

ARTICLE

THE PLAGUE OF CAUSATION IN THE NATIONAL CHILDHOOD VACCINE INJURY ACT

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The last twenty years have seen a sea-change in the area of proving causation in the toxic tort setting, with courts demanding stronger, scientifically tested evidence. At the same time, a closely related debate has been raging about separating cause from coincidence under the National Childhood Vaccine Injury Act compensation program for injuries that might have been the result of vaccinations. The Vaccine Act created a no-fault compensation fund financed by a tax on childhood vaccines to address harms resulting from those vaccines. Unfortunately, Congress gave little direction with regard to the level of causal certainty that would be required under the program in the initial legislation, assuming that better science would be developed on vaccine causation. The science has not developed as anticipated, mostly because vaccine side effects are so low that they are hard to study. The Department of Health & Human Services, intimately involved in the program, takes the position that causal proof must be backed by “hard science” under the program. The Federal Circuit, the federal court charged with overseeing the program, has gradually relaxed the sufficiency standard for causal proof. This Article argues that the Federal Circuit, while implementing a program with different policy goals and not constrained by toxic tort law, has gone too far under the Act as written, but that the logic of its decisions should cause Congress to amend the Act to conform to the more relaxed causation standard.

I. INTRODUCTION

Much ink has been spilled about what level of certainty should be required for proving toxic tort causation.¹ Much less has been devoted to a closely related debate raging in the administrative dispute context. For the last twenty years, the difficulty of separating cause from coincidence has

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¹ See, e.g., 3 DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 21:2 (2009-2010); David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 BROOK. L. REV. 51 (2008); 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 (2007).

plagued thousands of claimants' right to recover under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "NCVIA")² for injuries that might have been the result of vaccinations. Driven by different policy concerns, the courts reviewing those claims have deviated from traditional tort standards to lower the amount of evidence necessary to prove causation. This Article concludes that they have gone too far under the Act as written, but that the logic of their decisions should spur Congress to amend the Act to conform with the courts' articulation of the causation requirement.

The Vaccine Act created a no-fault compensation fund financed by a tax on childhood vaccines to address harms resulting from those vaccines.³ In creating this Vaccine Fund, Congress recognized that "[w]hile most of the Nation's children enjoy great benefit from immunization programs, a small but significant number have been gravely injured."⁴ Congress found that the state common law tort system had not provided effective redress "because it resulted in lengthy delays, high transaction costs, and sometimes no recovery."⁵ Congress was also acutely aware that the threat of tort claims caused vaccine manufacturers to consider abandoning the creation of vaccines altogether.⁶ Responding to these concerns, the federal no-fault compensation system, which claimants must exhaust before seeking redress in court, was intended to compensate vaccine-injured individuals "quickly, easily, and with certainty and generosity."⁷ With special masters appointed by the Court of Federal Claims serving as the initial decisionmakers, the vaccine courts have confronted diverse claims, including that a preservative in vaccines causes autism,⁸ that a causal link exists between vaccines and demyelinating disorders,⁹ and that there is a connection between vaccines

² National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 to -34 (2006).

³ See *id.* § 300aa-11(c); Vaccine Injury Compensation Trust Fund, I.R.C. § 9510 (2006).

⁴ H.R. REP. NO. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345.

⁵ *Lowry v. Sec'y of Health and Human Servs.*, 189 F.3d 1378, 1381 (Fed. Cir. 1999); see H.R. REP. NO. 99-908, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347 (noting that tort system was inadequate to compensate victims whose "futures [had] been destroyed" by a vaccine related injury).

⁶ See H.R. REP. NO. 99-908, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347.

⁷ H.R. REP. NO. 99-908, at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6344; see also *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011) ("The Act establishes a no-fault compensation program 'designed to work faster and with greater ease than the civil tort system.'") (quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)).

⁸ See *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. 2009); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. 2009); *Hazelhurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. 2009).

⁹ See Whitney S. Waldenberg & Sarah E. Wallace, *Empirical Study, When Science is Silent: Examining Compensation of Vaccine-Related Injuries When Scientific Evidence of Causation is Inconclusive*, 42 WAKE FOREST L. REV. 303 (2007) (describing claims brought under the program for demyelinating disorders). Demyelinating diseases are conditions resulting in damage to the myelin sheath, which protects the nerves in the brain and spinal cord. See *id.* at 311-15.

and Sudden Infant Death Syndrome (“SIDS”).¹⁰ Proponents of the system advocate its further use to address the risks of bioterrorism vaccines,¹¹ to encourage manufacturers to produce vaccines against flus that threaten to become pandemics,¹² and to serve as a model for resolving claims in the medical malpractice area.¹³ The program may also serve as a model for the vaccine compensation program being considered by Canada.¹⁴

The central problem in the Vaccine Act system is defining a compensable harm. A claimant can present a claim under the no-fault scheme in one of two ways: as a “Table” claim or an “off-Table” claim. The Vaccine Injury Table is a statutorily created list of vaccines, adverse effects associated with those vaccines, and time limits for raising claims related to a listed vaccine, which can be amended through a complex regulatory and legislative process headed by the Department of Health and Human Services (“HHS”) and informed by the scientific community.¹⁵ An injury that falls under the Table framework receives a presumption of proven causation.¹⁶ Claimants whose injuries do not meet these criteria may bring an off-Table claim by proving that the injury was caused by the vaccine.¹⁷ HHS acts as the respondent to both Table and off-Table claims.¹⁸

How off-Table claims are resolved has huge consequences for the claimants and the fund. Although Congress intended the Table to be the centerpiece of the program, the number of off-Table claims has come to far surpass the number of Table claims.¹⁹ They now likely account for 90% of

¹⁰ See RICHARD GOLDBERG, CAUSATION AND RISK IN THE LAW OF TORTS: SCIENTIFIC EVIDENCE AND MEDICAL PRODUCT LIABILITY 164 (1999) (describing numbers of cases dealing with diphtheria, pertussis, and tetanus vaccines and Sudden Infant Death Syndrome).

¹¹ Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J.L. & PUB. POL’Y 537, 545 (2009) (arguing that with biological threats to the public “comes the age-old question of the risks posed by vaccines and how the risks ought to [be] distributed among the public, individuals, manufacturers, and governments”); see Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government’s Lackadaisical Liability and Compensation Policies in the Context of Pre-event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL’Y 7 (2005) (H1N1 pandemic compensation proposal).

¹² Andrew Pollack, *Lessons From a Plague That Wasn’t*, N.Y. TIMES, Oct. 23, 2005, at C5 (comparing the 1976 swine flu scare and the threatened 2005 avian bird flu pandemic).

¹³ See PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION 145–51 (1993) (Harvard Medical Practice Study Group description of a no-fault medical injury insurance plan); David M. Studdert & Troyen A. Brennan, *Toward a Workable Model of “No Fault” Compensation for Medical Injury in the United States*, 27 AM. J.L. & MED. 225, 229 (2001) (citing vaccine compensation program as a model over tort litigation).

¹⁴ See Program, Ninth Canadian Immunization Conference: Immunization: A Global Challenge for the 21st Century, 14 (Dec. 6, 2010), <http://www.phac-aspc.gc.ca/cnic-ccni/2010/pdf/CIRID%20Prelim%20program%20ENG%20FINAL%200622.pdf> (early discussions regarding a national no-fault compensation program for vaccine related injuries in Canada, and discussing United States program).

¹⁵ See *infra* notes 71–78 and accompanying text.

¹⁶ See *infra* notes 79–80 and accompanying text.

¹⁷ 42 U.S.C. § 300aa-11(c)(1)(C)(ii) (2006).

¹⁸ *Id.* § 300aa-12(b)(1) (2006).

¹⁹ See U.S. GOV’T ACCOUNTABILITY OFFICE, GAO/HEHS-00-8, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 1 (1999); Katherine

all claims,²⁰ and off-Table claimants have received billions of dollars in compensation.²¹

With off-Table claims, the critical question—and the focus of this Article—is defining the level of proof sufficient to show causation. The Vaccine Act itself does not supply a standard, nor has precedent under the Act clarified the issue. The primary question is whether the program should, or could, require the same sufficiency of evidence standard used in the common law tort context and still promote the goals of the program. Striking the appropriate balance on the causation issue is critical because requiring too high a standard would leave worthy victims uncompensated and potentially threaten the vaccine manufacturing market, while too low a standard could open the floodgates to unworthy claims and suggest to the public that vaccines present risks that outweigh their benefits.

Three entities can control the sufficiency of causal proof required in off-Table claims: (1) Congress, in its ability to amend the statute; (2) HHS, indirectly in its ability to amend the Table;²² and (3) the Federal Circuit, in its interpretation of the Act and oversight of implementation of the program. The latter two entities have been at odds in defining the primary goals of the program and, consequently, the level of certainty required to prove causation. Congress, through inaction, has not resolved the debate.²³

Congress provided little guidance on the sufficiency of causal proof question in the initial legislation, although legislative history suggests that Congress assumed that better evidence regarding harms caused by vaccines would develop over time.²⁴ Congress apparently expected that as evidence developed HHS would expand the Table to list additional combinations of injuries and vaccines, and the need for off-Table claims would be reduced or eliminated. Congress's assumptions have not been realized, however, because the science has not developed as anticipated—mostly because vaccine side effects are so rare that they are hard to study. Congress has considered the causal proof issue in three oversight hearings since the enactment of the Act but has not amended the Act to clarify the causation requirement.²⁵

E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 444–45 (2007) (describing shift from Table claims to off-Table claims).

²⁰ See *Stevens v. Sec'y of Health & Human Servs.*, 2001 WL 387418, at *8 (Fed. Cl. Mar. 30, 2001); Strong, *supra* note 19, at 445–48 (explaining that due to changes in the Vaccine Injury Table, 90% of claims are now off-Table claims).

²¹ *National Vaccine Injury Compensation Program: Statistics Reports*, HEALTH RES. AND SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited Feb. 20, 2011).

²² HHS can also affect the sufficiency of causal proof in approving settlements of claims in its capacity as respondent to petitions filed under the program. See 42 U.S.C. § 300aa-12(b)(1) (naming Secretary of HHS as respondent).

²³ See *infra* notes 76–78 and accompanying text (describing HHS position); *infra* notes 340–428 and accompanying text (describing Federal Circuit jurisprudence); *infra* notes 134–150 and accompanying text (describing congressional inaction).

²⁴ See *infra* notes 112–113 and accompanying text.

²⁵ See *infra* notes 134–150 and accompanying text.

HHS has amended the Table over time, but instead of expanding it, HHS has generally made it more restrictive.²⁶ HHS maintains that its Table amendments are closely tied to the views of the scientific community, placing “hard science” and protection of the integrity of vaccines over other policy concerns.²⁷

The increased frequency of these claims, combined with Congress’s lack of direction regarding their resolution, have left the special masters and courts in charge of implementing the program to struggle with the sufficiency of evidence question and how much to be influenced by traditional tort law.²⁸ The Federal Circuit, in interpreting the sufficiency of evidence for causal proof in off-Table claims, has leaned toward lower sufficiency standards, thereby increasing the pool of claimants compensated under the program and reducing the potential number of claimants who could later seek redress in court.²⁹

In the broadest terms, the substantive elements demanded in a common law toxic tort case and in an off-Table claim are comparable.³⁰ Although the language defining the respective causal tests varies, both systems require the claimant to prove general causation (the fact that the toxin or vaccine can cause the injury) and specific causation (the fact that the toxin or vaccine caused the particular claimant’s injury). Both systems nominally require claimants to prove causation by a preponderance of the evidence.

However, the Vaccine Fund system, as judicially applied, frequently collapses the two inquiries and accepts a lesser quantity and quality of evidence as meeting the preponderance standard. In a traditional toxic tort case, if an expert witness merely makes an educated guess (without supportive empirical data) either that a substance can cause an illness, or that it did cause illness in an individual, the legal system’s response frequently would be to rule against the claimant.³¹ The same may not be true under the vaccine compensation program.

Although claims brought under the Table enjoy a relaxed burden of proof on causation on the theory that the Table reflects the causal effects and

²⁶ See *infra* note 74 and accompanying text.

²⁷ See *infra* notes 76–77 and accompanying text.

²⁸ See *The National Vaccine Injury Program: Is it Working as Congress Intended? Hearings Before the H. Comm. on Gov’t Reform*, 107th Cong. 138 (2001) [hereinafter *2001 Hearing*] (statement of Rep. Burton (R-Ind.)); DIV. OF VACCINE INJURY COMP., U.S. DEP’T OF HEALTH & HUMAN SERVS., NATIONAL VACCINE INJURY COMPENSATION PROGRAM STRATEGIC PLAN 1 (2006), ftp://ftp.hrsa.gov/vaccinecompensation/strategic_Plan_20060411.pdf (noting the “dramatic shift” from “nearly all” Table claims to a majority non-Table claims, which “raises questions as to how the current causation standard is applied to VICP claims”).

²⁹ See *infra* Part IV.

³⁰ Toxic torts are a subset of tort cases that are a close analog to vaccine injury claims because they involve exposures to agents, such as pharmaceutical drugs or chemicals, which cause physical injury. See *infra* note 159.

³¹ See Margaret A. Berger & Lawrence M. Solan, *A Cross-Disciplinary Look at Scientific Truth: What’s the Law to Do? The Uneasy Relationship Between Science and Law: An Essay and Introduction*, 73 BROOK. L. REV. 847, 851 (2008).

time frames of onset recognized by the scientific community,³² controversy remains over whether the lax standard should be applied to off-Table claims as well. Until the overriding objective of the vaccine program is clarified, the appropriate level for sufficiency of causal proof cannot be determined. Is the principal objective to ensure adequate vaccine supplies by minimizing liability against manufacturers and administrators? If so, that would mitigate in favor of a laxer sufficiency standard. Or, is the Act's primary objective to encourage widespread vaccination of the population by ensuring that vaccines are not incorrectly blamed for causing injury? If that is the case, it would argue in favor of a more stringent standard. Even assuming that the policies suggested by the vaccine program's legislative history support a lowered level of sufficiency for meeting the preponderance standard in off-Table cases, the special masters as well as the federal courts have reached inconsistent conclusions about how low that level should be. Similarly, the special masters and the federal courts have been inconsistent on the issue of who bears the burden of proving or eliminating alternative causes—the claimant or the respondent.³³

This Article advocates an approach to resolving the issues that have permeated off-Table claims. The proposed model would require Congress to amend the Vaccine Act to remove the concept of “causation” that has so beguiled the courts and replace it with an intermediate proof standard such as “association.” This change would relax the tort law implications of causal proof and shift the risk of scientific uncertainty to the respondent (or the Vaccine Fund) to a greater degree than is found in the common law tort system. Under this model, petitioners would need to demonstrate two elements of association: (1) the theoretical capacity of the vaccine to cause this type of injury; and (2) proof that the vaccine should be associated with the harm of which the petitioner complains.

To meet the first element, a petitioner would need to demonstrate that such a link is theoretically or biologically possible with sound scientific evidence. Petitioners would also be obligated to demonstrate that an association between the vaccine and the alleged harm has not been ruled out by the scientific or medical community. Although this is similar to the test currently used by the Federal Circuit, it clarifies that petitioners do not have to affirmatively demonstrate beyond a preponderance of the evidence that the scientific community has recognized a general causal link to the injury. If the petitioner could meet this *prima facie* test and it was not refuted by the respondent, then the petitioner would need to demonstrate that it is appropriate to link the vaccine to this particular petitioner's harm. Under this second prong of the inquiry, the petitioner would need to demonstrate that the timing of the injury's onset was consistent with a link to the vaccine and that the elapsed time between vaccination and the onset was within a period of time

³² See *infra* notes 71–79 and accompanying text.

³³ See *infra* notes 402–428 and accompanying text.

that is biologically sufficient and has not been ruled out by the scientific or medical community. The petitioner would also need to demonstrate that he or she had no pre-existing medical history of the disease at issue.

Once the petitioner met these two elements, the burden would shift to the respondent to prove by a preponderance of the evidence that a factor unrelated to the vaccine is more likely associated with the injury. If the respondent could not meet this burden, the petitioner would be entitled to compensation from the Vaccine Fund.

Although this model lowers the sufficiency of evidence standard such that experts would not have to demonstrate a theory of causation that has survived rigorous testing, petitioners would still need to rely on sound scientific evidence to the extent it is available. This standard is discussed more fully below.

Some background is necessary to put this proposed model in context. Part II of this Article describes the program established by the Vaccine Act and reviews the legislative history. It concludes that in adding the off-Table option late in the process, Congress provided little guidance for its implementation and assumed that the need for off-Table claims would be reduced or eliminated as the science on vaccine injuries improved. Part III reviews the standards for proving causation in toxic tort cases brought in the traditional common law tort setting, which have grown more demanding over time, while Part IV explores the causation principles that have been developed under the Vaccine Act by the special masters and the federal courts, which have grown more lax. Part V examines different potential approaches to off-Table claims. It concludes that although it is appropriate to relax the sufficiency standard for causal proof, the vaccine courts have gone beyond the bounds of the Act. The Article concludes with a proposed model for legislative reform in more detail.

II. THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

A. *Background*

The use of vaccines designed to prevent childhood diseases became widespread in the twentieth century.³⁴ Despite the tremendous health benefits of vaccinations, a small percentage of patients suffer a variety of ailments, ranging from minor fever to anaphylactic shock and, in some cases, death.³⁵ Concluding that the public health benefits from vaccination far outweigh these risks, all fifty states and the District of Columbia require chil-

³⁴ See Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 *FOOD & DRUG L.J.* 351, 351 (2001).

³⁵ See H.R. REP. NO. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345; Scott, *supra* note 34, at 353 (discussing risks of harm from vaccines).

dren to receive certain vaccines before entering school.³⁶ Because of the overwhelming success of vaccines in reducing the incidence of preventable childhood diseases, public health experts view the immunization program as one of the most effective health intervention programs ever implemented.³⁷

With the increased use of vaccines, the relationship between the federal government and individuals who have been injured by the recommended vaccines has changed significantly. Originally, plaintiffs who claimed injury as a result of a vaccine designed to prevent childhood diseases relied solely on the common law tort system for compensation.³⁸ This system proved unsatisfactory to both plaintiffs and defendant manufacturers, however. For the plaintiffs, redress under the traditional tort system was “limited, time-consuming, expensive, and often unanswered.”³⁹ Nonetheless, vaccine manufacturers began to feel the impact of the expansion of the doctrine of strict liability in the 1960s and 1970s.⁴⁰ Although vaccine claims often fell under the protection of the *Restatement (Second) of Torts*, which created an exception from strict liability for “unavoidably unsafe” products whose benefits to the public outweighed their harms,⁴¹ the Fifth Circuit in *Reyes v. Wyeth Laboratories* held polio vaccine manufacturers strictly liable for failing to

³⁶ See Theodore H. Davis, Jr. & Catherine B. Bowman, *No-Fault Compensation for Unavoidable Injuries: Evaluating the National Childhood Vaccine Injury Compensation Program*, 16 U. DAYTON L. REV. 277, 280 & n.21 (1991). All the states have exemptions for medical reasons, and virtually all allow exemptions for religious reasons. See, e.g., Timothy J. Aspinwall, *Religious Exemptions to Childhood Immunization Statutes: Reaching for a More Optimal Balance Between Religious Freedom and Public Health*, 29 LOY. U. CHI. L.J. 109 (1997); K. Shaw, C. Stanwyck & M. McCauley, *Vaccination Coverage Among Children Entering School—United States, 2002–03 School Year*, 52 CDC MORBIDITY AND MORTALITY WKL. REP. 791, 791–93 (2003), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5233a3.htm> (state laws requiring vaccination of school children associated with elimination of many vaccine-preventable diseases in that setting); *State Vaccination Requirements*, CTNS. FOR DISEASE CONTROL AND PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.cdc.gov/vaccines/vac-gen/laws/state-reqs.htm> (last modified June 7, 2010) (listing state immunization requirements for school entry).

³⁷ See H.R. REP. NO. 99-908, at 4, reprinted in 1986 U.S.C.C.A.N. at 6345 (“Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken.”); Leslie K. Ball et al., *Risky Business: Challenges in Vaccine Risk Communication*, 101 PEDIATRICS 453, 453 (1998) (finding that the vaccine immunization program is one of “the single most effective [means of] health intervention”); Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure and Stress*, 24 HEALTH AFF. 599, 599–60 (May/June 2005) (“Few measures in preventive medicine can compare with the impact of vaccines.”).

³⁸ H.R. REP. NO. 99-908, at 6, reprinted in 1986 U.S.C.C.A.N. at 6347. See generally Henson, Comment, *Inoculated Against Recovery: A Comparative Analysis of Vaccine Injury Compensation in the United States and Britain*, 15 TULSA J. COMP. & INT’L L. 61, 69–73 (2007) (describing traditional tort remedies before passage of the Act).

³⁹ H.R. REP. NO. 99-908, at 6, reprinted in 1986 U.S.C.C.A.N. 6344, 6347 (describing difficulties plaintiffs had in succeeding on claims).

⁴⁰ See, e.g., *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968) (manufacturer of polio vaccine strictly liable in tort).

⁴¹ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

provide product warnings directly to vaccinees.⁴² The *Reyes* decision sent shock waves through the pharmaceutical community.⁴³

The tension concerning liability for vaccine injury came to a head in 1976, when a soldier died from influenza at Fort Dix, New Jersey.⁴⁴ Because public health officials feared his death was caused by a strain of influenza similar to the strain present in the pandemic of 1918, in which twenty million people died worldwide,⁴⁵ they encouraged the federal government to start mass immunization against influenza.⁴⁶ Congress responded by authorizing the procurement of 200 million batches of flu vaccine for a mass inoculation program in April 1976.⁴⁷ Government officials assumed that they would have no difficulty procuring the needed vaccine from manufacturers.⁴⁸ Yet insurers declared that they would end coverage for all vaccine manufacturers as of June 30, 1976, in large part in response to the *Reyes* decision,⁴⁹ and vaccine manufacturers balked at providing the needed vaccine without some form of liability protection.⁵⁰

Congress responded quickly by passing the National Swine Flu Immunization Program (“Swine Flu Act”) in August 1976.⁵¹ Most significantly, the Swine Flu Act transferred liability from the vaccine manufacturers to the federal government for any injuries that resulted from the swine flu vaccines, creating a federally funded compensation fund for victims.⁵² The Act did not create an alternative dispute scheme for resolving swine flu cases—it left the resolution of those cases to the court system.⁵³

Between October 1, 1976 and December 16, 1976, over 45 million people were vaccinated.⁵⁴ The government halted the program abruptly on December 16, 1976, when it became clear that the flu pandemic seemed unlikely to develop and suspicions arose that the vaccine caused a rare side

⁴² 498 F.2d 1264, 1295 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974) (oral polio vaccine).

