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A TOUGH PILL TO SWALLOW: THE INSURMOUNTABLE BURDEN IN TOXIC TORT CLAIMS AGAINST MANUFACTURERS OF CHILDREN'S MEDICATIONS

*Susanne L. Flanders**

INTRODUCTION

The recent removal of many over-the-counter children's cough and cold medications from pharmacy shelves has raised public concern about the dangers of children's medications.¹ Many drug manufacturers voluntarily withdrew these drugs from the market after the Food and Drug Administration (FDA) recommended that they not be used in children under the age of six.² The recommendation came after studies showed that in 2004 more than 1500 infants had experienced "adverse events"³ following their ingestion of cold and cough medications,⁴ and between 1969 and 2006, more than 120 children aged two and younger had died from overdoses and toxicity associated with these drugs.⁵ Despite these

* Brooklyn Law School, Class of 2008; B.S., Villanova University, 2002. The author would like to thank the staff of the Journal of Law and Policy. The author would also like to thank her friends and family for their love and support.

¹ See, e.g., Gardiner Harris, *Makers Pull Infant Cold Medicines*, N.Y. TIMES, Oct. 11, 2007, at A18.

² Christopher Hollis, *Advisory Committees Recommend Against Cough and Cold Medications in Children Under 6*, DRUG INDUSTRY DAILY, Oct. 22, 2007.

³ Bob Meadows, *Baby Cold Medicine*, PEOPLE, Oct. 29, 2007, at 74.

⁴ *Id.*

⁵ Debra Sherman, *Drugmakers Recall Infant Cough/Cold Medicine*, REUTERS, Oct. 11, 2007.

findings, many pharmaceutical manufacturers have continued selling their products.⁶ Furthermore, until a withdrawal is mandated, manufacturers will continue to profit from these medications while children continue to suffer the harmful consequences.⁷

Every year, hundreds of thousands of people report to the FDA that they have sustained a possible adverse drug reaction.⁸ In fact, adverse reactions to medications are one of the leading causes of death in the United States, accounting for more than 100,000 fatalities yearly.⁹ Further, it has been suggested that this number may be a gross underestimate because more than ninety percent of adverse reactions go unreported or undetected.¹⁰

Adverse drug reactions create serious, widespread social problems including increased morbidity and mortality rates, longer

⁶ See, e.g., Gardiner Harris, *Experts Seek Ban on Cold Medicine for Very Young*, N.Y. TIMES, Sept. 28, 2007, at A1.

⁷ Catherine Larkin, *Wyeth, J&J Halt U.S. Sales of Infant Cold Medicines*, Oct. 11, 2007, <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aYrOYusxh3jI> (“U.S. sales of non-prescription cold remedies for children rose [twenty] percent to \$311 million in year ended Sept.8 [2007], according to market research firm AC Nielson.”).

⁸ Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data to Promote Patient Welfare*, 49 CATH. U. L. REV. 449, 452 (2000) (citing CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEP’T OF HEALTH & HUMAN SERVS., 1998 REPORT TO THE NATION 22 (1998), available at <http://www.fda.gov/cder/reports/rptntn98.pdf>).

⁹ Noah, *supra* note 8, at 449 (citing Denise Grady, *Study Says Thousands Die from Reaction to Medicine*, N.Y. TIMES, Apr. 15, 1998, at A1; U.S. Gen. Accounting Office, Pub. No. GAO/PEMID-90-15, *FDA Drug Review: Postapproval Risks 1976-85*, at 3 (1990); Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies*, 279 JAMA 1200, 1202 (1998); John A. Anderson, *Allergic Reactions to Drugs and Biological Agents*, 268 JAMA 2845, 2845 (1992)).

¹⁰ One reason is that overburdened health care providers often fail to issue Adverse Reaction Reports to manufacturers, who in turn, are unable to identify when there is a problem with a medication they have produced. See Margaret Berger & Aaron Twerski, *Uncertainty and Informed Choice: Unmasking Daubert*, 104 MICH. L. REV. 257, 261 (2005) (citing Michael A. Friedman, *What Is the Value of an FDA Approval in a Judicial Matter?*, 12 J.L. & POL’Y 559, 570 (2004)).

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hospital stays, and decreased quality of patient care.¹¹ This places high financial burdens on both patients and the health care system as a whole.¹² Perhaps more importantly, it puts the public in harm's way.

Many of the adverse drug reactions that were reported in the past could be traced back to a lack of adequate safety testing that resulted in insufficient data about the drugs.¹³ Of the "230,000 reports of possible adverse drug reactions" that the FDA receives each year, "approximately ten percent of th[em] raise concerns about serious reactions that pre-approval clinical trials failed to detect."¹⁴ The chairman of Pfizer recently acknowledged that clinical trials often fail to reveal problems with the drugs, stating "'You put the drug in the general population, and then everyone is taking it We just hold our breath and wait to see if there is something unique with the drug.'"¹⁵

¹¹ David W. Bates et al., *The Costs of Adverse Drug Events in Hospitalized Patients*, 277 JAMA 307, 307, 311 (1997); Noah, *supra* note 8, at 450 (citing David C. Classen et al., *Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality*, 277 JAMA 301, 301, 305 (1997)).

¹² Bates, *supra* note 11, at 311; Noah, *supra* note 8, at 450 (citing David C. Classen et al., *Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality*, 277 JAMA 301, 301, 305 (1997)).

¹³ See Nathaniel Garrett, Note, "Life is a Risk We Cannot Refuse:" *A Precautionary Approach to Toxic Risks We Can*, 17 GEO. INT'L ENVTL. L. REV. 517, 531 (2005) ("This problem has even been documented by industry, such as in a Chemical Manufacturers Association study which noted that significant data is lacking in over ninety percent of the high-volume chemicals used in United States commerce.") (citing David Roe, *Ready or Not: The Coming Wave of Toxic Chemicals*, 29 ECOLOGY L.Q. 623, 627-28 (2002)).

¹⁴ Noah, *supra* note 8, at 452 (citing CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEP'T. OF HEALTH & HUMAN SERVS., 1998 REPORT TO THE NATION 22 (1998), available at <http://www.fda.gov/cder/reports/rptntn98.pdf>).

¹⁵ Melody Petersen, *Unforeseen Side Effects Ruined One Blockbuster*, N.Y. TIMES, Aug 27, 2000, at § 3 (Money and Business/Financial Desk), at 11 (quoting William C. Steere Jr., the chairman of Pfizer, following the removal of its drug, Trovan, from the market). Trovan was a popular antibiotic that was prescribed to approximately 300,000 patients a month before it was shown to have caused serious side effects including liver toxicity and death. *Id.* These side effects hadn't been detected in the clinical trials that Pfizer conducted prior to

Children's medications undergo even less safety testing.¹⁶ In fact, approximately seventy-five percent of medications that are prescribed to pediatric populations have only been studied for use in adults,¹⁷ indicating that any information about the safety and efficacy of most pediatric drugs is inadequate or simply absent.¹⁸ As a result, pediatricians and other health care providers are often forced to prescribe drugs that lack adequate pediatric dosing information and that have not been proven safe and effective for use in children.¹⁹ Because child-tested drugs rarely exist,²⁰ it is very common for physicians, after the FDA has approved a drug for adult use, to issue *off-label* prescriptions to children wherein they must use physiological and pharmacokinetic principles from adults to make judgments about what dosages and usages of medications are safe for children.²¹ This method, however, is often flawed because children vary from adults in many respects, including the methods and rates at which they metabolize drugs.²² Further, the FDA does not regulate this practice in any manner whatsoever.²³ Children, therefore, are regularly exposed to medications that are, at best, ineffective in treating their ailments, and at worse, pose

FDA approval). *Id.*

¹⁶ See David Wendler et al., *Quantifying the Federal Minimum Risk Standard*, 292 JAMA 826 (2005).

¹⁷ *Id.* (citing R. Roberts, W. Rodriguez, D. Murphy & T. Crescenzi, *Pediatric Drug Labeling: Improving the Safety and Efficacy of Pediatric Therapies*, 290 JAMA 905, 905–11 (2003)).

¹⁸ Peter P. Budetti, *Ensuring Safe and Effective Medications for Children*, 290 JAMA 950, 950 (2003) (citing R. Roberts, W. Rodriguez, D. Murphy & T. Crescenzi, *Pediatric Drug Labeling: Improving the Safety and Efficacy of Pediatric Therapies*, 290 JAMA 905, 905–11 (2003)).

¹⁹ *Id.*

²⁰ *See id.*

²¹ *Id.*

²² Duane Alexander, *Regulation of Research With Children: The Evolution From Exclusion to Inclusion*, 6 J. HEALTH CARE L. & POL'Y 1, 1 (2002) ("It had been amply demonstrated that children were not just small adults, and in many instances attempts to extrapolate from adult studies to applications in children were folly.")

²³ Alexander, *supra* note 22, at 1 (citing *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000)).

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dangerous risks that often result in serious injury and sometimes death.²⁴

Sometimes drug manufacturers make a “willful, strategic choice” not to conduct adequate testing.²⁵ For example, “[m]akers of . . . Bendectin [and] DES . . . dug in their heels and resisted conducting safety research on their products, even when preliminary study indicated that the [medications] harmed the public.”²⁶ This approach is still common among manufacturers, despite instances when they have been held at least partially liable for failing to adequately test their products and for the resulting harm the products caused.²⁷

Worse yet, sometimes manufacturers are fully aware of the dangers associated with their products, but still keep them on the market without adequately warning consumers:

Numerous industries that have had exclusive information about the risk posed by their product have concealed information to protect their bottom-line: examples include the tobacco industry, which long denied a causal link between smoking and disease; the asbestos industry, which concealed evidence associating asbestos with lung disease

²⁴ See Wendler et al., *supra* note 16, at 826 (citing P.H.Y. Caldwell, S.B. Murphy, P.H. Butow, & J.C. Craig, *Clinical Trials in Children*, 364 LANCET 803, 803–11 (2004)).

²⁵ Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1638 (2004).

²⁶ *Id.* at 1638–39 (2004) (citing Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 321 (1992) (explaining that Bendectin’s manufacturer, Merrell Dow, faced a great deal of claims alleging the product was linked to birth defects because the company did not conduct substantial testing before the drug was marketed); *Bichler v. Eli Lilly & Co.*, 436 N.E.2d 182 (N.Y. 1982) (DES was a drug that was prescribed to help prevent miscarriages. However, the drug was marketed by Eli Lilly & Co. before adequate testing had been conducted. It was later determined that if the company had properly tested the drug in mice, its carcinogenic tendencies would have been detected)).

²⁷ Wagner, *supra* note 25, at 1639 (2004) (citing James A. Henderson, Jr., *Product Liability and the Passage of Time: The Imprisonment of Corporate Rationality*, 58 N.Y.U. L. REV. 765, 779 (1983)).

for thirty years; the Industrial Bio-Test (IBT) scandal in which a contract toxicology facility that conducted forty percent of all United States toxicological testing systematically understated cases of cancer in animals in laboratory tests of pesticides; and historical concealment by the lead, silica and vinyl industries.²⁸

We now know that corporations involved in the manufacturing of many widely used products did not conduct adequate pre-market testing, did not disclose information regarding potential harmful side effects when the information was ascertained, and chose not to conduct additional testing in light of information about adverse effects.²⁹ ““These companies just do it again and again They try to create much larger markets for these drugs than is warranted, particularly given what they know about the risks.”³⁰

Drug manufacturers’ failure to conduct adequate safety testing and disclose known risks persists despite FDA regulation.³¹ The studies that are required by the FDA are often insufficient to establish a causal link between a plaintiff’s injury and the medication because they don’t account for latent effects, rare reactions, population variations, drug interactions, and pre-existing susceptibilities to injury.³² Moreover, after the FDA has approved a drug, it does not have the authority over drug manufacturers to require further research, even when physicians prescribe the drug for uses that have not been adequately tested.³³ As a result of

²⁸ Garrett, *supra* note 13, at 559 (2005) (citing WILLIAM LEISS & CHRISTINA CHOCIOLO, *RISK AND RESPONSIBILITY* 53 (1994)).

²⁹ Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2135 (1997) (citing PETER H. SCHUCK, *AGENT ORANGE ON TRIAL* (1986); PAUL BRODEUR, *OUTRAGEOUS MISCONDUCT* (1985); MICHAEL D. GREEN, *BENEDICTIN AND BIRTH DEFECTS* 96–120 (1996); MARCIA ANGELL, *SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE* (1996); KAREN M. HICKS, *SURVIVING THE DALKON SHIELD IUD* (1994); RICHARD KLUGER, *ASHES TO ASHES* (1996)).

³⁰ Alex Berenson, *Drug Industry Braces for New Suits Over Even More of Its Products*, N.Y. TIMES, Apr. 22, 2006, at C1.

³¹ Berger, *Eliminating General Causation*, *supra* note 29, at 2136.

³² Berger & Twerski, *supra* note 10, at 261.

³³ Berger & Twerski, *supra* note 10, at 261 (citing Steven R. Salbu, *Off-*

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budget cuts and policy changes within the agency, the FDA's power to monitor drugs has decreased even further over the past decades.³⁴

Parts I.A and I.B of this Note discuss the history of medication testing for pediatric use in the United States, including the ethical debate surrounding experimentation in children and the resulting financial disincentives for pharmaceutical manufacturers. Part I.C focuses on recent developments in the safety regulation of children's medications. Part II.A suggests that the legal tort system is a well-suited device for protecting children from unsafe medications. Parts II.B and II.C address the causation burden that plaintiffs face in toxic tort cases,³⁵ opining that it presents an insurmountable burden for children who have been injured and bring a subsequent lawsuit. Part III surveys a series of proposals as suggested by legal scholars to address this burden.

I. THE HISTORY OF RESEARCH ON CHILDREN'S MEDICATIONS

A. *The Early Ethical Dilemmas*

In the early twentieth century, there was very little knowledge in the United States regarding childhood health and development.³⁶ Research that was conducted on children, which "sometimes included infants, orphans, and wards of the state," did not receive much attention and was not well-regulated.³⁷ For instance, the

Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy, 51 FLA. L. REV. 181 (1999).

