAR, *supra* note 104, at 167-68, 192 (noting that in product safety where potential for injuries is small, but harm to individuals is serious, "[t]he skewed distribution can lead and, in this context, appears to have led to overrepresentation of the position of the potential injurer group" in the political process).

<sup>224</sup> Exposures would also have to occur after the grace period for plaintiffs to benefit from the reformed causation rule. Common-law courts would obviously be unable to establish such a grace period as precedent, although they could recommend in dicta that common-law courts adopt such a reform in the future, after defendants have notice of the proposed change.

<sup>225</sup> This reform has the potential to encourage a large number of plaintiffs to file claims. *Cf.* Richard A. Nagareda, *Turning from Tort to Administration*, 94 MICH. L. REV. 899, 913 (1996) (discussing how plaintiff attorneys are inclined to file marginal claims in mass toxic tort cases after claim is well established because these claims are not costly to try but "amount, in aggregate, to a significant vehicle for cost spreading by a plaintiffs' firm laden with fixed costs"). In select cases, the proposed reform may penalize negligent manufacturers to the point of bankruptcy, despite the five-to-ten year grace period. Thus, damages may need a cap at some point, such as ten-thousand times the unjust enrichment to defendant.

<sup>226</sup> *See infra* notes 253-57 and accompanying text. Under the proposal, the manufacturer can conduct the minimal toxicity research itself, purchase the research from another manufacturer or research laboratory, or "pool" with other firms to produce the information. *See, e.g.*, 15 U.S.C. § 2603(c)(2)-(4) (1994) (providing an exemption and reimbursement plan under the TSCA for manufacturers whose required research has already been completed by another manufacturer); 40 C.F.R. pt. 791 (same); Hoerger et al., *supra* note 100, at 73 (discussing how the chemical industry pools together to conduct toxicology tests on a limited number of high priority chemicals through the Chemical Industry Institute of Toxicology, Chemical Manufacturers Association, and other "ad hoc industry groups"). The manufacturer cannot, however, merely provide citations to studies conducted by other manufacturers. *See infra* Part V.B.2.

<sup>227</sup> Ideally, a scientific panel should determine minimal testing, *see infra* Part V.B.1, but in the interim minimal testing would likely consist of one or two short-term laboratory studies. *See infra* note 257 and accompanying text. Note that this reform would require courts that currently refuse to admit laboratory animal studies as proof of causation to admit those studies as evidence of manufacturers' satisfaction of their duty to test. *See supra* note 76 and accompanying text.

able<sup>228</sup> exposure to the product,<sup>229</sup> and (3) serious harm that might be causally linked to exposure to the product.<sup>230</sup> The plaintiff could satisfy the harm element, depending on jurisdiction, by demonstrating the existence of latent physical harms (e.g., cancer, reproductive ailments), emotional harms, medical monitoring costs, or an increased risk of latent physical harm.<sup>231</sup> The defendant then bears the

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<sup>228</sup> See, e.g., RESTATEMENT (SECOND) OF TORTS § 402A cmt. h (1965) ("A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal [use] . . . the seller is not liable."); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. 1 (foreseeability of use and risks) (Tentative Draft No. 2, 1995).

<sup>229</sup> The courts will need to define what constitutes an "exposure" to a particular product. One approach would require plaintiffs to demonstrate sufficient "exposure" contact (either in time or concentration) to pose a risk of latent harm of greater than 1 in 10,000 or 1 in 1 million. See *infra* note 241. This approach, of course, assumes that some information exists from which to make this determination. If no information exists to allow calculation of risk thresholds for the substance, then courts could hold any non-de-minimis concentration sufficient to constitute an exposure.

Statutes of limitations would continue to run from discovery of the harm, from the date of exposure, or from other points in time as defined by the jurisdiction. See generally *Developments in the Law—Toxic Waste Litigation*, 99 HARV. L. REV. 1458, 1605-09 (1986) (describing prevailing approaches to statute of limitations in toxic tort cases).

<sup>230</sup> The plaintiff would have to establish that the defendant violated its duty to test and that, based on existing information which presumably would include at least the chemical structure of the product, it is not biologically implausible that exposure to the product caused plaintiff's harm. A defendant could raise affirmative defenses of comparative fault (e.g., smoking) to rebut the presumption of causation as well as to reduce damages, but the defendant will bear the burden of proof.

<sup>231</sup> Some courts permit causes of action by victims who do not yet have cancer or some other latent, debilitating physical injury through the recognition of medical monitoring, increased risk, and cancerphobia claims. See, e.g., *Mauro v. Raymark Indus., Inc.*, 561 A.2d 257 (N.J. 1989) (recognizing medical monitoring, emotional distress, and enhanced risk claims for the future onset of cancer, but limiting availability of claims to specified circumstances). The medical monitoring claim typically provides a plaintiff with necessary medical surveillance costs if there is a relative increase in the chance of disease resulting from exposure to defendant's product or waste. This claim takes a variety of forms and requires varying levels of proof, depending on the jurisdiction. For a brief overview of the different tests courts use, see Allan Kanner, *Review of Toxic Tort Litigation*, in 2 ENVTL. LITIG. 621, 676-83 (ALI-ABA Course of Study, June 20-24, 1994), available in WESTLAW, C921 ALI-ABA 621; see also *supra* note 157 and accompanying text (discussing causation burden in medical monitoring claims). Although less widely accepted, "increased risk" claims provide a cause of action prior to the onset of a disease. See, e.g., *Hagerty v. L & L Marine Servs., Inc.*, 788 F.2d 315, 319 (5th Cir. 1986) (holding that claim for increased risk of cancer is allowed when plaintiff "can show that the toxic exposure more probably than not will lead to cancer");  *Eggen, supra* note 63, at 906-07 (observing some judicial resistance to increased risk claims due to their speculative nature and the possibility of overcompensation or undercompensation). Some common-law courts also hold that emotional distress for fear of future harm is compensable in select circumstances following exposure to toxic chemicals. See, e.g., *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1205-07 (6th Cir. 1988) (affirming availability under Tennessee law of damages for fear of increased risk of contracting cancer and other diseases, but reducing amount of plaintiffs' awards based on each plaintiff's exposure to defendant's wastes); cf. *Jasanoff, supra* note 17, at 130-31 (arguing that cancerphobia may constitute a legitimate "loss of trust and social anomie that many see as a condition of life in technologically advanced societies"). But see *Schweitzer v. Consolidated Rail Corp.*, 758 F.2d 936, 942 (3d Cir. 1985) (plaintiff generally has no cause of action



burden of rebutting this presumption of causation. In cases where the manufacturer can convince the jury that its product is benign, either by post-complaint testing or by other means (e.g., chemical family analogy), it will succeed in avoiding liability even without conducting this minimal pre-litigation testing. Otherwise, the defendant manufacturer will have the difficult task of resolving in its favor not only the preventable gaps in scientific knowledge,<sup>232</sup> but also the various trans-scientific uncertainties that currently lie beyond the reach of scientific experimentation.<sup>233</sup>

If the manufacturer has conducted minimal testing and successfully rebuts the showing of inadequate testing, the burden of proving causation returns to the plaintiff, and traditional tort rules determine recovery.<sup>234</sup> The possibility of false positives in laboratory and animal testing, however, may present some manufacturers with the quandary of whether, when faced with adverse preliminary test results, to continue to test beyond the floor prescribed by the common-law reform.<sup>235</sup> If manufacturers take their cues from the caselaw, they will

absent an "identifiable, compensable injury"); Eggen, *supra* note 63, at 906-07 (observing that some courts refuse to grant increased risk or medical monitoring claims, even when some physical harm is present).

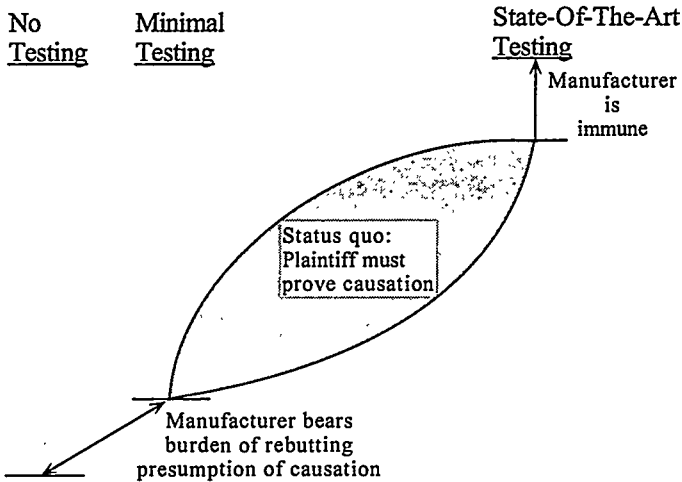
<sup>232</sup> Proposals recently offered by two other commentators are more general than the reform presented here, but both suggest a burden-shifting based to some extent on inadequate safety testing. See Feldman, *supra* note 1, at 46 (suggesting that courts should hold manufacturers liable for injuries to exposed populations if they are unable to "eliminate strong uncertainty about the causal powers of their products"); Kanner, *supra* note 168, at 582-83 (asserting that a "solution . . . to [the underdeterrence of testing in toxic tort cases] . . . will be a greater call on the duty to test *prior* to marketing, and greater accountability for those companies that fail this test," and that courts can accomplish this by shifting the burden on causation or instructing the jury to "draw an adverse inference from this failure to test") (footnote omitted).

