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TRANS-ATLANTIC REACH: THE POTENTIAL IMPACT OF THE EUROPEAN UNION’S NEW CHEMICAL REGULATIONS ON PROOF OF CAUSATION IN U.S. FEDERAL COURTS

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Abstract: On June 1, 2007, a new set of regulations governing nearly all chemical substances took effect throughout the EU’s twenty-seven member states. The primary goal of the legislation, called REACH, is to improve the protection of human health and the environment from risks posed by toxic chemical exposure. No equivalent federal legislation exists in the United States. As a result, chemicals that the EU will soon ban or restrict under REACH will continue to enter American homes and workplaces. This Note explores how private law—particularly in the form of toxic tort litigation—may fill the gap in U.S. chemicals regulation, and induce manufacturers to produce safer products for U.S. consumption. Focusing on the potential of REACH to influence the establishment of general causation in toxic tort litigation, it analyzes whether and to what extent REACH data is likely to assist toxic tort plaintiffs in U.S. federal courts. The Note concludes that, although REACH is likely to provide plaintiffs with additional evidentiary support of general causation in some instances, it seems unlikely that REACH data alone will be sufficient to support causation claims at the federal level.

INTRODUCTION

We live in a world of chemicals. From household cleaners to children’s toys, to shower curtains, lipstick, and nail polish, chemicals comprise tens of thousands of consumer and commercial products—they are the ingredients in the conveniences of modern society.1

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Despite the widespread use of chemical substances, for more than fifty years government policies have allowed the production and importation of an overwhelming majority of chemicals without questioning their safety, even though governments, consumers, and chemical manufacturers have known little to nothing about the health and environmental risks that everyday chemicals might pose. In recent years, however, scientific studies have provided evidence that our presumptions of chemical safety were often wrong.

As science has focused increasingly on the effects of long-term exposure to everyday chemical-containing products, it has become clear that our world of chemicals and convenience comes with serious health and environmental consequences. “We now know that some of these chemicals have accumulated in the bodies of virtually all people, and in wildlife and the ecosystems of the remotest regions on Earth.” Results from a 2005 cross-generational study by the U.S. Center for Disease Control revealed the accumulation of nearly 150 toxic chemicals “in the bodies of Americans of all ages.” Supported by wildlife, animal,
and human studies, moreover, scientists suggest that exposure to even low-level contaminants is causally linked to increasing rates of cancers, reproductive disorders, and neurological diseases, which affect millions of people worldwide. Alarmingly, a recent World Health Organization estimate partly attributes the deaths of at least five million people per year to exposure to toxic chemicals.

For nearly a decade, as more scientific studies have observed the carcinogenic, mutagenic, and neurotoxic effects of human exposure to chemicals, European Union (EU) legislators have worked towards the implementation of a new set of regulations to govern the EU-market presence of nearly all chemical substances. The resulting legislation—Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)—took effect throughout the EU’s twenty-seven member states on June 1, 2007. Now the world’s strictest chemical safety regime, REACH’s primary goal is to improve the protection of human health and the environment from risks posed by toxic chemical exposure. To achieve this objective, REACH will require generation of en-

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7 See id. at 3–4. For example, based on extensive peer-reviewed scientific studies, many scientists now believe that early exposure to phthalates—a member of the polyvinylchloride plastic softener family—can cause reproductive deformations such as lower testosterone levels and sperm counts, incompletely descended testes, and hypospadias. See id. at 42, 44–45. Exposure to phthalates can come from a multitude of sources, including “dust in the air, . . . plasticized wall coverings or flooring, . . . [and] plastic toys and teething rings.” Id. at 43. Studies also have linked exposure to perfluorinated chemicals, like those used in Teflon pans, to liver damage and “increased risk of bladder and possibly other cancers.” Id. at 128. These are just two of thousands of examples of the potentially serious health consequences of everyday exposure to chemical substances. See generally id.

8 Id. at 3–4.


10 Austin & Bowden, supra note 9, at 1; see European Parliament and Council Regulation 1907/2006, Concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, 2006 O.J. (L 396) 1 (EC), available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=oj:l:2006:396:0001:0849:en:pdf [hereinafter REACH]. It is important to note that, because REACH is only in its initial implementation phase, “many critical elements of REACH remain to be developed, and how all of its provisions will work in practice remains to be seen.” Denison, supra note 1, at I-6. For an account of the intense lobbying by chemicals manufacturers worldwide, and even by the U.S. government, that accompanied the REACH development process, see Schapiro, supra note 1, at 143–55.

11 Denison, supra note 1, at I-6. For an account of the intense lobbying by chemicals manufacturers worldwide, and even by the U.S. government, that accompanied the REACH development process, see Schapiro, supra note 1, at 143–55.

environment- and health-toxicity data on the majority of chemicals used in modern society.\textsuperscript{13}

By substantially improving the chemical health and safety information available to manufacturers, regulators, and the public, REACH promises to confer significant health and environmental benefits on European consumers.\textsuperscript{14} As Stavros Dimas, the EU Commissioner for the Environment, has stated:

If REACH succeeds in reducing chemicals-related diseases by only 10 per cent, which is a conservative assumption, the health benefits are estimated at more than €50 billion ($64 billion) over 30 years. This means tens of thousands of avoided cases of infertility, cancer, skin diseases, neurological disorders and other illnesses.\textsuperscript{15}

Even in its early stages, REACH has impacted manufacturers throughout the world, including American producers of chemical substances.\textsuperscript{16} Because chemicals and chemical-containing products made in the United States for export to the EU must meet the same standards as their European-made counterparts, the EU’s new chemicals regulations confront U.S. companies with a choice: “either adapt to Europe’s more aggressive standards for protecting the health of its citizens, or risk losing what is now the biggest and most affluent market in the world.”\textsuperscript{17}

While some companies are choosing to replace dangerous chemicals with safer alternatives in products for both U.S. and European consumption, many U.S. companies that have adapted their products to comply with the EU’s higher standards maintain that they are unable to make the same changes for American consumers—and continue to take advantage of less rigorous chemicals regulation in the United States.\textsuperscript{18}

Whether REACH will eventually influence Congress to adopt legislation similar to the EU’s new chemicals rules remains to be seen.\textsuperscript{19} No-


\textsuperscript{14} See generally Schapiro, supra note 1.

\textsuperscript{15} Austin & Bowden, supra note 9, at 1 (quoting Stavros Dimas, EU Commissioner for the Environment, Speech at the American Chamber of Commerce in the EU: Climate Change and REACH (July 19, 2005)).

\textsuperscript{16} See Schapiro, supra note 1, at 157. “U.S. firms sell about $27 billion a year in chemicals to Europe . . . .” Id. at 139. For a discussion of the worldwide economic impact of REACH, see id.

\textsuperscript{17} See id. at 10.

\textsuperscript{18} Id. at 10–11.

\textsuperscript{19} See id. at 10–11, 157.
tably, while the EU marched forward, creating new protections for its citizens, the United States steadfastly regarded these changes with an icy glare: from the time REACH was just a proposal in Europe, the official policy of the U.S. executive branch has been to vociferously oppose the new regulations. Thus, for the time being, chemicals that soon will be banned or restricted in the EU under REACH will continue to enter the American market—as well as American homes and workplaces.

Fortunately for Americans,

[the United States has long had two legs to its structure of consumer protections: regulation on the one hand, and a receptive legal system on the other, giving citizens the right to pursue redress in the courts as a means of obtaining both compensation and punishment for damages to their . . . health and environment.]

Therefore, while U.S. public law may leave Americans exposed to dangerous chemicals for the time being, private law, particularly in the form of toxic tort litigation, could prove a powerful inducement to manufacturers to produce safer products for U.S. consumption. Historically, the prospect of litigation has been a powerful deterrent, forcing manufacturers at the very least to assess, and sometimes to internalize, the costs associated with failures to adequately protect consumers. Thus, “[b]y requiring the generation of massive amounts of new data

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20 See id. at 143–54.
22 See Schapiro, supra note 1, at 142. In response to REACH, the Bush administration launched “an unprecedented international lobbying effort . . . to block [the new European legislation] from being passed into law.” Id. at 145. While it appears that, for the foreseeable future, U.S. federal law will continue to deny Americans protections comparable to those that REACH will afford Europeans, a few U.S. states, including California, Massachusetts, and New York, “have begun implementing elements of REACH into their state regulations; other states, such as Maine and Washington, have cited Europe’s precedent in their efforts to ban particular chemicals.” Id. at 188.
23 Id. at 36.
24 See id. at 37.
25 Id. Some notable defendant-corporations include “Dow Corning (silicone breast implants), Merck (Vioxx pain reliever), the Ford Motor Company (the Pinto), AH Robins (the Dalkon Shield contraceptive), WR Grace (asbestos), and Philip Morris (tobacco).” Id.
on the health risks of chemicals,” REACH may equip plaintiffs with valuable evidence in support of toxic tort claims.26

Focusing exclusively on the potential of REACH to influence the establishment of general causation in toxic tort litigation, this Note explores whether and to what extent REACH data is likely to assist toxic tort plaintiffs in U.S. federal courts.27 Part I provides a detailed explanation of REACH provisions pertinent to this inquiry. Part II discusses toxic tort litigation, as well as the types of evidence most commonly relied upon in both the scientific and legal realms to infer causal links between toxic agents and human disease. Part III describes the standards that U.S. federal courts apply in decisions on the admissibility of scientific evidence and expert testimony, while Part IV surveys how courts have applied admissibility standards in the context of toxic tort litigation. Part V analyzes the likelihood that REACH data will assist plaintiffs in proving general causation. This Part specifically considers the issues of inclusion, accessibility, reliability, and admissibility of REACH data. The Conclusion of this Note suggests that, while REACH is likely to provide plaintiffs with additional evidentiary support of general causation in some instances, it seems unlikely that REACH data alone will be sufficient to support causation claims in federal courts.