⁴³ Greenberger, *supra* note 11, at 11.

⁴⁴ Lainie Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 PENN. ST. L. REV. 681, 682 (2007).

⁴⁵ Greenberger, *supra* note 11, at 11.

⁴⁶ Rutkow et al., *supra* note 44, at 682 n.8.

⁴⁷ Greenberger, *supra* note 11, at 11 n.28.

⁴⁸ Rutkow et al., *supra* note 44, at 682.

⁴⁹ Greenberger, *supra* note 11, at 11; *see also In re Swine Flu Immunization Prods. Liab.*, 495 F. Supp. 1188, 1190 (D. Colo. 1980) (describing collapse of the commercial liability insurance market for manufacturers of swine flu vaccine in part because of *Reyes*).

⁵⁰ Rutkow et al., *supra* note 44, at 682.

⁵¹ National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (codified as amended at 42 U.S.C.A. § 247b (West, Westlaw through P.L. 112-3 approved Dec. 17, 2010)).

⁵² National Swine Flu Immunization Program § 2, 90 Stat. at 1114–15; INST. OF MED., VACCINE SUPPLY AND INNOVATION 93 (1985), available at http://www.nap.edu/openbook.php?record_id=599&page=93.

⁵³ Greenberger, *supra* note 11, at 12.

⁵⁴ *Id.* at 13.

effect, Guillain-Barre syndrome.⁵⁵ Many lawsuits ensued, and the federal government became embroiled in an expensive campaign to defend the claims, eventually paying out over \$90 million.⁵⁶ Given the large number of compensation payments stemming from a vaccine program created to react to a pandemic that never transpired, the swine flu vaccine compensation program is generally considered a failure.⁵⁷

The early 1980s also saw an increase in other vaccine tort litigation, partly because claimants began to argue that injuries previously unconnected to childhood vaccines were, in fact, caused by those vaccines.⁵⁸ One manufacturer even stopped producing vaccines temporarily in 1984,⁵⁹ and others threatened to follow suit.⁶⁰ This threat led to fears in Congress about the possibility of a shortage in vaccines and a consequent decline in the number of children vaccinated.⁶¹ But Congress did not want to respond to these fears by replicating the Swine Flu Act, with all of the litigation it entailed.⁶² Instead, Congress created a no-fault, streamlined alternative compensation system to compensate families of victims injured by childhood vaccines, funded solely by an excise tax on each recommended childhood vaccine.⁶³ Thus, the Vaccine Act was born from a need to achieve a delicate balance—to support a particular industry by protecting it from civil liability⁶⁴ while ensuring that victims would receive compensation in an expeditious manner.

B. Compensation Scheme

Congress intended the Vaccine Act's no-fault compensation system, administered by special masters appointed by federal judges,⁶⁵ to act as a less burdensome alternative for both claimants and manufacturers. Claimants

⁵⁵ Rutkow et al., *supra* note 44, at 682–83.

⁵⁶ Greenberger, *supra* note 11, at 13.

⁵⁷ Sharon L. Begley, *The Failure of the 1976 Swine Influenza Immunization Program*, 50 YALE J. BIOLOGY & MED. 645, 645, 655 (1977); Rutkow et al., *supra* note 44, at 683.

⁵⁸ H.R. REP. NO. 99-908, pt. 1, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345; *see also* STANLEY A. PLOTKIN & WALTER A. ORENSTEIN, VACCINES 1592 (Elsevier, 4th ed. 2004) (“[E]fforts of plaintiffs to establish common-law, strict tort liability on the part of pharmaceutical houses . . . appeared to increase after *Reyes* and the swine flu episode.”).

⁵⁹ H.R. REP. NO. 99-908, pt. 1, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347.

⁶⁰ *See* PLOTKIN & ORENSTEIN, *supra* note 58, at 1594.

⁶¹ H.R. REP. NO. 99-908, pt. 1, at 7, *reprinted in* 1986 U.S.C.C.A.N. at 6347 (“[T]he withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence in preventable diseases.”).

⁶² Greenberger, *supra* note 11, at 13.

⁶³ 42 U.S.C. §§ 300aa-1 to -34 (2006).

⁶⁴ 2001 *Hearing*, *supra* note 28, at 138 (2001) (opening statement of Rep. Dan Burton, Chairman, House Comm. on Gov't Reform) (“The first goal was to protect vaccine manufacturers from lawsuits. That's been successful.”).

⁶⁵ The special masters are appointed by federal judges of the United States Federal Claims Court and serve for a period of four years. 42 U.S.C. § 300aa-12(c)(1), (4). The special masters are not required to have a medical or scientific background. *See* Apolinsky & Van Detta, *supra* note 11, at 551.

must exhaust this option before they can pursue their claims in court.⁶⁶ By eliminating the need to prove that the manufacturer was negligent in the marketing, production, or distribution of the vaccine or that the vaccine was defective, Congress hoped that more claimants would not later pursue the claim in court.⁶⁷ This would induce manufacturers to continue supplying vaccines—considered critical to the public interest—by shielding them from the costs of defending traditional tort suits, while also making it easier for plaintiffs to recover damages by allowing them to avoid the proof requirements associated with traditional tort actions.

The Vaccine Act left it to the Court of Federal Claims to promulgate case processing rules to be recommended by the special masters and guided only by five general statutory guidelines. All of the guidelines were designed to relax the rules of evidence, discovery, and procedure.⁶⁸ While parties could seek review of the special master's decision by the Court of Federal Claims, that court could set aside a special master's findings of fact or conclusions of law only if "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."⁶⁹ Thus, Congress intended to spare petitioners the formal rules and time-consuming procedures of the tort system and give broader discretion to the special masters to manage cases.⁷⁰

Central to the compensation scheme is the Vaccine Injury Table, which lists specific injuries resulting from particular childhood vaccinations that are recognized as compensable.⁷¹ This list also specifies time periods within which vaccine-related injuries must manifest themselves to be recognized.⁷²

The Act authorizes the Secretary to amend the Table as necessary,⁷³ based on the research and findings of the Institute of Medicine ("IOM") and the Advisory Commission on Childhood Vaccines ("ACCV").⁷⁴ The Secre-

⁶⁶ 42 U.S.C. § 300aa-11(a)(2)(A). Claimants can accept the decision of the special master, waiving the right to future civil litigation, or reject it and file a civil suit against the vaccine manufacturer in state or federal court, but they do not need to appeal the special master's decision to the Federal Circuit before filing the common law tort claim. *Id.*

⁶⁷ See H. R. REP. NO. 99-908, at 12, *reprinted in* 1986 U.S.C.C.A.N. at 6353.

⁶⁸ 42 U.S.C. § 300aa-12(d)(2).

⁶⁹ *Id.* § 300aa-12(e)(2)(B).

⁷⁰ See Apolinsky & Van Detta, *supra* note 11, at 578.

⁷¹ 42 U.S.C. § 300aa-14(a). The Table lists specific vaccines and also allows for the addition of "any new vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children" after publication of a notice of coverage by the Secretary of HHS. *Id.*

⁷² *Id.* § 300aa-13(a)(1); *id.* § 300aa-14(a)(1).

⁷³ *Id.* § 300aa-14(c)(3).

⁷⁴ *Id.* § 300aa-19. The IOM is a division of the National Academies. The ACCV is composed of health care professionals, legal experts, federal officials, and interested citizens. The Commission is charged with recommending changes to the Table and advising the Secretary "on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines." *Id.* § 300aa-19(f)(4).

Congress requested the IOM to review the medical literature on vaccines covered by the program administered under the Vaccine Act, and the IOM issued reports in 1991 and 1994. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 19, at 1; ADVERSE EFFECTS OF PERTUSSIS AND RUBELLA VACCINES (Christopher P. Howson et al. eds., 1991). Based on the findings of

tary also must amend the Table to include any childhood vaccines recommended by the Centers for Disease Control (“CDC”).⁷⁵ HHS maintains that its decisions to amend the Table are “science driven.”⁷⁶ For example, in a public notice announcing the final rule to a Table Amendment in 1997, HHS stated:

The Secretary is charged with revising the Table where such revisions are in keeping with scientific evidence. The goal is to have the Table . . . reflect current scientific knowledge on the relationship between certain adverse events and covered vaccines. Where that scientific research concerning the relationship between a disorder and a vaccine is incomplete or nonexistent, the Secretary believes it would be inappropriate and inconsistent with her statutory responsibility to revise the table to establish a presumption that a relationship exists.⁷⁷

Despite its emphasis on science as driving its decisions, however, HHS has been criticized for a lack of transparency when it comes to its decisionmaking criteria.⁷⁸

If a petitioner is able to show that his injury falls within the listed criteria, then he is entitled to a rebuttable presumption of causation.⁷⁹ Permitting this presumption relieves the petitioner from proving that the vaccine actually caused the injury, a substantial hurdle in a traditional product liability or toxic tort suit.⁸⁰ After the petitioner has established his *prima facie* case, the respondent—the Secretary of HHS—may try to defeat the claim by, for example, proving an alternative cause of the injury.⁸¹ The Secretary bears the

the IOM and other public policy considerations, HHS added seven injuries and removed four others from the Table in 1995 and 1997. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 19, at 13.

⁷⁵ 42 U.S.C. § 300aa-14(e).

⁷⁶ When the standard that IOM used to evaluate scientific evidence was challenged during the notice-and-comment period for the 1995 amendments, the Secretary responded that the IOM standard “had to be consistent with the standard applied throughout the science of epidemiology, policy considerations notwithstanding.” National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7,678, 7,683 (Feb. 8, 1995) (codified as amended at 42 C.F.R. pt. 100) (rejecting commentators’ argument that IOM should develop a confidence level that is more lenient than 95 percent).

⁷⁷ National Vaccine Injury Revisions and Additions to the Vaccine Injury Table-II: Final Rule, 62 Fed. Reg. 7,685, 7,685–86 (Feb. 20, 1997) (codified as amended at 42 C.F.R. pt. 100).

⁷⁸ The GAO criticized HHS because HHS “did not have a clear and transparent methodology to demonstrate” that it consistently applied the same factors for each injury change. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 19, at 1, 3, 15. HHS responded that it is not practical to create a formula for scientific causation because scientific and public policy considerations vary on a case-by-case basis. *Id.* at 43. Instead, it proposed to explain each decision on Table changes in the Federal Register. *Id.* at 22. Although HHS purported to rely on the IOM reviews in amending the Table, it did not publish in the Federal Register the specific methodology it used in reaching its conclusions. See National Vaccine Injury Revisions and Additions to the Vaccine Injury Table-II: Final Rule, 62 Fed. Reg. at 7,685–86.

⁷⁹ 42 U.S.C. § 300aa-13(a)(1)(A).

⁸⁰ See *infra* Part III.

⁸¹ 42 U.S.C. § 300aa-13(a)(1)(B).

ultimate burden of persuasion that the vaccine did not cause the Table injury for which compensation is sought.⁸² If the petitioner cannot satisfy the causation element of his claim by proving that the injury was of the type and manifested within the time limits listed in the Vaccine Injury Table, he still can pursue his claim as an off-Table (“non-Table” or “cause-in-fact”) claim.⁸³ Under this option, which will be further discussed below, the petitioner must prove by a preponderance of the evidence that his injury was “caused” by a listed vaccine.⁸⁴

Once the special master reaches a decision with regard to a petition under either track, the petitioner can either accept the decision of the special master, waiving his right to future civil action, or he can reject it and file a civil suit against the vaccine manufacturer in state or federal court.⁸⁵ Although the special master’s decision has no *res judicata* effect,⁸⁶ the Act discourages the claimant from pursuing redress in court by raising the evidentiary requirements for the claimant in civil litigation.⁸⁷

C. Proving Cause-in-Fact in Off-Table Claims

1. Statutory Language

A petition filed for an off-Table claim proceeds differently from a Table claim in two ways. First, the Act does not create any presumption of causation in favor of the petitioner, but instead requires the petitioner to demonstrate by a preponderance of the evidence that the vaccine actually caused the injury.⁸⁸ The Act requires an affidavit and supporting documentation⁸⁹

⁸² *Id.* § 300aa-13(a)(1).

⁸³ *Id.* § 300aa-11(c)(1)(C)(ii).

⁸⁴ *Id.*; see also *id.* § 300aa-13(a)(1)(A).

⁸⁵ *Id.* § 300aa-21(a); see also Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1100 n.23 (2011) (Sotomayor, J., dissenting) (citing records from the Department of Justice that 99.8% of successful claimants have accepted their awards, foregoing civil actions against manufacturers); Gordon Shemin, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 477 (2009) (citing government data to suggest that very few petitioners reject a favorable judgment under the program and file a civil action); Stephen D. Sugarman, *Cases in Vaccine Court—Legal Battles over Vaccines and Autism*, 357 NEW ENG. J. MED. 1275, 1277 (2007) (“[F]ew who have been denied compensation by the program have then sued” in court.).

⁸⁶ 42 U.S.C. § 300aa-22(d).

⁸⁷ See *id.* § 300aa-22(b)(2) (creating presumption in the civil lawsuit that the manufacturer exercised due care in both the manufacture and packaging of the vaccine, as long as it complied with applicable federal regulations); *id.* § 300aa-22(c) (barring liability based on any failure to warn the injured party—as opposed to the vaccine administrator—of the risks associated with vaccination, which was aimed at reversing the *Reyes* decision); *id.* § 300aa-22(b)(1) (banning application of strict tort liability based on the unavoidable adverse side effects of an inherently dangerous product). See generally Bruesewitz, 131 S. Ct. 1068 (Act preempts all design-defect claims for vaccine injury in civil actions against claimants). The Act also encourages use of the vaccine program by awarding attorneys’ fees at the administrative level even when the petitioning party fails to qualify for other compensation, so long as the petition was brought “in good faith and on a reasonable basis.” 42 U.S.C. § 300aa-15(e)(1).

⁸⁸ 42 U.S.C. § 300aa-11(c)(1); *id.* § 300aa-13(a)(1)(A).

that show either that a Table vaccine caused or “significantly aggravated” an injury either not listed in the Table,⁹⁰ or listed in the Table but occurring outside of the time period allowed by the Table.⁹¹ Second, a petitioner who establishes a prima facie case is entitled to compensation as long as “factors unrelated to the . . . vaccine” did not cause the injury.⁹² This broad, two-pronged test leaves much to the discretion of the special master and raises two significant issues: (1) how much evidence (and what kind of evidence) the petitioner must provide to establish a prima facie case of causation in an off-Table claim; and (2) who bears the burden of proving that factors unrelated to the vaccine caused the injury—the petitioner or the respondent.

The Vaccine Act itself provides little guidance on these questions. The Act merely instructs the special master or court to consider, if contained in the record, “all other relevant medical and scientific evidence” and “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report . . . regarding the nature, causation, and aggravation” of the injury, as well as “the results of any diagnostic or evaluative test . . . and the summaries and conclusions.”⁹³ But the Act states explicitly that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court.”⁹⁴ Instead, the special master or court should determine the weight to give to such evidence by “consider[ing] the entire record and the course of the injury.”⁹⁵ Special masters may conduct hearings and require evidence, testimony, and the submission of such information “as may be reasonable and necessary,” and the only discovery allowed is that “required by the special master.”⁹⁶ The Vaccine Act thus grants the special master great control over how much weight to accord the evidence proffered by the parties subject to review only for abuse.

Outside of this broad language, there is no statutory guidance for special masters to follow when considering an off-Table claim. Special masters have complained about this lack of direction,⁹⁷ which can lead to inconsistent results.⁹⁸ Other commentators have argued that the lack of statutory direction has resulted in the proceedings becoming more prolonged and closer

⁸⁹ *Id.* § 300aa-11(c)(1).

⁹⁰ *Id.* § 300aa-11(c)(1)(C)(ii)(I).

⁹¹ *Id.* § 300aa-11(c)(1)(C)(ii)(II).

⁹² *Id.* § 300aa-13(a)(1)(B) (providing that compensation must be granted unless there is “a preponderance of the evidence that the illness, disability, injury condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition”).

⁹³ *Id.* § 300aa-13(b)(1).

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.* § 300aa-12(d)(3)(B). The special master also has the authority to appoint independent experts, but this option is rarely exercised. *Id.* § 300aa-12(d)(3)(B)(iii).

⁹⁷ *See, e.g.,* *Stevens v. Sec’y of Health & Human Servs.*, 2001 WL 387418, at *11–12 (Fed. Cl. Mar. 30, 2001).

⁹⁸ *See infra* Part IV.A.

to traditional tort litigation, but with less adversarial control and fewer procedural rights for the parties.⁹⁹

Given the lack of guidance in the Act itself, this Article next examines the legislative history of the Act, concluding that the history strongly signals Congress's overarching goals of protecting the vaccine industry while ensuring compensation to vaccine victims in an expeditious manner, but does little to clarify Congress's intent regarding proof of "causation" in off-Table claims.

2. Legislative History

The legislative history of the Vaccine Act suggests that the off-Table claims mechanism was an afterthought, with little attention given to problems of causal proof. As Chief Special Master Gary Golkiewicz observed, the "little bit of legislative history" available shows that "Congress imparted little guidance as to what proof would be necessary to show causation."¹⁰⁰

Consideration of the Act was dominated by the larger concerns of how to balance the needs of vaccine-injured individuals, the interests of vaccine manufacturers, and the public health interest in maintaining a vaccine supply as well as public confidence in mass childhood immunization.¹⁰¹ Given these weighty issues, repeated efforts to pass a vaccine compensation bill failed.¹⁰²

⁹⁹ See Myron Levin, *Vaccine Injury Claims Face Grueling Fight*, L.A. TIMES, Nov. 29, 2004, at A1; Scott, *supra* note 34, at 358–59.

¹⁰⁰ Stevens, 2001 WL 387418, at *7.

¹⁰¹ For a comprehensive description of the legislative history leading to the creation of the VICP, see Rutkow et al., *supra* note 44.

¹⁰² During the 98th Congress, Senator Paula Hawkins (R-Fla.) introduced the bill in the Senate, see S. 2117, 98th Cong. (1984), while Congressman Henry Waxman (D-Cal.) introduced the bill in the House, H.R. 5810, 98th Cong. (1984). The 98th Congress did not pass either bill and both Senator Hawkins and Representative Waxman reintroduced their bills in the next session of Congress. S. 827, 99th Cong. (1985); H.R. 5546, 99th Cong. (1986).

Vaccine manufacturers began to leave the market a few months after the first Senate hearing on the proposed compensation program, responding to lawsuits brought by parents who believed their children had been injured by the pertussis vaccine. Elizabeth Wehr, *Concern in Congress: Looming Vaccine Shortage Blamed on Threat of Lawsuits*, CONG. Q., Dec. 22, 1984, at 3146; see also S. REP. NO. 99-483 at 3 (1986). This exodus forced Congress to recognize the sharp conflict among the relevant constituencies, many of whom were active participants throughout consideration of these bills: parents of injured children who wanted to be able to sue the vaccine manufacturers directly and vaccine manufacturers who would rather exit the market than face the lawsuits. See Wehr, *supra*, at 3146; *National Childhood Vaccine-Injury Compensation Act: Hearing on S. 2117 Before the S. Comm. on Labor and Human Res.*, 98th Cong. 49–51 (1984) [hereinafter *Hearing on S. 2117*]. Even so, Congressman Waxman warned that the shortage of pertussis vaccines should not "'stampede' Congress into assuming all the legal risks of immunization programs." Stephen Engelberg, *Can Medicine Rely on the Rule of the Marketplace?*, N.Y. TIMES, Jan. 6, 1985, at A8.

Both Senator Hawkins and Representative Waxman reintroduced their bills in the next session of Congress. Senator Hawkins's bill, S. 827, provided that the seven mandated childhood vaccines would be listed on a table that would include covered side effects and the appropriate time frame in which they would have to occur. INST. OF MED., *supra* note 52, at 184; *Special Report: Legislative Summary HEALTH*, CONG. Q., Dec. 28, 1985, at 2741. In addition, the

The bill ultimately was passed as part of an omnibus health package, Senate Bill 1744, in 1986.¹⁰³

Examination of the legislative history reveals how little attention was paid to the off-Table mechanism. Generally, most misgivings about the need to prove actual vaccine responsibility manifested themselves in debate about the breadth of the Vaccine Injury Table and the limitations of contemporary scientific understanding.¹⁰⁴ While Congress consciously provided an off-Table claim option, its inclusion was not nearly as deliberate as the inclusion of the major provisions of the Act. It first appeared in Senate Bill 827 relatively late in the process, but the legislative focus remained on the scope of the Vaccine Injury Table itself. Further, the ubiquity of the preponderance standard in the final bill, House Bill 5546, as a multipurpose catch-all for vaccine causation disputes may have been a compromise that hastily borrowed language from the Republican version, House Bill 1780, to protect manufacturers from joint and several liability.¹⁰⁵ It certainly was not a measured attempt to calibrate an evidentiary standard. This Subsection examines the legislative history in order of general importance for statutory construction: contemporaneous congressional reports, pre-enactment legislative history, contemporaneous floor debate, and congressional oversight.¹⁰⁶

a. Contemporaneous Congressional Reports: House Report No. 99-908

House Bill 5546, the version that ultimately became the Vaccine Act, was accompanied by a favorable report from the House Committee on Energy and Commerce (“House Report 908”), which is the most thorough and authoritative source on the legislation’s history.¹⁰⁷ Unfortunately, there is virtually no direct attention paid to the amount of causal proof required in off-Table cases. House Report 908’s oft-cited explanation of off-Table claims does little to clarify the legislation’s casual use of the term “caused” in that context:

program would allow families to elect for compensation under the program or to pursue civil litigation against the vaccine manufacturers. *Special Report: Legislative Summary HEALTH*, *supra*, at 2741; INST. OF MED., *supra* note 52, at 184. Congressman Waxman’s bill, H.R. 5546, was very similar to the Senate bill. Emphasizing the importance of the tort system as an incentive to manufacturers to develop safer products, Waxman refused to make the compensation program an exclusive option. *Vaccine Injury Compensation: Hearing on H.R. 178, H.R. 4777, and H.R. 5184 Before the Subcomm. on Health and the Env’t of the H. Comm. on Energy and Commerce*, 99th Cong. 2 (1986).

¹⁰³ S. 1744, 99th Cong. (1986). Congress passed the package on October 18, 1986 and President Reagan signed it into law on November 14, 1986. Robert Pear, *Reagan Signs Bill on Drug Exports and Payment for Vaccine Injuries*, N.Y. TIMES, Nov. 15, 1986, at 1.