<sup>233</sup> See FIGURE 6. One could argue that this proposal in fact imposes a punitive charge on manufacturers that have failed to conduct minimal safety testing on their products. Under the circumstances, however, such a charge is justified. First, according to economic models, punitive charges are appropriate when the costs of compliance are low and the probability that a noncomplying manufacturer could escape notice is high. See, e.g., SHAVELL, *supra* note 86, at 284 (justifying imposition of criminal sanctions in certain cases because "[t]he greater the chance that injurers would escape the notice of a social authority, the higher is the monetary sanction necessary to control their behavior"). Second, the potentially punitive aspect of the reform may be temporary (provided the testing requirements are clearly defined, see *infra* notes 253-58 and accompanying text)—future manufacturers would soon know what is required and comply. As Daniel Farber argued in his insightful commentary on the *Lone Palm* case: "By awarding supercompensatory damages against this one [flagrantly negligent] defendant, we can, it is hoped, prevent any significant number of similar accidents." Farber, *supra* note 221, at 732. Third, this punitive element may be exactly how juries currently apply liability rules. See *supra* Part IV.C.

<sup>234</sup> See *supra* Part II.A.

<sup>235</sup> See, e.g., Fanny K. Ennever et al., *The Predictivity of Animal Bioassays and Short-term Genotoxicity Tests for Carcinogenicity and Non-carcinogenicity to Humans*, 2 MUTAGENESIS 73, 76-77 (1987) (reporting on general lack of specificity of fifteen short-term tests used to determine carcinogenicity, but also noting that four of these tests are relatively sensitive (correctly predict carcinogens) and specific (correctly predict noncarcinogens)). The single

FIGURE 6  
MECHANICS OF THE PROPOSED REFORM



conclude that even with some preliminary adverse data, the possibility of liability is essentially zero: the current trend of courts to require extensive scientific evidence for proof of causation, generally including epidemiological evidence, leaves plaintiffs unable to prove their case.<sup>236</sup> Thus, if a manufacturer does decide to conduct follow-up testing, it will likely be due to market or related pressures,<sup>237</sup> rather than to the threat of tort liability.<sup>238</sup>

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laboratory screening test recommended here as an interim standard for minimal testing, *see infra* note 257, however, has a very low false-positive rate. *See, e.g.,* Errol Zeiger et al., *Evaluation of Four In Vitro Genetic Toxicity Tests for Predicting Rodent Carcinogenicity: Confirmation of Earlier Results with 41 Additional Chemicals*, 16 ENVTL. & MOLECULAR MUTAGENESIS 1, 11-12 (Supp. 18, 1990) (reporting that high predictivity of Salmonella assay of .89 "suggests that few false-positive responses will be produced"). In any case, there is no question that even with the possibility of false positives, preliminary screening tests will be consistently valuable. This preliminary information provides a vital first step to regulatory decisions regarding, for example, priorities for future testing.

<sup>236</sup> *See supra* note 76 and accompanying text; *see generally supra* Part II.A (discussing plaintiffs burden of proving causation in toxic-tort cases).

<sup>237</sup> Additional testing beyond what minimal standards require might provide manufacturers with a competitive advantage in some circumstances. For example, if a minimally tested chemical is "suspect" based on preliminary testing results, there may be market pressures to conduct additional tests and/or identify substitutes.

<sup>238</sup> Failure of the reform to require additional testing on initial, adverse results is likely to be considered more of a deficiency than an asset. Problems with a more refined approach to testing requirements are significant, particularly the seemingly insuperable difficulties associated with ensuring that more refined testing requirements are also clear and unambiguous. *See infra* note 253; *see also* Weisburger & Williams, *supra* note 33, at 405-06 (discussing how animal tests for carcinogenicity must be done "selectively" and hence testing regimes involve considerable scientific discretion). The instant proposal is thus likely to be the "least imperfect" of the alternatives. Given the large penalties associated with a failure to conduct minimal testing, *see supra* note 233, and the enormous transaction costs associated with an unclear rule, *see infra* note 289 and accompanying text, clarity of the

The reform also rewards socially responsible manufacturers by providing a much more uniform and predictable immunity once they have conducted comprehensive safety testing.<sup>239</sup> Successful completion of a battery of tests sufficient to fully assess the health hazards a chemical poses would provide the manufacturer with a state-of-the-art defense.<sup>240</sup> Plaintiffs can, of course, scrutinize the manufacturer's conduct based on the results of the testing, but if the testing revealed a low potential for risk,<sup>241</sup> the reform would provide a blanket immunity even if later tests reveal that the product is harmful. The results of the manufacturer's safety research would also need to be publicly

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testing requirements must be the first priority for a reform. Nevertheless, if a dependable decision tree for testing became available, it would obviously be a substantial improvement to the more rudimentary approach proposed here.

<sup>239</sup> Providing manufacturers with immunity for unknowable risks also comports with research by Alan Schwartz that suggests that imposing liability for remote risks is not only unfair, but also "frustrate[s] the law's compensation and efficiency goals." Schwartz, *supra* note 63, at 706; see also Schwartz, *supra* note 137, at 902-05 & n.49 (discussing inadequate justifications for imposition of strict liability on manufacturers). In contrast, in the context of toxic torts, it appears that the primary advantages to imposing strict liability on manufacturers for all risks causally linked to their products or wastes, including those that were unforeseeable at the time of manufacture, are simplification of the litigation process, loss spreading, and fairness and consistency. See, e.g., Wade, *supra* note 79, at 754-56 (discussing the advantages and disadvantages of the hindsight standard, which uses the time of trial to determine what knowledge was available to a manufacturer). If practice bears out the theoretical prediction that a state-of-the-art immunity will actually lead to greater research, and ultimately to fewer injuries and safer products, than occurs under strict liability, then these advantages to strict liability seem illusive at best, at least with regard to the manufacture of potentially toxic products. For a comprehensive analysis of the doubtful benefits and adverse consequences resulting from the imposition of strict liability on manufacturers for post-distribution knowledge of product hazards, see Henderson, *supra* note 80, at 939-52.

A state-of-the-art defense also allays concerns that liability rules may overdeter and dampen innovation of socially useful products like drugs and vaccines. See, e.g., Boston, *supra* note 16, at 368 (citing cases in which courts expressed "the apprehension that an expansion of liability rules would retard the development and availability (i.e., increase the price of) new drugs and vaccines"); Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in *THE LIABILITY MAZE* 334, 341-45 (Peter W. Huber & Robert E. Litan eds., 1991) (discussing how liability currently deters development and research of new vaccines).

<sup>240</sup> See *infra* notes 258-59 and accompanying text (specifying interim recommendation for state-of-the-art testing). Many states have already adopted this defense or something similar. See *supra* notes 77-81 and accompanying text. In other jurisdictions, some courts tend to admit evidence of a manufacturer's compliance with regulations as probative on the adequacy of a product design. See, e.g., Garey B. Spradley, *Defensive Use of State of the Art Evidence in Strict Products Liability*, 67 MINN. L. REV. 343, 367 (1982).

<sup>241</sup> Common-law courts could consider regulatory standards for determining when a risk becomes significant. Typically, Congress and regulatory agencies consider risks greater than one in one million to be publicly unacceptable, although risks of one in ten thousand have been considered acceptable under certain circumstances. See, e.g., 40 C.F.R. § 300.430(e)(2)(i)(A)(2) (1996) (requiring for purposes of Superfund cleanup that a person should encounter no more than a one-in-ten-thousand to one-in-one million risk of cancer).

available, and the manufacturer would bear the burden of proving that its testing met state-of-the-art standards.<sup>242</sup>

This reform, at least in theory, goes a long way towards correcting the failure of the common law to encourage research on the long-term safety of potentially toxic products.<sup>243</sup> Rather than an incentive system that penalizes research with litigation and leads manufacturers to choose ignorance, the reform presents manufacturers with reduced liability as their long-term safety research progresses.

This added testing will enhance our knowledge of the toxicity of products we use, increase consumer participation in product safety, and initiate a database from which we can develop more complex testing regimes for such pressing concerns as adverse synergistic reactions among products and chemicals. The reform also begins to address the nullification tendency that may undercut litigants' sense of "justice" in a number of important toxic tort suits.<sup>244</sup>

This reform also has the advantage of providing a workable and immediate fix for the problems the traditional causation rule creates without constituting a radical departure from tort law's current evolu-

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<sup>242</sup> See, e.g., Wade, *supra* note 79, at 760-61 (recommending negligence rule for determining safety, but arguing that "if the defendant contends that the knowledge available at the time of trial was not available at the time of distribution, he should bear the burden of proof on this issue"). In a sense, this defense is not dissimilar to the "process defense" presented by Twerski et al. These authors argue that courts should not impose liability when "a manufacturer defends an action by revealing a well-documented safety review process," and that "[i]f the process leading to a [product] design decision has a high degree of integrity the court should restrict its review of the design itself to instances in which the industry has clearly erred." Aaron D. Twerski et al., *Shifting Perspectives in Products Liability: From Quality to Process Standards*, 55 N.Y.U. L. REV. 347, 358 (1980). The immunity proposed here differs from the Twerski proposal, however, because it entails very specific testing requirements so that the process requirements are unambiguous and even the quality of testing cannot deviate from pre-determined protocol. See *infra* Part V.B.1.