I. REACH: The EU’s Regulatory Response

REACH represents an overhaul of European chemicals regulations promulgated in the early 1980s.28 REACH’s predecessor regulations closely mirrored the United States’s Toxic Substance Control Act (TSCA) of 1976, which remains in effect today.29 The old European regulations failed to provide an adequate basis for understanding the potential risks posed by chemicals.30 Under the former EU chemicals regime, no data were available on the impact of ninety-nine percent of the 30,000 substances currently on the EU market because the old rules exempted from testing requirements chemical substances “existing” at

26 See Karmel, supra note 13.
27 The author recognizes the potential for REACH data in general, and European Chemicals Agency (ECHA) decisions in particular, to impact the establishment of more than one prima facie element of toxic tort suits involving chemicals regulated by REACH. It is beyond the scope of this Note, however, to address issues of breach and duty.
28 Schapiro, supra note 1, at 137; Austin & Bowden, supra note 9, at 1.
29 See Schapiro, supra note 1, at 132. For a detailed comparison of TSCA and REACH, see generally Denison, supra note 1.
30 REACH in Brief, supra note 12, at 3.
the time of regulation.\textsuperscript{31} Moreover, public authorities rarely acquired adequate safety data on new chemical substances because pre-REACH regulations required government to point to “information sufficient to document potential risk, or at the very least, extensive exposure” before it could require manufacturers to submit risk data on products for the assessment of actual risk.\textsuperscript{32} Because the former legislation only set out general guidelines for manufacturers in providing safety information to the government, chemical producers typically submitted little, if any, data on risk and toxicity and, as a result, public authorities rarely procured the evidence needed to mandate further testing.\textsuperscript{33} Thus, under the old system, not only governments but even manufacturers sometimes were unaware of the properties of chemicals used in products.\textsuperscript{34}

REACH aims to diminish the information deficit by acquiring specific environment- and health-toxicity data on most of the chemicals used in modern society.\textsuperscript{35} By conservative estimates, REACH will lead to the development of €10 billion in toxicity and exposure data in the next two decades.\textsuperscript{36} To accomplish its goals, REACH requires importers and manufacturers to supply “scientifically valid” health and safety data on the chemical substances they import and/or produce.\textsuperscript{37} Notably, industry, rather than government, is responsible for developing data that demonstrate that chemicals can be used safely.\textsuperscript{38}

\textsuperscript{31} See Austin & Bowden, \textit{ supra} note 9, at 1.
\textsuperscript{32} See \textit{Denison}, \textit{ supra} note 1, at iii. From 1993 to 2007, the EU ordered risk assessments on only 141 high-volume “new” chemicals. \textit{REACH in Brief, supra} note 12, at 3.
\textsuperscript{33} See \textit{Denison}, \textit{ supra} note 1, at v.
\textsuperscript{34} \textit{Id.} at iii–iv; \textit{Schapiro, supra} note 1, at 136.
\textsuperscript{35} Austin & Bowden, \textit{ supra} note 9, at 1; Karmel, \textit{ supra} note 13. “All substances are covered by [REACH] unless they are explicitly exempted from its scope.” \textit{REACH in Brief, supra} note 12, at 5. Some REACH exemptions include medicinal products and cosmetics, which are already regulated under comprehensive EU directives. \textit{REACH, supra} note 10, art. 2, ¶ 6(a)–(b). Also exempted are substances that “generally present such low risks as not to require registration, like water [and] oxygen.” \textit{REACH in Brief, supra} note 12, at 6.
\textsuperscript{36} See Karmel, \textit{ supra} note 13.
\textsuperscript{37} \textit{REACH, supra} note 10, pmbl. ¶ 64; see \textit{REACH in Brief, supra} note 12, at 5.
\textsuperscript{38} \textit{REACH, supra} note 11, pmbl. ¶¶ 18–19; \textit{Denison, supra} note 1, at 1-7 to -8. Thus, the new regulations “[flip] the . . . [old] presumption of innocent until proven guilty on its head . . . .” \textit{Schapiro, supra} note 1, at 138.
A. The REACH Process: Registration, Evaluation, Authorization, and Restriction of Chemicals

REACH substantially eliminates distinctions previously made between “new” and “existing” chemicals and requires all importers and manufacturers of chemicals produced or used in quantities exceeding one ton per year to register with the new European Chemicals Agency (ECHA, or, the Agency). Failure on the part of manufacturers to submit the appropriate registration materials to ECHA will result in a ban on the manufacture or import of unregistered or improperly registered substances.

To register, manufacturers must submit technical dossiers containing information on the identities, properties, and uses of substances they produce. Manufacturers must also disclose relevant hazard classifications and labeling requirements and must provide guidance on the safe use of substances. Further, technical dossiers should summarize any existing pertinent hazard information, as well as details and results from new studies and information on testing proposals. REACH mandates that “one or more competent person(s) who have appropriate experience and received appropriate training” shall prepare chemical safety assessments, which compare possible negative effects of sub-
stances “with the known or reasonably foreseeable exposure of man . . . to [those] substance[s],” given a variety of exposure scenarios.\textsuperscript{45}

The scope of information REACH requires varies according to the tonnage of the manufactured or imported substance; an increase in the marketed quantity of a substance automatically triggers additional information requirements.\textsuperscript{46} For example, the dossiers of substances produced in quantities of ten metric tons or more per year must also contain chemical safety reports (CSRs). These reports detail information about the physiochemical, toxicological, and ecotoxicological properties of substances, the risks posed by their use, and whether and any risks may be adequately controlled.\textsuperscript{47} CSRs are intended to supply ECHA with adequate data to evaluate whether a particular substance should be classified as “persistent, bioaccumulative, and toxic” (PBT) or “very persistent and very bioaccumulative” (vPvB).\textsuperscript{48} PBTs can cause a wide range of serious health problems, including “cancer, endocrine disruption, reproductive dysfunction, behavioral abnormalities, birth defects, disturbance of the immune system, [and] damage to the liver and nervous system.”\textsuperscript{49} REACH further requires data on human and animal exposure risks for substances identified as PBTs or vPvBs.\textsuperscript{50}

Additionally, REACH requires applicants registering such substances of “high concern” to analyze whether safer, suitable alternatives or technologies exist.\textsuperscript{51} Substances determined to pose “potentially significant threat[s] to human health or the environment”—namely,
PBTs, vPvBs, substances with endocrine-disrupting properties, and carcinogenic, mutagenic, and reproductive toxins—require specific ECHA authorization before they can appear on the European market.\(^{52}\)

Annexes to REACH specify the scientific methodologies upon which registrants are to rely in acquiring requisite data.\(^{53}\) Depending on the quantity and properties of the chemical in question, REACH requires that registration dossiers contain data based on scientific studies involving animal toxicology (in vivo testing), in vitro studies (Petri dish or test tube studies on cells, organs, and sometimes embryos), and/or structure-activity relationships (SARs) analysis.\(^{54}\)

While REACH provides standard guidelines for developing data for the registration process, in many instances it allows manufacturers to deviate from these standard testing regimes in their studies, provided that they clearly explain how their analysis and methodologies differ from REACH guidelines and why such adaptations are justified.\(^{55}\) Specifically, REACH states that when certain conditions are met, manufacturers may omit data, replace it with other information, provide it at a different stage, or adapt it in a different way.\(^{56}\)

Further, registrants can submit statements as to why they should be exempt from testing requirements altogether, citing a lack of necessity or feasibility.\(^{57}\) While registrants are expected to apply Good Laboratory Practice (GLP) standards for toxicological and eco-toxicological studies and assessments, in many other instances, registrants may satisfy data requirements using “nonstandard methods.”\(^{58}\) Finally, REACH encourages registrants to substitute direct testing methods, such as live animal studies, with in vitro data, SAR modeling, and weight-of-evidence approaches.\(^{59}\)

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\(^{52}\) Austin & Bowden, supra note 9, at 3.

\(^{53}\) See, e.g., REACH, supra note 10, Annex VIII.

\(^{54}\) See, e.g., id., Annexes VIII, XI & ¶¶ 1.3–1.4; see also Denison, supra note 1, at IV-28.

\(^{55}\) See REACH, supra note 10, Annexes VII–X; see also Denison, supra note 1, at IV-28 to -29.

\(^{56}\) Denison, supra note 1, at IV-28 & n.145 (“This language appears in the introduction to each of the [REACH] Annexes VII-X.”).

\(^{57}\) REACH, supra note 10, Annex XI; Denison, supra note 1, at IV-28.

\(^{58}\) Denison, supra note 1, at IV-28; see REACH in Brief, supra note 12, at 7. GLP standards concern “the selection and handling of laboratory animals, the number of animals per cage, their diet, the statistical procedures to be used, etc. . . . . Adherence to GLP in routine safety assessment is the norm and is subject to examination in litigation.” David L. Faigman et al., Science in the Law: Standards, Statistics and Research Issues 387 (2002).