¹⁰⁴ See *infra* notes 112–113, 117–124 and accompanying text.

¹⁰⁵ See *infra* notes 127–129 and accompanying text.

¹⁰⁶ See NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION § 48 (7th ed. 2007) (ranking the order of importance of sources of legislative history).

¹⁰⁷ See H.R. REP. NO. 99-908, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6344.

[In cases of off-Table claims,] the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. . . . The Committee does not intend, however, to suggest [sic] that variance from the Table should act as a presumption against the petitioner but rather only that such a petitioner is not to be deemed to be eligible for compensation without further showings of causation.¹⁰⁸

The passage does little more than state what is *insufficient* proof of injury causation. Although Congress indicated that it expected some form of scientific evidence to support a cause-in-fact claim, it did not indicate its type or amount, or the weight such evidence should be accorded. And while the “further showings of causation” language appears to provide some insight unique to off-Table claims, its usefulness is limited because the Report uses similar language to explain that in Table and off-Table claims alike, “[t]he court may not [determine that vaccine causation exists by a preponderance of the evidence] on the basis of the petitioner’s claims alone, without other medical records or opinion.”¹⁰⁹ A description found later in the Report addressing the program’s relative advantage over traditional litigation is similarly vague, saying nothing specifically about causal proof and conceding that the Act specifies only “most” evidentiary requirements.¹¹⁰

The Report’s analysis of the *res judicata* portion of the legislation reveals similar imprecision. When discussing the non-preclusive effect of special masters’ decisions, the Report, like the bill, does not distinguish between the proof standards for Table and off-Table claims, broadly reasoning that “[c]ompensation standards, evidence, and proceedings are sufficiently different from civil proceedings in tort that the findings made in compensation are not likely to be based on the more rigorous requirements of a tort proceeding and might confuse such civil actions.”¹¹¹ This language indicates how the presumptive Vaccine Injury Table overshadowed those portions of the legislation that address proof of actual causation.

Despite its vagueness on the issue of causation, in addressing the contentious issue of when and how the Vaccine Injury Table was to be revised, House Report 908 importantly recognized the need to err on the side of compensation when the scientific evidence was equivocal. The Committee anticipated that future research would yield more definitive information about the incidence of vaccine injury that would inform future revisions. However, until that occurrence, the legislation was designed to favor broad

¹⁰⁸ *Id.* at 15, reprinted in 1986 U.S.C.C.A.N. at 6356.

¹⁰⁹ *Id.* at 18, reprinted in 1986 U.S.C.C.A.N. at 6359.

¹¹⁰ *Id.* at 36, reprinted in 1986 U.S.C.C.A.N. at 6359.

¹¹¹ *Id.* at 29, reprinted in 1986 U.S.C.C.A.N. at 6370.

compensation even if children whose injuries were not vaccine-related would likely also be compensated.¹¹² As the House Report states:

The Committee . . . recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. . . . Until such time [as research on vaccine injury and vaccine safety provides more definitive answers], however, the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.¹¹³

Thus, the Committee recognized the need, either as a practicality or as a policy matter, to err on the side of over-inclusion—at least with regard to Table claims.¹¹⁴

b. Pre-Enactment Legislative History

Examination of the pre-enactment history further indicates how little thought was given to the off-Table claims mechanism, and, more specifically, to the level of proof that would be required to show causation under that statutory option.

i. Senate Bill 2117

Senate Bill 2117, the earliest version of the National Childhood Vaccine Injury Act, introduced by Senator Paula Hawkins (R-Fla.), is striking in that it contains no off-Table claims mechanism. Under that version, injuries not found on the Vaccine Injury Table would be strictly non-compensable.¹¹⁵ For on-Table claims, respondents carried the burden of disproving actual vaccine causation, which would be accomplished if the injury was “better explained and documented by factors unrelated to the administration of the vaccine.”¹¹⁶

The subject of off-Table injuries did not arise during the Senate hearing on Senate Bill 2117. Instead, the hearing focused on basic questions about the Vaccine Injury Table and whether the program would be an optional or a mandatory alternative to the civil tort system.¹¹⁷

¹¹² *Id.* at 18, reprinted in 1986 U.S.C.C.A.N. at 6370.

¹¹³ *Id.*

¹¹⁴ Nothing in the 1989 Amendments to the Act addresses the issue of the sufficiency of evidence to establish causation, so this Article does not discuss this part of the legislative history.

¹¹⁵ S. 2117, 98th Cong. § 2114(a) (1984).

¹¹⁶ S. 2117, § 2114(b)(11).

¹¹⁷ See *Hearing on S. 2117*, *supra* note 102, at 6–8, 118–19, 190, 255.

ii. *House Bill 5810*

Criticism of the proposed legislation's failure to adequately address off-Table injuries—and proof of cause-in-fact more generally—was more forceful during the hearing held by the House Committee on Energy and Commerce in December 1984. The stakeholders in the program—the pharmaceutical industry,¹¹⁸ HHS,¹¹⁹ a parents' group,¹²⁰ and the American Medical Association¹²¹—all expressed concerns about the limitations of creating a Table, recognizing the connection between the breadth of the Table, causal proof, and the number of claims filed in traditional civil courts.

iii. *Senate Bill 827 and House Bill 1780*

Senate Bill 827 was introduced by Senator Hawkins on April 2, 1985.¹²² The bill, which provided for an election between the no-fault compensation program and filing a traditional tort action, was the first proposed version of the National Childhood Vaccine Injury Act to include an off-Table mechanism:

Notwithstanding the compensability (or lack thereof) of a claim under any other provision of this part, a petition for compensation shall be granted if the petitioner meets the requirements of sections

¹¹⁸ In a prepared statement, Lederle Laboratories' position was that, on one hand, respondents would not be able to rebut the Table's causal presumption, even in circumstances where the Table itself conflicted with "prevailing medical opinion," while, on the other hand, denial of compensation based on a successful "factors unrelated" defense would drive petitioners out of the program to take their chances with tort actions. *Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health and the Env't of the H. Comm. on Energy and Commerce*, 98th Cong., pt. 1, 244–45 (1984).

¹¹⁹ When Representative Waxman asked Dr. Brandt, who was testifying on behalf of HHS, how to prove cause-in-fact and whether he favored a system that would only compensate individuals whose injuries could be proven, Dr. Brandt answered:

It may very well be impossible to do that in individual cases, at least certainly over the near term. And I think . . . one has to rely upon secondary bits of evidence regarding cause. For example, one would look at epidemiological data and other kinds of data to establish that at least there is a reasonable probability—and I will have to leave "reasonable" undefined for a moment—that a particular adverse event is associated with a vaccine.

Id. at 74. This suggests that Representative Waxman, the bill's sponsor, had at least considered the possibility of a compensation system in which traditional proof of causation might not be required.

¹²⁰ Jeffrey Schwartz, the president of the Dissatisfied Parents Together group, argued that the three methods most important in separating "cause from coincidence" are (1) the temporal proximity between vaccination and reaction; (2) whether the injury is consistent with the type of vaccine administered; and (3) whether "an alternative explanation [exists] that is more persuasive." *Id.* at 114–15.

¹²¹ The AMA questioned whether "eligibility for compensation" is as "carefully [and narrowly] defined in both clinical and legal terms" as it should be, *id.* at 151, and as it could be, according to the AMA, if the Table were a regulatory, rather than a legislative, creation, *id.* at 155.

¹²² 131 CONG. REC. 7,030 (1985).

2103 [Petitions for Compensation] and 2104 [Determination of Eligibility and Compensation] and if the petitioner *demonstrates on the basis of credible evidence* that the illness, disability, injury, or condition suffered by petitioner was caused by a vaccine listed in the Vaccine Injury Table.¹²³

With regard to Table injuries, vaccine causation would be presumed unless respondent disproved causation based on “persuasive evidence which is documented . . . [that] causation is due to factors entirely unrelated to the administration of the vaccine,”¹²⁴ a standard for rebuttal roughly equivalent to that listed in other earlier bills.¹²⁵

House Bill 1780, the Republican version of the National Childhood Vaccine Injury Act, was introduced on March 27, 1985.¹²⁶ The bill proposed that panels composed of individuals selected by the Secretary of HHS, petitioners, and respondents make decisions regarding whether an injury was vaccine-related.¹²⁷ If the injury was determined to be “vaccine-related,” manufacturers in the action would be held jointly and severally liable up to an aggregate amount of one million dollars, and each named manufacturer would bear the burden of proving by a preponderance of the evidence that it did not produce the vaccine that harmed the petitioner.¹²⁸ The terminology “preponderance of the evidence” was used several times throughout House Bill 1780, but only to describe respondent’s burden of proof necessary to escape joint and several liability; nowhere was the phrase used in connection with a petitioner’s burden to prove that an injury was caused by a vaccine.¹²⁹

The Senate Committee on Labor and Human Resources held a two-part hearing on the bills on July 18 and December 9, 1985.¹³⁰ The Department of Justice provided the most pointed and far-sighted comments at the hearing pertaining to causation issues under Senate Bill 827’s proposals, including its new off-Table claims mechanism:

[A]ny reduction in transaction costs associated with individual claims may be overwhelmed by the increase in the number of

¹²³ S. 827, 99th Cong. § 2105(a)(2) (1985) (emphasis added). House Bill 5184, introduced on July 17, 1986 by Representative Waxman, is the immediate predecessor to House Bill 5546, which would be the version of the National Childhood Vaccine Injury Act adopted by Congress. H.R. 5184, 99th Cong. (1986). This version differed from Representative Waxman’s 1985 proposal (House Bill 5810) in that it contained an off-Table mechanism, albeit limited to non-Table injury types and not yet providing for delayed-onset injury compensation. H.R. 5184 § 2111(c)(1)(C)(ii). Compare H.R. 5184 § 2111(c)(1)(C), with H.R. 5546, 99th Cong. § 2111(c)(1)(C) (1986).

¹²⁴ S. 827 § 2103.

¹²⁵ Compare *id.*, with S. 2117 § 2114(b)(11).

¹²⁶ H.R. 1780, 99th Cong. (1985).

¹²⁷ *Id.* §§ 2102, 2105(b), 2106(a), 2106(b).

¹²⁸ *Id.* §§ 2106(c), 2107(b).

¹²⁹ See, e.g., *id.* §§ 2106(b), 2111(a).

¹³⁰ See *National Childhood Vaccine Injury Compensation Act of 1985: Hearing Before the S. Comm. on Labor and Human Res.*, 99th Cong. (1985).

claims that may be filed (and the resulting increase in *overall* transaction costs) for what claimants believe may arguably be vaccine-related injuries.

Second, adoption of a no-fault approach will not significantly simplify the process of determining which claimants should receive compensation. The time and resource consuming issue in vaccine-related injury cases is not fault, but causation; . . . [b]ecause the epidemiological evidence indicates that there are only a handful of childhood vaccine-related injury cases every year, it may be far more cost effective to leave such cases in the tort system which is well designed to ascertain causation.¹³¹

These remarks proved perceptive, anticipating the problems associated with the off-Table claims mechanism.

c. Contemporaneous Floor Debate

Congressional debate over the National Childhood Vaccine Injury Act of 1986 reveals almost nothing about how Congress intended the off-Table claims mechanism to function. The issue of proving vaccine injury causation was simply glossed over. For example, Representative Henry Waxman (D-Cal.) repeatedly explained that the program was intended to compensate “those children who are injured” or “those innocent statistics of the . . . war . . . on diseases,” giving the impression that the no-fault compensation program made the issue of causation self-explanatory.¹³² Senate debate was similarly devoid of comments about the off-Table claims mechanism.¹³³

d. Post-Enactment Congressional Oversight

Three oversight hearings held between 1999 and 2002 by the House Committee on Government Reform reveal ongoing concerns about the program. The first hearing, held on September 28, 1999,¹³⁴ revealed general congressional dissatisfaction with the workings of the Act, including its standards for proving cause-in-fact in off-Table claims.¹³⁵ According to Repre-

¹³¹ *Id.*, pt. 1, at 231.

¹³² 132 CONG. REC. 33,116 (1986); 132 CONG. REC. 30,760 (1986).

¹³³ For example, Senator Hatch’s introductory remarks about the Act’s inclusion in Senate Bill 1744, An Act to Require States to Develop, Establish and Implement State Comprehensive Mental Health Plans, S. 1744, 99th Cong. (1986) (incorporating H.R. 5546 as passed by the House of Representatives), include reservations about the cost, the potential proliferation of no-fault compensation systems, and whether the program’s manufacturer liability limitations would be an adequate disincentive to litigation under the tort system. *Id.*

¹³⁴ *Compensating Vaccine Injuries: Are Reforms Needed? Hearing Before the Subcomm. on Criminal Justice, Drug Pol’y, and Human Res. of the H. Comm. on Gov’t Reform*, 106th Cong. 1–2 (1999).

¹³⁵ See *id.* at 2–4 (statement of Rep. Mica (R-Fla.)) (stating that “the standard of proof requirements may need to be reexamined”); *id.* at 11–13 (statement of Rep. Burton); *id.* at 13 (statement of Rep. Mink (D-Haw.)) (“The Congress has attempted to make various amend-

sentative Waxman, the Act's author, he and the rest of the 99th Congress had attempted "to strike an important balance that we thought should have been respected" between causal proof, the Table, and compensation,¹³⁶ "[b]ut it is clear this program isn't working perfectly."¹³⁷

Much of the 1999 hearing focused on how adversarial the program had become with regard to proving causation,¹³⁸ focusing in particular on the standards for causal proof. For example, in contrast to the way the statute was being interpreted, Representative Mica (R-Fla.) floated the idea that "a claimant's burden might be one of simply demonstrating that the vaccine was related to the injury. The Department of Justice [representing HHS, the respondent,] could be required to show by clear and convincing evidence that the injury resulted from something else in order to defeat the claim."¹³⁹ An expert and a petitioner's attorney both testified that the application of the preponderance standard had effectively defeated the purpose of having a compensation scheme,¹⁴⁰ and the attorney urged Congress to adopt a burden of proof that explicitly gave the benefit of the doubt to the petitioner.¹⁴¹

Representative Waxman commented, in the context of Table revisions, on the need to strike a balance between erring on the side of compensation and the need to comport with medical and scientific fact:

There have been disputes about the science and epidemiology of vaccine injury. *We have always erred on the side of compensating children, if there was a scientific argument that injuries were vaccine related.* At least that was always our intent—to err on the side of making sure that we compensated people who were injured.

We have tried to rely on the best available scientific evidence when revising the vaccine injury table. Injuries have been added, and injuries have been removed from that table. But in 13 years, it has never been Congress' rule to second-guess the scientists. It

ments to the law designed to make it less adversarial, but obviously we have not gone far enough."); *id.* at 101 (statement of Rep. Mica).

¹³⁶ *Id.* at 9.

¹³⁷ *Id.* at 10.

¹³⁸ *See id.* (statement of Rep. Waxman); *id.* at 52, 55 (statement of Dr. Marcel Kinsbourne); *id.* at 13 (statement of Rep. Mink).

¹³⁹ *Id.* at 4 (statement of Rep. Mica). Rep. Mica stated that such changes would ensure fairness given the incomplete status of science. *Id.*

¹⁴⁰ *Id.* at 56 (statement of Dr. Marcel Kinsbourne) (presumption of causation is so restricted as to be equivalent to proof required in traditional courts); *see also id.* at 82 (prepared statement of Clifford Shoemaker) ("If anything, the Table . . . has almost made it more difficult to prove causation in cases that do not fit it precisely.").

¹⁴¹ *Id.* at 73. Mr. Shoemaker repeated his suggestion several times, emphasizing its importance with respect to off-Table claims. He also suggested adopting the standard used in veterans' claims, "[t]he benefit of the doubt in resolving each such issue shall be given to the claimant." *Id.* at 98.

The Department of Justice objected to Mr. Shoemaker's proposed change to the standard for proving vaccine causation, cautioning that "further relaxation of the minimal standards currently in place could threaten the medical integrity of the Program." *Id.* at 124.

would be a disservice to the public health if we were to start to do that today.¹⁴²

This discussion captures the tension at the heart of the program between promoting certain policy concerns and the need to rely on hard science to determine a sufficient causal connection, a tension that applies to both Table and off-Table claims.

The second oversight hearing, *The National Vaccine Injury Compensation Program: Is it Working as Congress Intended?*¹⁴³ was held in two parts on November 1 and December 12, 2001.¹⁴⁴ At the hearing, Representative Dave Weldon (R-Fla.) referred to proposals in House Bill 1287 that he had previously introduced,¹⁴⁵ calling for three changes to the standard for proving vaccine causation for off-Table claims: (1) replacing the preponderance of the evidence standard in 42 U.S.C. § 300aa-13(a)(1) by “evidence sufficient to justify a belief by a fair and impartial individual that petitioner’s claims are well grounded”;¹⁴⁶ (2) giving petitioners the benefit of the doubt after considering all the evidence;¹⁴⁷ and (3) heightening the government’s burden for proving that injuries were caused by factors unrelated to vaccine administration by imposing a “clear and convincing evidence” standard and forbidding defenses made on the basis of “a repudiation of the Vaccine Injury Table.”¹⁴⁸ These proposed changes to the burden of proof met with varying degrees of enthusiasm, but were not adopted.¹⁴⁹ More generally, Representative Burton (R-Ind.) noted with concern that fewer Table cases were being filed.¹⁵⁰

¹⁴² *Id.* at 10 (emphasis added).

¹⁴³ 2001 Hearing, *supra* note 28.

¹⁴⁴ *Id.*

¹⁴⁵ Vaccine Injured Children’s Compensation Act of 2001, H.R. 1287, 107th Cong. (2001). The bill called for relaxing the statute of limitations, *id.* at § 5, and providing for interim attorney and expert costs, *id.* at § 4(3).

¹⁴⁶ *Id.* at § 3(1)(A).

¹⁴⁷ *Id.* at § 3(1)(B). This proposal provided that if, “after consideration of all evidence and material of record in a case, there is an approximate balance of positive and negative evidence . . . the benefit of the doubt in resolving each issue shall be given to the petitioner.” *Id.*

¹⁴⁸ *Id.* at § 3(3); *see also* 2001 Hearing, *supra* note 28, at 106–08.

¹⁴⁹ Representative Burton endorsed the “benefit of the doubt” provision, 2001 Hearing, *supra* note 28, at 4, and Representative Weldon spoke in favor of the bill that he had introduced, *id.* at 23. Representative Waxman spoke against the changes, characterizing the proposed standard as “a very different and lower standard” and noting his concern that it would “open this thing too wide open.” *Id.* at 16–17. The Department of Justice opposed House Bill 1287 throughout the hearing, *id.* at 84–86, 129–30, stressing the importance of maintaining high public confidence in vaccines and the public health system. *Id.* at 86.

¹⁵⁰ *Id.* at 138. A third hearing concerning the program was held on September 18, 2002. *The Continuing Oversight of the National Vaccine Injury Compensation Program: Hearing Before the Comm. on Gov’t Reform*, 107th Cong. (2002). Three bills (House Bill 3741, Senate Bill 2053, and House Bill 5282) were included in the record, all of which dropped the amendments to the standards governing proof of causation. *Id.* Representative Burton nonetheless repeated his opinion that the preponderance standard as applied was contrary to congressional intent:

e. Legislative History Conclusion

The legislative history of the National Childhood Vaccine Injury Act of 1986 indicates that the inclusion of an off-Table mechanism was deliberate, but that it was not nearly as well considered as the other major provisions of the Act. Congress did not draw a distinction between Table and off-Table injuries with regard to the overarching goals of making awards for vaccine-related injuries “quickly, easily, and with certainty and generosity,”¹⁵¹ while reducing suits against manufacturers.¹⁵² Congress intended for Table claims and off-Table claims alike to be tethered to the science underlying adverse vaccine reactions, but did not explain the degree to which other policy concerns should be taken into account. Nor did Congress address whether tort standards for proof of causation must be followed to meet the preponderance of evidence standard for off-Table claims.¹⁵³ While Congress fixed several of the system’s problems over time, it retained the Act’s original approach to proof of causation despite complaints and three oversight hearings highlighting problems with that statutory provision.

By using the language of “causation” in the Act and not otherwise defining it, Congress strongly implied the applicability of the common law tort concept. To understand the context of the causation issue, it is first necessary to describe how the issue is resolved at common law and in toxic tort cases in particular, an area of tort law uniquely relevant to the vaccine injury arena. As described below, in the toxic tort context, courts have become increasingly more demanding of the evidence required to make out a prima facie case of causation.

III. PROVING CAUSE-IN-FACT IN TOXIC TORT CASES

“[E]vidence preponderates when it is more convincing to the trier than the opposing evidence.”¹⁵⁴ In tort cases, the law creates burdens of proof to determine which party should prevail when the evidence is in equipoise.¹⁵⁵ Traditionally, the law places the burden of proof in a civil tort case with

All Congress required is a showing, based on good science, that the vaccine is the likely cause of the injury [P]roof of scientific certainty in these cases is almost never available, any expert testimony offered by any expert from either side is subject to valid attack. Accordingly, the Secretary, with its requirement for scientific certainty, can and does make proceedings in the vaccine program as adversarial as any civil, traditional, tort litigation. Congress never intended for this to happen. It intended for claims to be resolved in the program with a showing that the vaccine was the likely cause of the injury, not the certain cause of the injury.

Id. at 93.

¹⁵¹ H.R. REP. NO. 99-908, at 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6344.

¹⁵² *Id.* at 13, reprinted in 1986 U.S.C.C.A.N. 6344, 6354.

¹⁵³ See *infra* Part III (describing standards for proof of causation in toxic tort cases).

¹⁵⁴ BROUN ET AL., MCCORMICK ON EVIDENCE § 339 (6th ed. 2006).

¹⁵⁵ GRAHAM C. LILLY, AN INTRODUCTION TO THE LAW OF EVIDENCE § 3.1 (3d ed. 1996) (“When the jury agrees that the probabilities of the existence or nonexistence of an element are

regard to causation on the plaintiff—the party trying to shift the loss away from him or her to the defendant.¹⁵⁶ Causation is a critical element in tort law because it ensures that defendants are not held responsible for injuries that they did not commit.¹⁵⁷ In this way, tort law aims to promote corrective justice as well as deter risky behavior.¹⁵⁸ It also aims to ensure confidence in the decisionmaking process and its judgments.