³⁴ Berger & Twerski, *supra* note 10, at 261.

³⁵ See generally Craig T. Smith, *Peering Into the Microscope: The Rise of Judicial Gatekeeping After Daubert And Its Effect on Federal Toxic Tort Litigation*, 13 B.U. J. SCI. & TECH. L. 218, 224 (2007) ("A toxic tort, in its most general sense, is a physical or psychological harm to an individual due to exposure to a chemical factor. Common examples include harm caused by asbestos, lead poisoning, and air pollution.").

³⁶ See Alexander, *supra* note 22, at 1.

³⁷ Alexander, *supra* note 22, at 1 ("There was some casual concern in the United States in the middle of the twentieth century about research that was conducted on healthy children, but it didn't rise to the level of protest that

individuals who wrote the Nuremberg Code of 1949, which was created after at the end of World War II to set forth principles regarding human experimentation, neglected to consider the issues surrounding research in children.³⁸ Similarly, the 1964 Declaration of Helsinki of the World Medical Association, which gave rise to a standard practice of “third party authorization for non-therapeutic research,”³⁹ failed to mention children altogether.⁴⁰

By the early 1970’s, however, the ethical debate regarding the appropriateness of clinical research on children was in full swing,⁴¹ and “informed consent” was at the forefront of the dispute.⁴² There was uncertainty as to what constituted informed consent and the extent to which it permitted research on children. In 1971, for example, the National Institute of Health published the Institutional Guide to the Department of Health, Education, and Welfare Policy on Protection of Human Subjects and required either the consent of the individual on whom the research was being conducted or the consent of his authorized representative.⁴³ However, the publication failed to specify exactly what constituted informed consent or the circumstances under which it would apply.⁴⁴ Scholars such as Paul Ramsey⁴⁵ argued, “any non-therapeutic research on children was absolutely unethical—even

existed in Europe at the time.”).

³⁸ Alexander, *supra* note 22, at 1–2 (citing Nuremberg Code, Principle 1 (1946), available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html>).

³⁹ Alexander, *supra* note 22, at 2.

⁴⁰ Alexander, *supra* note 22, at 2 (citing World Med. Ass’n, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (1964), available at <http://www.wma.net/e/policy/b3.htm>).

⁴¹ See Alexander, *supra* note 22, at 2 (“the existing guidelines [regarding research in children] had come under attack from a number of fronts.”).

⁴² See Alexander, *supra* note 22, at 3–7 (discussing the primacy of informed consent amidst debates regarding the clinical research on children).

⁴³ Alexander, *supra* note 22, at 2.

⁴⁴ Alexander, *supra* note 22, at 2 (citing NIH, The Institutional Guide To DHEW Policy on Protection of Human Subjects (Pub. No. 72–102) (1971)).

⁴⁵ PAUL RAMSEY, THE PATIENT AS PERSON 11–19 (3d ed., 1973) (1970). Paul Ramsey is a nationally recognized scholar from Princeton University, who is well-regarded for his writings and lectures regarding medical ethics.

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with parental approval.”⁴⁶

The debate caught the eye of the scientific community, particularly after it became the subject of several lawsuits. In one suit,⁴⁷ a professor at the University of California in San Francisco (the “University”) filed for an injunction because a study conducted at the University involved paying families \$300 for allowing their child to participate in allergy/asthma pharmaceutical testing.⁴⁸ The study proposed to perform invasive medical procedures on otherwise healthy children in order to study the effects.⁴⁹ The complaint “asked the court to declare that ‘a parent or a guardian of a normal, healthy minor may not subject that child to experimental medical procedures not intended to benefit such child and that the approval of such conduct by the defendants is unconstitutional, invalid, and void.’”⁵⁰ Although the professor’s “application was denied on the grounds that he failed to show sufficient standing and irreparable injury to warrant issuance of injunctive relief,” his case brought widespread attention to the informed consent debate.⁵¹

Another case that examined the limits of parental consent was *Strunk v. Strunk*,⁵² which centered around a twenty-eight year old man who suffered from a fatal kidney disease. His brother, a physically healthy twenty-seven year old, had been committed to a state institution due to his mental incompetence which rendered him the mental equivalent of a six year old. The mother consented

⁴⁶ Alexander, *supra* note 22, at 2.

⁴⁷ Alexander, *supra* note 22, at 3 (citing *Nielson v. Regents of the Univ. of Cal. et al.*, *dismissed*, No. 665-049 (Super. Ct. San Francisco, Cal. 1973)).

⁴⁸ Alexander, *supra* note 22, at 3 (citing Letter from Oscar L. Frick, M.D., Professor Pediatrics, University of California, San Francisco, School of Medicine, Department of Pediatrics To The Committee of Human Experimentation, University of California, San Francisco, School of Medicine, Department of Pediatrics (on file with the Journal of Health Care Law & Policy)).

⁴⁹ Alexander, *supra* note 22, at 3.

⁵⁰ Alexander, *supra* note 22, at 3–4 (citing *Nielson*, No. 665-048 at 13).

⁵¹ Gerald P. Koocher & Patricia C. Keith-Spiegel, *Children, Ethics, and the Law: Professional Issues and Cases* 155 (1990) (original manuscript of out-of-print work), *available at* http://www.kspope.com/ethics/Children_Ethics_and_the_Law.pdf.

⁵² 445 S.W.2d 145 (Ky. Ct. App. 1969).

to the removal and transplant of the incompetent brother's kidney into the ailing brother.⁵³ However, the court "held that parental control alone was not sufficient for a minor child to serve as a kidney . . . donor to a sibling and that court approval was required, given that the parents had a conflict of interest and that the donor did not stand to benefit from the procedure."⁵⁴ The threat of further suits like these stifled clinical research on children and highlighted the need for clear guidelines in this area of the law.⁵⁵

The Federal government became involved in 1977 when "the [National] Commission [for Protection of Human Subjects in Biomedical and Behavioral Research] issued its report and recommendations on research involving children."⁵⁶ The Commission recommended a change in the terminology associated with child research; specifically, that parental "consent" be changed to "permission" to reflect the notion that parents lacked the authority to unilaterally subject their children to clinical research without the child's assent.⁵⁷ The Commission also included a system that categorized all types of research on children into one

⁵³ *Id.* at 146.

⁵⁴ Alexander, *supra* note 22, at 2–3.

⁵⁵ See Alexander, *supra* note 22, at 2–4.

⁵⁶ Alexander, *supra* note 22, at 7 (citing NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAV. RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN (DHEW Pub. No. (OS) 77-0004) (1977), available at http://www.bioethics.gov/report/past_commissions/Research_involving_children.pdf).

⁵⁷ See NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAV. RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN 12–13 (DHEW Pub. No. (OS) 77-0004) (1977), available at http://www.bioethics.gov/report/past_commissions/Research_involving_children.pdf (stating:

The Commission uses the term parental or guardian "permission," rather than "consent," in order to distinguish what a person may do autonomously (consent) from what one may do on behalf of another (grant permission). Parental permission normally will be required for the participation of children in research. In addition, assent of children should be required when they are seven years of age or older. The Commission uses the term "assent" rather than "consent" in this context, to distinguish a child's agreement from a legally valid consent.).

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of four risk levels, each of which contained elements of permission and/or benefit to the child that had to be satisfied before the research could continue.⁵⁸ It took six years for the Department of Health to finish implementing the Commission's numerous recommendations.⁵⁹ The result was the implementation of guidelines aimed at allowing important clinical research to proceed while protecting children from exploitation.⁶⁰

B. Financial Disincentives For Safety Testing in Children's Medications

In addition to the ethical considerations that hamper clinical research of children, there are also economic hurdles.⁶¹ Because "children consume a relatively small proportion of prescription" drugs,⁶² pharmaceutical manufacturers have little incentive to conduct clinical studies on children's medications; rather, their efforts are better spent, financially speaking, on testing and producing adult medications. Widespread *off-label* use of adult medications in children further decreases the financial incentive for manufacturers to conduct child safety testing because they stand to profit from pediatric sales of drugs even without such studies.⁶³ As a result, pharmaceutical manufacturers, who are often concerned about the "bottom line" above all else, are unlikely to conduct pediatric testing on the drugs they produce, thereby leaving

⁵⁸ Alexander, *supra* note 22, at 9–10 (citing NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAV. RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN 7–8, 14 (Pub. No. (OS) 77-0004) (1977) ("The Society for Research on Child Development and a developmental psychologist provided valuable information [to the National Committee for Protection of Human Subjects in Biomedical and Behavioral Research] on the ability of children of various ages to make choices about participating in research.")).

⁵⁹ Alexander, *supra* note 22, at 10 (citing Additional Protections For Children Involved As Subjects in Research, 45 C.F.R. § 46, 409 (1983)).

⁶⁰ Alexander, *supra* note 22, at 10.

⁶¹ Budetti, *supra* note 18, at 950 (citing R. Steinbrook, *Testing Medications in Children*, 347 NEW ENG. J. MED. 1462, 1462–70 (2002)).

⁶² Budetti, *supra* note 18, at 950.

⁶³ Budetti, *supra* note 18, at 950.

children vulnerable to dangerous drugs.⁶⁴

C. The Current State of Affairs

Although things have changed since the days when “the dosage was just extrapolated from adult doses, effectiveness and side effects were assumed with fingers crossed, and physicians who prescribed these drugs for children did so at their own risk,”⁶⁵ the current state of affairs is nonetheless alarming. In 1996, members of the American Academy of Pediatrics and the National Institute of Health (“NIH”) examined a wide array of clinical studies that the NIH had funded during the previous year and found that children were often excluded from testing populations in which they could have appropriately been included.⁶⁶ They concluded, therefore, that children were not receiving the best possible care.⁶⁷

In response to this situation, Congress and the NIH have implemented laws and policies intended to increase pediatric testing where it is safe and responsible to do so.⁶⁸ In 1997 and 2002, for example, Congress passed the Better and Best Pharmaceuticals for Children Acts which extended patent protection afforded to drug companies who conducted pediatric testing.⁶⁹ In 1998, the NIH endorsed a policy that required clinical investigators to “describe their plans for including children [in

⁶⁴ See Budetti, *supra* note 18, at 950.

⁶⁵ Alexander, *supra* note 22, at 11.

⁶⁶ Alexander, *supra* note 22, at 11.

⁶⁷ Alexander, *supra* note 22, at 11 (citing National Institute of Child Health & Human Development, Inclusion of Children In Clinical Research Workshop (Sept. 5, 1996) (on file with the Journal of Health Care Law & Policy)).

⁶⁸ See Alexander, *supra* note 22, at 12.

⁶⁹ Alexander, *supra* note 22, at 12 (citing Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105–155, 111 Stat. 2305 (1997); Best Pharmaceuticals Act for Children of 2002, Pub. L. No. 107–109, 115 Stat. 1408 (2002), available at <http://thomas.loc.gov>); see also Budetti, *supra* note 18, at 951 (“Congress has passed two laws to encourage pharmaceutical manufacturers to test their products in the pediatric population, relying heavily on the financial incentives from extended marketplace exclusivity (delaying introduction of generic drugs).”).

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clinical trials] or justify the exclusion.”⁷⁰ This policy has increased the number of clinical studies in which children are properly included.⁷¹

While these measures have achieved some positive results, not every effort to increase pediatric testing has been successful. First, it is important to remember that ethical considerations often preclude manufacturers from including children in clinical trials even when legislation encourages them to do so. Additionally, new regulations are not always upheld. For example, in 1998, the FDA implemented the Pediatric Rule, which empowered the agency to “require the testing of new drugs in children.”⁷² However, in 2002, the D.C. Circuit Court⁷³ struck down the rule for “exceeding the FDA’s statutory authority.”⁷⁴ Finally, sometimes the benefits of lawful corporate behavior are outweighed by the incentives to violate regulatory statutes. In other words, as long as pharmaceutical manufacturers stand to lose less money from non-compliance with new legislation and regulations than they stand to gain from the sale of under-tested and potentially hazardous pediatric medications, this dangerous practice will continue. As a result, additional legal safeguards are necessary to protect children from medications that have not been proven safe for pediatric use.⁷⁵

⁷⁰ Alexander, *supra* note 22, at 12.

⁷¹ Alexander, *supra* note 22, at 12.

⁷² Alexander, *supra* note 22, at 12 (citing Regulations Requiring Manufacturers to Assess the Safety And Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998) (codified at 21 C.F.R. §§ 201, 312, 314, 601)).

⁷³ Ass’n of Am. Physicians and Surgeons, Inc., et al., v. U.S. Food and Drug Admin., 226 F. Supp. 2d 204, 222 (D.C. Cir. 2002).

⁷⁴ Alexander, *supra* note 22, at 12; *see also* Budetti, *supra* note 18, at 951.

⁷⁵ Budetti, *supra* note 18, at 951.

II. THE TORT SYSTEM

A. *Using the Tort System to Protect Children From Dangerous Medications*

The tort system is one tool that children may turn to for protection from toxic drugs. Tort law has been used somewhat effectively in the past to deal with manufacturers who have placed harmful drugs and medical devices on the market.⁷⁶ In many of those cases, “it appears that the corporations took virtually no steps to determine or minimize the possibility of harm until their hands were forced, usually by litigation.”⁷⁷ Once litigation ensued, materials uncovered during discovery often revealed “smoking gun” documents that demonstrated that the manufacturers knew that there were problems with their products before the victims suffered injury.⁷⁸

The goals of tort law are well-suited to defending children against unsafe and inadequately tested medications. Children who have been injured as a result of their ingestion of a toxic medication can seek to be compensated for their injuries by bringing a tort claim against the manufacturer of the drug.⁷⁹ Such claims, if successful, can be used to deter risky or negligent behavior⁸⁰ on the part of manufacturers by making it economically beneficial to take measures that reduce the occurrence and severity of toxic exposures.⁸¹ Successful claims also spread the losses associated

⁷⁶ Such as in litigation of “Agent Orange, asbestos, Bendectin, breast implants, the Dalkon Shield, thalidomide, tobacco, and other substances.” Berger, *Eliminating General Causation*, *supra* note 29, at 2135.