\(^{59}\) See REACH, supra note 10, Annexes VII–X; see also Denison, supra note 1, at IV-28 to -29.
REACH provisions which permit adaptations to testing methodologies reflect the legislation’s express purpose of replacing, reducing, or refining animal testing wherever possible and scientifically justifiable.\textsuperscript{60} These allowances are intended to address concerns about both animal protection and industry costs.\textsuperscript{61} Accordingly, REACH also encourages registrants to submit existing information in lieu of conducting new tests.\textsuperscript{62} REACH requires new tests only when alternative possibilities have been exhausted.\textsuperscript{63} For instance, “[f]or substances in quantities of 100 tonnes per year or more (i.e. cases where more expensive tests, many on vertebrate animals, may be necessary), the manufacturer or importer who does not already possess the required information only needs to submit proposals for testing.”\textsuperscript{64}

While REACH requires ECHA to examine all submitted testing proposals, the Agency is responsible for subjecting only “a percentage” of registrations to further evaluation.\textsuperscript{65} Evaluation is the process by which ECHA determines whether the data submitted are reliable and accurate.\textsuperscript{66} In conjunction with EU member states, ECHA is tasked with developing criteria for prioritizing substances for further evaluation which take into account hazard and exposure information, as well as tonnage.\textsuperscript{67}

Based upon evaluations of registered data, ECHA may request information beyond that required by the registration provisions of REACH.\textsuperscript{68} However, ECHA must first seek the approval of EU member states.\textsuperscript{69} Moreover, REACH grants registrants the opportunity to comment on and appeal requests for additional information.\textsuperscript{70}

Where the evaluation process raises Agency concerns that a substance possesses substantial environmental or human health risks, ECHA must grant explicit authorization before registrants may proceed to manufacture or import that substance into the EU.\textsuperscript{71} Upon further

\textsuperscript{60} Denison, supra note 1, at IV-29.
\textsuperscript{61} Id.; see REACH in Brief, supra note 12, at 7.
\textsuperscript{62} See REACH, supra note 10, Annexes VII–X.
\textsuperscript{63} REACH in Brief, supra note 12, at 7.
\textsuperscript{64} Dep’t for Env’t Food & Rural Affairs, Environmental Protection: Chemicals, http://www.defra.gov.uk/environment/chemicals/reach/qanda/registration.htm (last visited Mar. 24, 2009) [hereinafter DEFRA]; see REACH in Brief, supra note 12, at 7.
\textsuperscript{65} REACH, supra note 10, pmbl. ¶ 65.
\textsuperscript{66} Id.; see REACH in Brief, supra note 12, at 11–12.
\textsuperscript{67} REACH, supra note 10, art. 44, ¶ 1.
\textsuperscript{68} Id., pmbl. ¶ 66.
\textsuperscript{69} Id., arts. 46, 50, 52; see also Denison, supra note 1, at IV-28.
\textsuperscript{70} REACH, supra note 10, art. 50; see also Denison, supra note 1, at IV-28.
\textsuperscript{71} REACH, supra note 10, art. 56.
analysis, the Agency may choose to restrict or altogether ban the production or importation of the substance to avoid exposures dangerous to humans and the environment.\textsuperscript{72} Substances most likely to be subject to ECHA bans or restrictions include those satisfying criteria for classification as carcinogens, mutagens, teratogens, endocrine disrupters, PBTs, and vPvBs.\textsuperscript{73}

**B. Public Access to REACH Data**

REACH substantially limits the data that companies can claim as proprietary.\textsuperscript{74} ECHA is responsible for making publicly available, via the internet, much of the health and environmental safety data prepared for it by chemical manufacturers.\textsuperscript{75} REACH will always make the following categories of information available, free of charge: (1) the name of the substance; (2) the classification and labeling of the substance; (3) physicochemical data concerning the substance, exposure pathways, and environmental fate; (4) the result of each toxicological and ecotoxicological study; and (5) analytical methods, if requested, which make it possible to detect a dangerous substance when discharged into the environment, as well as to determine the direct exposure risks for humans.\textsuperscript{76}

In some instances, however, REACH grants manufacturers an opportunity to submit justifications for why ECHA should not disclose registered information.\textsuperscript{77} If the Agency deems those reasons valid, study summaries or robust study summaries of toxicological data and the trade name of the substance may remain undisclosed.\textsuperscript{78} Further, ECHA will automatically classify certain REACH data, such as specific details on a preparation’s full composition, as “confidential business information” (CBI).\textsuperscript{79} Access to that information will be granted only “where

\textsuperscript{72} See REACH IN BRIEF, supra note 12, at 12–13.
\textsuperscript{73} REACH, supra note 10, art. 57.
\textsuperscript{74} Schapiro, supra note 1, at 138.
\textsuperscript{75} See REACH, supra note 10, art. 119. Notably, though the official TSCA website notes that most public libraries own copies of the TSCA inventory, the U.S. government charges $161 through its website for consumers to purchase their own searchable CD-ROM copy. U.S. Envtl. Prot. Agency, New Chemicals Program, What is the TSCA Chemical Substance Inventory?, http://www.epa.gov/oppt/newchems/pubs/inventory.htm (last visited Mar. 24, 2009).
\textsuperscript{76} REACH, supra note 10, art. 119, ¶ 1; see also Denison, supra note 1, at VII-6.
\textsuperscript{77} REACH, supra note 10, art. 119, ¶ 2; see also Denison, supra note 1, at VII-6.
\textsuperscript{78} REACH, supra note 10, art. 119, ¶ 2(c); see also Denison, supra note 1, at VII-6 & n.281.
\textsuperscript{79} See REACH, supra note 10, art. 118, ¶ 2; see also Denison, supra note 1, at VII-5, VII-7.
urgent action is essential to protect human health, safety or the environment, such as emergency situations.\textsuperscript{80}

II. TOXIC TORT LITIGATION AND SCIENTIFIC EVIDENCE

Toxic tort law addresses civil wrongs where an individual or the environment has suffered injury or harm due to exposure to a toxic product, substance, or process.\textsuperscript{81} Through toxic tort litigation, victims may recover compensatory damages to meet the costs of medical expenses, foregone wages, and pain and suffering. In addition, courts sometimes award punitive damages, which are designed to deter defendants and others from engaging in the same or similar harmful behavior in the future.\textsuperscript{82} In toxic tort cases, as in conventional tort suits, plaintiffs must establish each of the elements of a prima facie case in order to prevail in litigation.\textsuperscript{83} These elements are duty, breach, injury, and causation.\textsuperscript{84} Establishing causation is almost always the biggest hindrance to plaintiffs' success.\textsuperscript{85}

A. Proving Causation in Toxic Tort Suits

In a toxic tort lawsuit, the plaintiff bears the burden of proving by a preponderance of the evidence that the defendant’s tortious conduct caused the plaintiff’s harm.\textsuperscript{86} Generally, in toxic tort bodily injury lawsuits, causation is established where the plaintiff proves that it is more likely than not that: (1) the plaintiff was exposed to the toxic substance; (2) the defendant was responsible for the exposure; and (3) the plaintiff’s exposure caused the claimed injury.\textsuperscript{87}

Proving causation typically involves establishing both specific and general causation.\textsuperscript{88} To prove specific causation, the plaintiff must demonstrate that the chemical in question did, in fact, cause plaintiff’s

\textsuperscript{80} REACH, supra note 10, art. 118, ¶ 2.
\textsuperscript{83} Plater et al., supra note 82, at 105.
\textsuperscript{84} See id.
\textsuperscript{85} See Margaret A. Berger, Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts, 97 COLUM. L. REV. 2117, 2121 (1997); Rollé, supra note 81, at 140.
\textsuperscript{86} Plater et al., supra note 82, at 227.
\textsuperscript{87} Rollé, supra note 81, at 142.
\textsuperscript{88} Faigman et al., supra note 58, at 30.
particular harm.\textsuperscript{89} General causation, on the other hand, involves convincing the jury that the toxic substance in question is capable of causing the disease or injury that the plaintiff has suffered.\textsuperscript{90}

Establishing general causation is especially challenging in toxic tort litigation for a number of reasons.\textsuperscript{91} First, while scientists have made remarkable advances in understanding biological mechanisms as related to the onset of illnesses such as cancer, neurological disorders, and reproductive malformations, much remains unknown about the causes of disease.\textsuperscript{92} Further, the fact that many illnesses have more than one potential cause can make it very difficult to prove that exposure to defendant’s product necessarily caused the injury.\textsuperscript{93} In addition, the “probabilistic” evidence that scientists rely upon in developing hypotheses and theories may not translate well to the preponderance of the evidence standard used by courts and juries.\textsuperscript{94} Acquiring adequate scientific evidence, moreover, can be prohibitively expensive.\textsuperscript{95} For toxic tort plaintiffs, “the trick often has been to find probative evidence that can be obtained without great cost.”\textsuperscript{96}

B. Types of Causation Evidence

In both the scientific and the legal world, establishing general causation usually involves complex explanations of causal relationships.\textsuperscript{97} Given that straightforward cause-effect linkages are rare in the context of toxic tort litigation, scientists rely upon generalizations of their findings to support causal inferences.\textsuperscript{98} Scientists most commonly look to

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\textsuperscript{89} Id. at 286.