<sup>243</sup> If the manufacturer has conducted the requisite minimal amount of testing, the reform leaves the current toxic tort landscape unaltered, which may not be desirable. See, e.g., Brennan, *supra* note 2, at 65 (observing that "[o]nly after society incurs mass injuries and scientists study exposed populations for a long period of time does it become clear that a certain fraction of diseases was caused by the exposure"). To the extent that further modifications are necessary to address the proportionality problem, there is an extensive body of literature on that subject. See generally Farber, *supra* note 16, at 1243-51 (proposing compensation scheme in toxic tort cases that places the "most likely victims" first in line for full compensation); John Makdisi, *Proportional Liability: A Comprehensive Rule to Apportion Tort Damages Based on Probability*, 67 N.C. L. REV. 1063 (1989) (proposing a proportional approach to adjudicating causation); Robinson, *supra* note 63 (same); Rosenberg, *supra* note 16, at 861-905 (same). For other reforms that may improve the common-law courts' adjudication of toxic tort cases, see Brennan, *supra* note 18, at 62-71 (suggesting that courts use science panels and scientific experts to improve scientific grounding of judicial determinations on admissibility and sufficiency of complex scientific evidence); Roe, *supra* note 192, at 917-20 (proposing amendment to the Bankruptcy Code to address the problems mass torts create); Schwartz, *supra* note 63, at 716-17 (recommending that corporate limited liability be abolished in certain situations when a "firm's assets . . . are insufficient to satisfy tort claims").

<sup>244</sup> See *supra* Part IV.C.

tion in response to the unique problems toxic substances pose.<sup>245</sup> Although proposals for expanded regulatory and government testing programs may also be necessary to effect a comprehensive reform,<sup>246</sup> there is little hope of immediate implementation. Even if government improves the regulatory scheme, regulation may fail to ensure that manufacturers will actually undertake even a minimal amount of safety research for a number of products.<sup>247</sup> Absent assurance that regulatory or government testing programs will produce needed in-

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<sup>245</sup> Market-share liability and medical monitoring claims both reduce the plaintiffs' burden of proving causation. See, e.g., Eggen, *supra* note 63, at 899-900 (citing market share and risk-contribution theories as examples of how tort law has adapted to causation problems introduced in toxic tort cases).

<sup>246</sup> See Applegate, *supra* note 1, at 318-32 (proposing modifications to TSCA to improve the EPA's ability to call on industry for the production of information); Lyndon, *supra* note 42, at 1835-41 (recommending private funding of a government "super study program" for toxicity testing of products).

<sup>247</sup> Regulatory reform may ultimately prove inferior to liability rules at encouraging minimal safety testing. Komesar persuasively argues that, as a political matter, when the probability of harm from a product is low, but the costs to those individuals they impact are high, common-law liability rules are more likely to approximate the public will than legislative resolutions. See KOMESAR, *supra* note 104, at 170; see also Peter H. Schuck, *Mass Torts: An Institutional Evolutionist Perspective*, 80 CORNELL L. REV. 941, 974-76 (1995) (discussing a variety of advantages common-law adjudication has over legislative or regulatory resolution of mass toxic torts, including a decentralized and hence de-politicized process of decision-making). Specifically, Komesar suggests that the liability rules are more likely to reflect society's values because of the minoritarian bias likely to prevail in the political process due to the diffuseness of society's *ex ante* interest in product safety. See KOMESAR, *supra* note 104, at 173 (concluding that "[t]he same high per capita stakes that make potential injurers deterrable targets for tort liability also make them politically active and quite probably overrepresented in the political processes of tort reform relative to low per capita stakes potential victims"). In addition, Komesar argues that victims of low probability, high cost harms are more likely to serve as superior plaintiffs than government bureaucrats who face the possibility of agency capture, lack of resources, and other politically-linked constraints. *Id.* at 171-73; see also SHAVELL, *supra* note 86, at 281, 283, 285 (arguing that economic analysis suggests that liability rules are superior to regulation in controlling behavior when injurers have superior information regarding the nature of risk and costs of reducing it and when victims are aware of their harm).

Additionally, a good deal of the current regulatory failure, particularly in the regulation of toxic products, appears systemic and potentially permanent, which raises doubts as to whether system modifications, even major ones, will really effect a noticeable improvement. See, e.g., Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1386 (1992) ("[M]any observers from across the political spectrum agree with [Professor E. Don Elliott] that [ossification of the regulatory process] is one of the most serious problems currently facing regulatory agencies."); Wager, *supra* note 28, at 1677-85 (outlining pervasive regulatory dysfunction resulting from regulatory "science charade").

Finally, focusing efforts exclusively on reform of the regulatory system still leaves a counter-productive liability rule in place that continues to undercut the effectiveness of regulatory requirements. Thus, even if the regulatory system made parallel administrative improvements—improvements that several authors have suggested in careful detail—reform of liability rules may still remain a priority in order to ensure that the choice of ignorance is never, or almost never, one that the legal system encourages.

formation on the long-term safety of potentially toxic products,<sup>248</sup> then, a workable reform of existing toxic tort rules seems the obvious, and perhaps the only, practical alternative.<sup>249</sup> In fact, in their study of product safety, Eads and Reuter concluded that even though products liability law generates at best an "indistinct signal," it may cause manufacturers to take safety considerations into account in design decisions to a much greater extent than market forces or the prospect of regulation.<sup>250</sup>

## B. Further Refinements

Despite its practicality and the relative ease with which it can be implemented, the proposed reform is not perfect. This final subsection presents possible criticisms of the reform and some potential refinements that address those criticisms.

### 1. *Competency of the Courts*

Perhaps the most worrisome criticism of the reform is that courts will not be competent to implement it. This concern is certainly not without foundation given the courts' historic inattention to the importance of separating trans-scientific from preventable scientific uncertainties in assigning burdens of proof.<sup>251</sup> Assuming that a significant

<sup>248</sup> See *Farber*, *supra* note 16, at 1243 (arguing that the regulatory system of toxic products "is fraught with problems of its own" and thus "[i]t would seem foolhardy to jettison the tort system on the basis of current knowledge").

<sup>249</sup> See, e.g., *JASANOFF*, *supra* note 17, at 205 (observing that many cases involve "instances in which courts almost by default were required to take the lead in constructing new social and political orderings around science and technology"); *Brennan*, *supra* note 2, at 72 (concluding that common-law liability rules are necessary because "an analysis of regulatory approaches to environmental toxins suggests that the administrative state has developed inadequate deterrence mechanisms"); cf. *Brennan*, *supra* note 28, at 531-32 (calling for a Science Panel to resolve toxic tort disputes because of common-law courts' inability to effectively adjudicate cases, but concluding that tort litigation should still exist alongside regulation and Science Panel); *William M. Landes & Richard A. Posner*, *Tort Law as a Regulatory Regime for Catastrophic Personal Injuries*, 13 J. LEGAL STUD. 417, 434 (1984) (concluding that it is premature "to give up on tort law as a method of regulating safety in cases of catastrophic accident"); *Lyndon*, *supra* note 1, at 138-41, 154-70 (arguing that tort law continues to serve vital function in concert with regulation); *Rosenberg*, *supra* note 16, at 927-28 (listing several advantages the tort system has over the administrative system in responding to and resolving mass exposure dangers).

<sup>250</sup> *EADS & REUTER*, *supra* note 44, at vii-viii. *But see Schwartz*, *supra* note 158, at 408 (criticizing the Eads & Reuter study as failing to support this observation adequately because the study revealed that products liability appeared to influence significantly only one of the nine companies interviewed).