⁷⁷ Berger, *Eliminating General Causation*, *supra* note 29, at 2135.

⁷⁸ Berger, *Eliminating General Causation*, *supra* note 29, at 2135 (citing PAUL BRODEUR, *OUTRAGEOUS MISCONDUCT* 99–102, 109–13, 143–44 (1985)).

⁷⁹ Anthony Z. Roisman, Martha L. Judy & Daniel Stein, *Preserving Justice: Defending Toxic Tort Litigation*, 15 *FORDHAM ENVTL. L. REV.* 191, 193 (2004); *see also* Stuart Taylor Jr., *Product Liability: The New Morass*, *N.Y. TIMES*, Mar. 10, 1985, § 3, at 1; Garrett, *supra* note 13, at 536.

⁸⁰ Taylor, *supra* note 79, at 1; *see also* Garrett, *supra* note 13, at 536.

⁸¹ Roisman, Judy & Stein, *supra* note 79, at 193.

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with the ingestion of dangerous medications from the victim to the manufacturer, which is both fair and economically efficient.⁸²

B. The Plaintiff's Causation Burden

Although victims may turn to the courts after they have suffered the harmful effects of unsafe medications, the tort system does not always provide the protection these individuals need. One reason is that there are inherent barriers that plaintiffs must overcome in order to bring successful tort claims. Specifically, they must not only prove that they suffered an injury, but also must prove “cause-in-fact” by a preponderance of the evidence.⁸³ “Cause-in-fact” usually encompasses two separate elements: general causation and specific causation.⁸⁴ In the context of allegedly toxic medications, “plaintiffs have the burden of proving that the defendant’s product was capable of causing the health effects in question (general causation) and then establishing, in addition, that the exposure to the defendant’s product was the specific cause of their injury (specific causation).”⁸⁵ Thus, the heavy burden falls on the plaintiff to establish both causation and damages.⁸⁶

Toxic tort claims turn, and often fail, on the causation issue because it is unusual for plaintiffs to be able to provide a “direct explanation of a causal process.”⁸⁷ In other words, a plaintiff often

⁸² See Garrett, *supra* note 13, at 535–36.

⁸³ Joseph Sanders & Julie Machal-Fulks, *The Admissibility of Differential Diagnosis Testimony to Prove Causation in Toxic Tort Cases: The Interplay of Adjective and Substantive Law*, 64 LAW & CONTEMP. PROBS. 107, 110 (2001) (citing DeLuca v. Merrell Dow Pharms., 911 F.2d 941, 958 (3d Cir. 1990)).

⁸⁴ *Id.*

⁸⁵ Margaret A. Berger, *Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court’s Trilogy on Expert Testimony in Toxic Tort Litigation*, 64 LAW & CONTEMP. PROBS. 289, 297 (2001) (citing *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1131 (2d Cir. 1995)).

⁸⁶ See Garrett, *supra* note 13, at 553.

⁸⁷ Berger, *Eliminating General Causation*, *supra* note 29, at 2120–21 (1997) (citing Mario J. Rizzo, *Foreword: Fundamentals to Causation, Symposium on Causation in the Law of Torts*, 63 CHI.-KENT L. REV. 397, 403 (1987) (citing JACK B. WEINSTEIN, *INDIVIDUAL JUSTICE IN MASS TORT*

does not know, and therefore cannot explain, the precise biological mechanism by which the medication they ingested produced their injuries, despite evidence that the causal relationship exists. While scientific experts⁸⁸ may be able to speculate about the way in which the medication allegedly caused the plaintiff's injury, that plaintiff will fail to prove causation if he is armed with nothing more than mere speculation.

In an effort to formulate an opinion based on more than mere speculation, a plaintiff's expert witness may rely upon several different kinds of evidence. Four common types of scientific studies used are: 1) structure-activity analyses, 2) animal bioassays, 3) in vitro studies, and 4) case reports/series. In structure-activity analyses, also called chemical-structure analyses, scientists examine substances that have a similar chemical structure to the medication the plaintiff claims caused their injury in order to determine if those substances have been associated with adverse health reactions.⁸⁹ If so, the expert can draw inferences about the medication that is the subject of the litigation.⁹⁰ Animal bioassays

LITIGATION 148 (1995) (Judge Weinstein observed that "causation is the central, decisive factor in mass tort litigation.")).

⁸⁸ In most toxic tort actions, plaintiffs often employ causation experts "who seek to link exposure and injury in order to establish both general and specific causation." See Laurie Alberts, *Causation in Toxic Tort Litigation: "Which Way Do We Go, Judge?"*, 12 VILL. ENVTL. L.J. 33, 40 (2001) (citing M. Neil Browne, Terri J. Keeley & Wesley J. Heirs, *The Epistemological Role of Expert Witnesses and Toxic Torts*, 36 AM. BUS. L.J. 1, n.19 (Fall 1998)). An expert witness is "one, who, by training, education, or experience, has acquired a special level of skill or knowledge in some art, science, profession, or calling." Alberts, *supra* note 88, at 39-40 (citing Hon. Mark I. Bernstein, *Expert Testimony in Pennsylvania*, 68 TEMP. L. REV. 699 n.2 (1995)). "Since causation is often the central issue in toxic tort claims, the success or failure of the case may well hinge on the expert testimony." Alberts, *supra* note 88, at 40 (citing Cynthia H. Cwik, *Guarding the Gate: Expert Evidence Admissibility*, 25 No. 4 A.B.A. J. SEC. LITIG. 6 (Summer 1999)).

⁸⁹ Berger, *Upsetting the Balance*, *supra* note 85, at 298-99; see also Berger, *Eliminating General Causation*, *supra* note 29, at 2123; Alberts, *supra* note 88, at 52 (discussing the use of pharmacological studies).

⁹⁰ Berger, *Upsetting the Balance*, *supra* note 85, at 298-99; see also Berger, *Eliminating General Causation*, *supra* note 29, at 2123; Alberts, *supra* note 88, at 52 (discussing the use of pharmacological studies).

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(or “in vivo” studies) are toxicological studies that utilize carefully controlled experimental conditions to determine the effects of the medication on laboratory animals.⁹¹ Experts use these studies to draw inferences about the effect of these medications on humans.⁹² In vitro studies examine the effects of the medication “on living cells, bacteria, body organs, or animal embryos . . . in isolation from the rest of the organism,”⁹³ providing a basis for experts to further extrapolate the impact the medication may have on an entire organism.⁹⁴ Finally, case reports and series are uncontrolled observational studies that follow an individual or series of individuals who have been exposed to the medication, taking into account factors such as gender and age.⁹⁵ Experts then use this information to draw conclusions about the general effects of the medication.⁹⁶

Although it is common for scientists to rely upon the results of these various types of studies,⁹⁷ reliance by toxic tort experts is

⁹¹ Berger, *Eliminating General Causation*, *supra* note 29, at 2124.

Using results of adverse reactions in animals to prove causation in humans requires at least two assumptions: first, that if a substance is toxic in animals it will also be toxic in humans, a conclusion that is known not always to be true, and second, 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.

Id.; see also *In re Phenylpropanolamine (PPA)*, Mass Tort Code 264, 2003 WL22417238, at *18–19 (N.J. Super. Ct. Law Div. July 21, 2003).

⁹² Berger, *Eliminating General Causation*, *supra* note 29, at 2124.

⁹³ Berger, *Eliminating General Causation*, *supra* note 29, at 2123–24.

⁹⁴ Berger, *Eliminating General Causation*, *supra* note 29, at 2123–24.

⁹⁵ See *In re Phenylpropanolamine (PPA)*, Mass Tort Code 264, 2003 WL22417238, at *12 (N.J. Super. Ct. Law Div. July 21, 2003).

⁹⁶ *Id.*

⁹⁷ See, e.g., *id.* at *17 (“In many scientific disciplines, the use of case reports is longstanding, as evidenced by the continued publication of such reports in peer-reviewed scientific journals.”); Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376, 394 (1986) (“Inferences from animal and *in vitro* studies . . . are widely supported by regulators and scientists.”); Berger, *Upsetting the Balance*, *supra* note 85, at 298–99; *In re Phenylpropanolamine (PPA)*, Mass Tort Code 264, 2003 WL22417238, at *18 (N.J. Super. Ct. Law Div. July 21, 2003)

controversial because the studies contain substantial uncertainties.⁹⁸ For instance, structure-activity analysis “is probative [of the toxicity of the accused drug] only if the adverse reaction [from the chemical that was studied] . . . is due to an attribute the substances have in common, rather than one that sets [the two chemicals] apart.”⁹⁹ Thus, if scientists have not identified how the substance in the study caused the adverse reaction, it cannot be said with any certainty that it was caused by an attribute the substance has in common with the accused medication, and the structure-activity analysis has no probative value.¹⁰⁰ The concern with *in vivo* studies is that they may attempt to oversimplify the human body by extrapolating from animals.¹⁰¹ Similarly, because *in vitro* research is conducted on cells that are isolated from the rest of the organism, scientists do not know if the substance would react the same way when exposed to the body as a whole.¹⁰² Lastly, case studies are often criticized because they do not control for outside variables¹⁰³ such as pre-existing health conditions; therefore, experts cannot say with certainty that an adverse reaction was caused by the accused medication and not the outside variables.

Although the aforementioned types of studies may not provide a legally adequate basis for an expert opinion on causation, epidemiological studies are generally viewed as the best proof of general causation.¹⁰⁴ Epidemiologists examine human

(“Toxicological research often provides the best scientific evidence about the risk of a disease from chemical exposure and the metabolic, cellular, and other physiological effects of chemical exposure . . .”).

⁹⁸ See Gold, *supra* note 97, at 394.

⁹⁹ Berger, *Eliminating General Causation*, *supra* note 29, at 2123.

¹⁰⁰ Berger, *Eliminating General Causation*, *supra* note 29, at 2123 (citing DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 27-1.3.1, at 263 n.26 (1997)).

¹⁰¹ Berger, *Eliminating General Causation*, *supra* note 29, at 2124 (citing Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1811 n.58 (1989)).

¹⁰² Berger, *Eliminating General Causation*, *supra* note 29, at 2123–24.

¹⁰³ See *In re Phenylpropanolamine (PPA)*, Mass Tort Code 264, 2003 WL22417238, at *27 (N.J. Super. Ct. Law Div. July 21, 2003).

¹⁰⁴ Berger, *Eliminating General Causation*, *supra* note 29, at 2125; see also Alberts, *supra* note 88, at 49 (“With respect to the establishment of

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populations¹⁰⁵ to ascertain the causes of health problems in those populations.¹⁰⁶ More specifically, when studying the effects of an accused medication, an epidemiological study compares a population of people who have been exposed to the drug with an unexposed population to determine whether associations can be made between the drug and its effects.¹⁰⁷ When epidemiological studies show correlations between exposure and adverse reactions, these associations are considered credible evidence of causation in the toxic tort setting.¹⁰⁸

causation in toxic tort litigation, this science is aimed at proving general, as opposed to specific, causation.”).

¹⁰⁵ Garrett, *supra* note 13, at 524 (citing Dinah Shelton, *The Impact of Scientific Uncertainty on Environmental Law and Policy in the United States*, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW* 219, 209–210 (David Freestone & Ellen Hey eds., 1996)); Alberts, *supra* note 88, at 49; Berger, *Eliminating General Causation*, *supra* note 29, at 2125; Gold, *supra* note 97, at 379.

¹⁰⁶ Alberts, *supra* note 88, at 49 (citing Christopher H. Buckley Jr. & Charley H. Haake, *Separating the Scientist’s Wheat from the Charlatan’s Chaff: Daubert’s Role in Toxic Tort Litigation*, 28 ENVTL. L. REP. 10293 (June 1998)). See also Douglas L. Weed, *Causation: An Epidemiologic Perspective (In Five Parts)*, 12 J.L. & POL’Y 43, 44 (2003) (“Epidemiology is the study of the distributions and [causal] determinants of disease in populations and the application of this study to control health problems.”).

¹⁰⁷ Gold, *supra* note 97, at 380 (citing Devin Brennan, Book Note, 30 HARV. ENVTL. L. REV. 565 (2006) (reviewing CARL F. CRANOR, *TOXIC TORTS: SCIENCE, LAW, AND THE POSSIBILITY OF JUSTICE* (2006)). See also Garrett, *supra* note 13, at 528 (stating:

The gold standard of epidemiological studies is a randomized, placebo-controlled double blind study where a sample population is exposed to an agent within a controlled environment and then compared to a group that has unwittingly been given a placebo. Neither the physician nor the patient knows which members of the trial are exposed to the real agent in hopes of isolating and determining the effects of a given agent to the greatest possible extent.)

¹⁰⁸ Gold, *supra* note 97, at 380 (citing Bert Black & David E. Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 *FORDHAM L. REV.* 732, 762–64 (1984)).

C. *Causation in Child Toxic Tort Cases: An Insurmountable Burden*

1. *The Federal Rules of Evidence and the Daubert Standard*

Given the varying degree of credibility attributed to different types of scientific studies, judges face a difficult task when determining whether to admit expert opinions based on such studies.¹⁰⁹ The Federal Rules of Evidence (“FRE”), which were enacted in 1975, provided some guidance on the issue. Specifically, FRE 702 created a standard of expert opinion admissibility that was based on a notion of reliability,¹¹⁰ and FRE 703 provided that experts may base their opinions on “the kind of information on which similar experts would rely in making non-litigation-oriented professional judgments.”¹¹¹ These rules gave federal judges direction when determining the admissibility of expert testimony based on scientific evidence.

In *Daubert v. Merrell Dow Pharm.*,¹¹² the United States Supreme Court elaborated upon the requirements of FRE 702.¹¹³ The petitioners in that case were children who claimed their

¹⁰⁹ See Alberts, *supra* note 88, at 40.