\textsuperscript{90} Id. Because it seems likely that REACH will have very little, if any, impact on the establishment of plaintiff-specific causation, this Note limits its analysis to proof of general causation. In any event, general causation is generally a threshold consideration for courts: it is normally the case that courts will exclude evidence on specific causation where plaintiff’s evidence is insufficient to establish general causation. Id. at 32.

\textsuperscript{91} See Berger, supra note 85, at 2120–21.

\textsuperscript{92} Id.

\textsuperscript{93} Id. at 2121–22.

\textsuperscript{94} See id. at 2122.

\textsuperscript{95} See Plater et al., supra note 82, at 212.

\textsuperscript{96} Id.

\textsuperscript{97} Berger, supra note 85, at 2120–21.

epidemiological and toxicological studies to provide evidence of a causal relationship.  

1. Epidemiology

Epidemiology is the statistical study of disease and the factors that cause illness in human populations. It concerns itself with the incidence and distribution of illnesses in groups of people, rather than individual patients. In the context of toxic tort litigation, epidemiological research can provide evidence of a causal relationship between exposure to chemical agents and human injury by assessing how much incidence of a disease is linked to the substance in question. Epidemiologists define the strength of the association in terms of relative risk. A relative risk of 1.0 indicates that the incidence of disease in exposed and unexposed populations is the same and suggests the absence of a causal relationship. A relative risk of greater than 2.0 is necessary for the study to indicate that it is more likely than not that subjects exposed to the substance will exhibit a certain disease or illness. “The higher the relative risk, the stronger or more powerful . . . the association between the [chemical] and the disease.” Correlation does not imply causation, however. Associations that imply a causal relationship, therefore, are strengthened by similar results from further epidemiological or other scientific studies.

Although epidemiological studies focus on human populations and thus are more easily extrapolated to populations outside the researched group than are other research methods—including live animal studies—they require significant sums of money and lengthy periods of time to conduct. Furthermore, subjecting human populations to suspected agents of disease raises serious ethical concerns.
2. Toxicology

Toxicological studies frequently provide scientifically valid alternatives or supplements to epidemiological research. The most common and reliable types of toxicological studies are live animal (in vivo) studies, in vitro (cell, tissue, organ, or embryo) testing, and structure-activity relationships (SARs) analysis.

a. Animal Studies

Despite several obvious distinguishing characteristics, human beings have much in common with other animal species. “With respect to the toxicological effects of chemicals on biological organisms, the similarities between humans and other animals are far greater than the differences.” Thus, by exposing live laboratory animals to chemicals and observing the results, scientists can assess the probable effects of human exposure to the same substances, as well as the risk that such exposure can cause human disease. The advantages of animal studies are numerous. First, live animal testing is much cheaper than epidemiological research. Likewise, because “many animal species reproduce readily and have short life cycles,” in vivo studies typically demand less time than their epidemiological counterparts. Animal studies, moreover, “are experimental, rather than observational, enabling the researcher to better control the environment and reduce the likelihood of biases affecting the results.” In addition, animal testing arguably avoids some of the ethical considerations inherent in human studies, thereby allowing researchers to conduct “a wider range of . . . tests . . . to provide a more complete picture of toxic effects than is available from epidemiological studies.” For example, after exposing lab animals to chemical substances and observing the results, researchers can dissect test subjects and observe “implicated tissue . . . to pro-

111 See Green, supra note 98, at 654.
112 See Faigman et al., supra note 58, at 349–54; Marks, supra note 99, at 176.
113 See Faigman et al., supra note 58, at 374.
114 Id. at 374–75.
115 Id. at 375.
116 Green, supra note 98, at 654.
117 See Marks, supra note 99, at 188.
118 Green, supra note 98, at 654 (noting that this is especially true of mice, rats, and hamsters).
119 Id.
vide additional information about the existence of disease and its biology.”

There are, however, drawbacks to animal studies. First, the fact that human beings and other animals differ in size, life span, metabolism, etc., means that causal inferences about the effects of human exposure to chemicals based upon observations in other species may be less reliable than results from epidemiological studies. Similarly, extrapolating results from animal studies to humans requires an assumption that “humans will suffer an adverse effect from a low dose of a substance, even though laboratory animals are given much higher and more constant dosages so as to induce a measurable reaction.” Further, scientists have yet to determine the extent to which in vivo studies “over- or underestimate” human toxicity. Despite these limitations, it is generally accepted in the toxicology field that animal studies play a critical role in predicting the incidence of disease in humans.

b. In Vitro Testing

In vitro testing is a common and inexpensive way to study the biochemical effects of agents on cells, organs, and even embryos. In vitro studies can provide important information on the toxicity of chemicals while limiting controversial testing on live animals. Because in vitro testing occurs in test tubes or Petri dishes, however, the problem of generalizing observed effects on cells or organs in isolation to live organisms must be considered. Specifically, in vitro research is sometimes criticized for failing to consider the “layers of metabolic activity” typically characteristic of live test subjects. Additionally, because scientists usually perform these tests on animal tissues, the difficulties with animal-to-human extrapolation characteristic of live animal studies are also present in in vitro analyses. Nonetheless, in vitro studies have contributed significantly to scientific understanding of the biological mechanisms of

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121 Green, supra note 98, at 654.
122 Id.
123 Id. Thus, animal studies raise questions of external validity—“the ability to generalize the results of a study of a given population to a different group.” Id.
124 Berger, supra note 85, at 2124.
125 Id.
126 See Green, supra note 98, at 656.
127 See Berger, supra note 85, at 2123; Green, supra note 98, at 657.
128 See Lin, supra note 120, at 578, 580–81.
129 Berger, supra note 85, at 2123–24; see Green, supra note 98, at 657.
130 Lin, supra note 120, at 580.
131 Green, supra note 98, at 657.
some toxic chemicals.\textsuperscript{132} Moreover, progress in the science of DNA and human stem-cell research promises to drastically reduce the problem of animal-to-human extrapolation in the in vitro setting.\textsuperscript{133}

c. Structure-Activity Relationships

Finally, scientists also use similarities in the molecular structures of chemical agents to assess toxicity.\textsuperscript{134} These tests are known as structure-activity relationships (SARs).\textsuperscript{135} SARs analysis is premised on the idea that similar molecules have similar effects.\textsuperscript{136} Because slight variations in the molecular structure of chemicals can create substantially distinct effects in humans, however, SARs are most useful for establishing the characteristics of certain molecular families, and thereby providing a basis for further analysis of chemical effects using other methodologies, such as epidemiology, animal, and in vitro studies, as discussed above.\textsuperscript{137}

III. STANDARDS FOR ADMISSIBILITY OF EVIDENCE IN U.S. FEDERAL COURTS

Given the highly technical nature of the evidence required to establish requisite causal links, proving general causation in toxic tort cases almost always requires the use of scientific experts to testify on the linkages between particular toxic substances and human injury.\textsuperscript{138} Because scientific evidence and expert testimony on that evidence are essential to nearly every toxic tort plaintiff’s case, the issue of whether a court should admit an expert’s testimony is a highly contentious one in many toxic tort suits.\textsuperscript{139} A court’s determination that a plaintiff’s evidence and testimony are inadmissible will often lead to dismissal of the case.\textsuperscript{140} Therefore, defendants often seek to exclude the testimony of causation experts as part of their defense strategy.\textsuperscript{141}

\begin{itemize}
\item \textsuperscript{132} See id. (noting that “the primary benefit from these tests is not the identification of [disease-causing agents] but studying the [ir] biological mechanisms”).
\item \textsuperscript{134} Marks, \textit{supra} note 99, at 176.
\item \textsuperscript{135} Id.
\item \textsuperscript{136} See Green, \textit{supra} note 98, at 658; Marks, \textit{supra} note 99, at 176.
\item \textsuperscript{137} Green, \textit{supra} note 98, at 658; Marks, \textit{supra} note 99, at 176.
\item \textsuperscript{138} Green, \textit{supra} note 98, at 658; Marks, \textit{supra} note 99, at 176.
\item \textsuperscript{139} Berger, \textit{supra} note 85, at 2122; Branch & Branch, \textit{supra} note 138.
\item \textsuperscript{140} Berger, \textit{supra} note 85, at 2122. Often, but not necessarily, judges decide on defendants’ motions to exclude expert testimony in \textit{in limine} hearings. \textit{Id.} at 2122 n.20; see Faig-}

To avoid exclusion of expert testimony from trial in federal court, plaintiffs must demonstrate that proffered evidence meets the requirements of Federal Rule of Evidence 702. Rule 702, which governs the admissibility of expert testimony in federal court, states that “[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.”

Prior to the implementation of Rule 702, federal courts applied the legal standard set forth in Frye v. United States to evaluate the admissibility of expert testimony. Under the Frye test, courts admitted evidence deemed “to have gained general acceptance in the particular field in which it belongs.” In 1993, the Supreme Court decided Daubert v. Merrell Dow Pharmaceuticals, Inc., ruling that the Federal Rules of Evidence superseded the Frye test. In its unanimous decision, the Court held that expert testimony should be excluded if it fails to meet certain standards of reliability and relevance.

Branch & Branch, supra note 138.

Faigman et al., supra note 58, at 13–16; see Fed. R. Evid. 702.