<sup>251</sup> A number of scholars have questioned the judiciary's competence to adjudicate cases involving disputes over complex scientific facts. See *JASANOFF*, *supra* note 17, at 1-2 (recounting criticism of courts for not deferring to scientists in adjudicating scientific and technical disputes); *Brennan*, *supra* note 28, at 498-99 (arguing that judicial incompetence "create[s] a great deal of uncertainty in the minds of litigants regarding liability because they cannot predict which mode of causation theory a court will use" and "raises fundamental questions regarding their ability to adjudicate hazardous-substance injury cases");

cause of the common-law courts' inattention to this problem stems from a lack of familiarity with science and its limitations,<sup>252</sup> a nationalized checklist of minimal and state-of-the-art testing requirements should be developed to provide both consistency and guidance to case-by-case adjudications.<sup>253</sup> It is not readily apparent which institu-

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Devra Lee Davis, *The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review*, 10 COLUM. J. ENVTL. L. 67, 85-86, 90-92, 98 (1985) (discussing disappointing record of judicial review of agency risk assessments); Green, *supra* note 21, at 680-82, 695-98 (questioning competence of "generalist judges" to master scientific and statistical issues underlying toxic tort cases). See generally Sheila Jasanoff, *What Judges Should Know about the Sociology of Science*, 32 JURIMETRICS J. 345 (1992) (discussing dangers of judicial activism based on insights in sociology of science). Some scholars have gone beyond criticizing the judiciary and have recommended replacing it or buttressing it with scientific experts in certain circumstances. See, e.g., Arthur Kantrowitz, *The Science Court Experiment*, 17 JURIMETRICS J. 332, 332 (1977) (proposing a "Science Court" to resolve disputed questions of fact); Joel Yellin, *Science, Technology, and Administrative Government: Institutional Designs for Environmental Decisionmaking*, 92 YALE L.J. 1300, 1330 (1983) (proposing science advisory board to assist judiciary).

Judges themselves have echoed these concerns, even in their own opinions. Judge Bazelon has made perhaps the best statement of judicial reluctance to engage in the review (or adjudication) of disputed scientific facts:

Socrates said that wisdom is the recognition of how much one does not know. I may be wise if that is wisdom, because I recognize that I do not know enough about dynamometer extrapolations, deterioration factor adjustments, and the like to decide whether or not the government's approach to these matters was statistically valid.

*International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 650-51 (D.C. Cir. 1973) (Bazelon, C.J., concurring) (footnote omitted); see also Jack B. Weinstein, *Litigation and Statistics*, 3 STAT. SCI. 286, 286 (1988) ("We [judges] are no more statisticians than we are physicians, and counsel who expect of us informed and consistent treatment of such proofs are well advised to proceed as do those who advance knotty medical problems for resolution.") (quoting *Wilkins v. University of Houston*, 654 F.2d 388, 410 (5th Cir. 1981)).

<sup>252</sup> It is also possible that the courts are avoiding reform of the causation rule in order to maintain some control over their continually growing dockets. See, e.g., Nagareda, *supra* note 225, at 915-16 (observing that courts, in order "to guard against a flood of claims," have recently "restricted increased risk and fear of cancer claims to situations in which the plaintiff can demonstrate a likelihood of future impairment"); cf. Robert M. Emerson, *Holistic Effects in Social Control Decision-Making*, 17 L. & SOC'Y REV. 425 (1983) (arguing that social decisionmakers are significantly affected by macro-considerations such as the "seriousness" of a case in relation to rest of caseload, the resources it demands in relation to other cases in the caseload, and its possible precedential value). By making pro-defendant rulings in toxic tort cases that threaten mass filings, courts can limit the number of future claims. Commentators have also raised concerns that fairness in mass toxic tort cases is taking a backseat to efficiency in the resolution of these cases. See, e.g., Roger H. Trangsrud, *Mass Trials in Mass Tort Cases: A Dissent*, 1989 U. ILL. L. REV. 69, 80 (criticizing the trifurcation of issues in mass tort cases because "it robs the jury of its traditional flexibility in tort cases to balance uncertainties in the plaintiff's case on liability against strengths in the plaintiff's case on damages").

<sup>253</sup> Theoretically, the ideal solution to inadequate testing would be to merge the minimal and state-of-the-art standards and require testing to the point that the tests reveal the product poses no significant risk of latent hazards. If a manufacturer has not conducted this level of testing, courts will presume causation; if it has been conducting this testing, the manufacturer will be immune from suit. See *supra* note 241 and accompanying text. If the testing is inconclusive, then the manufacturer would be expected to conduct continuous epidemiological studies to monitor the chemical's effect on exposed populations. The

tion is best able to develop this checklist,<sup>254</sup> although specific congressional action would provide the most definitive statement of what constitutes adequate testing. Before the appropriate institution formally develops some standards, individual courts may be able to develop a rough checklist on their own by relying on existing agency regulations<sup>255</sup> and various toxicity testing reports produced by the National Academy of Sciences and other entities.<sup>256</sup> Such an interim checklist, for example, might consist of a single in vitro test, like the widely accepted Salmonella assay, for minimal testing;<sup>257</sup> and either

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practical problems with such a theoretically ideal solution are significant, however. First, it will be difficult (to put it modestly) to reach consensus on a single testing regime that would provide both a reliable and cost-effective decision-tree for adequate safety testing. See, e.g., John Ashby et al., *The Challenge Posed by Endocrine-disrupting Chemicals*, 105 ENVTL. HEALTH PERSP. 164, 165 (observing considerable confusion among scientists in defining an "endocrine disrupter," a definition that is obviously an essential first step to identifying appropriate testing strategies). The alternate proposal this Article presents avoids this difficulty by adopting a much more rudimentary two-tiered incentive system, which virtually ensures a very low level of testing, but provides some encouragement for a comprehensive investigation into latent product hazards. See FIGURE 6. Second, even if a perfect decision-tree for safety testing could be identified, it would likely lack the clarity and hence the predictability of my proposal since some scientific judgment would almost inevitably be required to determine an appropriate stopping point. When liability rules impose such potentially large penalties, see *supra* note 233, it is essential that the requirements are specific and unambiguous. Cf. Rosenberg, *supra* note 16, at 864-65 (noting that excessive liability and overinvestments in safety could likely result if courts do not "accurately discern the true level of optimal care").

<sup>254</sup> Each branch of government carries its own unique limitations. See, e.g., *supra* notes 223, 241 (discussing the problems with legislative and regulatory action). Each branch also has its own cadre of expert advisors. Both Congress and the Executive Branch periodically call upon several respected nonprofit institutions, such as the National Academy of Sciences or the Carnegie Commission to provide consulting advice to the government on science-policy problems, while judges often rely on the Federal Judicial Center to provide detailed, nationalized guidelines or related assistance for adjudications involving complex science policy issues. Cf. Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 181-208 (1994) (providing a summary of the scientific issues that often arise in toxic tort cases).

<sup>255</sup> See, e.g., *supra* note 34 and accompanying text (describing federal regulations). But see *Pesticides: Status of Administration's Response to NAS Recommendations Released to NACA*, Daily Env't Rep. (BNA) No. 209, at A-8 (Nov. 1, 1993) (reporting that National Academy of Science committee found EPA's toxicity testing guidelines for pesticides inadequate in some areas, particularly with regard to assessing effects of pesticides on neonate and adolescent animals).

<sup>256</sup> See *supra* note 32 and accompanying text. See generally TOXICITY TESTING, *supra* note 29 (presenting a framework for the testing of substances that pose a potential adverse risk to the public health); SCIENCE AND JUDGMENT, *supra* note 22 (reporting the importance of risk assessments in improving the evaluation of chemical testing).

<sup>257</sup> Currently, the Salmonella assay provides a reliable, low cost, short-term test that is "central to any scheme that is intended to screen for carcinogens." Raymond W. Tennant et al., *Prediction of Chemical Carcinogenicity in Rodents From In Vitro Genetic Toxicity Assays*, 236 SCIENCE 933, 934 (1987); see also S. Stanley Young, *Do Short-Term Tests Predict Rodent Carcinogenicity?*, 241 SCIENCE 1232, 1232 (1988) (identifying "great interest" in short-term laboratory tests as initial screening alternative to expensive (\$1 to \$2 million) and time-consuming (3 to 4 year) rodent studies). It also appears to offer reliable results without the need for additional short-term in vitro tests. See Tennant et al., *supra*, at 938; see also



the EPA's protocol for safety testing of new pesticides, or if direct ingestion of the product is within its "normal" uses,<sup>258</sup> the FDA's drug safety testing requirements for state-of-the-art testing.<sup>259</sup> Although rigid testing requirements in checklist form may lead to some inefficiencies—overtesting in some cases and undertesting in others—a clear outline of testing requirements, at least for the minimal level of safety research, is essential to avoid extended litigation over the nature and extent of the testing requirements.<sup>260</sup>

An equally vexing problem is how to ensure that the judiciary effectively oversees the quality of a manufacturer's testing.<sup>261</sup> If a

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Errol Zeiger, *Strategies for the Use of Genetic Toxicity Tests*, 22 DRUG METABOLISM REVIEWS 765, 773 (1990) (concluding that combinations of various short-term tests "do not improve upon the effectiveness of the individual tests, and none of these tests are complementary"). This test is quite specific: over eighty percent of the time, the positive Salmonella assay results accurately predict cancer in rodents. See Zeiger et al., *supra* note 235, at 11-12. It does have a high false-negative rate, however, and current estimates are that over 50% of possible rodent carcinogens may be missed by the Salmonella assay. See *id.* at 12. The actual false-negative rate may ultimately be determined to be lower, pending future scientific findings regarding the human effects of nongenotoxic rodent carcinogens. See, e.g., *id.* at 13; see also M.D. Shelby & Errol Zeiger, *Activity of Human Carcinogens in the Salmonella and Rodent Bone-Marrow Cytogenetics Tests*, 234 MUTATION RES. 257, 260 (1990) (observing the considerable uncertainty regarding whether nongenotoxic chemicals (as opposed to genotoxic) ultimately cause cancer in humans). For guidelines for conducting the Salmonella assay, see generally D. Gatehouse et al., *Recommendations for the Performance of Bacterial Mutation Assays*, 312 MUTATION RES. 217 (1994) (providing consensus document on guidelines); Errol Zeiger et al., *Salmonella Mutagenicity Tests: V. Results from the Testing of 311 Chemicals*, 19 ENVTL. & MOLECULAR MUTAGENESIS 2 (Supp. 21, 1992) (describing test used by scientists in the National Toxicology Program).