Proof of causation in a toxic tort suit tests the limits of these goals.¹⁵⁹ A causal claim in a toxic tort case usually does not have the type of connection to an event that can be easily documented and directly observed, such as are found in a typical car accident. Instead, in these cases, the causal claim is a scientific hypothesis that is more supported or less supported depending on the available evidence.¹⁶⁰ When the scientific community has reached a consensus on the observable phenomena, the legal community can fairly easily accept this knowledge in its factfinding. Before a scientific consensus has been reached, scientists may continue their investigation and continue to search for more certainty. But in those tort cases occurring before scientific consensus coalesces, courts must determine what level of uncertainty or probability is acceptable to satisfy causation.¹⁶¹

In reality, setting an acceptable level of proof, either in science or law, is ultimately dictated by the needs and goals of the relevant community. For

equal, the *allocation of the burden of persuasion becomes decisive in determining who prevails.*"').

¹⁵⁶ Limited exceptions to this rule exist, aimed at promoting certain policy goals. *See, e.g., Sindell v. Abbott Labs.*, 607 P.2d 924 (Cal. 1980) (creating market share liability); *Summers v. Tice*, 199 P.2d 1 (Cal. 1948) (both defendants negligent in hunting accident; burden of causation shifted to defendants to prevent unfairness to plaintiff based on failure of proof).

¹⁵⁷ *See generally* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 28 (2010) ("[T]he fact of the defendant's tortious conduct and harm to a plaintiff within the scope of the risk created by that conduct cannot alone be sufficient in all cases to permit an inference of causation."').

¹⁵⁸ *See* Apolinsky & Van Detta, *supra* note 11, at 562, 584 n.332; David Rosenberg, *Class Actions for Mass Torts: Doing Individual Justice by Collective Means*, 62 IND. L.J. 561, 562–63, 579–81 (1987).

¹⁵⁹ Toxic torts are defined as tort cases in which the plaintiffs allege that exposure to agents—usually pharmaceutical drugs or chemicals—have caused illness, injury, or death. Neal C. Stout & Peter A. Valberg, *Bayes' Law, Sequential Uncertainties, and Evidence of Causation in Toxic Tort Cases*, 38 U. MICH. J.L. REFORM 781, 782 (2005).

¹⁶⁰ *See* Shelly Brinker, *Opening the Door to the Indeterminate Plaintiff: An Analysis of the Causation Barriers Facing Environmental Toxic Tort Plaintiffs*, 46 UCLA L. REV. 1289, 1301 (1999) (direct observation of toxic tort exposure is often impossible, unlike typical tort case in which injury to the victim is immediately observable); *see also* Note, *Navigating Uncertainty: Gatekeeping in the Absence of Hard Science*, 113 HARV. L. REV. 1467, 1472 (2000) (A "generic" toxic tort is "a case in which a complicated causal chain, a long latency period, or low levels of exposure render the argument for causation inherently weak."').

¹⁶¹ *See* Carl F. Cranor & David A. Eastmond, *Scientific Ignorance and Reliable Patterns of Evidence in Toxic Tort Causation: Is There a Need for Liability Reform?*, 64 LAW & CONTEMP. PROBS. 5, 18–26 ("Science is relatively open-ended By contrast, the law seeks to resolve disputes in a timely and conclusive manner."); Albert C. Lin, *Beyond Tort: Compensating Victims of Environmental Toxic Injury*, 78 S. CAL. L. REV. 1439, 1452 (2005) (describing clash between scientific and legal causation); Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301 (1992).

example, scientists generally accept statistical significance as a probability level of .05, but that is just a convention; sophisticated researchers change that level when circumstances justify running the greater risk of false positives to reduce the risk of false negatives.¹⁶² Setting the significance level at .05 does not mean that an association with a significance level of .10 is not probative; it is just less conservative about avoiding false positives.

The same is true in law. In toxic tort cases, it is difficult to reach a finding of causation to a philosophical certainty, so courts struggle with the level of certainty they should demand of the plaintiff's proof. As discussed below, in *Daubert v. Merrell Dow Pharmaceuticals*,¹⁶³ the Supreme Court formulated a test for admissibility of expert testimony for the trial court to administer as the "gatekeeper" and to aid it in determining how to control the level of scientific uncertainty allowed in the courtroom. Excluding evidence in toxic tort cases under *Daubert* and its progeny does not come without cost. On one hand, failure to exercise the gatekeeping function and allowing the jury to consider proof based on an educated scientific guess may result in shifting the costs of injury to a defendant whose actions might not have caused the injury. On the other hand, applying the *Daubert* or similarly strict standards and failing to admit evidence may result in disallowing recovery for seriously injured plaintiffs whose illness, some scientists believe, were caused by the defendant's actions.¹⁶⁴ This may in turn remove the incentive for defendants to research the potential harmfulness of their product.

Furthermore, the unique features of toxic tort causal proof have led courts to develop special causal tests in this area. In particular, courts break down proof of cause-in-fact in toxic tort cases into two substantive categories: general causation and specific causation.¹⁶⁵ General causation involves satisfactory evidence of a relationship between the toxin and the type of injury—i.e., that the toxin can cause the injury—while specific causation requires proof demonstrating that the toxin caused the injury to this particular claimant.¹⁶⁶ The toxic tort plaintiff must demonstrate both elements by a preponderance of evidence—that it is more likely than not that the toxin can cause the injury at issue and that it is more likely than not that the toxin caused this plaintiff's injuries. But, as the *Restatement (Third)* notes, "[W]hen group-based evidence is unavailable or inconclusive, and other forms of evidence are used, the general and specific-causation issues may merge into a single inquiry."¹⁶⁷

¹⁶² FAIGMAN ET AL., *supra* note 1, § 25:38.

¹⁶³ 509 U.S. 579 (1993).

¹⁶⁴ Berger & Solan, *supra* note 31, at 851.

¹⁶⁵ FAIGMAN ET AL., *supra* note 1, § 21:2; Bernstein, *supra* note 1, at 23–53; Smith, *supra* note 1, at 224.

¹⁶⁶ FAIGMAN ET AL., *supra* note 1, § 21:2; Smith, *supra* note 1, at 224.

¹⁶⁷ RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 28 (2010).

Proving these elements may be difficult for several reasons. The science often is not developed on the general causation issue: the question may be novel and not yet subject to study, or science may not have focused on the question for other reasons, like lack of funding or lack of interest.¹⁶⁸ And the fact that exposures to toxins can vary significantly either by amount or timing also may impose impediments to study.¹⁶⁹ The possibility of multiple causes of harm also poses a vexing problem in linking exposure to harm. Some toxins uniquely cause “signature” diseases, such as asbestos and asbestosis, but most do not.¹⁷⁰ When other known causes of the harm also exist, it is difficult to attribute a specific harm to exposure to a particular toxin.¹⁷¹

The problem of multiple causation clouds the proof with regard to specific causation as well. Even assuming that the plaintiff can show general causation, it may be difficult to prove that the cause of an individual’s injury was exposure to that toxin.¹⁷² For example, exposure to asbestos has been strongly linked to lung cancer, which meets the requirement of general causation, but there are many other known and interacting causes of lung cancer, too, like smoking and genetics.¹⁷³ The plaintiff often turns to clinical medical testimony to prove specific causation, which relies in turn on a differential diagnosis, a medical determination of what disease caused a patient’s symptoms.¹⁷⁴ An expert must not only rule in the toxin as the possible cause of the injury but rule out other causes as well.¹⁷⁵

Since proof of causation in toxic tort litigation has received significant treatment elsewhere,¹⁷⁶ this Part takes the liberty of abbreviating its review

¹⁶⁸ See FAIGMAN ET AL., *supra* note 1, § 21:2-3.

¹⁶⁹ *Id.* § 21:2; Smith, *supra* note 1, at 226–27.

¹⁷⁰ FAIGMAN ET AL., *supra* note 1, § 21:2.

¹⁷¹ *Id.*; Smith, *supra* note 1, at 243–45.

¹⁷² FAIGMAN ET AL., *supra* note 1, § 21:2; Bernstein, *supra* note 1, at 52; Smith, *supra* note 1, at 241–42.

¹⁷³ Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 647 (1992).

¹⁷⁴ FAIGMAN ET AL., *supra* note 1, § 21:2; Bernstein, *supra* note 1, at 64; Smith, *supra* note 1, at 224. A differential diagnosis aids in determining what disease a patient has (diagnosis), but does not explain what caused that disease (etiology). For a discussion of the differences between “differential diagnosis” and “differential etiology,” see Justice Berman’s dissent in *San Francisco v. Wendy’s International, Inc.*, 656 S.E.2d 485, 505–08 (W. Va. 2007); see also *infra* notes 219–223 and accompanying text.

¹⁷⁵ David L. Faigman, *A Preliminary Exploration of the Problem of Reasoning from General Scientific Data to Individualized Legal Decision-Making*, 75 BROOK. L. REV. 1115, 1131 (2010).

¹⁷⁶ For a thorough review of causation in toxic tort cases, see generally RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 27 (2010); FAIGMAN ET AL., *supra* note 1; Michael D. Green et al., *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333 (2d ed. 2000); Margaret A. Berger & Aaron D. Twerski, *Uncertainty & Informed Choice: Unmasking Daubert*, 104 MICH. L. REV. 257, 260–67 (2005); Bernstein, *supra* note 1, at 51; David E. Bernstein, *Keeping Junk Science Out of Asbestos Litigation*, 31 PEPP. L. REV. 11, 19–27 (2003); Green, *supra* note 173, at 644–58; Smith, *supra* note 1, at 218.

of methods of proof in such cases. In addition, the overview provided is not intended to be comprehensive; it selectively reviews methods of proving general and specific causation that have been considered by courts and that are most relevant to vaccine causation.

A. Proof of General Causation

Proof of general causation involves two components: (1) examining the effects of the agent from a molecular biology or organic chemistry point of view; and (2) determining whether there is any association between exposure to the toxin and the claimed effect.¹⁷⁷

To demonstrate that a certain agent could cause a plaintiff's disease, the ideal proof would involve tracing each of the biological steps in the development of the disease, including the role of the agent.¹⁷⁸ Unfortunately, science has not reached that degree of knowledge for most diseases—for instance, the cause of cancer is still unknown—so researchers sometimes compare the biological mechanisms of other known agents to determine whether it is at least plausible that exposure to the agent at issue could cause the effect being studied.¹⁷⁹ This mode of reasoning is considered weak.¹⁸⁰

Given these limitations, researchers and expert witnesses turn to other scientific methods to separate cause from correlation or coincidence, in particular examining observed phenomena to infer causation.¹⁸¹ Scientists examine how often, if at all, one observation leads to another.¹⁸² To carry out this inquiry, scientists traditionally study toxicity with three different forms of empirical evidence: anecdotal case reports,¹⁸³ observational population studies,¹⁸⁴ and controlled experiments.¹⁸⁵

¹⁷⁷ Green et al., *supra* note 176, at 335; Bernstein, *supra* note 1, at 53; Smith, *supra* note 1, at 224–25.

¹⁷⁸ FAIGMAN ET AL., *supra* note 1, § 21:8.

¹⁷⁹ Green et al., *supra* note 176, at 378; Bernstein, *supra* note 1, at 53–54, 64.

¹⁸⁰ Bernstein, *supra* note 1, at 64 (“[E]ven though different chemicals of the same general type, e.g. solvents, may have some common effects, they may also differ dramatically in other effects.”).

¹⁸¹ Green et al., *supra* note 176, at 374–75. Under Karl Popper's influential framework, researchers use observed phenomena to create a hypothesis and then test the hypothesis by attempting to disprove or falsify the theory. Thus, a hypothesis is falsified and not affirmatively proved, but if the hypothesis withstands repeated tests of falsification then science begins to accept it, even if conditionally, as true. *See generally* KARL R. POPPER, *THE LOGIC OF SCIENTIFIC DISCOVERY* (2d ed. 1965).

¹⁸² Stout & Valberg, *supra* note 159, at 807.

¹⁸³ Anecdotal case reports examine a temporal relationship between exposure to an agent and the onset of a disease. *See* Bernstein, *supra* note 1, at 61. This study can be complicated because the effect reported may simply be coincidental. The causal effect can be subsequently validated in epidemiologic studies, but until that point, the usefulness of such anecdotal reports is difficult to evaluate. *Id.* at 61–62; *see also* Green et al., *supra* note 176, at 338–40; Bernstein, *supra* note 1, at 61; Smith, *supra* note 1, at 226–27, 244.

¹⁸⁴ Epidemiology is the study of the cause and distribution of illness in human populations. Green et al., *supra* note 176, at 338; Bernstein, *supra* note 1, at 53.

Researchers examine case reports, individual reports from doctors and other sources, but these are considered weak associational evidence because they are based on anecdotal reports of a temporal relationship between exposure to an agent and manifestation of a disease. “[A]necdotal reports . . . are more useful as a stimulus for further inquiry than as a basis for establishing association or causation.”¹⁸⁶ Courts routinely reject or assign little weight to them as proof of causation¹⁸⁷ in order to avoid the *post hoc ergo propter hoc* (after which therefore because of which) fallacy in reasoning; although some courts have allowed such speculative evidence.¹⁸⁸

Observational population studies, known as epidemiological studies, are considered a stronger basis for causal inference,¹⁸⁹ although the structure of these studies relies on correlational inferences.¹⁹⁰ Ideally, they compare the incidence of disease in a population exposed to one particular agent, such as tobacco, asbestos, or a specific drug, to an unexposed, yet otherwise similar, population.¹⁹¹ The rate of incidence should be higher among the exposed group if exposure to the agent causes the disease. But the exposed group and the unexposed group may differ in other important ways.¹⁹² “Observational studies can establish that one factor is associated with another, but considerable analysis may be necessary to bridge the gap from association to causation.”¹⁹³ Given that the subjects themselves (and not a researcher in a controlled environment) knowingly or unknowingly expose themselves to the agent, observational studies have inherent limitations, such as confounding variables and bias.¹⁹⁴ Because of these inherent limitations, obser-

¹⁸⁵ See Richard W. Clapp & David Ozonoff, *Environment and Health: Vital Intersection or Contested Territory?*, 30 AM. J.L. & MED. 189, 201 (2004).

¹⁸⁶ DAVID KAYE ET AL., THE NEW WIGMORE, A TREATISE ON EVIDENCE: EXPERT EVIDENCE § 11.5.1 (Richard D. Friedman ed., 2004).

¹⁸⁷ Green, *supra* note 173, at 658; see, e.g., Wells v. SmithKline Beecham Corp., 601 F.3d 375, 380 (5th Cir. 2010); Glastetter v. Novartis Pharm. Corp., 107 F. Supp. 2d 1015, 1028 (E.D. Mo. 2000); Haggerty v. Upjohn Co., 950 F. Supp. 1160, 1164 (S.D. Fla. 1996).

¹⁸⁸ See, e.g., Brasher v. Sandoz Pharm. Corp., 160 F. Supp. 2d 1291, 1296 (N.D. Ala. 2001); Hayman & Armstrong, P.S.C. v. Gunderson, 279 S.W.3d 93, 104–06 (Ky. 2008).

¹⁸⁹ Green, *supra* note 173, at 646.

¹⁹⁰ MICHAEL J. SAKS ET AL., ANNOTATED REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 516–57 (2d ed. 2004).

¹⁹¹ Observational clinical trials are executed on groups of people who have knowingly or unknowingly exposed themselves to certain agents, such as cigarettes, alcohol, or diets high in trans-fats. See generally John Concato, *Overview of Research Design in Epidemiology*, 12 J.L. & POL'Y 489, 493–97 (2004). Exposed individuals comprise the exposed cohort while a control group is created from people with similar characteristics minus the exposure. *Id.* Some cohort studies are “follow-up” studies, in which the cohort and the control groups are followed over time to observe the incidence of disease in each group. See Green et al., *supra* note 176, at 340–42. In case-control studies, individuals who already have the disease in question are compared to a controlled group of individuals without the disease. *Id.* at 342–43, 363–64.

¹⁹² KAYE ET AL., *supra* note 186, § 11.5.1.

¹⁹³ *Id.*

¹⁹⁴ See Bernstein, *supra* note 1, at 66. For example, selection bias may occur when the exposed group was already susceptible or not susceptible to the disease for reasons independent from exposure to the agent at issue. Green et al., *supra* note 176, at 363–65. Diagnostic bias may occur when the disease at issue is incorrectly diagnosed. Green, *supra* note 173, at

vational studies must be interpreted with caution, but they can be very useful to support a causal inference.¹⁹⁵

Controlled experiments, in which the investigators choose which subjects are exposed to the agent being studied and which go into the control group, are the gold standard of proving general causation.¹⁹⁶ Randomly assigning groups tends to balance them with regard to possible confounders, and the impact of remaining confounders can be evaluated through statistical techniques. As a result, “inferences based on well-executed randomized experiments are more secure than inferences based on observational studies.”¹⁹⁷ Although the outcomes of controlled experiments are considered the best scientific evidence for ascertaining causation, they have limitations that can make them difficult to administer.¹⁹⁸

Scientists also use animal studies to demonstrate a causal connection, but these are considered a weaker form of evidence of causation in humans because of the high doses of exposure used and interspecies variations.¹⁹⁹ As one court explained, “[b]ecause of the difference in animal species, the methods and routes of administration of the suspect chemical agent, maternal metabolisms and other factors, animal studies, taken alone, are unreliable predictors of causation in humans.”²⁰⁰

B. Proof of Specific Causation

Scientists study population groups to determine whether the association between an agent and a disease is sufficiently strong to infer causation generally, but plaintiffs in a toxic tort suit must also show that the agent specifically caused their disease. In other words, plaintiffs must show by a preponderance of the evidence that their injury fell into the risk group af-

649–50. Recall bias can occur when exposure is determined by the recollection of the individual who has been exposed to the agent. For example, people with a disease recall exposure at a higher rate than those in a control (non-diseased) group. Green et al., *supra* note 176, at 365–66. Confounders may also exist that will skew the results of a study. This occurs when another factor may be associated with a higher or lower disease rate, but is not related to the agent being studied. *Id.* at 369–72. Random sampling errors may occur because some results are simply due to chance. Green, *supra* note 173, at 651.

¹⁹⁵ KAYE ET AL., *supra* note 186, § 11.5.3.

¹⁹⁶ Green et al., *supra* note 176, at 338–39.

¹⁹⁷ KAYE ET AL., *supra* note 186, § 11.5.2.

¹⁹⁸ Controlled experiments are often used to evaluate new drugs seeking FDA approval, but are not broadly used beyond that purpose, since it is a very expensive method to implement and has obvious ethical limitations once an agent is suspected to be toxic. Green et al., *supra* note 176, at 338–39.

¹⁹⁹ Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181, 225–31 (1993) (discussing the ongoing debate about the reliability of using animal tests to predict risk levels in humans).

²⁰⁰ Nat’l Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1527 (E.D. Ark. 1996), *aff’d*, 133 F.3d 1132 (8th Cir. 1998); *see also* Green et al., *supra* note 176, at 345–47; Bernstein, *supra* note 1, at 62–63.

fectured by the disease, and was not due to genetics, lifestyle, age, health, gender, or exposure to other environmental factors.²⁰¹

Typically, plaintiffs rely on medical testimony from their treating physician to show specific causation. This testimony, in turn, relies on a differential diagnosis, a standard medical technique that identifies what disease the patient has (diagnosis) in order to determine treatment, although the technique does not necessarily identify what caused the disease (etiology).²⁰²

C. Determining Admissibility and Sufficiency of Causal Evidence in Toxic Tort Cases

Given these various types of empirical data, each with its relative strengths and weaknesses, science often views causation as a question of degree, moving from weaker association to stronger association. Because courts deciding causation in tort cases require certainty over sliding scales, however, they have tried to establish bright line tests that are simpler to apply: courts have developed evidentiary thresholds for admissibility and a hierarchy of weight accorded particular forms of evidence that influence that evidence's sufficiency. Courts have also adjusted causation standards to deal with the multiple causation problem, in particular by adopting a "substantial factor" test.

1. Evidentiary Thresholds

Two lines of Supreme Court cases encourage the use of evidentiary thresholds in toxic tort cases. One trilogy of cases emphasizes the use of summary judgment based on the sufficiency of evidence to avoid the need for a jury trial.²⁰³ The focus of this Subsection is on a second series of Supreme Court decisions, beginning with *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,²⁰⁴ which requires trial courts to act as gatekeepers by using robust evidentiary threshold tests before admitting expert testimony for the factfinder's consideration.

The Court chose *Daubert*, a toxic tort case involving the drug Bendectin, to address the concern that expert testimony on causation was being admitted too easily, permitting the use of "junk science."²⁰⁵ In the *Daubert*

²⁰¹ FAIGMAN ET AL., *supra* note 1, § 23:26; Smith, *supra* note 1, at 242; Michael Duffy, *Climate Change Causation: Harmonizing Tort Law and Scientific Probability*, 28 TEMP. J. SCI. TECH. & ENVTL. L. 185, 207 (2009) (describing proof of specific causation in toxic tort litigation).

²⁰² Smith, *supra* note 1, at 224–25.

²⁰³ See *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986).

²⁰⁴ 509 U.S. 579 (1993). The other two cases are *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), and *General Electric Co. v. Joiner*, 522 U.S. 136 (1997).

²⁰⁵ *Daubert*, 509 U.S. at 579; see also PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 1–2 (1993) (giving examples of tort theories based on junk science); Bernstein, *supra* note 1, at 60; James M. Sabovich & Sarah L. Mayhew, *Bendectin's Revenge*:

line of cases, the evolving standard is phrased in terms of “evidentiary reliability” rather than “general acceptance,”²⁰⁶ but the critical point is that the test for admissibility of expert testimony requires a showing of validity based on adherence to appropriate professional or technical standards, seeking “good grounds” for the conclusion.²⁰⁷ “Daubert adopts and employs the scientific community’s self-understanding about what science is, requiring the party proffering the expert witness to demonstrate that the data and opinions offered satisfy science’s ground rules.”²⁰⁸ Thus, courts should examine the bases for the expert’s opinion, looking to whether the expert relies on studies that have been published and undergone peer review, as well as whether the conclusion posited by the expert can be tested.²⁰⁹ This screening is necessary “to ensure that all expert testimony is sufficiently helpful” to educate the trier of fact.²¹⁰ For this reason, federal courts and most state courts have a gatekeeping duty under *Daubert* to bar the jury from hearing unreliable expert opinion evidence.²¹¹

Following these signals from the Supreme Court, courts have created a range of admissibility thresholds for causal evidence in toxic tort cases. These thresholds come in various forms, but two significant ones involve setting cut-offs based on either relative risk in epidemiological studies or statistical significance. Some courts will only admit in evidence epidemiological studies that demonstrate a relative risk of at least 2.0 (meaning more than double the background level of disease found in individuals not exposed to the agent), which, according to these courts, translates into a showing of “more likely than not” that the effect has occurred.²¹² Thus, if a toxic substance is associated with an incidence of a disease that has a relative risk of at least 2.0, courts assume that the associational evidence is within the realm of legal causation.²¹³ Other courts have allowed epidemiological stud-

The Fall of the Vaccine-Autism Litigation to Judicial Scrutiny, 25 TOXICS L. REP. 385 (2010) (describing the junk science of the Bendectin litigation).