Fed. R. Evid. 702. In 2000, Congress amended Rule 702 to further describe admissible expert testimony and supporting scientific evidence. Faigman et al., supra note 58, at 11–12; see Fed. R. Evid. 702. Specifically, the 2000 amendment provided that an expert may testify where: (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.” Fed. R. Evid. 702; see also Faigman et al., supra note 58, at 11–12 n.7. This Note focuses exclusively on the admissibility of the evidence underlying an expert’s testimony and assumes, for the purpose of its analysis, that the expert in question is qualified to testify. For a general discussion of expert witness qualifications, see Faigman et al., supra note 58, at 19–23.

293 F. 1013 (D.C. Cir. 1923).

Faigman et al., supra note 58, at 7.

Frye, 293 F. at 1014; see Faigman et al., supra note 58, at 7.


Id. at 587; see also Marks, supra note 99, at 170. In Daubert, the mothers of Jason Daubert and Eric Schuller sued Merrell Dow Pharmaceuticals, Inc., alleging that ingestion of the company’s anti-morning-sickness drug, Bendectin, during pregnancy had caused their sons’ birth defects. 509 U.S. at 582; Marks, supra note 99, at 169. The Daubert plaintiffs proposed that their experts would testify that Bendectin has a chemical structure similar to known teratogens (agents that cause birth defects), that it causes injuries to animal cells in test tubes and to animals in laboratories, and that re-analysis of published epidemiological studies showed a statistical correlation between exposure to Bendectin and incidence of birth defects.
sion, the *Daubert* Court explained the new legal standard for admissibility of expert testimony and scientific evidence under Rule 702.\(^{149}\)

Whereas *Frye* had instructed judges to defer to the general consensus of scientific opinion, the Court in *Daubert* assigned judges the task of determining whether the science upon which expert witnesses base their testimony is reliable.\(^{150}\) The Court found that Rule 702 obliges the trial judge to act as a “gatekeeper,” responsible for evaluating scientific evidence for relevance and reliability.\(^{151}\) The Court declared that, according to Rule 702, judges must determine at the outset of trials “whether the reasoning or methodology underlying the testimony is scientifically valid and ... whether that reasoning or methodology properly can be applied to the facts in issue.”\(^ {152}\) The relevance part of the inquiry—whether the expert testimony will “assist the trier of fact” in assessing a fact in issue—ultimately asks whether an expert’s testimony pertains to the facts of the case.\(^ {153}\) The Court held that, under Rule 702, an expert’s opinion must “relate to an issue that is actually in dispute and must provide a valid scientific connection to the pertinent inquiry” as a precondition to admissibility.\(^ {154}\)

As to reliability, the Court suggested that trial courts consider the following non-exhaustive list of factors: (1) whether the theory or technique at issue can be tested; (2) whether the science has been subject to peer review and publication; (3) whether the technique at issue has a known rate of error; and (4) whether and to what extent the theory or technique has gained general acceptance in the relevant field.\(^ {155}\) In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, (Daubert II), the Ninth Circuit described an additional factor for judges to consider—“whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.”\(^ {156}\) Emphasizing that a judge’s ruling on admissibil-

\(^{149}\) 509 U.S. at 587–92.

\(^{150}\) Id. at 597.

\(^{151}\) Id.

\(^{152}\) Id. at 592–93.


\(^{154}\) Id. (citing Margaret A. Berger, *Procedural Paradigms for Applying the Daubert Test*, 78 MINN. L. REV. 1345, 1351 (1994)); see Daubert, 509 U.S. at 591.

\(^{155}\) Daubert, 509 U.S. at 593–94; see also Graham, 993 F. Supp. at 130.

\(^{156}\) 43 F.3d 1311, 1317 (9th Cir. 1995) [Daubert II]; see also Faigman et al., supra note 58, at 25 n.73.
ity should focus on principles and methodology—not on conclusions—Daubert instructed judges to apply such factors in determining whether an expert’s “methods and reasoning validly support [his/her] proffered . . . testimony.”157

According to Daubert, the trial court should admit a plaintiff’s scientific evidence where it concludes that such evidence is both relevant and reliable.158 It then becomes the fact finder’s task to decide whether the evidence—either by itself or in conjunction with other testimony—supports a finding of general causation.159 As the Court recognized in Daubert, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking . . . admissible evidence.”160

Since Daubert, the Court has issued three other notable opinions that have further shaped admissibility analysis in federal courts.161 In General Electric Co. v. Joiner, the Supreme Court instructed appellate courts to use the deferential “abuse of discretion” standard when determining whether to reverse or uphold district court rulings admitting or excluding scientific evidence.162 In practice, application of the abuse of discretion standard makes it unlikely that appellate courts will undertake de novo review of lower courts’ admissibility rulings.163

The Joiner Court also retreated from Daubert’s emphasis on methodology, asserting that “conclusions and methodology are not entirely distinct from one another.”164 Joiner requires courts to determine the likelihood that an expert witness’s conclusions could reliably result

157Faigman et al., supra note 58, at 25; see Daubert, 509 U.S. at 592–93.
159 See Kennedy, 161 F.3d at 1230; see also Relkin, supra note 158, at 453.
160 Daubert, 509 U.S. at 596.
162 522 U.S. at 139; see also Ned Miltenberg, How to Prevail in Daubert Challenges, available in Westlaw, 2 Ann.2003 ATLA-CLE 2517 (2003). The plaintiff in Joiner, a cigarette smoker, alleged that his exposure to PCBs had caused him to develop lung cancer at a faster rate than he would have from his nicotine addiction alone. Joiner v. Gen. Elec. Co., 78 F.3d 524, 528 (11th Cir. 1996), rev’d, 522 U.S. 136. Applying the “abuse of discretion” standard, the Supreme Court upheld the district court’s finding that the plaintiff’s scientific evidence was inadmissible. Joiner, 522 U.S. at 139.
163 See Branch & Branch, supra note 138.
164 Joiner, 522 U.S. at 146; see also Faigman et al., supra note 58, at 30; Branch & Branch, supra note 138.
from the facts and methodologies upon which they were based.\textsuperscript{165} In Joiner, the Court held that a trial court must exclude evidence which “is connected to existing data only by the ipse dixit of the expert.”\textsuperscript{166} Under Joiner, moreover, “[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”\textsuperscript{167}

A year and a half later, Kumho Tire, Co. v. Carmichael reaffirmed the abuse of discretion standard established in Joiner and extended this standard to courts’ decisions concerning which factors to consider when evaluating the dependability of expert testimony.\textsuperscript{168} Kumho Tire, which expanded the Daubert relevance and reliability tests to non-scientific expert testimony, also described the judge’s task in making a Daubert ruling as ensuring that experts “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”\textsuperscript{169}

Finally, in Weisgram v. Marley Co., the Court ruled that plaintiffs are entitled to only one opportunity to present admissible scientific evidence and testimony to support causation arguments.\textsuperscript{170} Specifically, the Court held that:

\begin{quote}
[A]n appellate court reversing a trial court’s decision to admit expert’s testimony need not remand the case to allow the party a second chance to cure what the appellate court regarded as unreliable evidence (either by allowing the newly disqualified expert an opportunity to provide a better explanation of his or her methodologies, reasoning, and conclusions, or by permitting the expert’s sponsoring party the chance to find other experts who can either validate the first expert’s work and/or substitute for the first expert).\textsuperscript{171}
\end{quote}

Justice Ginsberg expressed the Weisgram Court’s reasoning:

Since Daubert, . . . parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet . . . . It is implausible to suggest, post-Daubert, that parties will initially present less than their best expert evi-

\textsuperscript{165} See Faigman et al., supra note 58, at 30.
\textsuperscript{166} Joiner, 522 U.S. at 146; see also Miltenberg, supra note 162.
\textsuperscript{167} Joiner, 522 U.S. at 146.
\textsuperscript{168} Kumho Tire Co. v. Carmichael, 526 U.S. 137, 142, 152 (1999); see also Berger, Expert Testimony Trends, supra note 140, at 553–54.
\textsuperscript{169} Kumho Tire Co. 526 U.S. at 147–49, 152; see also Miltenberg, supra note 162.
\textsuperscript{170} See 528 U.S. 440, 457 (2000); see also Miltenberg, supra note 162.
\textsuperscript{171} Miltenberg, supra note 162.
dence in the expectation of a second chance should their first try fail.\textsuperscript{172}

Notably, the Committee Notes on the 2000 revisions to Rule 702 mention additional factors that other courts have considered when deciding whether scientific expert testimony should be admitted.\textsuperscript{173} These factors include whether the expert has adequately accounted for obvious alternative explanations, whether the expert “is being as careful as he would be in his regular professional work outside his paid litigation consulting,” and whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.\textsuperscript{174}

IV. Application of \textit{Daubert} to Toxic Tort Cases

An examination of relevant case law reveals that courts generally prefer, and commonly admit, evidence based on epidemiological studies.\textsuperscript{175} In \textit{Brock v. Merrell Dow Pharmaceuticals, Inc.}, the court stated that epidemiological proof was “the most useful and conclusive type of evidence.”\textsuperscript{176} Similarly, in \textit{Pick v. American Medical Systems, Inc.}, the Eastern District of Louisiana noted “that epidemiological data is very important” in determining the relative risk of a product.\textsuperscript{177} Courts have admitted testimony based on epidemiological studies in cases alleging injury caused by asbestos, electro-magnetic radiation, tobacco products, benzene, solvents, and PCBs, to name a few.\textsuperscript{178}