Other latent harms such as reproductive and neurotoxic effects should ideally also be screened using one or more minimal tests. Unfortunately, scientists have not yet developed comparable low-cost, quick screening tests for these endpoints in part because of their more diverse mechanisms of toxicity. See Telephone Interview with Dr. Mike Shelby, Laboratory of Toxicology, National Institute of Environmental Health Sciences, Research Triangle Park, N.C. (March 25, 1997). If scientists do ultimately develop these low-cost screening tests, they of course should be included in the minimal testing requirements. In fact, even in the interim it might be appropriate to expand minimal testing to require more extended testing for reproductive harms (e.g., a short-term animal test lasting 5 weeks) if a particular chemical structure falls within a "suspect" chemical family. Such fine-tuning, however, must be extraordinarily clear and would require the attention of a panel of scientists. See *supra* note 253 (discussing import of clear minimal testing requirement).

<sup>258</sup> See *supra* note 228.

<sup>259</sup> See, e.g., 21 C.F.R. Part 312 (1996) (listing testing requirements imposed for drugs under Food, Drug, and Cosmetic Act (FDCA)); 40 C.F.R. Part 158 (1996) (identifying testing requirements imposed under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registration).

<sup>260</sup> See *infra* Part V.B.3.

<sup>261</sup> It is possible that some required testing will be of questionable quality, ranging from outright scientific fraud to systematic biases in scientific judgment. This problem is potentially a serious one, but it is not fatal. In a worst case scenario, where some or even many manufacturers are actively engaged in deceptive or biased research that remains undetected, the overall level of knowledge, deterrence, compensation, and consistency encouraged by a modified causation rule will almost certainly continue to improve the current state of safety research.

manufacturer conducts tests based on improper methodologies or fraudulently developed data, it is possible that the judiciary may not catch the errors.<sup>262</sup> Indeed, scientific misconduct has plagued some research in the past,<sup>263</sup> including safety testing.<sup>264</sup> A liability system that encourages manufacturers to undertake safety testing without adequately policing the accuracy of those tests<sup>265</sup> could lead to more scientific cheating.<sup>266</sup> Thus, the creation of federal or state statutes that increase the government and public oversight of scientific misconduct, including added criminal sanctions, may prove essential to the reform.<sup>267</sup>

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<sup>262</sup> Cf. Robert M. Andersen, *The Federal Government's Role in Regulating Misconduct in Scientific and Technological Research*, 3 J.L. & TECH. 121, 133-35 (1988) (discussing why institutions might not actively or adequately police scientific misconduct of its researchers). If manufacturers are allowed to purchase safety research from one another, see *infra* Part V.B.2, however, the market might encourage internal policing because only the most rigorous testing, which will provide the best protection from liability, will be purchased. It is also possible that manufacturers are in fact *anxious* for a legal system that counteracts the variety of incentives that cause producers to market potentially hazardous products and to emit wastes in relative ignorance of their long-term effects on human health. Reformed rules may not only ease the ethical dilemmas presented by the current laws, but may also ultimately impose higher relative burdens on competitors who have benefitted the most from inadequate safety research. Cf. Paul J. Quirk, *Food and Drug Administration*, in *THE POLITICS OF REGULATION* 191, 193 (James Q. Wilson ed., 1980) (reporting some members of the pharmaceutical industry welcomed creation of FDA because it drove out small producers).

<sup>263</sup> See William Broad & Nicholas Wade, *Fraud and the Structure of Science*, in *ETHICAL ISSUES IN SCIENTIFIC RESEARCH: AN ANTHOLOGY* 69 app. (Edward Erwin et al. eds., 1994) (providing a "list of cases of known or strongly suspected fraud in science, from ancient Greece to the present day").

<sup>264</sup> See, e.g., Lyndon, *supra* note 1, at 148-49 (discussing why companies distort and conceal information regarding the safety of their products); Jon Nordheimer, *Johnson & Johnson Sued Over Dismissal*, N.Y. TIMES, Nov. 13, 1994, at 50 (describing a former Johnson & Johnson researcher's claim that he was pressured to produce misleading test data).

<sup>265</sup> Currently, federal sanctions fall only on researchers who engage in scientific misconduct in projects that are federally funded. See Andersen, *supra* note 262, at 124; Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 GEO. MASON INDEP. L. REV. 305, 320 (1995). Penalties for such misconduct range from a mild reprimand to debarment from receiving grants in the future. See 45 C.F.R. § 689.2 (1996). In rare cases, this scientific misconduct can be prosecuted criminally under various federal statutory authorities. See Burk, *supra*, at 322-23 (describing authorities).

<sup>266</sup> Allowing manufacturers a grace period of several years before the reform takes effect may actually provide manufacturers with a window during which they can remove particularly dangerous products from the market. This period would reduce some of the manufacturers' incentive to produce distorted studies that incorrectly suggest that a product is safe. Cf. Lyndon, *supra* note 1, at 152 & n.52 (discussing how initial decisions regarding technology become established and later lead to manipulation of information on "detrimental side effects").

<sup>267</sup> For a detailed discussion of the limitations of the current federal statutory framework for policing scientific misconduct and a proposed statute that would provide added criminal sanctions, see Susan M. Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. MICH. J.L. REFORM 357, 399-420 (1992); see also Portney, *supra* note 41, at 138 (recommending stiff penalties for falsifying data in order to ensure high quality private testing); cf. Andersen, *supra* note 262, at 147-48 (recommending development and enforce-

Research tainted by a manufacturer's bias that plausibly can be represented as a matter of "scientific judgment" poses another obstacle to effective reform. Although the extent and nature of industrial bias in testing has not been determined, it is well-established that such a bias exists.<sup>268</sup> The objectivity of research is, of course, much more difficult for courts to ensure than asking them to compare the number and types of tests a manufacturer conducts against a checklist. If testing bias is a significant problem, additional refinements to the reform, such as detailed testing protocols<sup>269</sup> and government certification programs for more complicated studies,<sup>270</sup> may be necessary to assist courts in overseeing research quality.<sup>271</sup>

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ment of more rigorous ethical standards for scientific misconduct). Although Congress has not prohibited scientific misconduct that occurs during research that is not federally funded, it has a "federal interest" in such misconduct because poor research can adversely affect the public welfare. *See, e.g., id.* at 124 (noting that scientific misconduct may be a federal concern if it reaches "the general public in the form of defective products"). A federal statute that penalizes scientific misconduct, regardless of its funding source, must be drafted carefully, however, because the line between scientific judgment and fraud is not always clear. For an insightful discussion of the difficulties in policing scientific misconduct, see Ullica Segerstrale, *The Murky Borderland Between Scientific Intuition and Fraud*, in *ETHICAL ISSUES IN SCIENTIFIC RESEARCH: AN ANTHOLOGY* 91, 91-109 (Edward Erwin et al. eds., 1994).

<sup>268</sup> *See, e.g., Kanner, supra* note 168, at 587-94 (citing examples of scientific deception and bias in industry); Sidney A. Shapiro, *Divorcing Profit Motivation from New Drug Research: A Consideration of Proposals to Provide the FDA with Reliable Test Data*, 1978 *DUKE L.J.* 155, 161-68 (providing evidence of lower quality testing conducted by manufacturers). The possibility of such a testing bias, in fact, has led more than one commentator to suggest that industry safety tests have little public value. *See Lyndon, supra* note 42, at 1816 (suggesting that various factors that adversely affect the quality of industry tests "limit the usefulness of toxicity data generated by private chemical producers"); Richard Peto, *Distorting the Epidemiology of Cancer: The Need for a More Balanced Overview*, 284 *NATURE* 297 (1980) (lamenting bias in research by private institutions and asserting that private data is generally distrusted).

<sup>269</sup> For animal and other non-human studies, existing protocols may be sufficiently detailed to leave little room for wide fluctuations in scientific judgment. *See Portney, supra* note 41, at 138 (recommending well-defined testing procedures to protect against bias in privately conducted research). The EPA has established relatively specific laboratory practice and testing standards under both FIFRA and TSCA that may provide sufficient guidance in this regard. *See, e.g.,* 40 C.F.R. pts. 160, 792, 795-98 (1996) (providing detailed "good testing" guidelines).