¹¹⁰ Alberts, *supra* note 88, at 43 (citing *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993)). FED. R. EVID. 702, as originally enacted, read: “If 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.” FED. R. EVID. 702. The rule was amended on December 1, 2000.

¹¹¹ Evidence Law News, Amendments to the Federal Rules of Evidence, http://forensic-evidence.com/site/EVID/EL00003_4.html (last visited Nov. 19, 2007) (stating that “under the Federal Rules of Evidence, the emphasis shifted, away from the admissibility of the facts upon which an expert’s opinion was based, to the reliability of these facts as determined by the profession in arriving at professional judgments independent of litigation.”).

¹¹² 509 U.S. 579 (1993).

¹¹³ See Alexandra B. Klass, *Pesticides, Children’s Healthy Policy, and Common Law Tort Claims*, 7 MINN. J.L. SCI. & TECH. 89, 111 (2005); see also Alberts, *supra* note 88, at 43.

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mothers' ingestion of the drug Bendectin caused their birth defects.¹¹⁴ They offered experts who opined that there was a causal relationship between the drug and the defects based on several types of studies including "animal studies, chemical structure analysis and unpublished reanalysis of previously published human studies."¹¹⁵ The Court "explicitly anointed the trial judge as the 'gatekeeper'"¹¹⁶ who must ensure that "an expert's testimony rests on a reliable foundation and is relevant to the task at hand."¹¹⁷ The Court advised that the judge should examine the reasoning and methodology that underlies the testimony of the expert in order to determine its reliability.¹¹⁸ The Court also offered some "'general observations' in order to 'help' federal judges determine whether a particular scientific theory or technique is 'scientific knowledge that will assist the trier of fact.'"¹¹⁹

The *Daubert* factors, which focus primarily on reliability are: 1) whether the theory or technique can be used or has been tested; 2) whether the theory or technique has been subjected to peer review and publication; 3) whether the theory or technique has been "generally accepted" within the scientific community; 4) whether a potential rate of error exists in cases involving particular scientific techniques; and 5) whether standards which control the technique's operation exist and were maintained.¹²⁰

The *Daubert* test is widely viewed as a flexible approach because

¹¹⁴ *Daubert*, 509 U.S. at 582.

¹¹⁵ Garrett, *supra* note 13, at 526 (citing *Daubert*, 509 U.S. at 583–84).

¹¹⁶ Berger, *Upsetting the Balance*, *supra* note 85, at 293 (citing *Daubert*, 509 U.S. at 589); *see also* Klass, *supra* note 113, at 111 ("In order to allow expert, scientific testimony to be presented at trial, the trial judge must determine at the outset whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts."); Berger, *Eliminating General Causation*, *supra* note 29, at 2122.

¹¹⁷ *Daubert*, 509 U.S. at 597; *see* Berger, *Upsetting the Balance*, *supra* note 85, at 293 (citing *Daubert*, 509 U.S. at 589); *see also* Klass, *supra* note 113, at 111; Berger, *Eliminating General Causation*, *supra* note 29, at 2122.

¹¹⁸ Sanders & Machal-Fulks, *supra* note 83, at 135.

¹¹⁹ Alberts, *supra* note 88, at 44 (citing *Daubert*, 509 U.S. at 593).

¹²⁰ Alberts, *supra* note 88, at 44 (citing *Daubert*, 509 U.S. at 593).

no single factor is dispositive of evidentiary reliability,¹²¹ not all factors are applicable in all cases,¹²² and some factors may take on more importance than others in appropriate circumstances.¹²³ Further, the Court's emphasis on the trial judge as gatekeeper "appear[ed] to liberalize admissibility requirements"¹²⁴ by giving the judge a high level of discretion in determining whether scientific evidence and testimony is based on reliable methodology.¹²⁵ Under *Daubert*, a judge should admit evidence so long as he determines that it is reliable and useful to the jury.¹²⁶

In 2000, the Advisory Committee on the Federal Rules of Evidence amended FRE 702 to reflect its endorsement of the *Daubert* standard.¹²⁷ However, while the amendment was intended to be consistent with the *Daubert* holding, its language was more restrictive than *Daubert* in terms of the rules for the admissibility of scientific evidence.¹²⁸ Specifically, the amended FRE 702

¹²¹ Steven B. Loomis, *The Daubert Test of Reliability: Fighting "Junk Science in the Courtrooms,"* SKEPTIC REPORT, Nov. 2002, <http://www.skepticreport.com/skepticism/daubertest.htm> (citing *Daubert*, 509 U.S. at 591–93).

¹²² *Id.*

¹²³ *Id.*

¹²⁴ Garrett, *supra* note 13, at 526 (citing Joseph Sanders et al., *Legal Perceptions of Science and Expert Knowledge*, 8 PSYCHOL. PUB. POL'Y & L. 139, 142 (2002)).

¹²⁵ Garrett, *supra* note 13, at 526 (citing *Daubert*, 509 U.S. at 592) (citing SHEILA JASANOFF, *SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA* 58 (Harvard 1995) (stating: "The judge does this through a voir dire examination, and on the basis of questions asked by counsel for both parties 'the trial judge forms an initial opinion of the expert's claim to specialized knowledge and determines whether the witness should be admitted or not.'")).

¹²⁶ Garrett, *supra* note 13, at 526–27 (citing Stephen Charest, *Bayesian Approaches to the Precautionary Principle*, 12 DUKE ENVTL. L. & POL'Y F. 265, 280 (2002)).

¹²⁷ Forensic Evidence.com, Amendments to the Federal Rules of Evidence, http://forensic-evidence.com/site/EVID/EL00003_4.html (last visited Nov. 19, 2007).

¹²⁸ David Bernstein, *Daubert and Amended FRE 702*, THE VOLOKH CONSPIRACY, Nov. 3, 2005, <http://volokh.com/posts/1131073785.shtml>. The current FED. R. EVID. 702 provides that an expert may issue an expert opinion in a case if that opinion will assist the trier of fact and "if (1) the testimony is

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requires that the proponent of the evidence not only convince the trial judge that it is sufficiently reliable, but must also demonstrate that the testifying expert has applied the evidence reliably to the particular facts in the case.¹²⁹ This restriction is indicative of an overall trend of a tightening of the *Daubert* standard.

2. The Epidemiology Requirement

Although the Federal Rules of Evidence, *Daubert*, and subsequent federal decisions¹³⁰ provide some direction for federal judges regarding the admissibility of scientific evidence, they are not bright-line standards.¹³¹ Trial judges, therefore, have a great deal of discretion when carrying out their role as evidentiary gatekeepers.¹³² This has opened the door for many courts to take a narrow interpretation of the seemingly liberal language of the *Daubert* decision.¹³³

One manifestation of this narrow approach to *Daubert* is that the tort system has become partial to epidemiological studies¹³⁴ to establish causation in toxic tort cases. This epidemiological

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.

¹²⁹ FED. R. EVID. 702.

¹³⁰ See, e.g., *Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167 (1999); *General Electric v. Joiner*, 522 U.S. 136 (1997).

¹³¹ Alberts, *supra* note 88, at 46 (citing *Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481, 1556–57 (1996)).

¹³² Alberts, *supra* note 88, at 46 (citing FED. R. EVID. 702).

¹³³ Carolyn Raffensperger & Nancy Myers, *Detox For Torts: How to Bring Justice Back to the Court System*, SCI. & ENVTL. HEALTH NETWORK, July 2003, at 8, available at <http://www.sehn.org/rtfdocs/white-paper.doc>; Garrett, *supra* note 13, at 527 (stating:

This inconsistency is partially due to the fact that the decision symbolized more than its words suggested. Hidden behind the Court’s decision lay the unspoken objective of finding a new rule that would keep so-called ‘junk science’ out of the courtroom. *Daubert*’s emphasis on reliability and the role of the judge as gatekeeper served as a message to lower courts to take admissibility requirements seriously.).

¹³⁴ Garrett, *supra* note 13, at 528.

preference may have originated with “the general judicial backlash against ‘junk science’¹³⁵ and more specifically to Judge Jack Weinstein’s highly influential” *Agent Orange* decision in 1985.¹³⁶ In that decision, Judge Weinstein found that epidemiological studies were “the only useful studies having any bearing on causation” because non-epidemiological studies “rest on surmise and inapposite extrapolation.”¹³⁷

Some judges have followed suit by entirely rejecting non-epidemiological evidence because they find it irrelevant to causation issues in humans.¹³⁸ For instance, some courts have refused to

¹³⁵ This term refers to scientific evidence that is flawed in its methodology or is for some other reason misleading or inaccurate. *See, e.g.*, Joelle Anne Moreno, *Beyond the Polemic Against Junk Science: Navigating the Oceans That Divide Science and Law With Justice Breyer At the Helm*, 81 B.U. L. Rev. 1033, 1091 n.18 (2001) (stating:

Junk science is the mirror image of real science, with much of the same form but none of the same substance. There is the astronomer, on the one hand, and the astrologist, on the other [Junk science] is a hodgepodge of biased data, spurious inference, and logical legerdemain, patched together by researchers whose enthusiasm for discovery and diagnosis far outstrips their skill. It is a catalog of every conceivable kind of error: data dredging, wishful thinking, truculent dogmatism, and, now and then, outright fraud.)

¹³⁶ Garrett, *supra* note 13, at 528–29 (citing *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff’d*, 818 F.2d 187 (2d Cir. 1987)). In *In re Agent Orange Prod. Liab. Litig.*, the plaintiffs consisted of veterans and their families who claimed to suffer from various injuries as a result of exposure to a chemical called “Agent Orange” which was used in Vietnam as an herbicide. The plaintiffs sued the makers of the chemical. The court, however, held that the opinions of the experts put forth by the plaintiffs were inadmissible because they lacked the requisite reliability and the complaints were dismissed. *Id.*

¹³⁷ Berger, *Eliminating General Causation*, *supra* note 29, at 2124 (citing *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. at 1231 (E.D.N.Y. 1985), *aff’d*, 818 F.2d 187 (2d Cir. 1987)).

¹³⁸ Raffensperger & Myers, *supra* note 133, at 8; *see also In re Phenylpropanolamine*, 2003 WL22417238, at *12 (“[S]ome courts have held that animal studies are not a valid basis for extrapolating conclusions about human disease causation.”); Alberts, *supra* note 88, at 51–52 (“[Animal studies] are of so little probative force and are so potentially misleading as to be inadmissible.”); *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193 (10th Cir.

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consider animal studies on the grounds that laboratory animals may react differently to medications than humans.¹³⁹ However, this is contrary to FRE 703 which permits experts to testify about their opinions when they are based upon the same types of studies relied upon by their colleagues when making non-litigation professional judgments.¹⁴⁰ It is also contrary to *Daubert* because *Daubert* included “general acceptance within the scientific community” as one of its factors for determining reliability.¹⁴¹ Since scientists regularly use non-epidemiological studies to assess whether particular substances pose a human risk,¹⁴² this type of evidence does “hold some utility in helping to establish causality in toxic tort cases.”¹⁴³ The absolute exclusion of non-epidemiological evidence is overly restrictive and omits “vast areas of scientific knowledge and . . . many legitimate tools of investigation.”¹⁴⁴

When judges exclude non-epidemiological evidence, they

2002) (citing *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (stating:

[C]ase reports are not reliable scientific evidence of causation, because they simply described reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation).

¹³⁹ Berger, *Upsetting the Balance*, *supra* note 85, at 302 n.81 (quoting *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1480 (D.V.I. 1994)).

¹⁴⁰ Forensic Evidence.com, Amendments to the Federal Rules of Evidence, http://forensic-evidence.com/site/EVID/EL00003_4.html (last visited Nov. 19, 2007) (stating that “under the Federal Rules of Evidence, the emphasis shifted, away from the admissibility of the facts upon which an expert’s opinion was based, to the reliability of these facts as determined by the profession in arriving at professional judgments independent of litigation.”).

¹⁴¹ *Daubert*, 509 U.S. at 593.

¹⁴² Alberts, *supra* note 88, at 51–52 (citing *Casey*, 877 F. Supp. at 1385); *see also In re Phenylpropanolamine*, 2003 WL 22417238, at *29; *see also Raffensperger & Myers*, *supra* note 133, at 4 (“Scientists themselves rely on animal studies, models, systematic field observations, and even causal observations as sources of knowledge—but ‘sound science’ advocates tend to discredit such knowledge.”).

¹⁴³ Garrett, *supra* note 13, at 531.

¹⁴⁴ Raffensperger & Myers, *supra* note 133, at 4.

unilaterally increase the plaintiff's causation burden by requiring that each piece of evidence not only be reliable, as required under the *Daubert* standard, but also that plaintiff's experts be able "to demonstrate before trial that each study relied upon can on its own prove the plaintiff's case."¹⁴⁵ Since many types of studies cannot meet this elevated burden, critical pieces of evidence are often excluded. As a result, many plaintiffs with legitimate claims are unable to proceed with their cases because they are left with little or no evidence.¹⁴⁶ Further, even if they are able to proceed, they are prejudiced because juries are left to render verdicts without having the opportunity to consider all of the relevant evidence.¹⁴⁷

Another problem plaintiffs face is that even when epidemiological data is available, the data is not always adequate proof that it is "more likely than not" that the medication can cause the type of injury that he or she has sustained.¹⁴⁸ Many courts require that an epidemiological study show a relative risk ratio¹⁴⁹ of

¹⁴⁵ Klass, *supra* note 113, at 112.

¹⁴⁶ Roisman, Judy & Stein, *supra* note 79, at 205–06 (citing PROJECT ON SCIENTIFIC KNOWLEDGE AND PUB. POL'Y, DAUBERT: THE MOST INFLUENTIAL SUPREME COURT RULING YOU'VE NEVER HEARD OF 3 (Tellus Institute June 2003), available at <http://www.defending-science.org/upload/Daubert-The-Most-Influential-Supreme-Court-Decision-You-ve-Never-Heard-Of-2003.pdf>); see also Garrett, *supra* note 13, at 519 (stating:

Causal mechanisms for toxic torts are notoriously complex, and because toxins cannot be directly tested on humans for obvious ethical reasons, even epidemiological studies are often unable to conclusively determine the effects of a suspected toxin Because epidemiological data are frequently inconclusive, imprecise, or unavailable for newly-developed toxins, the tort system's single-minded faith in epidemiology prevents victims of toxic torts from recovering even when they have a legitimate claim.).