The admissibility of expert opinion on all forms of non-epidemiological studies has been more controversial, and defendants frequently attempt to convince courts that \textit{Daubert} and the Federal Rules require epidemiological evidence to establish general causation in toxic tort cases.\textsuperscript{179} Such attempts are usually in vain.\textsuperscript{180} While it is true that courts sometimes have dismissed cases lacking statistically sig-

\textsuperscript{172} \textit{Weisgram}, 528 U.S. at 455.
\textsuperscript{173} \textit{Fed. R. Evid.} 702 advisory committee’s note; see also \textit{Miltenberg}, \textit{supra} note 162.
\textsuperscript{174} \textit{Fed. R. Evid.} 702 advisory committee’s note.
\textsuperscript{175} \textit{Plater et al.}, \textit{supra} note 82, at 236.
\textsuperscript{176} 874 F.2d 307, 311 (5th Cir. 1989), \textit{modified on reh’g}, 884 F.2d 166 (5th Cir. 1989).
\textsuperscript{177} 958 F. Supp. 1151, 1158 (E.D. La. 1997).
\textsuperscript{178} \textit{Faigman et al.}, \textit{supra} note 58, at 285. According to Faigman et al., “[b]ecause the techniques of epidemiological analysis are now so well accepted, a body of statistically significant and substantively important epidemiological evidence would probably suffice to prove general causation even if the plaintiff were unable to provide a good scientific theory as to how the exposure caused a given injury.” \textit{Id.} at 292.
\textsuperscript{179} \textit{See Relkin}, \textit{supra} note 158, at 441, 454.
\textsuperscript{180} \textit{See id.} at 454.
nificant epidemiological evidence, the same courts that have required epidemiological support in certain cases have also specifically declined to hold that epidemiological studies are required in all toxic tort litigation. For example, in Brock, a pre-Daubert decision which Daubert cited approvingly, the Second Circuit expressly stated that its holding should not be read to signify “that epidemiological proof is a necessary element in all toxic tort cases.”

One leading commentator in this area has suggested that courts are most likely to require epidemiological studies in mass tort litigation, whereas judges tend to admit toxicological and other support in cases involving just one or a few plaintiffs. Courts seem especially reluctant to require epidemiological studies of small numbers of plaintiffs where such data is unavailable.

Often, a court’s determination of whether to admit non-epidemiological evidence has depended on the existence of contradictory epidemiological evidence. For example, in Richardson v. Richardson-Merrell, Inc., the D.C. Circuit refused to admit evidence based on structure-activity, in vitro, and animal studies because a vast body of epidemiological data on the substance in question had failed to link exposure to that substance to the kind of reproductive problems suffered by the plaintiff. There, the court held that the law “[u]niquely . . . ha[d] the benefit of twenty years of scientific study, and the published [epidemiological] results [required] . . . their just due.” Similarly, the D.C. Circuit in Raynor v. Merrell Pharmaceuticals, Inc. found that the plaintiffs’ evidence of causation based on live-animal studies, animal-cell studies, and chemical-structure analyses was insufficient to reach the jury, given the extensive epidemiological data supporting the opposite conclusion.

184 Id. at 289.
185 Id. at 347–48.
186 857 F.2d 823, 832 (D.C. Cir. 1988); see also Faigman et al., supra note 58, at 347.
187 Richardson, 857 F.2d at 832.
188 104 F.3d 1371, 1374–75 (D.C. Cir. 1997) (granting summary judgment in favor of defendant and finding plaintiff’s expert’s methodology unsound in light of epidemiology
In the absence of epidemiological studies, plaintiffs are more likely
to succeed at having expert testimony based on toxicology reach the
jury.\textsuperscript{189} For instance, in \textit{Benedi v. McNeil-P.P.C., Inc.}, a case in which nei-
ther plaintiff nor the defendant proposed epidemiological evidence of
a causal connection between Tylenol and liver damage, the Fourth Cir-
cuit explained: “Under the \textit{Daubert} standard, epidemiological studies
are not necessarily required to prove causation, as long as the method-
ology employed by the expert in reaching his or her conclusion is
sound.”\textsuperscript{190} Likewise, in \textit{Ambrosini v. Labarraque}, the court noted that,
“[e]ven where a party has admitted that no biochemical or epidemi-
ological test has been done that can conclusively establish a link between
a drug and an illness . . . expert evidence on the subject is not rendered
inadmissible.”\textsuperscript{191} Quoting an EPA toxicologist, the Third Circuit in \textit{In re
Paoli R.R. Yard PCB Litigation} stated that, “[i]n the absence of epidemi-
ologic proof in humans we must drop to our second tier in the under-
standing of human [disease] prediction: Animal testing.”\textsuperscript{192}

Courts have also admitted toxicological data where no epidemi-
ological studies exist due to ethical considerations.\textsuperscript{193} For example, in
\textit{Dawsey v. Olin Corp.}, a federal court admitted toxicological evidence
based on animal studies, where construction-worker plaintiffs suffered
injuries after being exposed to a cloud of phosgene gas at work.\textsuperscript{194}
There, conducting epidemiological studies would have required expos-
ing humans to potentially toxic substances; such studies would have
been unethical.\textsuperscript{195} The court concluded that the absence of epidemi-
ological evidence was not grounds for dismissal because “[s]hort of intention-
ally exposing humans to phosgene, it would be difficult to learn
any more about the effects of [the chemical].”\textsuperscript{196}

In such circumstances, courts repeatedly have observed that objec-
tions to the admissibility of non-epidemiological evidence are better
suited to “‘the traditional and appropriate means of attacking shaky but admissible evidence,’ i.e., ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof . . . .’”197 It would seem, therefore, that toxicological evidence is rarely per se inadmissible.198 Courts often express concerns, however, about the questions of external validity that may be raised by using toxicological evidence to support causal inferences.199 Accordingly, courts look closely at the analytical leaps an expert may have taken to extrapolate toxicological data to human injury—the greater the gap, the less willing a court is likely to be to allow testimony to reach a jury.200

Courts generally find in vivo studies to be the most reliable type of non-epidemiological evidence.201 Still, many courts are hesitant to allow testimony based on animal studies to reach a jury, if the studied substance, injury, or dose rate differs from that at issue in the case.202 Testimony based on in vitro studies and SARs are least likely to be admitted.203 “For most courts, the admissibility of toxicological evidence turns on the quality of other types of admissible data—especially epidemiological data—and the degree to which toxicological findings address the specific causal questions . . . .”204

V. WILL REACH DATA ASSIST PLAINTIFFS WITH ESTABLISHING GENERAL CAUSATION?

A. WILL REACH COVER THE CHEMICAL IN QUESTION?

In analyzing the likelihood that REACH will assist U.S. plaintiffs in establishing general causation, the first step is to determine whether the new regulations will generate data on the chemical substance claimed to have caused the plaintiff’s injury. Because REACH requires the submission of data on the majority of chemicals in use today, in most instances REACH likely will cover the chemical in question.205

198 See Faigman et al., supra note 58, at 347–57.
199 Id. at 349.
200 See id.
201 Id.
202 Id. at 352 & n.48.
203 Id. at 349.
204 See Faigman et al., supra note 58, at 369.
205 See Karmel, supra note 13.
There are notable exceptions, however, that may limit REACH’s utility to some American plaintiffs.\textsuperscript{206} For example, REACH exempts manufacturers and importers of substances in quantities of less than one ton per year from REACH registration.\textsuperscript{207} This exception to the “no data, no market” principle\textsuperscript{208} reflects a policy decision by EU member states that the limited risk of exposure in such instances fails to warrant regulatory action.\textsuperscript{209} The fact that EU regulators have determined that the costs of testing and compliance with the REACH process sufficiently outweigh the benefits of extending REACH requirements to these substances, however, does not mean that injuries from exposure to such chemicals are impossible or will not occur.\textsuperscript{210} Thus, in exempting such low-volume substances, REACH may fail to provide at least some plaintiffs with probative evidence on general causation.\textsuperscript{211}

REACH also provides registrants with the opportunity to appeal ECHA decisions that demand testing beyond that required for registration compliance.\textsuperscript{212} Notably, this appeals process provides manufacturers and importers with an additional means of attempting to avoid the submission of complete data on chemicals and may likewise result in an information gap for interested plaintiffs.\textsuperscript{213}

Moreover, for manufacturers and importers of certain substances, REACH only requires testing proposals—not actual safety and health data.\textsuperscript{214} The extent to which the “testing proposal” provisions of REACH will limit the chemicals actually studied under the legislation remains to be seen. While REACH instructs ECHA to evaluate all testing proposals to determine whether proposed studies are needed to adequately assess health risks of particular substances, it seems likely that ECHA will refrain from requiring actual testing of some chemicals.\textsuperscript{215} Further, at least some manufacturers and importers can be expected to submit testing proposals in lieu of actual data, so as to mini-

\textsuperscript{206} See REACH in Brief, supra note 12, at 6–7.
\textsuperscript{207} Id. at 6.
\textsuperscript{208} Denison, supra note 1, at I-6; Karmel, supra note 13.
\textsuperscript{209} See REACH in Brief, supra note 12, at 6, 12.
\textsuperscript{210} See id. (noting that authorization “\textit{may} be granted where socio-economic benefits outweigh the risks and there are no suitable alternative substances or processes”).
\textsuperscript{211} See id.
\textsuperscript{212} REACH, supra note 10, art. 50; see also Denison, supra note 1, at IV-28.
\textsuperscript{213} See Denison, supra note 1, at IV-28.
\textsuperscript{214} REACH in Brief, supra note 12, at 7; DEFRA, supra note 65.
\textsuperscript{215} See REACH, supra note 10, art. 40; Denison, supra note 1, at V-3.
mize costs and limit REACH scrutiny. The more rigorously ECHA pursues actual testing, the more likely it will be that data concerning chemicals under scrutiny in American litigation will be available to plaintiffs.