<sup>270</sup> For those studies (most likely epidemiology studies) for which "cookie-cutter" protocols do not or cannot exist, the government might certify various national consulting firms as "objective testing centers" or approve individual testing methodologies before or after the study is conducted. *See, e.g., Portney, supra* note 41, at 138 (recommending government verification as another option to protect against bias in privately conducted research). Courts would presume that manufacturers who use these "gold-star" programs have undertaken quality tests. Plaintiffs could possibly be allowed to challenge the wisdom of individual certifications, but they would bear the burden of proving that the testing was not conducted properly or the requirements were inadequate. This refinement has the obvious disadvantage of requiring the expenditure of agency resources—a demand that may prove unrealistic.

<sup>271</sup> It is also possible that once testing and disclosure is mandated by law, the efforts of "better" manufacturers to comply will exert competitive market pressures on others who

## 2. *The "Public Good" Problem Posed by Safety Research*

Although the proposed reform goes a long way towards curing the market failure that plagues safety testing of potentially toxic products, it could create a "free rider" problem: some manufacturers might attempt to rely on the results of other manufacturers' safety research in order to satisfy the requirements of this reform. Obviously, if such behavior is allowed, those who are first to invest in safety research will be put at a competitive disadvantage.<sup>272</sup> To protect against this practice, manufacturers can claim copyright privileges on their studies.<sup>273</sup> These privileges allow them to collect licensing fees from other manufacturers who disseminate the studies or otherwise

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do not conduct the testing through negative advertising or other media campaigns. It is also possible that the emergence of a market for testing data, *see infra* Part V.B.2, will make only high quality (and thus court-friendly) testing profitable. This latter possibility, however, will likely depend on the scrutiny the courts give to privately conducted research.

<sup>272</sup> Because the reform requires manufacturers to make research publicly available, other manufacturers will benefit from the information at no cost. *See, e.g.,* Shavell, *supra* note 99, at 360 (identifying inability of party generating information "to capture its full value [when] others can learn of the information without paying for it," which may result in either "wasteful, duplicative expenditures" on testing or a free-rider problem, both of which deter cooperation between parties).

A similar problem that occurs in the development of innovative drugs is due in part to delays in FDA approval. These delays may cut the effective life of a patent in half, which in turn, suppresses economic incentives for innovation by making it less likely that a firm can recoup its expenditures through long-term sales. *See, e.g.,* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATN. U. L. REV. 433, 451-54 (1986) (describing potential adverse effects on new drug innovation of FDA approval process which shortens the effective life of a patent). A patent may expire before the costs of innovation have been fully recouped, due in part to the delays resulting from FDA approval. In recognition of this problem, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156 (1994), which provides pharmaceutical companies with up to a five-year extension of their patents on innovative drugs as long as they meet several conditions. *See id.* At the same time, the Act benefits generic drug manufacturers by expediting the FDA approval process for generic drugs. *See, e.g.,* THE LEGISLATIVE HISTORY OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, at v (Allan M. Fox & Alan R. Bennett eds., 1987) (discussing compromise between brand-name and generic drug manufacturers). Despite this legislative effort to extend the property right for certain socially beneficial products in order to spur further research and development, the Patent Term Restoration Act appears to have only partially succeeded. *See, e.g.,* Suzan Kucukarslan & Jacqueline Cole, *Patent Extension Under the Drug Price Competition and Patent Term Restoration Act of 1984*, 49 FOOD & DRUG L.J. 511, 522 (1994) (criticizing law as providing insufficient patent extensions (averaging 2.39 years) to compensate for lengthy regulatory review (averaging 5.36 years)).

<sup>273</sup> Copyright protection attaches to published studies and to unpublished studies provided certain requirements have been met. *See, e.g.,* 17 U.S.C. § 102(a) (1994) (copyright protection extends to "original works of authorship fixed in any tangible medium of expression, now known or later developed"); *see generally* MARSHALL A. LEAFFER, UNDERSTANDING COPYRIGHT LAW §§ 2-4 (2d ed. 1995) (providing comprehensive overview of copyright law protection).

make them publicly available as the reform requires.<sup>274</sup> Ultimately, once safety research is treated as a property right *and* is required as a matter of law, it could actually stimulate a profitable market in toxicity testing, which in turn could lead to more and higher quality research.<sup>275</sup>

### 3. *Costs*

A final criticism of the reform is cost. The type of cost-benefit analysis needed to evaluate this criticism is difficult to conduct because the benefits of testing remain unknown until *after* testing is complete. Costs of the proposal, however, can be estimated in rough form.

The most obvious expense associated with the reform is the cost of testing. Testing expenses will depend on the final study or "checklist" of studies required for minimal safety research.<sup>276</sup> Assuming that this checklist is no more demanding than one laboratory screening study, such as the Salmonella assay, the cost per chemical would run from \$2000-\$4000.<sup>277</sup> The resulting aggregate costs to the chemical

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<sup>274</sup> See, e.g., 17 U.S.C. §§ 106-107 (1994) (granting author of copyrighted material "exclusive rights to do and to authorize" reproduction and public display of material unless very specific "fair use" exceptions are met). In fact, courts have prohibited commercial researchers from making unauthorized copies of publicly available research. See *American Geophysical Union v. Texaco, Inc.*, 60 F.3d 913, 918-25 (2d Cir.) (finding copyright violation as a result of a single Texaco scientist's photocopying of several published scientific studies in journals that scientist intended to use only as a reference in future research), *cert. denied*, 116 S. Ct. 592 (1995). See also *supra* note 226 (discussing reform requirements regarding a manufacturers' dissemination of safety research).

<sup>275</sup> Manufacturers conducting long-term safety research might actually stand to profit under this reform proposal. A shrewd manufacturer, with a reputation for high-quality safety research, might theoretically be able to earn more from sharing the research with two or more other manufacturers than it expended in conducting the research in the first place. The price of "sharing" a study with the manufacturer-author will ultimately hinge on many factors, including the nature of the competition in safety research, the resources of the buyer to conduct the test itself, the quality of the research, and the ease of conducting transactions. If manufacturers can charge fees for safety testing, they may become more willing to disclose the contents of their products to encourage other producers manufacturing similar products to purchase partial rights to their published safety tests. The creation of a market in long-term safety research, in fact, might drive testing to much higher levels than prescribed by either the common-law claim for minimal testing or existing regulatory authorities.

<sup>276</sup> See *supra* Part V.B.1. When determining the appropriate level of testing certainly one must consider both the minimal and the state-of-the-art level.

<sup>277</sup> See Telephone Interview with Dr. Errol Zeiger, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, N.C. (March 18, 1997); see also Young, *supra* note 257, at 1232 (suggesting that battery of short-term genetic toxicology tests that include Salmonella assay "costs approximately \$10,000"). See generally *supra* note 257 (discussing interim solution of Salmonella assay as meeting minimum testing requirement). Although this initial basic test should lead to further testing if it indicates a hazard, in the reform proposed here, a manufacturer discharges their duty to test for purposes of burden-shifting if they conduct only the minimal screening test or

industry for conducting this minimal testing for the tens of thousands of untested chemicals in commerce could theoretically be over one-hundred million dollars.<sup>278</sup> For a variety of reasons, however, the more flexible common-law incentives are likely to make total testing costs less. In some cases, manufacturers may already be routinely conducting minimal toxicity tests on their products. The only added cost introduced by the reform in such cases, then, is the requirement that the results of this testing be made publicly available. In other cases, a manufacturer may still find it more cost-effective to forgo testing. For example, if exposure potential is de minimis,<sup>279</sup> if the manufacturer is confident that it can disprove causation without testing,<sup>280</sup> or if a manufacturer believes potential liability and transaction costs are less than the costs (tangible and intangible) of testing, common-law liability will not produce incentives for testing.

Even if the "worst case" prediction of millions of dollars of testing costs materialized, the economic realities of chemical manufacture should allow such costs to be assimilated rather easily.<sup>281</sup> First, testing for a single new drug averages \$231 million,<sup>282</sup> a figure that may be roughly equivalent to the costs of "minimally testing" all products in commerce. Second, in most cases chemical manufacturers appear large enough to absorb the costs of testing and to pass them on to consumers.<sup>283</sup> Third, prudent manufacturers, both small and large,

tests. See *supra* Part V.A and note 253 (explaining why a more refined system may be inferior).

<sup>278</sup> If there are at least 36,000 chemicals in commerce for which no safety testing has been conducted, see *supra* notes 37-38 and accompanying text, and if testing costs \$3,000 per chemical, then the total costs would be over \$100 million.

<sup>279</sup> See *supra* note 228 and accompanying text.

<sup>280</sup> See *supra* text accompanying notes 232-33.

<sup>281</sup> Indeed, a strong normative argument exists that regardless of the minimal testing costs, they should be internalized by the manufacturer. See *supra* Part III.

<sup>282</sup> See *supra* note 35.

<sup>283</sup> In requiring manufacturers to conduct a subacute and a subchronic test on animals for several chemicals, EPA determined that manufacturers' concerns about overburdensome costs were not supported. Specifically, EPA calculated that the annualized test costs, using a 7 percent cost of capital over 15 years, range from \$24,000 to \$36,000. Given that these costs are less than one-tenth of one percent of the annual revenues from sales for each of these four substances, EPA believes that the potential for adverse economic impact resulting from the costs of testing is low.