¹⁴⁷ Raffensperger & Myers, *supra* note 133, at 7; see also Garrett, *supra* note 13, at 531 ("[P]laintiffs are unfairly prejudiced by the tort system's reluctance to allow animal studies, in vitro studies, chemical structure analysis, and case reports.").

¹⁴⁸ Alberts, *supra* note 88, at 50 (citing *Daubert v. Merrell Dow Pharm. Corp.*, 43 F.3d 1311, 1321 (9th Cir. 1995)).

¹⁴⁹ See generally Smith, *supra* note 35, at 236 (stating:

Relative risk is commonly calculated by dividing the risk of developing a disease observed in an exposed group by the risk observed

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at least 2.0 to be considered sufficiently significant to meet the “more likely than not” burden.¹⁵⁰ In other words, the study must show that the risk of injury was at least twice as high for individuals who ingested the medication.¹⁵¹ Even if a study showed that the ingestion of a particular medication resulted in a 99% increased risk of a particular injury, it would not satisfy this admissibility standard¹⁵² and would be excluded in the *Daubert* hearing.¹⁵³ Therefore, this bright-line standard may preclude the

in an unexposed, but otherwise similar group. If the risks of the unexposed and exposed are the same, then the relative risk estimate is 1.0. . . . Thus a relative risk of 1.0 means that the agent has no effect on the incidence of disease. Similarly, if the relative risk estimate is 1.3, then risk appears to be 30% higher among the exposed compared to the non-exposed. When the relative risk reaches 2.0, the risk has doubled, indicating that the risk is twice as high among the exposed group as compared to the non-exposed group.).

¹⁵⁰ Raffensperger & Myers, *supra* note 133, at 8; Alberts, *supra* note 88, at 50 (“Although on remand the Ninth Circuit in *Daubert* held that a relative risk ratio of greater than two is not an absolute prerequisite when establishing causation, courts have generally disallowed evidence that does not meet this standard.”); *see also* Berger, *Eliminating General Causation*, *supra* note 29, at 2126 (stating:

The strength of the association is typically expressed by epidemiologists in terms of relative risk. A relative risk of 1.0 indicates no observed difference between the groups being compared. A relative risk over 1.0 is not, however, an irrefutable indicator of causation. As an abstract proposition, unless the ratio is at least 2.0, no plaintiff will be able to prove that his or her disease was more likely than not attributable to the defendant’s product.).

¹⁵¹ Sanders & Machal-Fulks, *supra* note 83, at 111 (citing *In re Joint E. & S. Dist. Asbestos Litig.*, 758 F. Supp. 199, 203 (S.D.N.Y. 1991); *rev’d on other grounds*, 964 F.2d 92 (2d Cir. 1992); *DeLuca v. Merrell Dow Pharm., Inc.*, 911 F.2d 941, 958–59 (3d Cir. 1990); *Landrigan v. Celotex Corp.*, 127 N.J. 404, 605 A.2d 1079, 1087 (1992)).

¹⁵² Sanders & Machal-Fulks, *supra* note 83, at 111.

¹⁵³ Alberts, *supra* note 88, at 50, 54; *see also* David L. Faigman, *Mapping the Labyrinth of Scientific Evidence*, 46 HASTINGS L.J. 555, 568 (1995) (“In deciding whether to admit scientific evidence into court, judges confront the same possibilities of error as scientists. The trial court makes what might be termed a type I error when it admits scientific evidence that is invalid; and it makes a type II error when it excludes evidence that is valid.”).

admissibility of important evidence that, when viewed in light of all the evidence, is probative of causation.¹⁵⁴

Epidemiological studies may also fall short of meeting the plaintiff's causation burden because they are uncontrolled studies that are "notoriously subject to confounders and bias."¹⁵⁵ Some epidemiological studies have been criticized for failing to be "gender, race or class neutral."¹⁵⁶ Critics also point out that the medication "may not have been tested in interaction with other substances, tested on a representative sample of the population, or had its effects tracked over time."¹⁵⁷ Further, epidemiological studies may underestimate the risk associated with a drug because they "favor . . . false negatives (a test result wrongly showing a risk not to be present when it is) rather than false positive (a test result wrongfully showing a risk to be present when it is not)."¹⁵⁸ As a result of these shortcomings, the studies may either be inadmissible at trial or may be useless in helping the plaintiff conclusively prove causation.¹⁵⁹

Evidentiary restrictions are particularly prejudicial to child-plaintiffs alleging injuries as a result of their ingestion of unsafe medications because children's medications are often inadequately tested.¹⁶⁰ Thus, epidemiological studies focusing upon children's

¹⁵⁴ See Alan Golansky, *General Causation At a Crossroads in Toxic Tort Cases*, 108 PENN ST. L. REV. 479, 488–96 (2003).

¹⁵⁵ Raffensperger & Myers, *supra* note 133, at 5.

¹⁵⁶ Berger, *Upsetting the Balance*, *supra* note 85, at 304 (citing Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 374 (1999)).

¹⁵⁷ Berger, *Upsetting the Balance*, *supra* note 85, at 303–04 (citing Petersen, *supra* note 15, at 11; Carl F. Cranor & David A. Eastonmond, *Scientific Ignorance and Reliable Patterns of Evidence in Toxic Tort Causation: Is There a Need for Liability Reform?*, 64 LAW & CONTEMP. PROBS. 5 (2001)).

¹⁵⁸ Garrett, *supra* note 13, at 519 (citing Lars Persson & Kristin Shrader-Frechette, *An Evaluation of the Ethical Principles of the ICRP's Radiation Protection Standards for Workers*, 80 HEALTH PHYSICS 225, 228 (2001)).

¹⁵⁹ Raffensperger & Myers, *supra* note 133, at 5.

¹⁶⁰ See Garrett, *supra* note 13, at 530 ("With suspected toxins, moral concerns preclude conducting controlled tests on human subjects.").

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medications frequently do not exist at all.¹⁶¹ Further, even when epidemiological studies on medications that are administered to children have been conducted, children are rarely included in the study population.¹⁶² As a result, the admissibility of the evidence is called into question because the subjects of the study did not have the same physical characteristics as the plaintiff, and therefore “even less scientific evidence on exposure levels and effect is available.”¹⁶³

As a result of *Daubert* and subsequent decisions regarding the admissibility of expert testimony, “the federal courts ha[ve] made it very difficult for a plaintiff to successfully prosecute a toxic tort case.”¹⁶⁴ While science tends “to be very conservative in reaching conclusions on cause and effect and to err on the side of showing no effects when there may indeed be effects,” courts take the *Daubert* mandate too far, putting forth unrealistic, “overly stringent and specific scientific standards” that plaintiffs simply cannot meet with the scientific evidence that is available.¹⁶⁵ If a defendant in a toxic tort case is successful in having the plaintiff’s evidence excluded in a pre-trial *Daubert* hearing, the plaintiff will be unable to prove causation—“a crucial element of the plaintiff’s case.”¹⁶⁶ Before the case has even gone to trial, it will end in summary judgment, which “means *the end of the case* for the plaintiff.”¹⁶⁷

The plaintiffs in *Rider v. Sandoz Pharm. Corp.* were unable to overcome the defendant’s motion for summary judgment.¹⁶⁸ In

¹⁶¹ See Garrett, *supra* note 13, at 530.

¹⁶² Klass, *supra* note 113, at 110 (citing JOHN WARGO, *OUT CHILDREN’S TOXIC LEGACY: HOW SCIENCE AND LAW FAIL TO PROTECT US FROM PESTICIDES* 177–78 (1996)).

¹⁶³ Klass, *supra* note 113, at 110.

¹⁶⁴ Berger & Twerski, *supra* note 10, at 260.

¹⁶⁵ Berger & Twerski, *supra* note 10, at 260.

¹⁶⁶ Berger, *Upsetting the Balance*, *supra* note 85, at 290.

¹⁶⁷ Raffensperger & Myers, *supra* note 133, at 8 (emphasis in original); see also Alberts, *supra* note 88, at 40–41.

¹⁶⁸ *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002) (Plaintiffs claimed that a drug they had used to suppress lactation after giving birth—Parlodel—had caused them to suffer hemorrhagic strokes).

Rider, the plaintiffs' experts relied primarily on case reports of other individuals who had suffered similar injuries after ingesting the drug in order to provide a causal link between the drug and the injury.¹⁶⁹ Since there was no epidemiological evidence, the court had to determine whether the plaintiffs had presented sufficient causation evidence to meet *Daubert* requirements.¹⁷⁰ In finding the case report evidence insufficient to establish causation, the court demonstrated its distrust of the evidence and noted that case reports "reflect only reported data, not scientific methodology."¹⁷¹ Further, despite pointing out that, generally speaking, a lack of epidemiological evidence "is not fatal to a plaintiff's case,"¹⁷² the court found that the case reports provided only "anecdotal support" and were not enough to overcome the lack of epidemiological evidence in this case.¹⁷³ Therefore, the Eleventh Circuit affirmed the district court's grant of summary judgment.¹⁷⁴

Norris v. Baxter Healthcare Corp. is a more recent example of the preclusive effect of a narrow *Daubert* interpretation.¹⁷⁵ The

¹⁶⁹ *Id.* at 1199.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.* at 1198.

¹⁷³ *Id.* at 1199 ("Some case reports do contain details of the treatment and differential diagnosis. Even these more detailed case reports, however, are not reliable enough, by themselves, to demonstrate the causal link the plaintiffs assert that they do because they report symptoms observed in a single patient in an uncontrolled context.").

¹⁷⁴ *Rider v. Sandoz Pharm. Corp.*, 295 F.3d at 1195–96 (citing *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)) (reasoning that:

In the absence of epidemiology, plaintiffs may still prove medical causation by other evidence. In the instant case, however, plaintiffs simply have not provided reliable evidence to support their conclusions. To admit the plaintiffs' evidence, the Court would have to make several scientifically unsupported "leaps of faith" in the causal chain. The *Daubert* rule requires more. Given time, information, and resources, courts may only admit the state of science as it is. Courts are cautioned not to admit speculation, conjecture, or inference that cannot be supported by sound scientific principles. "The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.").

¹⁷⁵ 397 F.3d 878 (10th Cir. 2005).

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plaintiff in *Norris* claimed that her silicone breast implants had caused her to experience a systemic allergic reaction.¹⁷⁶ The plaintiff's expert relied on case studies that "showed a correlation between women with breast implants and the development of systemic disease."¹⁷⁷ However, the Tenth Circuit held that the case studies "did not provide an adequate scientific basis from which to conclude that breast implants in fact cause disease"¹⁷⁸ and "emphasiz[ed] the district court's finding that epidemiological evidence is the best evidence of general causation in a toxic tort case."¹⁷⁹ Accordingly, the court affirmed the grant of summary judgment.¹⁸⁰

Children with toxic tort claims are adversely affected by narrow interpretations of the *Daubert* decision. For instance, in 1998 and 1999 the Eighth Circuit heard two cases involving plaintiffs who claimed that their birth defects resulted from their mothers' pesticide exposure during pregnancy.¹⁸¹ The plaintiffs' experts

¹⁷⁶ *Id.* at 880 (stating:

Beginning in 1987, Plaintiff began to suffer from a variety of ailments including pain in her right shoulder and foot and pain and swelling in her right knee, hip, and other joints. On October 23, 1989, Plaintiff had both implants removed because her doctor believed that she had silicone-induced lupus. The diagnosis was subsequently changed by Dr. Vasey, one of Plaintiff's proffered experts, to silicone-associated connective tissue disease-autoimmune disease caused by silicone which leaked from breast implants. This disease allegedly caused Plaintiff to suffer tenderness in the muscles of her mid and low back in addition to joint swelling in her upper extremities.)

¹⁷⁷ Nina Adatia, *Recent Developments in Health Law: Select Recent Court Decisions: Expert Testimony: Experts Must Address Negative Epidemiology to Survive Summary Judgment in Products Liability Cases Involving Silicone Breast Implants—Norris v. Baxter Healthcare Corp.*, 397 F.3d 878 (10th Cir. 2005), 31 AM. J.L. & MED. 384, 385 (2005) (citing *Norris*, 397 F.3d at 885).

¹⁷⁸ Adatia, *supra* note 177, at 385.

¹⁷⁹ *Id.* (citing *Norris*, 397 F.3d at 882); *but see* Adatia, *supra* note 177, at 386 ("The Tenth Circuit emphasized that epidemiological evidence is not always required to establish causation in toxic tort liability suits.").

¹⁸⁰ Adatia, *supra* note 177, at 386.

¹⁸¹ *Klass*, *supra* note 113, at 112–13 (citing *Nat'l Bank of Commerce, of El Dorado, Ark. v. Dow Chem. Co.*, 165 F.3d 602, 605 (8th Cir. 1999) (stating:

relied upon scholarly articles, studies conducted by the manufacturer, letters from the manufacturer to the Environmental Protection Agency, and animal studies.¹⁸² However, the experts were unable to point to any epidemiological evidence which “consistently and repeatedly demonstrate[ed] any statistical association between the exposure of pregnant women to Dursban [—the pesticide—] and any increase in human birth defect” in their children.¹⁸³ As a result, the court of appeals found in both cases that the plaintiffs could not meet the scientific evidentiary requirements of *Daubert*, and therefore, could not go forward with the litigation.¹⁸⁴

Jerry and Patricia Arnold had problems with roaches and other household insects. To eliminate the problem, they allegedly purchased and applied three pesticides . . . [which they] contend they were using . . . when their son and daughter-in-law, Michael and Debra Arnold, moved into their home in December of 1992. Around the time they moved in, Debra Arnold became pregnant with Matthew Arnold who was born September 7, 1993. The use of pesticides allegedly continued throughout the early stages of Debra Arnold’s pregnancy, that is until April 1, 1993. When Matthew Arnold was born, he suffered from multiple birth defects. The Arnolds filed this action in federal district court alleging negligence, products liability, and breach of warranty claims.);

Nat’l Bank of Commerce, of El Dorado, Ark. v. Dow Chem. Co., 133 F.3d 1132, 1132 (8th Cir. 1998) (per curiam), *aff’d* 965 F. Supp. 1490 (E.D. Ark. 1996) (“Ashley Smits was born with severe birth defects. During her pregnancy, Ashley’s mother had been exposed to Dursban LO (a pesticide) and Firefog 404 (a reoderant). Plaintiffs filed suit against various defendants contending that these chemical agents, either singly or in combination, were the cause of Ashley’s abnormalities.”).