Finally, REACH may not cover certain chemicals because manufacturers or importers may choose not to market them in the post-REACH EU. For example, registrants may decide to switch to safer, less toxic alternatives for EU consumers prior to REACH registration deadlines. Since REACH only applies to chemicals manufactured in or imported into the European Union, some substances that manufacturers continue to produce for American consumption may never be registered under REACH, thereby depriving U.S. plaintiffs of access to health-toxicity data that REACH otherwise would have provided.

B. Will Plaintiffs Have Sufficient Access to REACH Data?

Assuming that REACH will generate data on a substance alleged to have caused a plaintiff’s injury, the next step is to consider whether REACH will provide U.S. plaintiffs, attorneys, and experts adequate access to the relevant information. On the positive side, REACH represents a significant improvement over previous European chemicals legislation which typically neither mandated nor encouraged public disclosure of environmental and health safety information. On the negative side, however, because REACH attempts to balance industry concerns for keeping certain “proprietary” information secret against the public’s need to access safety data, the new chemicals legislation may not always provide plaintiffs with adequate information.

At a minimum, the data that REACH promises to make available to the public on the ECHA website should familiarize plaintiffs with the list of substances most scrutinized under REACH, including chemicals

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216 See Denison, supra note 1, at I-9.
217 See Austin & Bowden, supra note 9, at 7.
218 See Schapiro, supra note 1, at 10–11; Austin & Bowden, supra note 9, at 7 (noting that REACH may “oblige some consumer products companies doing business in Europe to change the formulations of their products . . . that they supply to [European] consumers”).
219 See REACH in Brief, supra note 12, at 5; Schapiro, supra note 1, at 10–11; Austin & Bowden, supra note 9, at 7.
220 See Denison, supra note 1, at VII-8 (also noting the stark contrast between REACH information disclosure provisions and those of TSCA); Schapiro, supra note 1, at 138.
221 See REACH, supra note 10, arts. 118, 119; see also Denison, supra note 1, at VII-5 to -8 (discussing categories of information to be disclosed or kept confidential under REACH); Schapiro, supra note 1, at 138.
that ECHA has determined pose the greatest and/or best understood risks to human health and the environment.\textsuperscript{222} For example, Article 119 of REACH provides that ECHA shall post data on the substances that ECHA has chosen to evaluate, dossiers prepared on substances proposed for authorization and restriction, and final Agency committee opinions concerning restriction decisions.\textsuperscript{223} Similarly, the ECHA website will publish information on the classification and labeling of substances and analytical methods that make it possible to detect a dangerous substance when discharged into the environment, as well as to determine the direct exposure to humans.\textsuperscript{224} Where this information enables experts and courts to understand which theories and methodologies REACH registrants have used in developing technical data, it should likewise aid plaintiffs in establishing \textit{Daubert} relevance and reliability.\textsuperscript{225}

Article 119 also requires that ECHA publish online physicochemical data concerning registered substances, information on pathways and environmental fate, and results of each toxicological and ecotoxicological study.\textsuperscript{226} For plaintiffs, having this information in most cases should be better than having none at all.\textsuperscript{227} Nonetheless, plaintiffs will likely require more detailed information if they are to convince U.S. federal courts of the admissibility of such evidence.\textsuperscript{228} Specifically, to make determinations about the admissibility of \textit{data} and \textit{results} under \textit{Daubert}, federal “gatekeeping” judges can be expected to inquire into the methodologies used to achieve them.\textsuperscript{229}

Fortunately for plaintiffs, REACH will make methodology-specific information available unless the manufacturer or importer petitions

\textsuperscript{222} See \textit{REACH}, supra note 10, art. 77, ¶ (2)(f), (n); see also \textit{Denison}, supra note 1, at VII-7 to -8.

\textsuperscript{223} See \textit{REACH}, supra note 10, art. 77, ¶ (2)(f); see also \textit{Denison}, supra note 1, at VII-7 to -8.

\textsuperscript{224} See \textit{REACH}, supra note 10, art. 119, ¶ 1(c), (h); see also \textit{Denison}, supra note 1, at VII-6.

\textsuperscript{225} See \textit{Gen. Elec. Co. v. Joiner}, 522 U.S. 136, 146 (1997); \textit{Daubert v. Merrell Dow Pharm., Inc.}, 509 U.S. 579, 592–93 (1993) (noting that trial judges must consider “whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue”); see also \textit{Branch & Branch}, supra note 138.

\textsuperscript{226} See \textit{REACH}, supra note 10, art. 119, ¶ 1(d); see also \textit{Denison}, supra note 1, at VII-6.

\textsuperscript{227} See \textit{Plater et al.}, supra note 82, at 212 (noting that “[f]or [toxic tort] plaintiffs, the trick often has been to find probative evidence that can be obtained without great cost”).

\textsuperscript{228} See \textit{Daubert}, 509 U.S. at 592–93; see also \textit{Branch & Branch}, supra note 138.

\textsuperscript{229} \textit{Daubert}, 509 U.S. at 592–93.
against its publication. It is reasonable to expect, however, that those registrants intent on protecting as much information about potentially harmful products as possible will petition early and often. ECHA has yet to develop criteria to evaluate the validity of nondisclosure requests. Therefore, it is presently unclear how severely plaintiffs’ access to methodological information will be limited under REACH. Seemingly, the more petitions that ECHA honors, the more difficult it will be for plaintiffs and their experts to access critical information.

C. Will Plaintiffs Want to Use REACH Data: Can Registrant Studies Be Trusted?

Further assuming that plaintiffs are able to access relevant data through REACH, the next step is to consider the likelihood that REACH data will point to a causal relationship between exposure to the substance in question and the applicable disease. Given that REACH makes manufacturers responsible for studying and managing the risks of the chemicals they produce, and that ECHA is responsible for evaluating only a “certain percentage” of the hundreds of thousands of registrations it will receive, it seems likely that some registrants will get away with submitting less-than-reliable data of little value to plaintiffs.

There can be no question that industry has every incentive to interpret data they develop to their advantage, thereby avoiding possible restrictions on access to the EU market. As such, “it is difficult to imagine that many of the assessments submitted by industry will indicate significant risk [posed by] the chemicals in question.” Because under REACH, “government largely plays an oversight role, with authority—but only limited obligation—to evaluate industry’s assessments, require more information or testing, or impose controls,” it seems that the reliability of REACH data for plaintiffs often will hinge

230 See REACH, supra note 10, art. 119, ¶ 2; see also Denison, supra note 1, at VII-6.
231 See Denison, supra note 1, at ¶ 2; see also Denison, supra note 1, at VII-6.
232 See id. at VII-6 n.281.
233 REACH, supra note 11, pmbl. ¶¶ 18–19; Denison, supra note 1, at I-7 to -9.
234 REACH, supra note 10, pmbl. ¶ 65.
235 See Denison, supra note 1, at I-8 to -9.
236 See id.
237 Id. at I-9.
on the extent to which ECHA and EU Member States take seriously their evaluation, authorization, and restriction roles.\textsuperscript{239} 

On the other hand, it is possible that REACH-registered data itself may be reliable, while the registrant’s risk assessments based on that data are questionable. This set of circumstances may pose less of a problem for plaintiffs, and for expert witnesses who may be able to draw different conclusions from the data in support of the plaintiff’s claims.\textsuperscript{240} In either situation, increasing the frequency, thoroughness, and independence of ECHA evaluations of industry data will lead to a greater likelihood that REACH will produce reliable information that is useful to plaintiffs in establishing causation.\textsuperscript{241}

D. Will REACH-Based Evidence Pass Daubert Muster?

Where REACH provides reliable data that a plaintiff would like to use to establish general causation, the litigant finally must consider whether the relevant REACH data will satisfy criteria for admission to U.S. federal courts, as stipulated in Federal Rule of Evidence 702.\textsuperscript{242} To determine whether REACH data will meet Rule 702 requirements, it is necessary to assess the information under the Supreme Court’s analysis in \textit{Daubert v. Merrell Dow Pharmaceuticals, Inc.}, and subsequent cases.\textsuperscript{243} According to \textit{Daubert}, success under Rule 702 requires that “the reasoning or methodology underlying the testimony [be] scientifically valid and . . . that [the] reasoning or methodology properly can be applied to the facts in issue.”\textsuperscript{244} The REACH data upon which an expert bases his or her testimony, therefore, must be both relevant and reliable.\textsuperscript{245}

The relevance inquiry is usually straightforward—a simple matter of whether the data upon which testimony is based provides evidence linking exposure to the substance in question to the disease suffered by the plaintiff.\textsuperscript{246} As long as the REACH data and the expert’s opinion on that data relate to the “issue that is actually in dispute [in the case] and