See 58 Fed. Reg. at 59,679.

Notably, the manufacture of chemicals (ranging from feedstock chemicals to final consumer or industrial products) is quite a diverse business and often escapes generalizations. J. Clarence Davies, *The Effects of Federal Regulation on Chemical Industry Innovation*, LAW & CONTEMP. PROBS., Summer 1983, at 41, 43 (citing statistics on a number of manufacturing entities at various stages of product development). Despite wide variation from chemical to chemical, large firms appear to dominate most phases of the market, and these firms appear capable of absorbing the modest costs of minimal testing without difficulty. See, e.g., *id.* at 47 & n.32 ("[I]n the early 1980s, seventy-one percent of the new chemical notifications under TSCA were submitted by companies with sales over \$500 million. Only 2%

can share testing costs among themselves as is currently done under TSCA.<sup>284</sup> Thus, even a total testing bill that falls in the hundreds of millions of dollars range would appear not to interrupt the manufacture of most chemicals.<sup>285</sup>

The costs of compliance with state-of-the-art standards will be considerably greater—as much as five orders of magnitude higher than minimal testing costs.<sup>286</sup> This much more substantial investment will only be beneficial in those instances where the manufacturer is already required to conduct testing pursuant to regulatory requirements, or where the cost of testing is justified by the probability and extent of liability. Thus, although it will provide heavily regulated industries with an opportunity for common-law immunity,<sup>287</sup> the state-of-the-art testing requirements may necessitate testing that is simply too expensive for all but the highest risk industries. Future experience with a reform such as this one may reveal that lower expectations for state-of-the-art testing will provide a better incentive for firms to conduct optimal testing on their products.

More difficult to measure, and of greater concern for some critics, is the possible increase in transaction costs that may result from lightening the burden of proof on plaintiffs in a subset of cases where a manufacturer fails to complete minimal safety testing.<sup>288</sup> The clarity

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of the notifications were submitted by companies with sales under \$10 million.”); Hoerger et al., *supra* note 100, at 71 (listing eleven major companies with extensive toxicological research facilities in 1983). It is possible, however, that the increased costs of testing may adversely affect smaller specialty chemical companies, even if they share some of the basic testing costs with other firms. See, e.g., Ashford & Heaton, *supra* note 97, at 153 (suggesting that “small companies and specialty chemicals have suffered a decline relative to the situation of large companies, particularly those whose products are targeted to large markets” as a result of federal health and safety regulation); Davies, *supra*, at 52 (noting the possible adverse impact of even modest regulatory costs on a firm producing small-volumes). An additional refinement to the reform could thus include the provision of hardship grants to finance minimal safety testing by these firms. Such a refinement obviously introduces the need for larger administrative and legislative costs and therefore warrants further investigation.

<sup>284</sup> See *supra* note 226 and accompanying text.

<sup>285</sup> As discussed in note 283, *supra*, however, hardship grants to finance minimal safety testing by smaller companies may be a desirable refinement to the proposed reform.

<sup>286</sup> This at least would be the case if standards prescribed by FIFRA or the FDCA are followed to determine what constitutes state-of-the-art testing. See *supra* notes 34-35, 259 and accompanying text.

<sup>287</sup> This is indeed a new benefit that many have suggested is essential. See, e.g., Huber, *supra* note 158, at 291-93, 314-16.

<sup>288</sup> The high transaction costs associated with tort adjudications seems to be conceded by most involved in close empirical analysis of the legal system. See, e.g., TILLINGHAST, TORT COST TRENDS: AN INTERNATIONAL PERSPECTIVE 3 (1992) (reporting the inefficiency of the U.S. tort system, which returns “less than 50 cents on the dollar to the people it is designed to help—and less than 25 cents on the dollar to compensate for actual economic losses”); Saks, *supra* note 194, at 1281-83 (stating that transaction costs are the most expensive part of litigation and reporting that in the middle 1980’s “it cost society \$1.92 to deliver \$1 of compensation to a victim of negligent injury”).

and reasonableness of the minimal testing requirement and the length of the grandfather period before the reformed rule takes effect will determine whether the reform will cause a precipitous rise in litigation. Both factors will significantly affect the number of valid claims that actually materialize.<sup>289</sup> If the minimal testing requirements are unambiguous, the relative ease of compliance should prevent the filing of an excessive number of claims, particularly with a lead time of five to ten years.<sup>290</sup> If the testing requirements for the state-of-the-art defense are also clear, litigation after implementation of the reform could actually decrease because of the increased availability of a predictable defense.<sup>291</sup> In addition, the high cost of toxic tort litigation,<sup>292</sup>

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<sup>289</sup> *But see* Marc Galanter, *Case Congregations and Their Careers*, 24 L. & SOC'Y REV. 371, 384 (1990) (cautioning that it is "impossible to know a priori what the net effect [of litigation] will be").

<sup>290</sup> It is possible that if too many valid and potentially lucrative claims remain, they could pose a danger of overwhelming the courts. In mass torts generally, plaintiffs' networks have formed around major class action litigation in toxic torts. *See* Galanter, *supra* note 289, at 387 (discussing lawyer networks "for information sharing and strategic coordination"); Nagareda, *supra* note 225, at 937 (describing role of plaintiffs' lawyers in pioneering toxic tort litigation); Paul D. Rheingold, *The Development of Litigation Groups*, 6 AM. J. TRIAL ADVOC. 1 app. (1982) (describing networks in swine flu, Dalkon Shield, Agent Orange, MER/29, birth control pills, asbestos, DES, and Ford transmission). It is thus also possible that they could form around testing claims. Recommending probabilistic causation as a reform in toxic tort cases, Glen Robinson similarly discusses the potentially overwhelming increase in litigation resulting from his proposed reform. *See* Robinson, *supra* note 143, at 796-98. His suggestions on how this litigation might be controlled, *id.* (noting the possibility of narrowing the class of claims entitled to probabilistic causations and using class consolidation to control costs), to some extent parallel some of the possibilities discussed in the remainder of the Article, *infra* notes 291-96 and accompanying text.

<sup>291</sup> *Cf.* Bruce, *supra* note 111, at 398 (noting that although there are "significant costs involved" with state-of-the-art testing in product liability claims, it is "well worth the price" because the defense, even with existing ambiguities, "currently represents the best option for manufacturers can [sic] pursue"); Landes & Posner, *supra* note 249, at 421 (suggesting based on economic models that "a negligence standard may give the injurer a greater incentive to use due care than strict liability" because by using due care "the injurer avoids all liability . . . whereas under strict liability expected damages fall as care rises but the injurer still pays something").

<sup>292</sup> Sanders reports that the "first plaintiff" case against Merrell, the manufacturer of Bendectin, had a severe shortage of funds so that "much of the second trial [on remand] was tried on the record of the first trial, without the benefit of live expert witnesses. Only a last minute infusion of \$25,000 from Mr. Belli [one of the more prominent plaintiffs' lawyers involved in the litigation] kept the second trial going." Sanders, *supra* note 70, at 351-52. A shortage of funds also occurred in the Agent Orange litigation and led to a new plaintiffs' counsel team, each of whom were required to invest \$250,000 in the litigation. *See id.* at 352 n.212 (citing John C. Coffee, Jr., *The Regulation of Entrepreneurial Litigation: Balancing Fairness and Efficiency in the Large Class Action*, 54 U. CHI. L. REV. 877, 901 (1987)). Both Coffee and Rosenberg have suggested that the expense often associated with mass toxic tort litigation may cause plaintiffs' attorneys to prefer more lucrative sporadic accident alternatives where the payoff is high and the investment small. *See* John C. Coffee, Jr., *Understanding the Plaintiff's Attorney: The Implications of Economic Theory for Private Enforcement of Law Through Class and Derivative Actions*, 86 COLUM. L. REV. 669, 676 (1986); Rosenberg, *supra* note 16, at 889-92.



the impediments to discovering untested products,<sup>293</sup> and a prerequisite of some harm and exposure<sup>294</sup> may act together to ensure that even in the worst cases of manufacturer neglect, litigation will rarely be overwhelming.<sup>295</sup> If it is, the claims may at least be capable of being consolidated for greater judicial efficiency.<sup>296</sup>

### CONCLUSION

The common-law approach to assigning responsibility for proving causation is outmoded and ultimately socially damaging for the important and growing subset of "toxic tort" cases. Within a market and regulatory environment that already discourages safety testing, causation rules that provide additional incentives for manufacturers to remain ignorant about the long-term safety of their products cannot be tolerated. This Article highlights the failure of the current liability rules, the consequences of that failure, and how these rules might be reformed without radically changing existing claims, rules, and doctrines. By adopting the proposed reform, choosing ignorance—the rational choice for manufacturers today—will become an irrational choice tomorrow, and needed scientific research on the long-term

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<sup>293</sup> Although claims established through litigation might be filed in the thousands, *see supra* notes 189-91 and accompanying text, "new cases" would likely be tried only when plaintiffs' attorneys believe they are likely to pay off. "In the parlance of sports fishermen, the goal is to keep the big fish for frying and to throw the little ones back." Nagareda, *supra* note 225, at 912.