²⁰⁶ General acceptance in the scientific community was the traditional standard for admission of expert testimony, derived from *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and supplanted in *Daubert*.

²⁰⁷ *Daubert*, 509 U.S. at 580.

²⁰⁸ Richard B. Katskee, *Science, Intersubjective Validity, and Judicial Legitimacy*, 73 BROOK. L. REV. 857, 871 (2008).

²⁰⁹ In *Daubert*, Justice Blackmun rejected the *Frye* “general acceptance” test, instead setting out a list of factors that a judge may use, in the position of gatekeeper, to determine the validity of scientific testimony. *Daubert*, 509 U.S. at 588, 592–94. These factors include whether the expert’s theory or technique can or has been tested and whether the technique or theory has been subject to peer review and publication. *Id.*

²¹⁰ KAYE ET AL., *supra* note 186, § 9.3.

²¹¹ Stout & Valberg, *supra* note 159, at 785.

²¹² See *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1320–21 (9th Cir. 1995) (Where plaintiffs rely solely on epidemiological studies, they are admissible only if they show plaintiff’s exposure at least doubled risk of birth defects.); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1403 (D. Or. 1996) (reasoning that “a relative risk of 2.0 implies a 50% likelihood that an exposed individual’s disease was caused by the agent”).

²¹³ See Duffy, *supra* note 201, at 207; Stout & Valberg, *supra* note 159, at 847–52.

ies to be admitted even though the relative risk in the study fell short of 2.0.²¹⁴

With regard to statistical significance, scientists conventionally assume that they have not proven a causal relationship “if they cannot reject the hypothesis that there is no such relationship with a ninety-five percent certainty.”²¹⁵ Courts borrow this probability level and apply it as a threshold for admissibility.²¹⁶ Use of statistical significance as a talisman for validity in law has been criticized for several reasons, including, on the one hand, that it addresses only random error and not systematic error, and on the other hand, that insufficient power to detect a real association does not mean that no real association exists.²¹⁷

2. Hierarchy of Evidence

In addition to evidentiary thresholds for causal evidence, courts have established a hierarchy of empirical research methodologies to determine the weight to assign to various types of studies. As one leading scholar in the area has explained, “[In the view of courts t]here plainly is a hierarchy to these different indirect forms of toxic effect evidence. Epidemiology is at the top, and structural similarity, in vitro testing, and case reports are at the bottom.”²¹⁸

Significantly for the purposes of this Article, some scholars argue that courts should assign less weight to a differential diagnosis determining a causal link to an external agent for reasons that are similar to those discounting anecdotal case studies.²¹⁹ While it is recognized that a treating physician is competent to describe which of several diseases caused the patient’s symptoms (differential diagnosis), that competency does not necessarily extend to which external factors caused the disease (differential etiology) because “many of the facts relevant to a determination of external causation rely on a body of scientific literature that is not routinely used by treating physicians.”²²⁰ As Professor Faigman states, “[e]xperts’ case-specific conclusions

²¹⁴ See *Grassis v. Johns-Manville Corp.*, 591 A.2d 671, 675 (N.J. Super. Ct. App. Div. 1991).

²¹⁵ Berger & Solan, *supra* note 31, at 852; see Boston, *supra* note 199, at 253; Duffy, *supra* note 201, at 218.

²¹⁶ Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307, 312 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); Nat’l Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1527 (E.D. Ark. 1996), *aff’d*, 133 F.3d 1132 (8th Cir. 1998).

²¹⁷ Green et al., *supra* note 176, at 359–60; see Stout & Valberg, *supra* note 159, at 853–54.

²¹⁸ Green, *supra* note 173, at 658; see also Jennifer L. Mnookin, *Expert Evidence, Partisanship, and Epistemic Competence*, 73 BROOK. L. REV. 1009, 1024 (2008).

²¹⁹ Bernstein, *supra* note 1, at 64–65; see also *supra* notes 174, 202 and accompanying text; Joseph Sanders, *Applying Daubert Inconsistently? Proof of Individual Causation in Toxic Tort and Forensic Cases*, 75 BROOK. L. REV. 1367, 1380 (2010) (arguing that differential diagnosis is judged by a lower methodological standard than evidence of general causation).

²²⁰ Mary Sue Henifin et al., *Reference Guide on Medical Testimony*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 439, 472 (2d ed. 2000).

appear to be based on an admixture of an unknown combination of knowledge of the subject, experience over the years, commitment to the client or cause, intuition, and blind-faith. Science it is not.”²²¹ In other words, the assumption is that physicians are trained to diagnose and treat medical problems, but not necessarily to present an expert opinion on causation of injury from external factors like exposure to toxic chemicals or drugs.²²² Thus, “in toxic tort cases a differential diagnosis, no matter how well done, can rarely, by itself, prove general causation.”²²³

Further, even if testimony comes from an expert in a field like genetics, epidemiology, or teratology, without a showing of general causation—i.e., that the agent *can* cause the harm—a differential diagnosis cannot logically determine specific causation merely by process of elimination.²²⁴ As a result, many courts exclude as unreliable differential diagnosis evidence used to support general causation,²²⁵ although some courts will allow the testimony, reasoning that the problems with such testimony go to weight, not admissibility.²²⁶

While temporal order is a critical factor for specific causation, proving a temporal relationship is not sufficient. Many courts note that merely observing that an adverse event occurred after exposure to a suspected agent does not establish causation.²²⁷

Courts also question the use of analogies to “similar” chemical agents to establish that the agent at issue also causes harm. In *DeLuca v. Merrell*

²²¹ Faigman, *supra* note 175, at 1134–35; *see also* Wynacht v. Beckman Instruments, Inc., 113 F. Supp. 2d 1205, 1209 (E.D. Tenn. 2000).

²²² Bernstein, *supra* note 1, at 64; *see also* Stout & Valberg, *supra* note 159, at 870–71.

²²³ FAIGMAN ET AL., *supra* note 1, § 21:6; *see also* Stout & Valberg, *supra* note 159, at 863 n.272 (“[M]any courts improperly have conflated a physician’s ‘scientific’ causation analysis with their ‘technical’ differential diagnosis and, consequently, have deferentially treated the causation opinions of physicians, according to them a less rigorous reliability analysis than accorded other causation scientists such as epidemiologists and toxicologists.”).

²²⁴ Bernstein, *supra* note 1, at 51; *see also* *In re* Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig., 693 F. Supp. 2d 515, 519 (D.S.C. 2010) (finding that differential diagnosis satisfies *Daubert* only if general causation has already been established); Marsh v. Valyou, 977 So. 2d 543, 565 (Fla. 2007) (Cantero, J., dissenting); Ranes v. Adams Labs., Inc., 778 N.W.2d 677, 690, 693 (Iowa 2010).

²²⁵ Smith, *supra* note 1, at 225 (“The majority of courts hold that an expert must ‘rule in’ an agent as a potential cause of the plaintiff’s injury, then ‘rule out’ other possible causes until only the most likely cause remains.”); Stout & Valberg, *supra* note 159, at 864 (“[D]ifferential diagnoses are often wrong, arguably among the least reliable of opinions allowed in front of a jury.”); *see also* Moore v. Ashland Chem. Inc., 151 F.3d 269 (5th Cir. 1998) (en banc) (upholding district court’s exclusion of differential diagnosis for causal proof); Cagle v. Cooper Cos. (*In re* Silicone Gel Breast Implants Prods. Liab. Litig.), 318 F. Supp. 2d 879, 892 (C.D. Cal. 2004) (differential diagnosis cannot demonstrate general causation).

²²⁶ *See* Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999); Zuchowicz v. United States, 140 F.3d 381, 387 (2d Cir. 1998) (relying on differential diagnosis based on temporal relationship to show causation). The reasoning in *Zuchowicz* has been heavily criticized. FAIGMAN ET AL., *supra* note 1, § 21:8.

²²⁷ *See* McClain v. Metabolife Int’l Inc., 401 F.3d 1233, 1243 (11th Cir. 2005) (proving a temporal relationship does not establish a causal relationship); Heller v. Shaw Indus., Inc., 167 F.3d 146, 154 (3d Cir. 1999).

Dow Pharmaceuticals,²²⁸ for example, the court found that evidence associating other drugs with chemical structures similar to Bendectin with birth defects was not admissible to show that Bendectin was associated with birth defects.²²⁹ Similarly, the court in *Lofgren v. Motorola Inc.*²³⁰ concluded that scientists did not generally accept data regarding one chemical in determining the carcinogenicity of another; it therefore excluded an expert's testimony relying on these data.²³¹

3. Substantial Factor Test

Some courts have responded to the multiple causation problem posed by toxic torts by expanding the basic causation test from "but-for causation"²³² to imposing liability if exposure to a toxin is proven to be a "substantial factor" in causing the injury.²³³ Under this more generous standard, plaintiffs can prove causation even if other non-toxin, contributing causes may exist.²³⁴ Courts base this test on the *Restatement (Second) of Torts*, which requires plaintiffs to demonstrate that exposure to the defendant's toxic agent was a "substantial factor" in causing or promoting the disease.²³⁵ If another agent is the predominant factor in bringing about the harm, however, the agent identified in the defendant's action is not considered a "substantial factor," and thus not the legal cause of the harm.²³⁶ The *Second Restatement* grants the factfinder discretion when dealing with multiple causes to pick and choose among the acts that are independently sufficient to cause the harm.²³⁷

The *Third Restatement* virtually abandoned the substantial factor test because of the confusion it engendered, and suggested that courts faced with multiple causal factors exercise caution in determining factual causation.²³⁸ The comments to the *Third Restatement* indicate that if the factfinder concludes that there are two competing causes, both sufficient to cause the

²²⁸ 791 F. Supp. 1042 (D.N.J. 1992), *aff'd*, 6 F.3d 778 (3d Cir. 1993).

²²⁹ *Id.* at 1054.

²³⁰ No. CV 93-05521, 1998 WL 299925 (Ariz. Super. Ct. June 1, 1998).

²³¹ *Id.* at *15 (relying on the test in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), which only allows testimony to be admitted if it is "sufficiently established to have gained general acceptance in the particular field in which it belongs," *id.* at 1014).

²³² The traditional version of tort causation, commonly referred to as "but-for" causation, is defined in the *Restatement (Third) of Torts*: "Conduct is a factual cause of harm when the harm would not have occurred absent the conduct." RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 26 (2010).

²³³ See Apolinsky & Van Detta, *supra* note 11, at 590.

²³⁴ *Id.*

²³⁵ RESTATEMENT (SECOND) OF TORTS §§ 431, 433 (1965).

²³⁶ *Id.* § 433 cmt. d.

²³⁷ *Id.* §§ 433-434.

²³⁸ RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 28 cmt. c (2010) (substantial factor test may potentially lead juries to erroneously believe they must search for a single or most significant factor); *id.* § 26 cmt. j (noting that the test has few supporters).

harm, then both are considered factual causes.²³⁹ As the Tenth Circuit explained in *June v. Union Carbide Corp.*²⁴⁰:

the use of the word *sufficient* in both Restatements does not mean that either of them would impose liability for conduct that is not a but-for cause if only the conduct *could* have caused the injury. Rather it is necessary for the plaintiff to show that the conduct (or the causal set of which it is a necessary part) *would* in fact have caused the injury.²⁴¹

Thus, the test is no different than the but-for causation test because it still requires a showing that the harm would not have occurred absent the defendant's actions.²⁴²

The *Third Restatement* specifically rejects the use of the "substantial factor" test in the toxic tort context because causes of diseases are much less well understood than traditional traumatic-injury cases.²⁴³ The comments note that many of the diseases at issue in toxic tort cases have significant latency periods, and even known causes for some conditions may only explain a small incidence, with the majority of causes due to unknown factors.²⁴⁴

In sum, in toxic tort cases, plaintiffs bear the burden to "rule in" an agent as the cause of the harm. But often the types of proof described above are not sufficient:

[C]ourts, bolstered by modern strict rules for the admissibility of expert testimony, are increasingly rejecting certain categories of expert evidence presented by plaintiffs—including testimony based on animal studies, case reports, analogies to 'similar' chemicals, unpublished epidemiological studies, and differential etiologies—when such testimony is misused to assert causal inferences that the underlying studies do not support.²⁴⁵

²³⁹ *Id.* § 27 cmt. b.

²⁴⁰ 577 F.3d 1234 (10th Cir. 2009).

²⁴¹ *Id.* at 1243 (discussing both but-for and substantial factor tests); see also RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 27 cmt. e illus. 2 (2010).

²⁴² RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 26 cmt. j (2010). The *Third Restatement* posits that the only situation where the substantial factor test may be useful is when there are "multiple sufficient causes"; in other words, where several causal factors occurred simultaneously and each was sufficient to cause the total harm, such as the classic two simultaneous fires situation. *Id.*

²⁴³ See *id.* § 27 cmt. g.

²⁴⁴ *Id.* Since Restatements are highly influential on courts, it can be expected that courts will be influenced by the Third Restatement's abandonment of the substantial factor test in the toxic tort area. See CHRISTINA KUNZ ET AL., THE PROCESS OF LEGAL RESEARCH 126 (7th ed. 2008) ("Restatements are widely viewed as the most authoritative commentary and . . . courts . . . routinely cite and . . . adopt Restatement rules.").

²⁴⁵ Bernstein, *supra* note 1, at 69 (discussing use of various types of unreliable causation evidence in toxic tort cases).

In cases in which only such evidence is offered, courts rule that plaintiffs have failed to make out a prima facie case of causation.

As the legal framework on causal proof in the toxic tort area became more demanding, the jurisprudence developed by the Federal Circuit for off-Table claims applied in vaccine cases moved in a different direction. Instead of tightening requirements of causal proof, it lowered the demands placed on the petitioner, reflecting the judgment that it is better to have false positives (allowing compensation of non-victims) than false negatives (failing to compensate victims of vaccines) to incentivize vaccinations. As a result, the jurisprudence suggests that linking injury to particular doses of a vaccine in the vaccine courts may be qualitatively unlike demonstrating vaccine injury causation from a scientific perspective.

IV. PROOF OF CAUSE-IN-FACT IN OFF-TABLE CLAIMS

The development of the applicable legal standards for sufficiency of causal proof in off-Table cases is a story of mixed signals from the Federal Circuit, ranging from requiring only a minimal showing of medical opinion and circumstantial temporal evidence to mirroring the more stringent standards developed in traditional toxic tort cases. These cases depart from requiring proof of the traditional elements of general and specific causation, often conflating the two elements, presumably because of the lack of hard science in the area.²⁴⁶ This has only deepened the confusion concerning the relationship between vaccine program claims and traditional tort law.

Decisions of the Federal Circuit divide into two different lines: (1) the early cases, particularly *Grant v. Secretary of Health & Human Services*,²⁴⁷ which required the petitioner to meet a three-part test to prove causation in fact, and *Shyface v. Secretary of Health & Human Services*,²⁴⁸ which required petitioners to show that the vaccine is both a “but-for cause” of the injury and a “substantial factor in bringing about the injury[;]”²⁴⁹ and (2) later cases reacting to the special master’s decision in *Stevens v. Secretary of Health & Human Services*.²⁵⁰ In that case, then-Chief Special Master Golkiewicz proposed a more stringent five-prong test for establishing causation in off-Table injury claims.²⁵¹ The Federal Circuit swiftly rejected this view in *Althen v. Secretary of Health and Human Services (Althen III)*²⁵² and its progeny. In these later cases, the Federal Circuit re-imposed on petitioners a three-part evidentiary test: “(1) a medical theory causally connecting

²⁴⁶ See generally Strong, *supra* note 19, at 445.

²⁴⁷ 956 F.2d 1144, 1148–49 (Fed. Cir. 1992).

²⁴⁸ 165 F.3d 1344 (Fed. Cir. 1999).

²⁴⁹ *Id.* at 1352.

²⁵⁰ No. 99-594V, 2001 WL 387418 (Fed. Cl. Mar. 30, 2001).

²⁵¹ See *infra* notes 318–322 and accompanying text.

²⁵² *Althen v. Sec’y of Health & Human Servs. (Althen III)*, 418 F.3d 1274 (Fed. Cir. 2005).

the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.”²⁵³ In reestablishing this test, the Federal Circuit signaled that the special masters should err on the side of compensation and not be bound by traditional tort standards for causal proof.

The major developments since *Althen* relate to the sufficiency of the evidence under each part of the more relaxed *Althen* test, the interrelation of the three parts of the test, and the identification of the point at which the evidentiary burden shifts from the petitioner to the respondent.²⁵⁴ Of particular importance is the Federal Circuit’s latest decision, *Moberly ex rel. Moberly v. Secretary of Health & Human Services*,²⁵⁵ in which it has seemingly changed course again, suggesting that the relaxed presumptions applicable to Table injuries may not satisfy causal proof for non-Table claims and that traditional tort standards should apply.²⁵⁶

The constant changes to the Federal Circuit causation standards as well as the lack of clarity as to the information considered to determine whether the standard has been met have left the area in disarray. At its inception, the vaccine program was not driven by the same policy concerns as those found in tort law—or at least not to the same extent.²⁵⁷ Accordingly, the decisions moved away from the traditional tort approach, with its emphasis on corrective justice and deterrence, to a broad-based system of categorical compensation, with its focus on insurance notions of pooling resources. To clarify the jurisprudence and return to the Vaccine Act’s original objectives, this Article proposes that the Vaccine Act needs to be amended to remove the terminology of “causation,” along with the tort concepts it imports, and replace it with an intermediate proof standard.

A. Early Developments

In one of the earliest Federal Circuit decisions on causal proof in off-Table cases, *Hines v. Secretary of Health & Human Services*,²⁵⁸ the court

²⁵³ *Id.* at 1278.

²⁵⁴ This Article does not address the petitions claiming that vaccinations cause autism. These claims are part of the largest omnibus proceeding in the history of the Vaccine Act and are being treated like a class action. See *Dwyer v. Sec’y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250, at *2 (Fed. Cl. Mar. 12, 2010); Autism General Order No. 1, 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002) (outlining procedure for handling approximately 5,000 petitions alleging that certain childhood vaccines were causing Autism Spectrum), available at <http://www.uscfc.uscourts.gov/node/2718>.

²⁵⁵ 592 F.3d 1315 (Fed. Cir. 2010).

²⁵⁶ *Id.* at 1322.

²⁵⁷ See Apolinsky & Van Detta, *supra* note 11, at 573 (Congress created NCVIA “with an eye toward purely instrumentalist goals like widespread vaccination levels and protection of vaccine manufacturers that facilitate continued production of vaccines,” as well as ensuring compensation to victims of vaccines.).

²⁵⁸ 940 F.2d 1518 (Fed. Cir. 1991).

defined the issue before the special master as “whether the evidence submitted by the petitioner warranted a conclusion that the vaccine caused the injury.”²⁵⁹ Relying on the arbitrary and capricious standard of review, the *Hines* court made clear that just what type of evidence—and how much of it—a petitioner had to present to merit such a conclusion generally was left to the special master’s discretion.²⁶⁰ In another early pivotal decision, *Grant v. Secretary of Health and Human Services*,²⁶¹ the Federal Circuit laid out a more specific, three-part test to prove causation in fact: petitioners had to (1) “show a medical theory causally connecting the vaccination and the injury”; (2) offer “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury”; and (3) support the “logical sequence of cause and effect” with a “reputable medical or scientific explanation.”²⁶² Once the petitioner satisfied these elements, the special master had to evaluate whether, based on a preponderance of the evidence, factors not related to the vaccine caused the injury.²⁶³ Thus, under *Grant*, an award of compensation required two findings by the special master: causation-in-fact and the absence of an alternative cause of injury.²⁶⁴ Although the burden clearly fell on the petitioner to establish causation-in-fact, the courts struggled with whether the petitioner or the respondent bore the burden of proving the absence of an alternative etiology.²⁶⁵

Later cases relied heavily upon the *Grant* framework for causal proof requirements. These cases, borrowing from the general causation factor in toxic tort cases, viewed the first factor, demonstrating a medical theory linking the vaccine to the injury, to require the petitioner to establish that the vaccine can in theory cause the injury suffered.²⁶⁶ The second factor, showing a “logical sequence of cause and effect” between the vaccine and the injury by applying the proffered medical theory,²⁶⁷ bridged the connection

²⁵⁹ *Id.* at 1527.

²⁶⁰ *Id.* at 1528 (stating that the arbitrary and capricious standard applies in reviewing special masters’ decisions and that this standard is highly deferential); *see also* *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (calling the deferential standard “especially apt in a case in which the medical evidence of causation is in dispute”); *McCarren v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 142, 150 (1997) (explaining that a special master “has broad discretion in determining credibility and drawing factual conclusions”).

²⁶¹ 956 F.2d 1144 (Fed. Cir. 1992).

²⁶² *Id.* at 1148 (award granted for injury from Quadrigen version of DPT vaccine).

²⁶³ *Id.* at 1149.

²⁶⁴ *Id.* at 1149–50.

²⁶⁵ *See* *Jay v. Sec’y of Health & Human Servs.*, 998 F.2d 979, 984 (Fed. Cir. 1993) (petitioners entitled to judgment as matter of law where HHS presented no evidence of alternative causation); *McCarren*, 40 Fed. Cl. at 150 (petitioner did not adequately refute alternative causation). *See generally* *Stevens v. Sec’y of Health & Human Servs.*, No. 99-594V, 2001 WL 387418, at *21–23 (Fed. Cl. Mar. 30, 2001) (describing cases with differing views on petitioner’s burden).

²⁶⁶ *See* *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1353 (Fed. Cir. 1999); *McCarren*, 40 Fed. Cl. at 150.

²⁶⁷ *See* *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994); *Jay*, 998 F.2d at 984; *Grant*, 956 F.2d at 1148; *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

from the theoretical to the injury in the claim at hand, and was similar to the specific causation factor of toxic tort cases. To satisfy this second factor, petitioners often had to demonstrate a temporal link between the vaccine and the injury and eliminate alternative causes of the injury.²⁶⁸ Merely meeting one or both of these criteria was not enough to establish a preponderance of the evidence, however.²⁶⁹ The third factor, “reputable” medical or scientific support, indicated that a petitioner must provide reliable evidence to support the second factor,²⁷⁰ but the test for reliability was not clearly defined.