¹⁸² Klass, *supra* note 113, at 113.

¹⁸³ Klass, *supra* note 113, at 113 (quoting Nat’l Bank of Commerce, of El Dorado, Ark. v. Dow Chem. Co., 965 F. Supp. 1490, 1528 (E.D. Ark. 1996)).

¹⁸⁴ Klass, *supra* note 113, at 112–13; *but see* Klass, *supra* note 113, at 116 (In 2003, the Florida Supreme Court in *Castillo v. E.I. Du Pont De Nemours & Co.*, 854 So. 2d 1264, 1270 (Fla. 2003) “held that human epidemiological studies were not necessary in this case because pesticide exposure of this kind was rare to begin with, and it would be unethical to expose humans to a substance known to cause birth defects in animals for testing purposes.”); *\$95 Million Award to 8-Year-Old Boy in Lawsuit on Drug*, N.Y. TIMES, July 15, 1987, at A25 (discussing a 1987 case in which an eight year old boy received a

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Children who brought claims against the manufacturers of cold medications containing Phenylpropanolamine faced similar evidentiary problems. Those plaintiffs claimed they suffered adverse reactions, including strokes and cardiac arrest, from the ingestion of Phenylpropanolamine (“PPA”), an ingredient that was in many children’s cough and cold medications.¹⁸⁵ PPA was removed from the market in 2000 after the FDA concluded that there was an association between PPA ingestion and hemorrhagic strokes.¹⁸⁶ The primary piece of evidence that led the FDA to this conclusion was the Yale Study—a five-year epidemiological study which found a “link between [PPA] and hemorrhagic stroke.”¹⁸⁷ The \$5 million study was funded by the Consumer Healthcare Products Association (the nonprescription drug industry’s trade group),¹⁸⁸ and “looked at 702 men and women . . . who had been hospitalized with hemorrhagic strokes, characterized by bleeding in the brain.”¹⁸⁹

\$95 million jury verdict after using animal test results to establish a causal connection between Bendectin, an anti-nausea drug used during pregnancy, and his birth defects).

¹⁸⁵ *Drugs Containing PPA*, USA TODAY, November 7, 2000, at 3B (Some children’s medications that contained Phenylpropanolamine included Triaminic DM Cough Relief, Triaminic Expectorant Chest and Head Congestion, Triaminic Syrup Cold and Allergy, and Triaminic Triaminicol Cold & Cough); see also Sheryl Stolberg, *Ingredient in Popular Medicines in Linked to Strokes*, PLAIN DEALER (Cleveland, Ohio), October 20, 2000, at 1A (“Phenylpropanolamine, or PPA, had been used for more than [fifty] years, primarily in nonprescription cold and cough remedies as well as in appetite suppressants and some prescription decongestants. Dozens of products contain PPA, including some intended for children; the food and drug agency said 6 billion doses were sold [in 1999] alone.”).

¹⁸⁶ Stolberg, *supra* note 185, at 1A (“In recommending that the ingredient be banned from over-the-counter drugs, the [Food and Drug Administration’s] staff ha[d] already concluded that phenylpropanolamine [wa]s responsible for between 200 to 500 strokes each year in people aged [eighteen] to [forty-nine], primarily women and first time users of the drug.”).

¹⁸⁷ Stolberg, *supra* note 185, at 1A.

¹⁸⁸ Stolberg, *supra* note 185, at 1A.

¹⁸⁹ Leigh Hopper, *Area Pharmacies Pull Medications After FDA’s Alert*, HOUS. CHRON., Nov. 8, 2000, at A41; see Stolberg, *supra* note 185, at 1A (After the results of the study were released, “scientists who spoke on behalf of

Because the Yale Study did not include any children, defendant manufacturers argued that the results of the study were not applicable to children and could not be used to prove general causation in that population.¹⁹⁰ Since this was the only epidemiological study that had been conducted to look at the effects of PPA, child plaintiffs faced a significant hurdle in proving general causation.

3. *The Goals of Tort Law Are Not Being Achieved*

A rigid judicial approach to the admission of causation evidence fails to serve many of the purposes of tort law, including “adequate compensation, deterrence, and loss spreading.”¹⁹¹ Children who have suffered injuries at the hands of manufacturers that have produced unsafe medications are not adequately compensated because the judicial system requires the victims to “produce evidence from nonexistent information.”¹⁹² As we have seen, the type of evidence that would satisfy the strict evidentiary standards that many courts have imposed following the *Daubert* line of cases simply does not exist in most of these cases because most children’s medications are not sufficiently tested on children, thereby perpetuating the dearth of admissible evidence for child-plaintiffs. “[T]he more stringently trial courts insist on epidemiological studies, . . . the more likely the . . . plaintiff[s] will be to lose.”¹⁹³

the nonprescription drug industry . . . insisted the . . . study, which was paid for by their own trade group,” was “‘a failed study’ because it ‘contained too few patients to be statistically significant and that the strokes occurring in people taking phenylpropanolamine could have been caused by other factors, such as drug and alcohol abuse.’”).

¹⁹⁰ See, e.g., *In re Phenylpropanolamine (PPA) Products Liability Litigation*, 289 F. Supp. 2d 1230, 1236 (W.D. Wash. 2003) (“Defendants . . . focus on the parameters and results of the [Yale Study], arguing that the study lacks reliability as to certain ‘sub-populations,’ including men, individuals below age eighteen and above age forty-nine, and individuals suffering strokes more than three days after ingestion of PPA.”).

¹⁹¹ Garrett, *supra* note 13, at 553.

¹⁹² Raffensperger & Myers, *supra* note 133, at 14.

¹⁹³ Berger, *Upsetting the Balance*, *supra* note 85, at 304.

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Excessively strict evidentiary standards also inhibit tort law's deterrence objective. Manufacturers will continue to put children's medications on the shelves despite a lack of adequate testing because they know that they will benefit from doing so: if manufacturers do not conduct epidemiological testing, plaintiffs' claims will be dismissed because they will not have adequate evidence to meet their causation burden.¹⁹⁴ In this way, a "[l]ack of data is actually protective of defendants in these circumstances. They are better off not knowing the risk posed by their products. If they test and litigation begins, they will have to turn over testing results during discovery."¹⁹⁵ Further, even when manufacturers do conduct safety testing, narrow evidentiary standards create a disincentive for them to disclose the findings if they are not favorable.¹⁹⁶ In this way, "the current system actually protects manufacturers who ignore or conceal evidence of toxicity"¹⁹⁷ rather than encouraging them to take responsible measures to minimize the risks to their consumers.

The tort system's goal of loss spreading¹⁹⁸ is also inhibited by

¹⁹⁴ Raffensperger & Myers, *supra* note 133, at 14.

¹⁹⁵ Raffensperger & Myers, *supra* note 133, at 14; *see also* Berger, *Eliminating General Causation*, *supra* note 29, at 2134 ("Current law encourages corporations to engage in ostrich-like behavior that keeps them from knowing or investigating risk, because the future likelihood that a causal connection can be proved between the corporation's conduct and plaintiffs' injury appears minimal compared to the cost of present compliance."); Wagner, *supra* note 25, at 1636-37 ("[A]ctors benefit from knowing nothing, in part because it deprives plaintiffs of the evidence that they need to bring their case.").

¹⁹⁶ Berger, *Eliminating General Causation*, *supra* note 29, at 2119 n.8 (stating:

The emerging field of toxic torts is characterized by its lack of information for decision making, and not by its ability to generate data [T]he industrial defendant is typically in the best position to create the necessary data, but its incentives are the reverse. In the absence of dramatic changes to encourage defendants to generate and disclose potentially inculpatory toxicity evidence, tort law is unlikely to be a major factor in creating toxics data.).

¹⁹⁷ Garrett, *supra* note 13, at 520.

¹⁹⁸ *See, e.g.*, Stephen R. Perry, *Tort Law*, in *A COMPANION TO PHILOSOPHY OF LAW AND LEGAL THEORY* 57, 68 (David Patterson ed., Blackwell Publ'g, 1996).

an overly restrictive application of the *Daubert* standard. The goal would be better served by a system that holds manufacturers, “who generally possess the most knowledge about the agent and the greatest resources for further research,”¹⁹⁹ financially responsible for the injuries that result from their defective products, rather than placing the financial burden of the injury on the victims. However, the current system often does the opposite by shielding manufacturers from liability through stringent evidentiary standards, while “the burden of proof is heavily skewed toward plaintiffs.”²⁰⁰ Thus, the victims bear the financial burdens of dealing with the sometimes catastrophic injuries that children suffer following their ingestion of unsafe medications, while large drug manufacturers continue to profit.

Finally, “[t]he causation model is . . . inconsistent with notions of moral responsibility underlying tort law.”²⁰¹ In addition to encouraging manufacturers to avoid behavior that could make their products safer, courts fail to reward manufacturers when they take steps to act responsibly.²⁰² As Professor Margaret Berger has noted, “a system that encourages a ‘don’t ask, don’t tell’ policy decouples liability from moral responsibility and thus threatens the basic underpinnings of corrective justice.”²⁰³

III. PROPOSALS

A. *New Legislation*

Some legal scholars suggest that reformers should concentrate less on causation issues and more on creating incentives for drug manufacturers to “keep [themselves] reasonably informed about the risks of [their] products.”²⁰⁴ Further, commentators have called

¹⁹⁹ Garrett, *supra* note 13, at 520.

²⁰⁰ Raffensperger & Myers, *supra* note 133, at 14.

²⁰¹ Berger, *Eliminating General Causation*, *supra* note 29, at 2117.

²⁰² Berger, *Eliminating General Causation*, *supra* note 29, at 2117.

²⁰³ Raffensperger & Myers, *supra* note 133, at 14.

²⁰⁴ Raffensperger & Myers, *supra* note 133, at 14.

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for manufacturers to share such information with the consumer.²⁰⁵ One way to accomplish this goal would be to “[reform] tort law by creating a new cause of action, sounding in negligence, under which manufacturers could be held liable for ‘failure to provide substantial information relating to risk.’”²⁰⁶ This proposal would ease plaintiffs’ causation burden because it would focus on the conduct of the manufacturer and would not “[require] proof that such failure ‘caused [the] plaintiff’s injury.’”²⁰⁷ Professor Margaret Berger has endorsed the creation of this “new toxic tort,” stating that “[i]f a corporation fails to exercise the appropriate level of due care, it should be held liable to those put at risk by its action.”²⁰⁸

Another proposal attempts to address the lack of epidemiological evidence, calling for the legislature to enact a law under which manufacturers of children’s medications would be required to contribute to an independent scientific research fund.²⁰⁹ The fund would then be used “to conduct comprehensive retrospective exposure analyses and epidemiologic studies of all the populations which have been exposed.”²¹⁰ In theory, this approach would help diminish the incentives that the current causation scheme creates for drug manufacturers “not to know and not to disclose” the risks associated with their products.²¹¹ However, because of the ethical, legal, and practical difficulties associated with the testing of medications in adolescent populations, such a law may prove infeasible.

²⁰⁵ Lisa Heinzerling, *Doubting Daubert*, 14 J.L. & POL’Y 65, 83 (2006).

²⁰⁶ Brennan, *supra* note 107, at 572 (quoting Berger, *Eliminating General Causation*, *supra* note 29, at 2143).

²⁰⁷ Brennan, *supra* note 107, at 572 (quoting Berger, *Eliminating General Causation*, *supra* note 29, at 2143).

²⁰⁸ Raffensperger & Myers, *supra* note 133, at 14 (quoting Berger, *Eliminating General Causation*, *supra* note 29, at 2134).

²⁰⁹ Roisman, Judy & Stein, *supra* note 79, at 224.

²¹⁰ Roisman, Judy & Stein, *supra* note 79, at 224.

²¹¹ Berger, *Eliminating General Causation*, *supra* note 29, at 2119.

B. A Broader Range of Admissible Evidence

Other proposals focus on the variety of scientific research and evidence that courts can and should admit in toxic tort cases.²¹² Plaintiffs would be permitted to introduce the types of evidence that scientists routinely rely upon to prove causation “such as animal studies, in vitro studies, chemical structure analysis, [and] case reports,”²¹³ thereby diminishing the epidemiological evidence requirement that many courts have adopted with respect to causation issues. This policy would be consistent with FRE 703, which allows evidence to be introduced when it is the type of evidence upon which scientists regularly rely. It would be also be consistent with the courts’ opinions in *Ferebee v. Chevron Chemical Co.*²¹⁴ and *Wells v. Ortho.Corp.*,²¹⁵ recognizing that

²¹² See, e.g., Gold, *supra* note 97, at 393–94.

²¹³ Garrett, *supra* note 13, at 528–29.

²¹⁴ 736 F.2d 1529, 1531–32 (D.C. Cir. 1984) (stating:

Ferebee, an agricultural worker at the Beltsville Agricultural Research Center (BARC), an installation of the United States Department of Agriculture located in Beltsville, Maryland, allegedly contracted pulmonary fibrosis as a result of long-term skin exposure to dilute solutions of paraquat, a herbicide distributed in the United States solely by Chevron. When Ferebee died before trial, his estate continued with a survival action and a wrongful death count was added on behalf of his minor children.).