<sup>294</sup> *See supra* note 229 and accompanying text.

<sup>295</sup> Both Saks and Hensler estimate that a small percentage of victims actually file a lawsuit to seek compensation. *See supra* note 194. Gillette and Krier hypothesize that there is an even lower incentive to sue in public risk cases as compared with other types of torts, *see* Gillette & Krier, *supra* note 42, at 1047 (arguing that "[i]ncentives to sue and disincentives to free ride usually diminish as risk moves from the private toward the public end of the spectrum"), even if coalition building is possible, *see id.* at 1048 (admitting that coalitions can exist but arguing that risk victims may still be too diffuse for effective coalition building); *cf.* Rosenberg, *supra* note 16, at 893-900 (providing a detailed series of arguments explaining why proportional liability would not result in unmanageable mass filings). In fact, it is possible that these impediments working together may cause this reform to provide *too little* litigation relative to the prevalence of misconduct in safety testing. In such a case, the common-law liability system may simply be too awkward to provide adequate enforcement of safety testing responsibilities, and the reform might be accomplished better through a statutory reform, enforced by civil and criminal penalties, and reinforced by citizen suits in which plaintiffs can recover expert expenses and attorney fees. For a somewhat similar "public" approach to ensuring that manufacturers comply with the disclosure obligations under EPCRA, see 42 U.S.C. § 11046(a) (1994); *see also* Robert W. Shavelson, *EPCRA, Citizen Suits and the Sixth Circuit's Assault on the Public's Right-to-Know*, ALB. L. ENVTL. OUTLOOK, Fall 1995, at 29. However, such reform is unlikely. *See supra* note 223 and accompanying text.

<sup>296</sup> *See, e.g.,* Rosenberg, *supra* note 16, at 855 (arguing that "uniformity of conditions [common in toxic tort cases] enables courts not only to adjudicate a multitude of mass exposure claims efficiently [in comparison to a case-by-case basis with sporadic accident cases], but also to increase the net compensation that each claimant receives").

safety of products will be produced in abundance, not irrespective of the law, but because of it.

## APPENDIX A: DATA TOTALS FOR EACH OF 43 EPCRA CHEMICALS

Chemical Name	PatT	PatA	RtxL	RtxS	Emp74	Emp83	RtxT	Dis94 (lbs)
Acetamide*	12851	299	9	11	4668	2074	20	466028
Aluminum Oxide	25606	1656	5	3	513250	1559336	8	121489
AminoAnthraquinone*	119	5	13	3			16	
Ammonium Nitrate (solution)	607	16	3	4	22884	57833	7	60545892
Ammonium Sulfate (solution)	1043	28	3	7	55229	159582	10	4554466
o-Anisidine*	430	1	11	6			17	1064
p-Anisidine*	912	4	11	8			19	15
o-Anisidine Hydrochloride	3	0	14	3		1108	17	
Anthracene*	6809	200	14	4			18	86808
Benzamide	3873	188	10	4			14	0
m-Xylene*	2733	45	7	13	4621	39864	20	966287
o-Xylene*	2820	98	7	9	5778	25994	16	1395879
p-Xylene*	4702	150	8	9	1912	20366	17	3431609
Butadiene	49748	2689	22	13	66326	51971	35	2711287
sec-Butyl Alcohol	1159	7	4	15	42853	126196	19	1144287
tert-Butyl Alcohol	1601	24	7	8	3121	171420	15	1879266
Butyraldehyde	3373	45	8	14	1258	5392	22	367790
Carbonyl Sulfide	884	78	3	6			9	17146171
Chloroacetophenone	731	10	4	25		2294	29	
Diaminoanisole*	282	4	8	4			12	0
Dibenzofuran	700	52	3	3		3292	6	26116
Hexachloronaphthalene	6	0	3	3		520	6	
Hydrazine Sulfate*	338	9	39	13		945	52	230002
Isobutyraldehyde	1670	66	3	9	705	4114	12	448132
Isopropyl Alcohol*	22646	242	11	30	3183554	4665524	41	995673
Melamine	19678	1201	6	12	31892	43104	18	
Methyl tert-Butyl Ether (MTBE)	27654	59	3	9		5996	12	3223885
Methylene Dianiline*	1736	36	6	9	9163	15170	15	36531
Molybdenum Trioxide	1203	88	3	7	5269	48418	10	471568
N,N-Dimethylaniline	9890	48	9	15	2456	7448	24	22676
N-Nitrosomorpholine*	12	0	57	10			67	
Nitrilotriacetic Acid	4068	102	4	5	13454	25216	9	3261
Nitro-o-Anisidine*	91	0	10	5			15	10
p-Nitrobiphenyl*	265	0	18	5			23	
Nitroglycerin	715	34	6	23	4331	38471	29	47619
Nitrosodiphenylamine*	273	13	12	2			24	24
Octachloronaphthalene	13	0	3	3			6	
p-Phenylenediamine*	12612	359	7	31	14983	49939	38	8827
Picric Acid	1502	26	6	10	21627	37003	16	43966
Sodium Sulfate (solution)	846	12	3	5	866411	1332131	8	
Terephthalic Acid	16734	899	3	5	22732	6456	8	
Thiodianiline*	176	0	15	5			20	
Chromium*	61002	6440	5	3	16576	43025	8	1804627

LEGEND: PatT: number of times chemical appeared in total patent  
PatA: number of times chemical appeared in patent abstract  
RtxL: number of long-term laboratory studies on chemical  
RtxS: number of short-term laboratory studies on chemical  
Emp74: number of employees potentially exposed to chemical in 1974  
Emp83: number of employees potentially exposed to chemical in 1983  
RtxT: total of long- and short-term studies on chemical  
Dis94: pounds of chemical discharged into environment in 1994

## APPENDIX A CONTINUED.

Chemical Name	CasTT	CasWC	CasT	EPI	Clinical	HumTot	SciTot
Acetamide*	0	0	0	1	0	1	21
Aluminum Oxide	0	2	2	10	17	27	35
AminoAnthraquinone*	0	0	0	0	1	1	17
Ammonium Nitrate (solution)	0	1	1	0	1	1	8
Ammonium Sulfate (solution)	0	0	0	0	18	18	28
o-Anisidine*	0	0	0	0	0	0	17
p-Anisidine*	0	0	0	0	0	0	19
o-Anisidine Hydrochloride	0	0	0	0	0	0	17
Anthracene*	0	0	0	0	5	5	23
Benzamide	0	0	0	0	0	0	14
m-Xylene*	4	10	14	16	28	44	64
o-Xylene*	4	10	14	16	27	43	59
p-Xylene*	4	10	14	16	27	43	60
Butadiene	3	3	6	12	5	17	52
sec-Butyl Alcohol	0	4	4	0	1	1	20
tert-Butyl Alcohol	0	4	4	0	2	2	17
Butyraldehyde	0	0	0	0	0	0	22
Carbonyl Sulfide	0	0	0	0	0	0	9
Chloroacetophenone	1	0	1	0	14	14	43
Diaminoanisole*	0	0	0	0	0	0	12
Dibenzofuran	2	0	2	0	1	1	7
Hexachloronaphthalene	0	0	0	0	0	0	6
Hydrazine Sulfate*	0	0	0	0	9	9	61
Isobutyraldehyde	0	0	0	0	0	0	12
Isopropyl Alcohol*	0	3	3	4	17	21	62
Melamine	0	2	2	0	3	3	21
Methyl tert-Butyl Ether (MTBE)	0	0	0	0	9	9	21
Methylene Dianiline*	0	0	0	2	10	11	
Molybdenum Trioxide	0	0	0	0	0	0	10
N,N-Dimethylaniline	0	0	0	0	0	0	24
N-Nitrosomorpholine*	0	0	0	0	0	0	67
Nitrilotriacetic Acid	0	1	1	0	0	0	9
Nitro-o-Anisidine*	0	0	0	0	0	0	15
p-Nitrobiphenyl*	0	0	0	0	0	0	23
Nitroglycerin	0	1	1	1	1131	114	143
Nitrosodiphenylamine*	0	0	0	0	0	0	24
Octachloronaphthalene	0	0	0	0	0	0	6
p-Phenylenediamine*	0	0	0	4	22	26	64
Picric Acid	0	0	0	0	2	2	18
Sodium Sulfate (solution)	1	2	3	0	4	4	12
Terephthalic Acid	0	0	0	0	0	0	8
Thiodianiline*	0	0	0	0	0	0	20
Chromium*	2	17	19	24	106	130	138

LEGEND: CasTT: number of toxic tort "case hits" on chemical

CasWC: number of occupational "case hits" on chemical

CasT: total of toxic tort and occupational "case hits" on chemical

EPI: number of epidemiology studies on chemical (>100 persons in study)

Clinical: number of clinical studies on chemical (<100 persons in study)

HumTot: total of epidemiological and clinical studies on chemical

SciTot: total of all studies on chemical (HumTot + RtxT)