Under these cases, appellate review emphasized the broad discretion accorded the special masters, and the outcome of off-Table claims depended almost entirely on the special masters’ acceptance and individualized weighing of evidence with regard to causation.²⁷¹ On review, the Federal Circuit examined three factors: whether the special master (1) “considered the relevant evidence of record”; (2) had “drawn plausible inferences”; and (3) “articulated a rational basis for the decision.”²⁷² If the special master performed all three tasks, reversible error would be “extremely difficult to demonstrate.”²⁷³

Given the broad discretion and high degree of appellate deference afforded the special masters, it is difficult to discern consistent patterns of sufficiency of evidence standards in early Federal Circuit off-Table cases. Some inconsistencies did surface, however. The best evidence—pathological markers²⁷⁴—was considered virtually dispositive from the start; but most vaccines simply leave no such footprints.²⁷⁵ Similarly, these early cases gave

²⁶⁸ See *Grant*, 956 F.2d at 1149–50 (“As a precondition to compensation, the Vaccine Act requires, in addition to a Table Injury or causation in fact, the absence of alternative causes.”).

²⁶⁹ See *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 960 (Fed. Cir. 1993) (finding that “the absence of an alternative cause of injury does not meet the affirmative duty to show causation”); *Grant*, 956 F.2d at 1148 (“Temporal association is not sufficient . . . to establish causation in fact.”).

²⁷⁰ *Hodges*, 9 F.3d at 961; *Jay*, 998 F.2d at 984; *Grant*, 956 F.2d at 1148.

²⁷¹ See, e.g., *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). *Lampe* is a significant decision. Petitioners argued that because the inoculated child was healthy before a DPT series began, because no other cause had been identified for her seizures, and because she experienced a seizure within one week of her third DPT shot, the evidence sufficed to show cause-in-fact. *Id.* at 1368. Over a vigorous dissent, the Federal Circuit found that although “a finder of fact might well have been persuaded” this constituted sufficient proof of cause-in-fact, the special master’s conclusion to the contrary was not “arbitrary or capricious.” *Id.*

²⁷² *Hines*, 940 F.2d at 1528.

²⁷³ *Id.*

²⁷⁴ Pathological markers are unique patterns of injury that identify the injury as stemming from a specific causative agent. See *Stevens v. Sec’y of Health & Human Servs.*, No. 99-594V, 2001 WL 387418, at *12 (Fed. Cl. Mar. 30, 2001) (citing examples of markers “as evidence of polio contracted from the oral polio vaccine or . . . as evidence of a rubella-related arthropathy”).

²⁷⁵ *Id.* at *14.

great weight to epidemiological studies demonstrating a relative risk greater than 2.0, similar to the toxic tort arena.²⁷⁶

Given the limited availability of these two forms of evidence, however, petitioners turned to weaker “circumstantial” evidence to prove causation, such as animal studies, case reports, treating physician testimony, medical textbooks, and comparable biological mechanisms.²⁷⁷ Special masters struggled with how to evaluate such evidence, and, in applying the *Grant* test, the special masters applied inconsistent standards to the same kinds of evidence and reached inconsistent results.²⁷⁸ They also struggled with what combinations of evidence sufficiently demonstrated causation.²⁷⁹ Another issue on which the vaccine courts did not agree was whether the petitioner had to proffer a precise biological or immunological mechanism that explained how the injury arose from the vaccine.²⁸⁰

The Federal Circuit’s response to the special masters’ confusion did nothing to alleviate it. Instead, the Federal Circuit emphasized the special masters’ discretion by stressing the importance of looking at the totality of evidence in determining causation.²⁸¹ In *Jay v. Secretary of Health & Human Services*,²⁸² for example, the Federal Circuit reversed a grant of summary judgment to the government, remanding the case for an award of compensation.²⁸³ The petitioners alleged that a DPT vaccination caused encephalopathy, which in turn led to their son’s death.²⁸⁴ The special master held that the medical expert could not establish encephalopathy based only on the prolonged crying that followed the vaccine,²⁸⁵ but the Federal Circuit

²⁷⁶ *Id.* at *13 (citing use of National Childhood Encephalopathy Study in context of DPT-related injuries); *Liabe v. Sec’y of Health & Human Servs.*, No. 98-120V, 2000 WL 1517672, at *12 (Fed. Cl. Sept. 7, 2000).

²⁷⁷ See *Stevens*, 2001 WL 387418, at *14.

²⁷⁸ *Id.* at *15–16 (listing inconsistencies in weight assigned to animal studies, case reports, peer-reviewed evidence and treating physicians’ opinions). For example, some special masters found that opinions of treating physicians should be given considerable weight, even to support a novel claim. See, e.g., *Rogers v. Sec’y of Health & Human Servs.*, No. 94-0089V, 2000 WL 1337185, at *13 (Fed. Cl. June 6, 2000); *McMurry v. Sec’y of Health & Human Servs.*, No. 95-682V, 1997 WL 402407, at *9 (Fed. Cl. June 27, 1997). Others found that clinical diagnosis alone may not be sufficient to show causation. See, e.g., *O’Leary v. Sec’y of Health & Human Servs.*, No. 90-1729V, 1997 WL 254217, at *3 (Fed. Cl. Apr. 17, 1998).

²⁷⁹ See *Stevens*, 2001 WL 387418, at *20 (citing examples of inconsistent results reached with various combinations of evidence).

²⁸⁰ *Id.* at *21 (citing cases trying to reconcile *Grant*’s requirement of showing a “logical sequence of cause and effect” without contravening *Knudsen*’s caution that the precise details of the mechanics of injuries are not required).

²⁸¹ See *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518 (Fed. Cir. 1991); see also *Golub v. Sec’y of Health & Human Servs.*, No. 99-5161, 2000 U.S. App. LEXIS 24858, at *13 (Fed. Cir. Oct. 3, 2000) (finding that “the special master abused her discretion by failing to consider the totality of the evidence”).

²⁸² 998 F.2d 979 (Fed. Cir. 1993).

²⁸³ *Id.* at 980.

²⁸⁴ *Id.* at 984. Petitioners also pursued the claim as a Table claim for encephalopathy within three days of vaccination, which the Federal Circuit held should also have been granted summary judgment. *Id.*

²⁸⁵ *Id.* at 981.

ruled that the special master failed to consider the evidence as a whole, particularly the temporal association and the fact that a death occurred.²⁸⁶ It held that the petitioners were entitled to compensation:

The undisputed facts of record . . . include that an otherwise healthy child received a DPT shot; the DPT shot caused fever, directly or indirectly limpness, and intermittent inconsolable extended screaming; the child missed his normal nightly feeding; the child died within 18 hours of the shot; the autopsy was inconclusive; and a medical expert testified, uncontradicted, that the DPT shot caused the death, the medical theory being that an encephalopathy occurred We therefore hold as a matter of law that on the undisputed facts of record a reasonable person could not conclude that the Jays failed to prove that the DPT vaccine was the likely cause of Matthew's death.²⁸⁷

Because the government did not dispute any of the petitioners' evidence, the medical records, the autopsy report, the parents' testimony, and medical expert testimony were sufficient to prove causation-in-fact.²⁸⁸ The Federal Circuit thus indicated that the floor for sufficiency on an off-Table claim was low and highly contextual, and the government's lack of evidence could support the petitioner's claim in favor of finding causation.

The Federal Circuit also resisted efforts to apply *Daubert* to test expert testimony. For example, in *Golub v. Secretary of Health & Human Services*,²⁸⁹ petitioner alleged that a DPT vaccination caused meningitis, which in turn caused a seizure disorder, developmental delay, and cortical damage.²⁹⁰ The special master denied compensation because petitioner's theory, although plausible, did not "rise to the level of scientific reliability."²⁹¹ The special master dismissed evidence of a temporal relationship, animal studies, and studies involving HIV patients, and dismissed a study involving children because it was not peer-reviewed or published.²⁹² Eschewing application of *Daubert* standards to this context, the Federal Circuit countered that a petitioner's expert theory on causation only had to be "reasonably reliable" and did not need to "rise to the level of being a scientific certainty."²⁹³ The court clarified that "while a proximate temporal association alone does not establish a causal link between the vaccination and the injury, where a strong temporal relationship exists, the additional showing of a reasonable medical

²⁸⁶ *Id.* at 983.

²⁸⁷ *Id.* at 984.

²⁸⁸ *Id.* at 981, 984.

²⁸⁹ No. 99-5161, 2000 U.S. App. LEXIS 24858 (Fed. Cir. Oct. 3, 2000).

²⁹⁰ *Id.* at *2-3.

²⁹¹ *Id.* at *7.

²⁹² *Id.* at *11.

²⁹³ *Id.* at *5. However, special masters were allowed to rely on *Daubert* "as a tool or framework for conducting the inquiry into the reliability of the evidence." *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999).

theory causally connecting the vaccination and the injury would suffice to establish a causal link.”²⁹⁴

Finally, the Federal Circuit relied on the confusing substantial factor test from *the Second Restatement of Torts* when more than one suspected causal factor existed. In *Shyface v. Secretary of Health & Human Services*,²⁹⁵ for example, the petitioner’s expert testified that the combination of the DPT vaccine and an unrelated factor—E. coli pneumonia—caused death.²⁹⁶ The expert testified that the death would not have occurred had only one of the factors been present and that it could not be determined which factor contributed more to the death.²⁹⁷ The government’s expert disagreed, testifying that the E. coli infection alone caused the death.²⁹⁸ The special master denied compensation because the petitioners could not prove that the vaccine caused the death,²⁹⁹ and the Court of Federal Claims upheld the denial, requiring the petitioners to establish the vaccine as the “predominant cause” of death to prevail.³⁰⁰ On appeal, the petitioners argued for a broader causal test requiring them to establish only that the vaccine was a “but-for,” not the “predominant,” cause of death.³⁰¹ The Federal Circuit stated that “the Vaccine Act’s requirement of causation in non-Table cases was not viewed as distinct from causation in the tort law”³⁰² and “adopt[ed] the [Second] Restatement rule for purposes of determining vaccine injury, that an action [was] the ‘legal cause’ of harm if that action is a ‘substantial factor’ in bringing about the harm, and that the harm would not have occurred but for the action.”³⁰³ Because, in the Federal Circuit’s estimation, the “undisputed” facts established that the DPT vaccine was both a substantial factor and a but-for cause of the death, the court held that the petitioners were entitled to compensation.³⁰⁴

Thus, the Federal Circuit’s jurisprudence gave minimal guidance to the special masters on the type and amount of causal proof to demand of petitioners and ignored the developments occurring in the tort context for causal proof. This lack of guidance resulted in disarray in the program.

B. *The Stevens Decision*

Twelve years into the program, special masters still reached inconsistent results regarding claims involving the same vaccine and similar inju-

²⁹⁴ *Golub*, 2000 U.S. App. LEXIS 24858, at *12–13.

²⁹⁵ 165 F.3d 1344 (Fed. Cir. 1999).

²⁹⁶ *Id.* at 1345–46.

²⁹⁷ *Id.* at 1346–47.

²⁹⁸ *Id.* at 1346.

²⁹⁹ *Id.* at 1347.

³⁰⁰ *Id.* at 1348.

³⁰¹ *Id.*

³⁰² *Id.* at 1351.

³⁰³ *Id.* at 1352.

³⁰⁴ *Id.* at 1353.

ries.³⁰⁵ Given the uncertainty regarding causal proof, adjudication of cause-in-fact cases continued to get costlier and lengthier.³⁰⁶ Faced with a system that did not appear to meet a main purpose of the Act—to compensate vaccine victims “quickly, easily, and with certainty and generosity”³⁰⁷—as well as a Congress that did not amend the Act even after focusing on the causal proof issue in an oversight hearing,³⁰⁸ Chief Special Master Golkiewicz, who had been involved with the program since its inception, undertook to clarify the standards for deciding cause-in-fact cases in *Stevens v. Secretary of Health & Human Services*.³⁰⁹

In *Stevens*, the petitioner claimed that a hepatitis B vaccination caused transverse myelitis.³¹⁰ In a motion for summary judgment, she argued that the vaccine generally could cause myelitis³¹¹ and did cause it in her case. She pointed to the temporal relationship between two separate vaccinations in the series and the onset of her symptoms—eight days after the first vaccination and nine days after the second—which she alleged was consistent with a demyelinating disorder.³¹² She presented her medical records to show that there was no likely alternative cause for her injury,³¹³ as well as her treating neurologist’s opinion to support a probable causal link between the vaccine and her illness.³¹⁴ The Chief Special Master, while carefully limiting his holding to the facts in the case, denied the petitioner’s motion for summary judgment, finding disputed issues on medical plausibility, temporal relationship, and absence of alternative causes.³¹⁵

Frustrated with the lack of consistency in sufficiency standards, however, the Chief Special Master moved beyond the case to analyze the conflicting law on causal proof and to propose a test closer to toxic tort sufficiency standards.³¹⁶ By introducing a five-prong test, the Chief Special Master hoped to set an evidentiary standard that would meet the statutory goal to expeditiously and fairly decide causation-in-fact cases.³¹⁷

³⁰⁵ *Stevens v. Sec’y of Health & Human Servs.*, No. 99-594V, 2001 WL 387418, at *11 (Fed. Cl. Mar. 30, 2001).

³⁰⁶ *Id.* at *7.

³⁰⁷ See H.R. REP. NO. 99-908, at 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347.

³⁰⁸ See *supra* notes 134–150 and accompanying text.

³⁰⁹ 2001 WL 387418, at *11–12.

³¹⁰ *Id.* at *1.

³¹¹ To show general causation, the petitioner relied on a study where four cases of transverse myelitis were reported following hepatitis B vaccinations, a report by the IOM finding several cases of transverse myelitis following vaccines, including the hepatitis B vaccine, and the manufacturers’ package inserts listing transverse myelitis as a possible side effect of the hepatitis vaccine. *Id.* at *2. In addition, she argued that it is “biologically plausible” that the hepatitis B vaccine can cause transverse myelitis. *Id.*

³¹² *Id.*

³¹³ *Id.* at *3.

³¹⁴ *Id.*

³¹⁵ *Id.* at *6.

³¹⁶ *Id.* at *27.

³¹⁷ *Id.* at *8.

Under the *Stevens* test, a petitioner would meet the preponderance test only by providing proof of the following: (1) plausibility of the biologic mechanism;³¹⁸ (2) confirmation of medical plausibility from the medical community and literature;³¹⁹ (3) an injury recognized by the medical plausibility evidence and literature;³²⁰ (4) a medically accepted temporal relationship between the vaccination and the onset of the alleged injury;³²¹ and (5) elimination of other causes.³²² The first two prongs were designed to demonstrate general causation while the last three prongs involve proving specific causation—the vaccine actually caused this harm to this petitioner. The *Stevens* prongs apply some of the *Daubert* threshold standards for testing scientific evidence in this context, particularly with regard to peer-reviewed literature, but on the whole are not as stringent as causal proof requirements in toxic tort cases.

To meet the general causation standard, the *Stevens* test required proof of some association between the vaccine and the injury. To satisfy the first prong of the *Stevens* test, petitioners could use scientific, medical, or other literature to establish the “biologic mechanism” by which the vaccine could cause the injury.³²³ The literature did not need to link the vaccine itself with the injury, but it needed to associate a component of the vaccine with the injury.³²⁴

Building on this proof, the petitioner then had to demonstrate under prong two that the scientific or medical community had moved beyond the theoretical to link the vaccine to the injury.³²⁵ Prong two required only that “the medical community is seeing and reporting a suspected or potential association” between the vaccine and the injury; it did not demand irrefutable scientific studies.³²⁶ Significantly, however, this prong required that the proof of an association between the vaccine and the injury must appear in peer-reviewed literature,³²⁷ including “epidemiological studies, animal studies, case series, case reports, anecdotal reports, journal articles, manufacturing disclosures, Physician Desk Reference citations, and institutional findings.”³²⁸

³¹⁸ *Id.* at *23.

³¹⁹ *Id.* at *24.

³²⁰ *Id.* at *25.

³²¹ *Id.*

³²² *Id.* at *26.

³²³ *Id.* at *22.

³²⁴ *Id.* at *23.

³²⁵ *Id.*

³²⁶ *Id.* at *24.

³²⁷ *Id.* at *18.

³²⁸ *Id.* at *24. Not all the items listed are peer-reviewed publications, such as manufacturing disclosures and the Physician Desk Reference. *Cf. id.* at *17–18 (noting inconsistent reliance by special masters on unpublished or non-peer-reviewed evidence).

Proof of specific causation under prong three—that the petitioner actually suffered the particular injury in question³²⁹—generally could be met through the petitioner’s medical records.³³⁰

To meet prong four, the critical factor of onset, petitioner needed to produce peer-reviewed literature to establish the medically acceptable time frame³³¹ and show that the temporal relationship between the date of vaccination and the onset of injury fit within the medically acceptable time frame.³³² Merely proving that the injury occurred after the vaccination was not enough to satisfy this prong.³³³

The final prong of the *Stevens* test placed the burden on the petitioner to disprove alternative causes by requiring the petitioner to “affirmatively demonstrate by a preponderance of the evidence that there is no reasonable evidence that an alternate etiology is the more probable cause of the alleged injury.”³³⁴ Under this prong, a petitioner had to supply evidence from a treating physician that “reasonable efforts” were made to “rule out known alternate causes.”³³⁵ However, a petitioner did not need to “eliminate potential unknown, unidentified, speculative, unapparent, or spontaneous causes with or without a subclinical nature.”³³⁶

Thus, *Stevens* attempted to lay out the requirements for meeting a preponderance of the evidence burden for causation, most significantly requiring some form of peer-reviewed literature to demonstrate both an association between the vaccine and the injury and a medically accepted temporal relationship. The Chief Special Master’s attempt to create uniform standards for determining the sufficiency of causal proof demonstrates the influence of *Daubert* and a move toward “harder science.”

C. *Reversal of Stevens Under the Althen Trilogy and Beyond*

The reaction of the Federal Circuit to *Stevens* was swift and direct; it used its review of the next series of vaccine cases, including *Stevens*, to hold that the *Stevens* test developed by the vaccine court was too demanding and in contravention of the Vaccine Act.³³⁷ The Federal Circuit attempted to clarify two major issues: (1) the petitioner’s burden to provide sufficient evi-

³²⁹ *Id.* at *25.

³³⁰ *Id.*

³³¹ *Id.*

³³² *Id.* at *25–26.

³³³ *Id.* at *25.

³³⁴ *Id.* at *26.

³³⁵ *Id.* Acceptable evidence included “oral testimony, written reports, and/or contemporaneous medical records showing the completion of a differential diagnosis.” *Id.*

³³⁶ *Id.* Overall, the Chief Special Master stressed that the five-prong test was flexible and that criteria might be adjusted to meet the needs of each case. *Id.* at *37. He also indicated that petitioners should not view the criteria as limiting—petitioners could present additional evidence if necessary. *Id.*

³³⁷ *Althen III*, 418 F.3d 1274, 1281 (Fed. Cir. 2005). The *Stevens* decision ultimately received direct review, with the same result. *Stevens*, 2001 WL 387418.

dence of general and specific causation; and (2) whether disputing alternative causes was part of the petitioner's case in chief or part of the government's rebuttal. In particular, it made clear that the treating physician's testimony is critical evidence, but that empirical data are not required to make out a claim.³³⁸ It also indicated that collapsing the inquiry of general and specific causation is appropriate in the Vaccine Fund context.³³⁹

1. *Sufficiency of Evidence for General and Specific Causation*

In *Althen v. Secretary of Health & Human Services (Althen I)*,³⁴⁰ the Chief Special Master had denied the petitioner, Althen, compensation because she could not meet prong two of the *Stevens* test, namely, recognition in the medical or scientific community of a general causal link between the vaccine and her injury.³⁴¹ Althen alleged a tetanus toxoid vaccination caused her optic neuritis and acute-disseminated encephalomyelitis.³⁴² To establish a medically plausible biologic mechanism, Althen's expert witness testified that once T cells³⁴³ respond to a component of the vaccine, T cells may then mistakenly respond to other antigens in the body, causing disorders like Althen's.³⁴⁴ Although Chief Special Master Golkiewicz found that Althen "clearly" satisfied prong one of the *Stevens* test,³⁴⁵ he found that she did not meet prong two because she failed to present sufficient evidence of recognition in the medical community of general causation, linking her type of injury to the tetanus toxoid vaccine.³⁴⁶ He stated:

It is the satisfaction of this second prong which moves petitioner's case beyond the theoretical causative connection towards the realm of probable or preponderance. Without proof that the theoretical has risen to the extent of recognition or confirmation within the medical community or literature, petitioner's case is, at best, speculative.³⁴⁷

³³⁸ See *infra* notes 350–351 and accompanying text.

³³⁹ See *infra* notes 350–384 and accompanying text.

³⁴⁰ *Althen v. Sec'y of Health & Human Servs. (Althen I)*, No. 00-170V, 2003 U.S. Claims LEXIS 163 (Fed. Cl. June 3, 2003).

³⁴¹ *Id.* at *65.

³⁴² *Id.* at *1.

³⁴³ T cells belong to a group of white blood cells known as lymphocytes and are active in controlling the immune response and attacking infections. See WEBSTER'S MED. DICTIONARY, www.medterms.com (last visited Feb. 15, 2011).

³⁴⁴ *Althen I*, 2002 U.S. Claims LEXIS 163, at *14.

³⁴⁵ *Id.* at *42.

³⁴⁶ *Id.* at *56.

³⁴⁷ *Id.* at *59.

Accordingly, the Chief Special Master denied Althen compensation.³⁴⁸ The Court of Federal Claims, finding that the test went beyond the bounds of the Act, reversed and remanded the decision (*Althen II*).³⁴⁹

On appeal, the Federal Circuit found that the Act specifically allows medical opinion to satisfy the preponderance test and that requiring peer-reviewed medical literature, even to prove general causation under prong two of the *Stevens* test, contravenes the statute: “This prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.”³⁵⁰ Thus, the Chief Special Master’s requirement of peer-reviewed literature to establish theoretical causation was unduly restrictive.

By removing the need for peer-reviewed literature and relying on circumstantial clinical evidence, the court virtually eliminated any evaluation of the reliability of scientific testimony based on the *Daubert* factors and seemingly suggested that no empirical data are required to prove general causation. It strongly signaled that the sufficiency standard was lowered under the Vaccine Act as compared to traditional evidence law to ensure that more petitioners receive compensation, even if it meant that claimants not harmed by vaccines similarly benefited.

Modifying the test from *Grant*, the court stated that the petitioner need only satisfy three elements: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.”³⁵¹ The Federal Circuit clarified that the petitioner does not need to show that the vaccination was the sole cause or predominant cause, but needs to show only that the vaccination was a “but-for” cause of the injury and a “substantial factor in bringing about the injury.”³⁵² After satisfying these elements, the

³⁴⁸ *Id.* at *65.