²¹⁵ 788 F.2d 741, 742–43 (11th Cir. 1986) (stating:

Katie Laurel Wells was born on July 1, 1981 with birth defects including deformity of her right hand, the complete lack of a left arm with only partial development of her left clavicle and shoulder, a cleft lip, and nostril deformity. A later diagnosis showed that she also has an optic nerve defect in her right eye. The plaintiffs alleged that these birth defects were caused by a spermicidal jelly used by the mother for approximately four weeks after conception until she discovered that she was pregnant. The spermicidal jelly used by Mary Maihafer, in conjunction with a diaphragm, was manufactured and marketed without a prescription by Ortho. Called Ortho-Gynol Contraceptive Jelly (“Ortho-Gynol”), this vaginal spermicide has as its active ingredient a non-ionic surfactant known as Octoxynol-9. The Ortho-Gynol label and package insert in 1980 contained only this warning—the spermicide

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“scientists ought to be allowed to testify even when epidemiological studies do not exist ‘as long as the basic methodology employed to reach such a conclusion is sound.’”²¹⁶ Finally, it would comport with Justice Stevens’s view that “*Daubert* was intended to allow a ‘weight of the evidence’ approach that considers all available scientific evidence, as opposed to a threshold approach that demands epidemiological studies.”²¹⁷

This policy would have many advantages over the current approach taken by many courts, as it would acknowledge the “subtlety, complexity, strengths, and weakness of different kinds of scientific evidence—and not . . . overly simpl[ify] [the] rules for admitting or barring available evidence.”²¹⁸ Such a shift in policy would also stay true to the nature of the adversarial process by allowing jurors to evaluate evidence that is currently being excluded by judges in pre-trial *Daubert* hearings, thus leaving “fact-finders free to decide which of the many inferences urged on them are reasonable.”²¹⁹ Finally, and perhaps most importantly, this approach would help to counteract the current state of affairs in which children who have been injured by unsafe medications are unable to recover damages because epidemiological evidence is either inapplicable or unavailable and the scientific evidence that is

might cause irritation to the female or male genitalia, is not 100 percent effective, and should be kept out of the reach of children. Plaintiffs brought suit against Ortho alleging that Ortho-Gynol caused Katie Wells’ birth defects, that Ortho negligently failed to warn that its spermicide could cause serious birth defects, and that Ortho’s failure to warn proximately caused the birth defects. Plaintiffs sought damages for Katie Wells’ pain and suffering, medical expenses and disability, as well as Mary Maihafer’s emotional distress and lost wages.).

²¹⁶ Garrett, *supra* note 13, at 555 (quoting *Ferebee*, 736 F.2d at 1535–36).

²¹⁷ Garrett, *supra* note 13, at 555 (citing *Joiner*, 522 U.S. at 153).

²¹⁸ Garrett, *supra* note 13, at 532 (quoting Carl F. Cranor, *Asymmetric Information, The Precautionary Principle, and Burdens of Proof*, in *PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE* 74, 89, 555 (1999) (“[S]cientific methodologies like animal studies, chemical structure analyses, in vitro analyses, and case studies can serve as reliable scientific evidence to establish causation.”)).

²¹⁹ Gold, *supra* note 97, at 394.

available is deemed inadmissible.²²⁰

C. Lower Causation Burden

In order to deal with the seemingly “insurmountable” causation burden that plaintiffs face when epidemiological evidence is unavailable, some scholars/critics suggest that the courts “[allow] the plaintiff to proceed with relatively less evidence than would be required if there were a substantial body of [evidence].”²²¹ This is the approach that the courts took in both *Heller v. Shaw Indus.*²²² and *Zuchowicz v. United States.*²²³ Plaintiffs’ experts would “be

²²⁰ See, e.g., *In re Phenylpropanolamine (PPA)*, Mass Tort Code 264, 2003 WL22417238, at *23 (N.J. Super. Ct. Law Div. July 21, 2003).

²²¹ Sanders & Machal-Fulks, *supra* note 83, at 131; *but see id.* at 132 (“Here, as in other areas of causal uncertainty, we are left with the question of how far the courts should go in easing the plaintiff’s burden of proof.”).

²²² 167 F.3d 146, 149 (3d Cir. 1999) (“This is an appeal by plaintiff Carol Heller (“Heller”), who sought to recover from defendant Shaw Industries (“Shaw”), for certain respiratory illnesses allegedly caused by volatile organic compounds emitted by Shaw carpet installed in Heller’s former home.”).

²²³ 140 F.3d 381, 383 (2d Cir. 1998) (stating:

This suit under the Federal Tort Claims Act, 28 U.S.C. § 1346(b), 2671-2680, was originally filed by Patricia Zuchowicz, who claimed to have developed primary pulmonary hypertension, a fatal lung condition, as a result of the defendant’s negligence in prescribing an overdose of the drug Danocrine. Following Mrs. Zuchowicz’s death in 1991, her husband, Steven, continued the case on behalf of his wife’s estate, claiming that the defendant was responsible for her death.).

See also Sanders & Machal-Fulks, *supra* note 83, at 131; *James v. Bessemer Processing Co.*, 155 N.J. 279, 300 (1998) (“In our toxic-tort precedents, this Court has tried to strike a balance with regard to proof of causation that is fair to both plaintiffs and defendants in view of the almost certain lack of direct scientific proof in such cases.”); *but see* Sanders & Machal-Fulks, *supra* note 83, at 131–32 (stating:

However, courts have not been willing to . . . adopt the proposals of some commentators argue that, in situations of irreducible causal uncertainty, the plaintiff should either be relieved of the burden of persuasion on the causal question or should be permitted some percentage recovery, as long as the plaintiff could establish strong uncertainty about causation.).

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permitted to render an opinion on general causation with little or no epidemiological evidence and sometimes with very little toxicological evidence.”²²⁴ It would then be up to the trier of fact to determine what weight to give the experts’ opinions. As a result, fewer plaintiffs’ cases would be dismissed on summary judgment and more victims of dangerous medical products would receive the compensation they deserve—or at least a fair review of their case.

D. Burden-Shifting

Another proposal that has received a great deal of attention from the scholarly community would “[shift] the burden of proof regarding general causation to defendants.”²²⁵ In this causation scheme, plaintiffs would still bear the initial burden of presenting a prima facie case. First, the plaintiffs would have to prove that they ingested the manufacturer’s medication. Next, they would have to show that the defendant sold an inadequately tested medication by “pointing to specific testing or data collection for evidence not already available through other means that the manufacturer could have conducted.”²²⁶ After the prima facie case had been proven, however, the burden would then shift to the defendants to disprove general causation and specific causation.²²⁷ In this way, “it would

²²⁴ Sanders & Machal-Fulks, *supra* note 83, at 131 (citing *Lakie v. Smithkline Beecham*, 965 F. Supp. 49, 56 (D.D.C. 1997)).

²²⁵ Brennan, *supra* note 107, at 573; *see also* Klass, *supra* note 113, at 134 (discussing burden-shifting in the context of toxic tort cases that involve chemicals that have been released into the environment).

²²⁶ Klass, *supra* note 113, at 134, 136.

²²⁷ Berger, *Eliminating General Causation*, *supra* note 29, at 2144–45; *see also* Garrett, *supra* note 13, at 556; Brennan, *supra* note 107, at 573. To disprove general causation, defendants would have to prove that the type of adverse reaction claimed by the plaintiff is not associated with the defendant’s medication. *See* Berger, *Eliminating General Causation*, *supra* note 29, at 2144–45; *see also* Garrett, *supra* note 13, at 556; Brennan, *supra* note 107, at 573. To disprove specific causation, defendants would have to prove that the specific injury that the plaintiff suffered was not caused by the medication, but rather by some alternative cause. *See* Berger, *Eliminating General Causation*, *supra* note 29, at 2144–45; *see also* Garrett, *supra* note 13, at 556; Brennan, *supra* note 107, at 573.

be the defendant manufacturer, not the plaintiff, who would bear the burden of scientific uncertainty,” because a lack of scientific evidence would signify an inability to disprove causation.²²⁸

Burden shifting was first discussed in 1944 by Justice Roger Traynor in *Escola v. Coca-Cola Bottling Co.*²²⁹ Justice Traynor noted that because “the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot,” the tort system was justified in shifting to the defendant the burden of proving that it had taken proper care to avoid the alleged harm.²³⁰ He further commented that “public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market.”²³¹ More recently, many states have shifted the burden in cases involving inadequate safety testing from the defendant to the plaintiff, thereby resulting in compensation for the victim.²³²

The burden-shifting doctrine has the potential to “restore the basic moral underpinnings to the law.”²³³ The implementation of burden-shifting principles could serve the tort system’s retributive purposes by holding manufacturers responsible for subjecting consumers to the risk of injury.²³⁴ In *Summers v. Tice*,²³⁵ the

²²⁸ Klass, *supra* note 113, at 134 (citing Lynda M. Collins, *Strange Bedfellows? The Precautionary Principle and Toxic Tort: A Tort Paradigm for the 21st Century*, 35 ENVTL. L. REP. 10,361, 10,370 (2005)).

²²⁹ 150 P.2d 436 (Cal. 1944).

²³⁰ Garrett, *supra* note 13, at 535 (quoting *Escola*, 150 P.2d at 440–41).

²³¹ Garrett, *supra* note 13, at 535.

²³² Klass, *supra* note 113, at 143.

²³³ Raffensperger & Myers, *supra* note 133, at 14 (“A corporation ought to exercise a responsible level of due care and be held liable to those who have been put in harm’s way by its action without regard to the actual harm. As Berger says, a corporation should be culpable if it has acted without taking into account the interests of those who will be affected by its conduct.”).

²³⁴ Raffensperger & Myers, *supra* note 133, at 14.

²³⁵ 199 P.2d 1 (Cal. 1948) (stating:

Plaintiff’s action was against both defendants for an injury to his right eye and face as the result of being struck by bird shot discharged from a shotgun. The case was tried by the court without a jury and the court found that on November 20, 1945, plaintiff and the two defendants were hunting quail on the open range. Each of the defendants was armed with

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“court . . . reasoned that if determining causation . . . was difficult, . . . ‘the innocent wronged party should not be deprived of his right to redress,’ and ‘the wrongdoers are not in a position to complain of uncertainty.’”²³⁶ Further, it is morally just for “those who stand to profit from the product” to be left “with the responsibility of demonstrating with a high level of confidence that harm will not occur.”²³⁷

Burden-shifting spreads the costs of injuries resulting from dangerous medications by placing the cost on the manufacturers who produced them because they are in the best position to “conduct the studies, to balance the cost of studies against the potential cost of tort suits, and to distribute those costs.”²³⁸ The court in *Sindell v. Abbott Laboratories*²³⁹ agreed, concluding that “as between an innocent plaintiff and negligent defendants, the

a 12 gauge shotgun loaded with shells containing 7 1/2 size shot. Prior to going hunting plaintiff discussed the hunting procedure with defendants, indicating that they were to exercise care when shooting and to “keep in line.” In the course of hunting plaintiff proceeded up a hill, thus placing the hunters at the points of a triangle. The view of defendants with reference to plaintiff was unobstructed and they knew his location. Defendant Tice flushed a quail which rose in flight to a 10-foot elevation and flew between plaintiff and defendants. Both defendants shot at the quail, shooting in plaintiff’s direction. At that time defendants were 75 yards from plaintiff. One shot struck plaintiff in his eye and another in his upper lip. Finally it was found by the court that as the direct result of the shooting by defendants the shots struck plaintiff as above mentioned and that defendants were negligent in so shooting and plaintiff was not contributorily negligent.).

²³⁶ Klass, *supra* note 113, at 140 (quoting *Summers*, 199 P.2d at 5).

²³⁷ Garrett, *supra* note 13, at 520 (citing David Freestone, *International Fisheries Law Since Rio: The Continued Rise of the Precautionary Principle*, in *INTERNATIONAL LAW AND SUSTAINABLE DEVELOPMENT PAST ACHIEVEMENTS AND FUTURE CHALLENGES* 135, 135 (Alan Boye et al. eds., 1999)).

²³⁸ Brennan, *supra* note 107, at 573; *see also* Taylor, *supra* note 79, at 1 (“the cost of injuries involving dangerous products should be borne by the manufacturers, who are in the best position to minimize the risks and to spread the cost through insurance.”)

²³⁹ 607 P.2d 924, 936 (Cal. 1980) (Plaintiffs were the children of women who had ingested DES during their pregnancy and alleged that the chemical resulted in injuries including a malignant bladder tumor).

latter should bear the cost of the injury and that ‘from a broader policy standpoint,’ defendants were better able to bear the cost of injury resulting from the creation of a defective product.’²⁴⁰ Under the current scheme, victims are often unsuccessful in bringing a claim against the defendant manufacturer, and therefore bear the entire costs of injury, including litigation fees, which can be financially devastating.²⁴¹ However with a burden-shifting framework, defendant manufacturers would be able to spread the associated costs of production, testing, and litigation defense to their insurance carriers,²⁴² consumers, and stockholders, and “the financial effect on each individual [would] likely [be] small.”²⁴³

Finally, shifting the causation burden to the manufacturers of dangerous medications would also deter dangerous behavior.²⁴⁴ The increased liability that pharmaceutical manufacturers would face would be an incentive to take steps to avoid litigation in the first instance.²⁴⁵ Drug companies would be more likely to conduct adequate safety testing on children’s medications and to disclose the results of that testing in an effort to disprove causation should litigation occur.²⁴⁶ If, on the other hand, safety testing is not feasible, manufacturers may be deterred from placing their product on the market altogether.²⁴⁷ In this way, pharmaceutical

²⁴⁰ Klass, *supra* note 113, at 141–42 (citing *Sindell*, 607 P.2d at 936).

²⁴¹ Garrett, *supra* note 13, at 558.

²⁴² Taylor, *supra* note 79, at 1.