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\textsuperscript{239} See \textit{Denison}, \textit{supra} note 1, at I-8. It seems likely that adequate staffing and funding for ECHA will be crucial to completion of timely reviews and discovery of deficiencies in industry assessments and management of risk. \textit{Id.}
\textsuperscript{240} See \textit{Schapiro}, \textit{supra} note 1, at 11–12 (noting that the same data reviewed by different scientists may yield “entirely different conclusions”).
\textsuperscript{241} See \textit{Denison}, \textit{supra} note 1, at I-9; \textit{REACH IN BRIEF}, \textit{supra} note 12, at 11–12.
\textsuperscript{243} 509 U.S. at 587–95; \textit{see also} \textit{Marks}, \textit{supra} note 99, at 170–71.
\textsuperscript{244} 509 U.S. at 592–93.
\textsuperscript{245} \textit{See id.}
\end{flushright}
provide a valid scientific connection to the pertinent inquiry,” there should be little serious questioning of the data’s relevance.247

The trial judge’s assessment of reliability, on the other hand, tends to be more complex.248 To determine whether “the subject of an expert’s testimony [is valid] scientific knowledge”—that is, an understanding of the information grounded “in the methods and procedures of science” and based upon “more than subjective belief or unsupported speculation”249—trial courts are likely to consider the following non-exhaustive list of factors suggested in Daubert: (1) whether the theory or technique at issue can be tested; (2) whether the science has been subject to peer review and publication; (3) whether the technique at issue has a known rate of error; and (4) whether and to what extent the theory or technique has gained general acceptance in the relevant field.250 Courts may also consider “whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation.”251 To predict whether courts will view REACH data as satisfying these factors, it is helpful to examine how courts since Daubert have confronted the issue of which types of scientific evidence are valid and whether REACH will generate these kinds of evidence.252

Courts generally have preferred and admitted testimony based on epidemiological studies.253 REACH, however, does not require manufacturers to develop and register epidemiological data.254 REACH does request that registrants submit pre-existing data, such as epidemiological studies, where available, during the registration process, but registrants are never required to include this information in technical dossiers or CSRs.255 Because epidemiological data often provides the strongest basis for inferences causally linking various chemicals to disease, it is unlikely that registrants would voluntarily submit epidemiological data demonstrating adverse effects.256 Nonetheless, where

247 See Daubert, 509 U.S. at 591; Graham, 993 F. Supp. at 130.
248 See Daubert, 509 U.S. at 593–94.
249 Id. at 590.
250 See id. at 593–94; Faigman et al., supra note 58, at 23–24.
251 Daubert II, 43 F.3d 1311, 1317 (9th Cir. 1995); see also Faigman et al., supra note 58, at 25 n.73.
252 See Faigman et al., supra note 58, at 283, 343.
254 See, e.g., REACH, supra note 10, Annex XI; see also Denison, supra note 1, at IV-28.
255 See REACH, supra note 10, Annexes VII–X.
256 See Faigman et al., supra note 58, at 283; Denison, supra note 1, at iv, I-9.
REACH data includes statistically significant epidemiological studies, federal courts are likely to deem them admissible.\footnote{See \textit{Faigman et al.}, \textit{supra} note 58, at 285.}

The fact that REACH will produce little if any epidemiological data—instead relying on non-epidemiological studies to evaluate the health and safety effects of chemical substances—should not, in and of itself, preclude plaintiffs from using REACH data as probative evidence of general causation in most cases.\footnote{See \textit{id.} at 347–57.} While it is true that courts sometimes have found a failure to present statistically significant epidemiological proof to be fatal to a case, the same courts that have required epidemiological evidence in some instances have also specifically declined to hold that epidemiological studies are required in all toxic tort litigation.\footnote{See \textit{Relkin, Motions In Limine}, \textit{supra} note 181, at 385–86.} Reliance on precedent indicates that if proffered, non-epidemiological REACH data contradicts extensive epidemiological data, its chances of survival are at their lowest ebb.\footnote{See \textit{Raynor v. Merrell Pharm., Inc.}, 104 F.3d 1371, 1374–75 (D.C. Cir. 1997); Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 832 (D.C. Cir. 1988); \textit{see also Faigman et al.}, \textit{supra} note 58, at 347–48.} In the absence of a vast body of epidemiological studies to the contrary, however, REACH data based on toxicological methods—such as animal studies, in vitro testing, and SARs—are likely to be admitted under \textit{Daubert}.\footnote{See \textit{Benedi v. McNeil P.P.C.}, Inc., 66 F.3d 1378, 1384 (4th Cir. 1995); Ambrosini v. Labarraque, 101 F.3d 129, 138–39 (D.C. Cir. 1996); \textit{see also Faigman et al.}, \textit{supra} note 58, at 356–57; \textit{Relkin, supra} note 158, at 457.}

Courts are least likely to require epidemiological support from individual plaintiffs.\footnote{Faigman \textit{et al.}, \textit{supra} note 58, at 288 (discussing \textit{Boston, supra} note183, at 303–05)).} Therefore, REACH toxicological data may be most beneficial to non-mass tort litigants.\footnote{See \textit{id.}} Further, according to the court in \textit{Dawsey v. Olin}, sometimes the ethical and practical dilemmas associated with epidemiological studies are insurmountable, and in vivo, in vitro, and SARs studies can provide methodologically sound substitutes for epidemiology.\footnote{Faigman \textit{et al.}, \textit{supra} note 58, at 356.} Accordingly, in situations where, “[s]hort of intentionally exposing humans to [the substance in question], it would be difficult to learn any more about the effects of [the] chemical” and its relationship to a particular disease without toxico-
logical studies, courts are likely to find it prudent to rely upon evidence based upon animal studies, in vitro testing, and SARs analyses.\textsuperscript{265}

Thus, the good news for REACH plaintiffs is that federal court precedent seems to establish that \textit{Daubert} allows for the admission of toxicological evidence—\textsuperscript{266}the type of data that REACH will provide.\textsuperscript{267} The downside, however, is that REACH simply is unlikely to provide plaintiffs with the most conclusive types of non-epidemiological evidence.\textsuperscript{268} While courts have generally found in vivo studies to be the most reliable form of toxicology,\textsuperscript{269} REACH expressly discourages animal testing out of concerns for animal welfare and a desire to minimize costs to industry.\textsuperscript{270} By providing for alternative methods to direct animal testing, REACH essentially invites industry to avoid the types of studies that are most likely—in a courtroom—to solidify causal links between substances and carcinogenic, teratogenic, and mutagenic effects.\textsuperscript{271} Courts may decide to admit REACH data based on in vitro studies and SARs analysis but are likely to do so only when other, weightier admissible evidence also supports the claimed causal connection.\textsuperscript{272}

\textbf{Conclusion}

While REACH may from time to time provide plaintiffs with access to additional evidence useful for establishing general causation in toxic tort litigation, plaintiffs should keep in mind that REACH data, by itself, is unlikely to support claims linking a particular substance to a claimed injury. To ensure that proffered evidence of general causation reaches the jury, plaintiffs are advised to rely primarily—and extensively—on traditional supporting sources.

Looking forward, one may also be hopeful that various amendments to REACH, closing current loopholes advantageous to regis-

\begin{footnotes}
\item[265] See \textit{Dawsey}, 782 F.2d at 1263; see also \textit{Faigman et al.}, supra note 58, at 356.
\item[266] See \textit{Faigman et al.}, supra note 58, at 347–57; \textit{Relkin}, supra note 158, at 457.
\item[267] See, e.g., \textit{REACH}, supra note 10, Annex VIII; see also \textit{Denison}, supra note 1, at IV-28 to -29.
\item[268] See, e.g., \textit{REACH}, supra note 10, Annex VIII; see also \textit{Denison}, supra note 1, at IV-28 to -29; \textit{Faigman et al.}, supra note 58, at 349.
\item[269] \textit{Faigman et al.}, supra note 58, at 349 (noting that “\textit{a}nimal studies are generally thought to be more probative than other types of toxicological data, and, therefore, courts are more likely to exclude testimony that is based solely on in vitro studies or on a structure-activity analysis”).
\item[270] See \textit{Denison}, supra note 1, at IV-28 to -29 (noting that REACH encourages the substitution of animal studies with in vitro and SARs data wherever possible).
\item[271] See id.; see also \textit{Faigman et al.}, supra note 58, at 349.
\item[272] See \textit{Faigman et al.}, supra note 58, at 350.
\end{footnotes}
trants, could render REACH data more beneficial to toxic tort plaintiffs. Moreover, as REACH amasses its chemical data, the scientific understanding of biological mechanisms and causal relationships to be derived from such data likewise will continue to grow. For this reason, REACH may prove increasingly useful to plaintiffs over time, despite its current limitations, assuming that courtroom evaluations of methodological validity adapt accordingly.

Although REACH may provide additional data in support of some toxic tort plaintiffs’ claims, it seems clear that reliance on the new EU chemicals regime is insufficient to adequately protect American consumers from the potential dangers of everyday chemicals. In light of increasing awareness of the serious health and environmental consequences associated with exposure to everyday chemicals, Americans deserve more from their government. Accordingly, immediate steps towards overhauling federal chemicals regulation—on this side of the Atlantic—are imperative.