³⁴⁹ *Althen v. Sec’y of Health & Hum. Servs. (Althen II)*, 58 Fed. Cl. 270, 287 (2003). Specifically, the court explained that prong one lowers the burden of proof by requiring only plausibility, not preponderance, *id.*, prong two both increases the burden of proof by requiring peer-reviewed literature and lowers it by requiring only a suspected link, *id.* at 284, and prong three fails because it relies on prongs one and two, *id.* at 285. The Act does not require peer-reviewed literature to meet the preponderance test, so denying Althen compensation was contrary to law. *Id.* at 284. Furthermore, the court held that Althen met her statutory burden by “proffer[ing] reliable medical records, a reputable medical opinion, a logical sequence of cause and effect, and a medical theory causally connecting the vaccination to the onset and development of her ‘demyelinating illness’” and thus found that she was entitled to compensation. *Id.* at 286–87.

³⁵⁰ *Althen III*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

³⁵¹ *Id.* at 1278. The Federal Circuit changed the third prong of the *Grant* test, which had required petitioner to support the “logical sequence of cause and effect” with a “reputable medical or scientific explanation.” See *supra* note 262 and accompanying text.

³⁵² *Althen III*, 418 F.3d at 1278 (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

petitioner is entitled to compensation unless the government establishes by a preponderance of the evidence an alternative cause of injury.³⁵³

In language that has become iconic, the Federal Circuit explained:

While this case involves the possible link between TT vaccination and central nervous system injury, a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.³⁵⁴

Further, meeting the preponderance standard permits the use of circumstantial evidence that relies on clinical records or medical opinion rather than scientific evidence.³⁵⁵ Thus, the Federal Circuit came down squarely on the side of lowering sufficiency standards, especially with regard to demonstrating general causation—even in the absence of hard science—to meet the policy goals of compensation and ensuring the continuation of vaccine production by protecting the industry from liability. Importantly, the court deviated from the statutorily mandated burden of preponderance—more likely than not—in its attempt to resolve close calls in favor of the petitioner.

The first application of the three-pronged *Althen* test to reach the Federal Circuit for review was *Capizzano v. Secretary of Health & Human Services*.³⁵⁶ In *Capizzano*, Chief Special Master Golkiewicz applied both the *Stevens* criteria—because it had not yet been overturned by the Federal Circuit—as well as the criteria devised by the Court of Federal Claims in *Althen II* to reject the claimant's position.³⁵⁷ The petitioner claimed that the hepatitis B vaccine caused her to suffer from rheumatoid arthritis.³⁵⁸ Based on rechallenge evidence³⁵⁹ in other injectees (the petitioner did not suffer rechallenge effects herself), the Chief Special Master concluded that the hepatitis B vaccine can, in general, cause rheumatoid arthritis, thus satisfying the first prong of *Althen*.³⁶⁰ The petitioner also met the third prong—temporal relationship—to the Chief Special Master's satisfaction.³⁶¹ But the Chief Special Master interpreted prong two—the “logical sequence of cause and effect”—as requiring one of the following four forms of evidence: (1) epidemiologi-

³⁵³ *Id.* at 1278.

³⁵⁴ *Id.* at 1280.

³⁵⁵ *Id.* at 1279–80.

³⁵⁶ 440 F.3d 1317 (Fed. Cir. 2006).

³⁵⁷ *Id.* at 1324. The briefing in *Capizzano*'s appeal to the Federal Circuit was completed after the Court of Federal Claims' decision in *Althen II* but before the decision was rendered by the Federal Circuit. *Id.*

³⁵⁸ *Id.* at 1320.

³⁵⁹ “Rechallenge evidence” occurs when an individual has an adverse reaction to a vaccine and then suffers worsened symptoms after receiving a second vaccine in a series. *Id.* at 1322.

³⁶⁰ *Id.* As the Chief Special Master explained, rechallenge cases are “such strong proof of causality that it is unnecessary to determine the mechanism of cause—it is understood to be occurring.” *Id.*

³⁶¹ *Id.* at 1326.

cal studies; (2) rechallenge in the petitioner; (3) presence of pathological markers or genetic predisposition; or (4) general acceptance in the medical and scientific communities that the vaccine can cause the injury.³⁶² Lacking peer-reviewed medical literature, the Special Master denied petitioner compensation despite the treating physicians' diagnoses attributing her rheumatoid arthritis to the hepatitis B vaccine.³⁶³ The Court of Federal Claims affirmed.³⁶⁴

The Federal Circuit vacated the decision and remanded the case, making clear that the Chief Special Master had demanded too much proof from petitioners to meet the second prong requirement.³⁶⁵ According to the court:

“A logical sequence of cause and effect” means what it sounds like—the claimant’s theory of cause and effect must be logical As far as the second prong is concerned, in our view, the chief special master erred in not considering the opinions of the treating physicians.³⁶⁶

Accordingly, treating physicians’ testimony based primarily on temporal proximity between the vaccination and injury could be used to demonstrate specific causation under both prongs two and three.³⁶⁷ The physicians’ reliance on the temporal proximity between vaccination and injury (prong three evidence) did not disqualify their diagnoses that the hepatitis B vaccine caused Mrs. Capizzano’s rheumatoid arthritis (prong two evidence).³⁶⁸

Thus, the showing petitioners must make to prove specific causation was rendered quite minimal—it can be based on treating physician testimony that in turn is based solely on temporal proximity to the inoculation. Recognizing how low the standard of proof had become, the Federal Circuit explained that the second *Althen* prong is “not without meaning,” and depends on the nature of the individual claim, submitting that:

A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.³⁶⁹

³⁶² *Id.*

³⁶³ *Id.* at 1323.

³⁶⁴ *Id.* (quoting *Capizzano v. Sec’y of Health & Human Servs.*, 63 Fed. Cl. 227 (2004)) (The Court of Federal Claims observed that “[g]iven the number of persons receiving hepatitis B vaccine and the percentage of the population developing RA, there are bound to be persons receiving the vaccine who would, in any event, develop RA.”).

³⁶⁵ *Id.* at 1327–28.

³⁶⁶ *Id.* at 1326.

³⁶⁷ *Id.*

³⁶⁸ *Id.*

³⁶⁹ *Id.* at 1327.

The Federal Circuit focused again on the significance of the treating physician's testimony in *Andreu ex rel. Andreu v. Secretary of Health & Human Services*,³⁷⁰ relying on the totality of circumstances test to reverse the special master's decision against the petitioner. Enrique Andreu suffered seizures shortly after receiving a DPT vaccination. No alternative cause was found for his seizures, and the parties disputed the nature of his seizures.³⁷¹ To support the argument that the vaccine had caused the seizures, the petitioner's expert presented a "blood-brain barrier" theory.³⁷² The special master did not accept the theory of the petitioner's expert because "'numerous medical studies' . . . 'failed to find a relationship between afebrile seizures and DPT vaccination.'" ³⁷³

The Court of Federal Claims remanded the case and ordered the special master to seek the testimony of Enrique's treating physicians on the question of specific causation.³⁷⁴ On remand, one treating physician testified that "because there was a concern about a reaction," he thought it would be "safer" to recommend that the child not receive further pertussis vaccinations.³⁷⁵ The other testified that despite extensive testing, he had "never found anything else" to explain the seizures and that the timing of the seizures was consistent with a causal link.³⁷⁶ The special master again found that the weight of the evidence did not support finding the pertussis vaccine to be the cause of the seizures.³⁷⁷ The Court of Federal Claims affirmed,³⁷⁸ but the Federal Circuit reversed.³⁷⁹

The Federal Circuit reiterated that hard science is not required to meet the first prong of the *Althen* test to support a theory of general causation, and that the special master had erroneously required conclusive evidence in the medical literature or epidemiological studies linking a reaction of afebrile seizures to the DPT vaccine.³⁸⁰ It contrasted the medical research standard of "very near certainty—perhaps 95% probability" to the standard that should

³⁷⁰ 569 F.3d 1367 (Fed. Cir. 2009).

³⁷¹ *Id.* at 1372.

³⁷² *Id.* at 1371. This theory suggested that the DPT vaccine contains toxins that can cross the blood-brain barrier and over-stimulate the cells of the brain to provoke seizures. *Id.*

³⁷³ *Id.* at 1377–78 (quoting *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs. (Vaccine Court Decision II)*, No. 98-817V, 2008 WL 2517179, at *8 (Fed. Cl. Spec. Mstr. May 29, 2008)). Although petitioners submitted data from the National Childhood Encephalopathy Study ("NCES"), a major epidemiological study, to link DPT vaccination to neurological injury, the special master found that Enrique would not have qualified as a "case child" under the study, so the findings were inapplicable to him. *Id.* at 1380.

³⁷⁴ *Id.* at 1372 (citing *Andreu ex rel. Andreu v. Sec'y of the Health & Human Servs. (Court of Federal Claims Decision I)*, No. 98-817V, 2008 WL 2009746 406, at *7–8 (Fed. Cl. Mar. 3, 2008)).

³⁷⁵ *Id.*

³⁷⁶ *Id.* at 1372–73.

³⁷⁷ *Id.*

³⁷⁸ *Id.* at 1373 (citing *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs. (Court of Federal Claims Decision II)*, No. 98-817V, 2008 WL 4725455, at *3 (Fed. Cl. Spec. Mstr. July 23, 2008)).

³⁷⁹ *Id.* at 1383.

³⁸⁰ *Id.* at 1377–79.

be applied under the Vaccine Act's preponderance standard, one of "logic" and "legal probability."³⁸¹ The court found that the petitioner had met the second prong—establishing a logical sequence of cause and effect—through the testimony of the treating physicians, emphasizing that a treating physician's recommendation to discontinue a vaccine "can provide probative evidence of a causal link."³⁸² Although one piece of evidence may not be sufficient, the totality of the evidence—the temporal relationship, the testimony of the treating physicians, and the scientific plausibility of the expert's theory of causation—was sufficient to meet the standard to prove cause-in-fact.³⁸³

Thus, the Federal Circuit's jurisprudence makes clear that petitioners do not need to proffer the same level of proof as in toxic tort cases to meet the preponderance standard in off-Table claims. Neither an expert other than a treating physician nor peer-reviewed scientific literature is a prerequisite for proving general causation. Evidence submitted should be examined in totality and not individually, and circumstantial evidence and "medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records,"³⁸⁴ may suffice to make out specific causation.

One empirical study suggests that the *Althen* jurisprudence and its relaxation of causation standards may have triggered a noticeable trend toward increased compensation of off-Table claims.³⁸⁵ This gradual relaxation of sufficiency standards seemingly came to a halt in the Federal Circuit's latest pronouncement in *Moberly ex rel. Moberly v. Secretary of Health & Human Services*.³⁸⁶ Although *Moberly* involved the blood-brain theory accepted in *Andreu*, the court took a very different tack and upheld the special master's denial of compensation.

Molly Moberly suffered recurring seizures beginning two days after she received her second DPT vaccination.³⁸⁷ The pertussis antigen was left out of the third vaccine in the series, but she experienced a seizure that afternoon. Several months later, she began to suffer prolonged seizures. A pediatric neurologist diagnosed her condition as "alternating hemiconvulsions . . . [with] etiology uncertain."³⁸⁸

Moberly's expert based his causation opinion on three factors: (1) the epidemiological study of the NCES, linking pertussis immunization and seizures; (2) the "blood-brain barrier" theory; and (3) the temporal relationship between the seizures and the vaccination, as well as the fact that the

³⁸¹ *Id.* at 1380 (quoting *Liabe v. Sec'y of Health & Human Servs.*, No. 98-120V, 2000 WL 1517672, at *61 (Fed. Cl. Spec. Mstr. Sept. 7, 2000)).

³⁸² *Id.* at 1376.

³⁸³ *Id.* at 1382.

³⁸⁴ *Bowes v. Sec'y of Health & Human Servs.*, No. 01-481V, 2006 WL 2849816, at *2 (Fed. Cl. Sept. 8, 2006).

³⁸⁵ See Waldenberg & Wallace, *supra* note 9, at 321–22.

³⁸⁶ 592 F.3d 1315 (Fed. Cir. 2010).

³⁸⁷ *Id.* at 1318.

³⁸⁸ *Id.* at 1319.

treating physicians did not identify any other cause for her seizure condition.³⁸⁹

The special master denied compensation, rejecting the “blood-brain barrier” theory and the application of the NCES to this case. He found that simply relying on the temporal relationship between the vaccination and Molly’s first seizures, even in the absence of an alternative explanation for the seizures, was insufficient to meet the preponderance standard.³⁹⁰ The Federal Circuit sustained the denial of compensation, drawing a strong distinction between the levels of proof required for Table and off-Table claims under the statute:

While the petitioners acknowledge that the statute requires proof of causation by a preponderance of the evidence . . . they appear to be arguing for a more relaxed standard. They repeatedly characterize the test as whether Molly’s condition was “likely caused” by the DPT vaccine. By that formulation, however, they appear to mean not proof of causation by the traditional “more likely than not standard” but something closer to proof of a “plausible” or “possible” causal link between the vaccine and the injury, which is not the statutory standard. Similarly, the petitioners object to the use of the term “causation in fact” . . . because they claim that proof that a vaccine “in fact” caused an injury would require conclusive scientific evidence. But this court has regularly used that term to describe the causal requirement for off-Table injuries and has made clear that the applicable level of proof is not certainty, but the traditional standard of “preponderant evidence.” The petitioners also invoke legislative intent and the purposes of the federal Vaccine Program to argue that a standard less demanding than the tort standards of causation is applicable. In doing so, however, they conflate the burden of proof imposed for off-Table injuries with the lenient presumptions applicable to Table injuries. As this court has made clear, the Vaccine Act “relaxes proof of causation for injuries satisfying the Table . . . but does not relax proof of causation in fact for non-Table Injuries.”³⁹¹

The court also distinguished *Andreu*, in which direct testimony from the treating physicians stated “unequivocally” that the DPT vaccine had caused *Andreu*’s seizures.³⁹² The court found that the acceptance by the *Andreu* court of the blood-brain barrier theory was not binding on this case, given

³⁸⁹ *Id.* at 1319–20.

³⁹⁰ *Id.* at 1320–21. The Court of Federal Claims upheld the denial of compensation, noting that none of the treating physicians had suggested that her DPT vaccine caused her seizures. *Id.* at 1321.

³⁹¹ *Id.* at 1322 (citations omitted).

³⁹² *Id.* at 1325.

the difference in the evidentiary record,³⁹³ and, while not demanding application of the *Daubert* tests, the Federal Circuit acknowledged that special masters may require “some indicia of reliability” to assess the testimony proffered by experts, including epidemiological studies and medical evidence,³⁹⁴ which was not provided here.

Moberly’s strong language seems to signal the Federal Circuit’s renewed attempt to resolve the inconsistent views on the sufficiency of evidence required in off-Table claims.³⁹⁵ At the very least, *Moberly* suggests a limit to lowering the sufficiency of evidence requirement, trying to ensure that the connection between the vaccination and the injury goes beyond mere coincidence.

Moberly leaves open many questions, however. Although the statute clearly requires application of the preponderance of the evidence burden of proof standard borrowed from tort cases to both Table and off-Table claims, the court leaves unclear whether the standard for sufficiency of evidence developed in toxic tort cases should also be strictly applied. If that were the case, it would probably result in very few successful off-Table claims, leading to the question of why Congress would make the option available in the first place.³⁹⁶ The decision leaves unanswered other questions as well. For example, it cites with approval the standards developed in *Daubert*,³⁹⁷ saying they “may be applied,” but does not decide whether they *must* be applied to determine the reliability of expert testimony.³⁹⁸ While *Daubert*’s interpretation of the Federal Rules of Evidence would not apply in this context, the *Daubert* jurisprudence stands for a broadly accepted standard to determine the reliability of scientific evidence.³⁹⁹ Along the same lines, it remains to be

³⁹³ *Id.*

³⁹⁴ *Id.* The court also affirmed the special master’s rejection of the NCES as inapplicable to this case, since “epidemiological studies are designed to reveal statistical trends only for a carefully constructed test group . . . [and] [s]uch studies provide no evidence pertinent to persons not within the parameters of the test group.” *Id.*

³⁹⁵ See Strong, *supra* note 19, at 448 (describing special masters’ inconsistent treatment of similarly situated petitioners).

³⁹⁶ Cf. Stevens v. Sec’y of Health & Human Servs., No. 99-594V, 2001 WL 387418, at *27 (Fed. Cl. Mar. 30, 2001) (“To demand that petitioners sue here first, apply a burden or judicial analysis no different than in the civil tort arena, and then offer the opportunity to reject the judgment and pursue a civil action, is illogical and a waste of judicial resources.”).

³⁹⁷ *Daubert* interprets Federal Rule of Evidence 702, which is not applicable to Vaccine Act cases. The Federal Circuit has cited it with approval in *Cedillo v. Secretary of Health & Human Services*, 617 F.3d 1328, 1338–39 (Fed. Cir. 2010), *Moberly ex rel. Moberly v. Secretary of Health & Human Services*, 592 F.3d at 1324, and *Andreu ex rel. Andreu v. Secretary of Health & Human Services*, 569 F.3d 1367, 1379 (Fed. Cir. 2009), but the Federal Circuit has not found its standards to be binding in the vaccine court context.

³⁹⁸ *Moberly*, 592 F.3d at 1324 (citing Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

³⁹⁹ The *Daubert* principle that expert testimony should be based on reliable methodology has begun to influence other areas beyond the evidentiary admissibility context. See, e.g., *Niam v. Ashcroft*, 354 F.3d 652, 660 (7th Cir. 2004) (Posner, J.) (Although *Daubert* does not strictly apply to administrative hearings, “the spirit of *Daubert* . . . does apply to administrative hearings.”); see also *Seaboard Lumber Co. v. United States*, 308 F.3d 1283, 1301–02 (Fed. Cir. 2002) (*Daubert* factors held applicable to bench trial to evaluate methodology of

seen whether petitioners can sufficiently prove general causation without some scientific or medical literature, which would be virtually required in a toxic tort case. Finally, *Moberly* continues to emphasize the critical role the treating physician's testimony can play in meeting each of the *Althen* prongs, and in particular, to show specific causation under prongs two and three. As described earlier, putting so much weight on a physician's observation or suspicions without other significant corroborating evidence may not withstand scrutiny in the tort system. The problem is that this approach relies heavily on idiosyncratic evidence—not every treating physician would make a causation notation in the medical records, and even if the doctor did so, it is hard to evaluate the observation, which is necessarily an intuitive speculation.⁴⁰⁰ At the very least, it is unlikely that the physician's assessment would be based on epidemiological or other scientific studies.⁴⁰¹ Placing so much weight on one piece of clinical observational evidence ultimately may undermine the validity of the compensation award.

2. Proving or Disproving Alternative Causes

While struggling with sufficiency standards in its post-*Stevens* jurisprudence, the Federal Circuit also tackled the question of which party bears the burden of eliminating alternative causes of injury. The plain language of the Vaccine Act does not squarely place this burden on either party,⁴⁰² but in three major post-*Stevens* decisions, the Federal Circuit has settled that the petitioner may need to eliminate alternative causes as part of the prima facie case when several contemporaneous or intervening events could also have caused the injury alleged. However, after the petitioner makes out a prima facie case on causation, the burden of persuasion shifts to the government to demonstrate an alternative cause.

In *Pafford v. Secretary of Health and Human Services*,⁴⁰³ the dispute centered on whether the petitioner had made out a prima facie case when

expert witness testimony); Alan Charles Raul & Julie Zampa Dwyer, "Regulatory Daubert": A Proposal to Enhance Judicial Review of Agency Science by Incorporating Daubert Principles into Administrative Law, 66 LAW & CONTEMP. PROBS. 7, 8 (2003) (*Daubert's* "good science" rationale should apply to science underlying regulatory decisionmaking); J. Tavener Holland, Comment, *Regulatory Daubert: A Panacea for the Endangered Species Act's "Best Available Science" Mandate?*, 39 MCGEORGE L. REV. 229, 326 (2008) ("By instituting a new framework for judicial review of methodologies behind agency science, regulatory *Daubert* will help agencies effect a needed separation between policy and science. This will result in a lower risk of substantive bias, greater accountability, and greater transparency."). But see Claire R. Kelley, *The Dangers of Daubert Creep in the Regulatory Realm*, 14 J.L. & POL'Y 165, 209 (2006) ("[*Daubert*] . . . is ill-suited to apply across the board to all agencies, it is likely to be used in a rhetorical and meaningless way, and it is likely to be overused, morphed, and stretched to fit any conceivable situation.").

⁴⁰⁰ See *Paulmino v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 1, 9, 12 (2005) (remanding a compensation denial based on the special master's interpretation of a circled plus sign in one page of shorthand notes taken by a treating physician).

⁴⁰¹ See Henifin et al., *supra* note 220, and accompanying text.

⁴⁰² See *supra* notes 88-92 and accompanying text.

⁴⁰³ 451 F.3d 1352 (Fed. Cir. 2006) (en banc).

other potential causes of infection existed. The petitioner developed a “faint maculopapular rash approximately seventeen days after receiving her third DTP and OPV [(oral poliovirus vaccine)] vaccinations and her first MMR vaccination.”⁴⁰⁴ Prior to and during this period, petitioner also tested positive for infection.⁴⁰⁵ The hospital doctor eventually diagnosed petitioner with system onset Juvenile Rheumatoid Arthritis, or Still’s disease.⁴⁰⁶

The special master accepted petitioner’s theory of general causation, but ultimately rejected her claim because she failed to produce enough evidence identifying the time period in which her injuries could be expected to manifest following vaccination, and therefore could not prove that her vaccination was a “but-for” cause of her injuries.⁴⁰⁷

The Federal Circuit affirmed the denial of compensation, reasoning that even under the “substantial factor” test, petitioners must still demonstrate that the vaccine was a “but-for” cause of the injury.⁴⁰⁸ Thus, this case demanded stronger temporal evidence to satisfy the specific causation component. “Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute ‘but-for’ causation to the vaccination.”⁴⁰⁹ The court insisted that its holding did not increase petitioner’s burden because Pafford had failed as an initial matter to establish that the vaccine was a “but-for” cause of her Still’s disease.⁴¹⁰

In *Walther v. Secretary of Health and Human Services*,⁴¹¹ the Federal Circuit reiterated that although petitioners are not required to disprove alternative causes, they may need to address them in making out the prima facie case. In *Walther*, the petitioner received several vaccinations, only one of which (tetanus-diphtheria, or “Td”) was listed on the Vaccine Injury Table.⁴¹² Petitioner was diagnosed with post-vaccinal acute disseminated encephalomyelitis (“ADEM”),⁴¹³ an injury that does not correspond with the Td vaccine on the Table. Two additional neurologists agreed with the diagnosis, and petitioner’s two experts opined that the ADEM was probably

⁴⁰⁴ *Id.* at 1354.