²⁴³ Garrett, *supra* note 13, at 558 (citing Sidney A. Shapiro, *Keeping the Baby and Throwing Out the Bathwater: Justice Breyer’s Critique of Regulation*, 8 ADMIN. L.J. AM. U. 721, 732 (1995)).

²⁴⁴ Roisman, Judy & Stein, *supra* note 79, at 225.

²⁴⁵ Roisman, Judy & Stein, *supra* note 79, at 225; *see also* Taylor, *supra* note 79, at 1 (“If injuries caused by dangerous products become a cost of doing business for a producer . . . there will be an incentive to make safer products to avoid liability.”).

²⁴⁶ *See* Brennan, *supra* note 107, at 573; *see also* Klass, *supra* note 113, at 135–37 (discussing the effect of burden shifting on pesticide manufacturers); Garrett, *supra* note 13, at 559 (“The precautionary principle . . . encourag[es] defendants to expose, not conceal, science so that they may escape liability by showing that they are not to blame.”).

²⁴⁷ Roisman, Judy & Stein, *supra* note 79, at 217. (“If the real cost of producing . . . a substance or product is so high when properly allocated that no

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manufacturers, who “have superior knowledge or access to knowledge about the[ir] product,”²⁴⁸ would be “force[d] . . . to fully take the costs of children’s health into account in analyzing which products to place on the market and to conduct the scientific studies necessary to ensure their safety.”²⁴⁹ Burden-shifting would then deter manufacturers from gambling with the lives of their customers and protect children from harm not only *after* injuries have been sustained, but more importantly, *before* injuries ever occur.²⁵⁰

E. A Recognized Right To Make An Informed Choice

Ethical concerns about children’s ability to give informed consent for involvement in clinical testing are one of the main reasons for the lack of safety testing on children’s medications.²⁵¹ This concern, however, is seemingly ignored once medications are on the shelf because inadequate safety information and nonexistent warnings deprive consumers “of the right to choose whether they wish to subject themselves to the material risk of . . . harm.”²⁵² In a

business can successfully survive, the solution is not to force innocent parties to continue to absorb those costs but to stop manufacturing . . . the product and develop a safer alternative.”); *see also* Klass, *supra* note 113, at 117–18 (stating:

In the end, the message to take away from the cases is somewhat mixed. Liability verdicts against manufacturers can influence which products are on the market and what warnings accompany those products. Although manufacturers warn that valuable products will not be available to consumers at low costs . . . it is not difficult to posit that higher consumer costs may be a legitimate tradeoff for the removal of products that are harmful to children’s health and that quite possibly incur even larger and longer-term health-related costs to society.).

²⁴⁸ Garrett, *supra* note 13, at 559.

²⁴⁹ Klass, *supra* note 113, at 145.

²⁵⁰ *See* Berger, *Eliminating General Causation*, *supra* note 29, at 2152 (“A chief objective of this proposal is to induce corporations to engage in far more scientific research when it matters—not to win lawsuits but to protect society against the risks posed by their products.”).

²⁵¹ *See, e.g.* Garrett, *supra* note 13, at 530 (“With suspected toxins, moral concerns preclude conducting controlled tests on human subjects.”).

²⁵² Berger & Twerski, *supra* note 10, at 288.

sense, therefore, children become unknowing participants in informal experiments conducted by the pharmaceutical industry, which nevertheless produce results (i.e., case studies) that are usually deemed inadmissible by the courts when injuries arise.

Some scholars have argued that courts should recognize the right of individuals to make an informed choice about whether or not to expose themselves to medications that may pose a risk to their health.²⁵³ To facilitate this patient right, pharmaceutical manufacturers would be required to warn consumers about risks that are reasonably foreseeable.²⁵⁴ The focus would therefore shift away from the plaintiff's burden in proving causation *after* an injury has occurred, and move toward informing consumers about the potential risks *before* the medication has been ingested.²⁵⁵

There have been many tort actions alleging that drug manufacturers did not adequately warn consumers about the dangers associated with their products.²⁵⁶ For instance, the manufacturer of Parlodel²⁵⁷—a drug taken by women after childbirth to suppress lactation—did not advise users about the risk of stroke associated with the drug or of the simple and possibly more effective alternative of ingesting aspirin. Subsequently, the drug was taken off the market by the FDA because the “possible risks outweigh[ed] the limited benefits.”²⁵⁸ However, women who had suffered the catastrophic effects of the medication prior to its removal were left with little remedy because most courts found that plaintiffs could not meet *Daubert* standards regarding the causation issue.²⁵⁹ Certainly, these women would not

²⁵³ See Berger & Twerski, *supra* note 10, at 267–70 (explaining that courts have held drug manufacturers liable in products liability cases where they have “fail[ed] to provide adequate information about risks associated with a . . . drug,” but that such liability has been contingent upon proof of a “causal relationship between the uncertain risk and the plaintiff’s harm.”).

²⁵⁴ See Berger & Twerski, *supra* note 10, at 267–68.

²⁵⁵ See Berger & Twerski, *supra* note 10, at 267–68.

²⁵⁶ See Berger & Twerski, *supra* note 10, at 269–70.

²⁵⁷ Sandoz/Novartis was the manufacturer of Parlodel. Berger & Twerski, *supra* note 10, at 269.

²⁵⁸ *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002).

²⁵⁹ In *Rider*, the plaintiff’s claims against the drug manufacturer were unsuccessful because United States Court of Appeals for the Eleventh Circuit

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have taken the medication in the first place if they had been warned of the dangers associated with the medication.

Bendectin is another example of a dangerous drug about which users were not adequately warned.²⁶⁰ It was used from 1957 through 1983 to treat morning sickness in expectant mothers, but the drug was taken off the shelves because of “widespread fears that it caused severe birth defects [including limb reduction] in the children whose mothers ingested the drug while pregnant.”²⁶¹ When parents of children who were born with the birth defects brought a suit against the manufacturer of the drug, they relied upon a variety of evidence, including “in vitro . . . studies, in vivo . . . studies, chemical structure analyses, and retrospective epidemiological studies.”²⁶² While some early plaintiffs were victorious, the majority of plaintiffs who brought claims against the manufacturer of Bendectin were unsuccessful because the evidence was deemed insufficient to establish a causal link.²⁶³ Perhaps a more equitable result would have been reached if the court had recognized an “informed choice” action because “[t]here is little doubt that the

determined that she could not meet *Daubert* standards on the issue of causation. 295 F.3d 1194.

²⁶⁰ See Berger and Twerski, *supra* note 10, at 268–69.

²⁶¹ Berger and Twerski, *supra* note 10, at 268 (citing MICHAEL D. GREEN, *BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION* 91, 180 (1996)).

²⁶² Berger and Twerski, *supra* note 10, at 268; see also Extension Toxicology Network, Epidemiology, <http://pmep.cce.cornell.edu/profiles/extoxnet/TIB/epidemiology.html> (last visited Nov. 13, 2007) (stating:

Epidemiological studies can be divided into two basic types depending on (a) whether the events have already happened (retrospective) or (b) whether the events may happen in the future (prospective). The most common studies are the retrospective studies which are also called case-control studies. A case-control study may begin when an outbreak of disease is noted and the causes of the disease are not known, or the disease is unusual within the population studied.)

²⁶³ Berger and Twerski, *supra* note 10, at 268 (citing *DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 943 (3d Cir. 1990) (“The district court held that [the testimony of the plaintiff’s expert in pediatric pharmacology] would be inadmissible at trial because it was not based on data of a type reasonably relied upon by experts in the pertinent fields in issuing opinions on these subjects, as is required by Federal Rule of Evidence 703.”).

vast majority of expectant mothers suffering from the discomfort of morning sickness would have refused to take Bendectin to alleviate their discomfort if told that the drug carried with it an uncertain risk of birth defects to their fetuses.”²⁶⁴

The right to make an informed choice is particularly important when the drugs are not necessary treatments, but rather, treat minor ailments, have “little therapeutic value,” or to which viable alternatives are available.²⁶⁵ When these situations occur in children’s medications, it is easy to understand that most parents would have chosen to give their children an alternative therapy or would have foregone treatment altogether had they been adequately warned of the possible dangers.²⁶⁶ Take, for instance, Phenylpropanolamine (“PPA”)—an ingredient that was found in many over-the-counter children’s cough/cold medications for decades.²⁶⁷ In recommending that PPA be taken off the market in 2000, the FDA considered that medications containing PPA were used to treat run of the mill, non-life threatening illnesses for which there were many viable alternative treatments, as well as the severe risk of hemorrhagic stroke associated with use of the drug.²⁶⁸ Certainly, if parents were given the choice between subjecting their child to a risk of hemorrhagic strokes or putting up with a runny nose, the choice would have been clear.²⁶⁹ Nonetheless, the manufacturers did not warn about the risks,²⁷⁰ and the total number

²⁶⁴ Berger and Twerski, *supra* note 10, at 269.

²⁶⁵ Berger and Twerski, *supra* note 10, at 268, 288.

²⁶⁶ Berger and Twerski, *supra* note 10, at 268.

²⁶⁷ *Drugs Containing PPA*, *supra* note 185, at 3B.

²⁶⁸ Hopper, *supra* note 189, at A41. Stolberg, *supra* note 185, at 1A (Before the drug was removed from the market, the FDA had received 44 reports of hemorrhagic strokes following the ingestion of PPA, and “officials said . . . that the true number [wa]s probably much higher, due to underreporting.”).

²⁶⁹ See, e.g., Sheba R. Wheeler, *Pharmacies Yank Products With FDA-Flagged Ingredient*, DENV. POST, November 8, 2000, at B-01 (reporting that one customer, whose child was born just three days before the recall, indicated that he was not worried about the news reports indicating that many cold remedies and diet pills that contained phenylpropanolamine had been linked to an increased rate of stroke, “until he realized that some children’s medications might contain the problematic drug.”).

²⁷⁰ See Stolberg, *supra* note 185, at 1A (noting that the Consumer

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of children who were adversely affected by PPA may never be known.

Safety concerns about children's cough and cold medications did not end when PPA-containing drugs were recalled.²⁷¹ In October 2007, the manufacturers of many popular children's medications withdrew their products from the market²⁷² after the FDA recommended that they should not be used in children under age six.²⁷³ Before the voluntary recall by manufacturers, these medications were widely available²⁷⁴ even though their safety or efficacy had not been tested in pediatric populations.²⁷⁵ More disturbingly, after the FDA's recommendations,²⁷⁶ some manufacturers of children's medications have chosen to keep their products on the market.²⁷⁷ Perhaps if the courts recognized an informed choice cause of action that was not contingent upon proof of causation, manufacturers would be less willing to ignore the reported dangers. In the meantime, children will continue to be injured by medications that their parents may not have chosen to give them had they received the proper information beforehand.²⁷⁸

Healthcare Products Association stated: "[o]ur members stand behind PPA as safe and effective products when used according to label directions.").

²⁷¹ See, e.g., Harris, *supra* note 1, at A18.

²⁷² Over-the-Counter Infant Cold Medications Recall Sparked by Safety Concerns, www.newsinferno.com/archives/1902 (last visited Nov. 11, 2007).

²⁷³ Hollis, *supra* note 2.

²⁷⁴ *Over-the-Counter Infant Cold Medications Recall Sparked by Safety Concerns*, *supra* note 273 ("Prior to this recall, there were about 800 different over-the-counter cold medications sold in the U.S. for use in young children.").

²⁷⁵ Meadows, *supra* note 3, at 74; *Over-the-Counter Infant Cold Medications Recall Sparked by Safety Concerns*, *supra* note 273 (The FDA previously replied upon safety and dosing information that had been extrapolated from adult studies).

²⁷⁶ *McNeil Consumer Healthcare is Voluntarily Withdrawing Infants' Cough and Cold Products*, LAB BUSINESS WEEK, October 28, 2007, at 445.

²⁷⁷ See, e.g., Harris, *supra* note 6, at A1 ("Despite the industry's recommendation, many companies—including such giants as Johnson & Johnson—continue to sell cough and cold medicines with 'infant' in their titles and pictures of babies on their labels.").

²⁷⁸ See Berger and Twerski, *supra* note 10, at 288.

CONCLUSION

Adverse drug reactions are one of the leading causes of death in this country. Children are particularly at risk because ethical and economic barriers often prevent or discourage children's pharmaceutical manufacturers from conducting adequate safety testing. The recent removal of many children's cough and cold medications from pharmacy shelves has highlighted the risks that result from inadequate safety testing. Federal legislative measures aimed at increasing the amount of testing that is conducted on pediatric medications have produced only limited success. Therefore, new measures must be developed and implemented in order to protect children from this disturbing threat.

The tort-system is well-suited for protecting children from the adverse effects of unsafe medications because it has the capacity to compensate victims, deter dangerous or negligent behavior by manufacturers, and spread losses amongst those who are in the best position to prevent them. However, narrow interpretations of *Daubert* evidentiary standards often result in the exclusion of non-epidemiological evidence of causation, leaving child plaintiffs with an insurmountable burden on this critical element of their toxic tort claims. In this regard, defendant manufacturers actually benefit from their own negligent behavior. That is, their failure to conduct product safety tests insulates them from liability by depriving plaintiffs of the critical scientific evidence they need to bring a successful claim. Therefore, while the tort system has the potential to protect children from dangerous pharmaceuticals, it is doing the opposite.

Legal scholars have proposed a variety of measures to help counteract the overwhelming challenges that plaintiffs face in bringing toxic tort claims, including new legislation, a broader range of admissible evidence, a lower causation burden, burden-shifting, and the implementation of the consumer's right to make an informed choice. If implemented, these proposals would create incentives for manufacturers to conduct adequate safety testing on children's medications or to keep such medications off the shelves altogether. Further, if manufacturers chose to follow neither of

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these paths, they would face an increased likelihood of liability for the injuries caused by their products. As a result, the tort system would not only be better equipped to compensate children after they sustain injuries from dangerous medications, but also, and more importantly, to protect children from injuries before they ever occur.