⁴⁰⁵ Petitioner had tested positive for mycoplasma, a type of bacteria, had x-rays taken that revealed a thickening of the sinus membrane consistent with a sinus infection, had suffered from tonsillitis, and had a cold accompanied by diarrhea. *Id.* at 1356.

⁴⁰⁶ *Id.*

⁴⁰⁷ *Id.* The Court of Federal Claims upheld the decision. *Pafford ex rel. Pafford v. Sec’y of Health & Human Servs.*, 64 Fed. Cl. 19 (2005).

⁴⁰⁸ *Pafford*, 451 F.3d at 1357.

⁴⁰⁹ *Id.* at 1358.

⁴¹⁰ *Id.* at 1357–58. The court distinguished its decision in *Shyface* where the vaccine was one of two “but-for” causes. *Id.* The dissent in *Pafford* argued that the majority’s holding amounted to an impermissible burden on petitioners to eliminate alternative causes of injury. *Id.* at 1360–64 (Dyk, J., dissenting).

⁴¹¹ 485 F.3d 1146, 1149–50 (Fed. Cir. 2007).

⁴¹² *Id.* at 1146–47, 1149 (yellow fever, typhoid, meningitis, and the rabies vaccinations were the non-Table vaccines also received by petitioner).

⁴¹³ *Id.* at 1149.

caused by the Td vaccine.⁴¹⁴ The special master denied compensation because the petitioner failed to eliminate other potential causes for the injury,⁴¹⁵ and the Court of Federal Claims affirmed.⁴¹⁶

The Federal Circuit vacated and remanded because requiring petitioner to eliminate alternative causes of injury was an incorrect standard.⁴¹⁷ The Federal Circuit's holding rested on three points. First, the Federal Circuit squarely addressed the ambiguity in the statute, finding that a plain reading of the whole statute and the fact that the legal system "rarely requires a party to prove a negative" strongly supported the conclusion that respondent bears the burden of proving alternative causation.⁴¹⁸ Second, it pointed to the *Second Restatement* to establish that "the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm."⁴¹⁹ Finally, the court reconciled its reasoning with the *Pafford* holding:

Petitioner is certainly permitted to use evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a prima facie case, as was true in *Pafford*. In such instances, clearly the special master must evaluate what evidence a claimant presents as part of determining whether the claimant makes a prima facie case.⁴²⁰

Thus, while the Vaccine Act does not require the petitioner to bear the burden of eliminating other causes, such proof may nonetheless be necessary where the petitioner's other evidence on causation—what is required under the three-part *Althen* test—"is insufficient."⁴²¹ This is consistent with the contextual, "totality of the evidence" approach the vaccine courts have developed under the program.

⁴¹⁴ The opinions were based on medical literature, the fact that the symptoms developed within the medically accepted timeframe, and because the other vaccines were unlikely to have caused the injury. *Id.* at 1147.

⁴¹⁵ *Id.* The special master rejected the testimony of one expert as unreliable. *Id.* at 1148.

⁴¹⁶ *Id.* (citing *Walther v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 123, 124 (2005)).

⁴¹⁷ *Id.* at 1152–53.

⁴¹⁸ *Id.* at 1150 (citing 42 U.S.C. § 300aa-13(a)(1)(A)–(B) (2006)). The court noted that a contrary construction of § 300aa-13(a)(1)(A) would render § 300aa-13(a)(1)(B) essentially inoperative. *Id.*

⁴¹⁹ *Id.* at 1151.

⁴²⁰ *Id.*

⁴²¹ *Id.* at 1149–50; *see also* *DeBazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) (onset of petitioner's injuries within hours of inoculation was earlier than medically recognized; petitioner failed to make out a prima facie case); James B. Currier, *Too Sick, Too Soon?: The Causation Burden under the National Vaccine Injury Compensation Program Following DeBazan v. Secretary of Health & Human Services*, 19 FED. CIR. B.J. 229, 251 (2009) (criticizing the *DeBazan* decision as too stringent and thwarting the spirit of generosity in the compensation program).

This same contextual approach was evident in *Doe ex rel. Estate of Doe v. Secretary of Health and Human Services (Doe V)*, in which the Federal Circuit reiterated that the petitioner may need to focus on possible alternative causes—including an idiopathic cause—in making out the prima facie case before the burden shifts to the government to prove an alternative cause.⁴²² In *Doe*, the Federal Circuit found that the special master was not wrong to consider the government’s evidence suggesting that the death of the petitioner was due to Sudden Infant Death Syndrome in evaluating whether petitioner had made out a prima facie case.⁴²³

On appeal, the petitioner argued that the special master had wrongfully considered the SIDS evidence as a possible alternative cause since the statute specifically excludes alternative causes that are “idiopathic, unexplained, unknown, hypothetical or undocumentable”⁴²⁴ from proof of a “factor unrelated” to the administration of the vaccine.⁴²⁵ In other words, if SIDS is an idiopathic disease, then the government cannot use it to defeat a petitioner’s prima facie case.

Here, the Federal Circuit found that the statutory restrictions did not apply because the petitioner never established a prima facie case in the first instance, so the burden to disprove the petitioner’s case never shifted to the respondent.⁴²⁶ As the court noted, “[e]vidence of SIDS was just one factor among many that the special master relied on in concluding that ‘the facts of the case’ did not support Doe’s theory of causation, and thus failed to establish a prima facie case.”⁴²⁷ Petitioners may need to focus on alternative causes, even idiopathic ones, to make out a prima facie case before the burden shifts to the respondents.

In sum, with regard to proving or disproving alternative causes, the Federal Circuit has interpreted the Vaccine Act to comport with burdens of production and proof in traditional toxic tort cases. Under both regimes, only when the plaintiff or petitioner has made out a prima facie case does the burden shift to the defendant to defeat it. In both contexts, the most significant way to rebut a prima facie case is to prove an alternative cause. At the

⁴²² 601 F.3d 1349, 1357 (Fed. Cir. 2010).

⁴²³ *Id.* at 1358. This case was heard by the special master twice. The first time, the special master concluded that Doe did not establish a prima facie case that the hepatitis B vaccine and not SIDS caused the petitioner’s death. *Id.* at 1353. The Court of Federal Claims reversed, holding that the special master had improperly shifted the burden of proof to the petitioner to affirmatively disprove SIDS as the cause of death under her prima facie case. *Doe ex rel. Estate of Doe v. Sec’y of Health & Human Servs. (Doe II)*, 83 Fed. Cl. 157, 158 (2008). On remand, the special master considered evidence relating to SIDS proffered by both sides, but only in evaluating whether Doe’s proposed sequence of cause and effect under the second or third prong of the *Althen* test was plausible. *Doe V*, 601 F.3d at 1353. The special master again found that the petitioner had failed to make out her prima facie case of causation. *Id.* The Court of Federal Claims upheld the decision. *Doe ex. rel Estate of Doe v. Sec’y of Health & Human Servs. (Doe IV)*, 87 Fed. Cl. 1 (2009).

⁴²⁴ *Doe V*, 601 F.3d at 1357 (quoting 42 U.S.C. § 300aa-13(a)(1), (2) (2006)).

⁴²⁵ 42 U.S.C. § 300aa-13(a)(1).

⁴²⁶ *Doe V*, 601 F.3d at 1358.

⁴²⁷ *Id.*

same time, however, the question whether the petitioner has sufficiently met his burden remains idiosyncratic, such that the petitioner may have to discount alternative causes—even unknown, idiopathic ones—before the burden shifts to respondent or the Second Restatement’s “substantial factor” test can be triggered.⁴²⁸

Thus, despite the ambiguity of the statutory language, the Federal Circuit jurisprudence seemingly settles the question regarding proof of alternative causes in a manner consistent with traditional tort jurisprudence, but still leaves questions unanswered about the sufficiency of proof with respect to the petitioner’s prima facie case. Given these unanswered questions stemming from the lack of clarity in both the statute and its legislative history, as well as the unique nature of the vaccine field, this Article next turns to examining alternative approaches to sufficiency standards of causal proof and proposes a model for the program to implement.

V. EXAMINATION OF ALTERNATIVE STANDARDS FOR SUFFICIENT CAUSAL PROOF IN THE FACE OF INADEQUATE INFORMATION

The discussion above shows how far vaccine courts have departed from the common law approach to causation. Courts in common law toxic tort cases increasingly have questioned the use of certain associational evidence to show causation, either finding the evidence inadmissible or giving it little weight. These courts perceive expert testimony based on case reports, animal studies, analogies drawn to similar chemical agents, and differential diagnoses as providing weak support of causation in those cases. But this is exactly the type of proof relied upon in the vaccine compensation fund context to support a showing of causation in off-Table claims.⁴²⁹ Given the dearth of empirical scientific data, the appellate courts in the vaccine program have allowed a plausible scientific theory, concurrent with a temporal association and a notation by a treating physician attributing causation to inoculation, to meet the sufficiency standards for the preponderance test on causation.⁴³⁰

Can the vaccine courts’ more relaxed approach to causation be justified? The answer to that question depends on how one defines the main objective of the program. If the primary objective is to minimize lawsuits against manufacturers and administrators of vaccines in order to create an economic environment encouraging the research, creation, and production of vaccines, a lower sufficiency standard seems appropriate. A less stringent standard makes it more likely that these sorts of claims can be resolved administratively, without resort to the traditional adversarial tort system. On the other hand, if the primary goal is to protect vaccines from being blamed

⁴²⁸ *Id.*

⁴²⁹ See *supra* notes 277–280 and accompanying text.

⁴³⁰ See, e.g., *Andreu ex rel. Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367 (Fed. Cir. 2009); *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144 (Fed. Cir. 1992).

for injuries whose exact cause cannot be proven, a higher sufficiency standard would appear to be necessary. Imposing a higher sufficiency standard has its own costs, however. It would likely result in prolonged proceedings, increased transaction costs, more difficult and more adversarial proceedings, along with fewer awards. These criticisms have already been leveled at the program.⁴³¹ Until this conflict over legislative objective is resolved, the appropriate sufficiency standard will remain a muddle. The Federal Circuit has not squarely addressed this question and although it directed the special masters in *Moberly* to apply the same “traditional tort standard of preponderant evidence”⁴³² to off-Table cases, merely holding that claimants must meet a preponderance threshold does not explain what evidence will satisfy that standard.

A. *Alternative Approaches to Causal Proof*

Given the competing concerns of the statute, several approaches could be taken to determine the amount of proof required to demonstrate causation under the off-Table option. The most direct approach—and the one more fully advocated below—would be for Congress to amend the statute to clarify its intent with regard to proving off-Table claims. Congress never anticipated the number of cause-in-fact cases that have been brought, expecting that the need for cause-in-fact cases would be eliminated as the science on causation improved and the Table expanded.⁴³³ The policy bearings of the original Act to provide quick, certain compensation while protecting the vaccine industry have gradually withered away. Using the word “causation” in the statute—a term that imports traditional tort concepts—to provide a mechanism to pursue novel claims has only served to confuse the issue. The program would benefit from a correction to the Act.

Alternatively, Congress could eliminate the off-Table claim mechanism altogether and send all cases lacking solid empirical proof on causation to the tort system, or strictly limit its availability by following the approach of the United Kingdom, which created a very high bar for causal proof and rejects the great majority of cases filed.⁴³⁴ Sending all novel theories to the tort system may be a more cost-effective way to ascertain causation from an

⁴³¹ See *supra* notes 138–141 and accompanying text.

⁴³² *Moberly ex rel. Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010).

⁴³³ See *supra* notes 112–113 and accompanying text.

⁴³⁴ Vaccine Damage Payments Act, 1979, c. 17 (U.K.). Under the U.K. program, the petitioner must establish “on the balance of probability” that the injury resulted from vaccination against one of the diseases listed in the Act. *Id.* § 3(5). The vast majority of claims are denied based on lack of proof of a causal connection. See RICHARD GOLDBERG, CAUSATION AND RISK IN THE LAW OF TORTS: SCIENTIFIC EVIDENCE AND MEDICINAL PRODUCT LIABILITY 170–78 (1999); Rob Henson, *Inoculated Against Recovery: A Comparative Analysis of Vaccine Injury Compensation in the United States and Great Britain*, 15 TULSA J. COMP. & INT’L L. 61, 86–88 (2007).

administrative point of view, since the tort system is already designed to determine causation in the toxic tort context. Eliminating or limiting the availability of the off-Table mechanism, however, could create other dangers. The option may act as a safety valve, and removing it might cause allegedly aggrieved individuals to voice novel theories in the public sphere,⁴³⁵ undermining the public's confidence in vaccines before the tort system has had the opportunity to resolve the claim. At the same time, setting too high a standard—e.g., requiring epidemiological evidence where few studies exist—could undermine the goal of compensating the majority of injuries caused by vaccines. At the very least, Congress should clarify how demanding the special masters should be in scrutinizing off-Table claims, as it has failed to do in previous oversight hearings.⁴³⁶ Short of clarification by statutory amendment, several approaches remain open to help special masters and courts navigate the delicate balance of promoting the conflicting purposes of the program in the face of inadequate information without turning it into a “no-causation” system: (1) use the same standard for inclusion of injuries and time limits in the Table for off-Table claims; (2) rigorously apply the standards demanded in common law courts for admissibility and sufficiency in toxic tort cases to off-Table claims; (3) shift the burden of proof in the *prima facie* case to the respondents to disprove causation; (4) adopt a system in which causation is proved by a preponderance of the *available* evidence; (5) create a minimum level of sufficiency of evidence by merely requiring some temporal relationship with some plausible scientific theory; or (6) expand the use of an educated science body, such as the IOM or science panels and experts appointed by the special masters, to help the program reach consistent decisions on general causation. Each of these approaches has some appeal but also presents its own set of problems.

One approach is to require the standard of causal proof for off-Table claims that HHS uses for including vaccine-related injuries on the Table. The Table provides a shortcut for recovery in categories of cases where it can be determined in advance that causation is sufficiently likely to exist. A strong argument exists that Congress could not rationally have meant to allow compensation for off-Table claims that do not rise to the same minimum level of certainty as those included on the Table.⁴³⁷ Under this view, Congress must have included the off-Table route to allow plaintiffs who could show that some injury not yet on the Table was just as likely to be the result of the vaccine as an injury already included. In that situation, the off-Table petitioner is as deserving of compensation as the on-Table one; the Table just has not yet caught up to science. This approach comports with the position taken by HHS that its decisions to amend the Table are based on “hard science”

⁴³⁵ The theory that vaccines cause autism could be seen as an example of this phenomenon.

⁴³⁶ See *supra* notes 135–150 and accompanying text.

⁴³⁷ See *supra* notes 112–114 and accompanying text (describing congressional expectations regarding creation of the Table).

about causation⁴³⁸ and that off-Table claims should be driven by “hard science” as well in order to protect vaccines from being blamed for harms that cannot be proven to be caused by them.⁴³⁹

Conceptually, this interpretation of congressional intent is appealing. Given the dearth of direction Congress provided for off-Table claims, the standard tacitly provided was the one for selection of injuries recognized by the Table. Under this interpretation, Congress rationally would not treat off-Table claimants more liberally than on-Table claimants. The statute, by its terms, structure, or legislative history, does not suggest otherwise.

Yet such an interpretation has practical limitations. HHS has become more stringent about what injuries are recognized on the Table.⁴⁴⁰ Combining a restrictive Table with heightened barriers to off-Table claims will reduce the value of the entire program. As both sides of the program gradually constrict, the whole program could become nothing more than a costly exercise that is a pre-condition for filing a tort suit, placing vaccine claimants in a worse position than they were in prior to the program’s enactment, since tort suits traditionally do not have antecedent administrative procedures that must be exhausted.

A second approach, to apply the standards used in toxic tort cases for causal proof in off-Table claims, has been proposed by the special masters.⁴⁴¹ Although initially rejected by the Federal Circuit as too demanding and not justified by the statutory scheme,⁴⁴² the court has subsequently permitted—but not required—this approach.⁴⁴³ Requiring traditional causal standards could be justified given that the Act requires proof of “causation,” a tort concept, and that off-Table claims are designed to be based on the type of individual proof usually found in traditional tort cases (as opposed to the causal averages represented in the Table).⁴⁴⁴

Borrowing tort standards would also mean engaging in the higher level of careful and sophisticated scrutiny of expert scientific testimony that now routinely accompanies proof of causation in toxic tort cases.⁴⁴⁵ By looking at

⁴³⁸ See *supra* note 76.

⁴³⁹ Cf. *supra* note 141 and accompanying text.

⁴⁴⁰ See *supra* notes 74–76 and accompanying text. Some petitioners argue that the decision is driven by politics. See Strong, *supra* note 19, at 443 (citing concerns raised by parents and advocates about the methodology HHS used to amend the Table).

⁴⁴¹ *Stevens v. Sec’y of Health & Human Servs.*, 2001 WL 387418, at *35 (Fed. Cl. Mar. 30, 2001).

⁴⁴² *Althen III*, 418 F.3d 1274, 1279–80 (Fed. Cir. 2005).

⁴⁴³ *Moberly ex rel. Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (“Although a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.”).

⁴⁴⁴ Cf. Waldenberg & Wallace, *supra* note 9, at 329 (arguing for individual, case-by-case examination of demyelinating disorders and vaccination claims “due to widespread uncertainty involving [those claims]”).

⁴⁴⁵ See Susan Haack, *Of Truth, in Science and in Law*, 73 BROOK. L. REV. 985, 1005–06 (2008) (“*Daubert* has shifted some questions formerly conceived as concerning the weight of the evidence into the category of questions bearing on admissibility.”).

the *Daubert* factors for substantiation, the vaccine court could more easily avoid the danger of accepting medical opinions that are unreliable *ipse dixit*. At the very least, application of the *Daubert* factors would help distinguish “differential diagnoses” from “causation analyses.”⁴⁴⁶ This would lend legitimacy to the decisionmaking process and help curtail the public’s misperception of the dangers of vaccines.⁴⁴⁷

But strictly applying causal tort standards would result in very few successful off-Table claims.⁴⁴⁸ Borrowing the standards from *Daubert* and its progeny to test the reliability of expert testimony would likely weed out a good part of that testimony, since much of it simply cannot meet all of the factors of testability, general acceptance, peer-reviewed publication, litigation independence, and low error rate.⁴⁴⁹ As one evidence expert notes, “[t]he likelihood that extremely rare events[, such as vaccine-related injuries,] will have been carefully studied is, well, extremely low.”⁴⁵⁰ Limiting the off-Table option in this way would eviscerate the program, since the vast majority of the claims are now off-Table ones.⁴⁵¹

At the other extreme, the vaccine courts could place the burden of persuasion on the respondents, requiring respondents to disprove causation in off-Table cases,⁴⁵² or allowing close calls to be decided in favor of the petitioner,⁴⁵³ much like the veterans’ no fault program.⁴⁵⁴ The most persuasive reason to shift the burden of proof is that it ensures the broadest level of compensation for individuals injured by childhood vaccines. It also could indirectly encourage the government to fund more vaccine research and de-

⁴⁴⁶ Stout, *supra* note 159, at 868–78 (In a differential diagnosis, a physician observes symptoms and conducts tests to diagnose a patient’s disease, while a causation analysis uses scientific means to determine the most likely cause of the disease.).

⁴⁴⁷ See Sabovich & Mayhew, *supra* note 205 (arguing that “thanks to the judicial-scrutiny standard established by *Daubert*, the vaccine-autism litigation is ending with less financial pain and much less legal criticism than its Bendectin counterpart”).

⁴⁴⁸ See Cranor & Eastmond, *supra* note 161, at 7 (When there is considerable scientific ignorance about the likelihood of what occurred, as in many toxic tort suits, “the party with the burden of proof will lose.”).

⁴⁴⁹ Cf. Berger & Solan, *supra* note 31, at 851 (finding that frequently the legal system’s answer to tentative scientific explanations on causation is to exclude the evidence).

⁴⁵⁰ Mnookin, *supra* note 218, at 1023.

⁴⁵¹ See *supra* notes 19–21 and accompanying text.

⁴⁵² See Apolinsky & Van Detta, *supra* note 11, at 625 (arguing that the vaccine program should shift the burden of proof to the government to show that the claimant’s injury was not caused by a vaccine).

⁴⁵³ In *Althen*, the Federal Circuit already suggested that this is the approach, interpreting the preponderance standard to allow “close calls regarding causation [to be] resolved in favor of injured claimants.” *Althen III*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

⁴⁵⁴ Veterans may make a claim to receive benefits for injuries or medical expenses incurred in connection with military service. 38 U.S.C. § 5103(A) (2006). Close cases must be resolved in favor of the injured veteran. *Id.* § 5107(b) (2006); see also Strong, *supra* note 19, at 451 (arguing for application of the veteran program’s benefit of the doubt standard to the vaccine program).

velopment.⁴⁵⁵ Even if this shift means that individuals harmed by causes other than vaccines will receive compensation, the legislative history of the program suggests that the risk of false positives and overcompensation is one that Congress is willing to take.⁴⁵⁶

The main concern in shifting the burden of proof on causation to respondents, however, is the impact it may have on the public perception of the safety of vaccines. Requiring the respondent to prove a negative—that the vaccine did not cause the harm alleged—is particularly difficult in this context because frequently the science simply does not exist.⁴⁵⁷ Moreover, even if empirical data or human experimental studies did exist,⁴⁵⁸ “science can never demonstrate the absence of hazard,” instead it “can only place an upper limit on risk.”⁴⁵⁹ Awarding compensation based on the respondent’s inability to disprove causation creates the impression that vaccines cause harm to a greater extent than they actually do, possibly making the public fearful of receiving inoculations. Thus, shifting the burden to the respondent to disprove causation might undermine another major purpose of the legislation, namely to continue widespread vaccination of the public.⁴⁶⁰

A fourth approach in the face of inadequate information, already tested by the vaccine courts, is to retain the burden of proof on the petitioner, but lower the amount and quality of evidence required to show causation. The jurisprudence has shifted back and forth on following this approach, with the post-*Stevens* trilogy embracing it but the more recent pronouncement in *Moberly* seemingly calling it to a halt. Assuming that promoting deterrence⁴⁶¹ and corrective justice are of lesser importance to the vaccine program than is the goal of compensating victims, causation has likely already lost its cen-

⁴⁵⁵ Apolinsky & Van Detta, *supra* note 11, at 625 (This approach would “incentivize the government to undertake an aggressive, proactive program of epidemiological studies in order to be ready to defend against vaccine injury claims.”).

⁴⁵⁶ See *supra* notes 112–114 and accompanying text.

⁴⁵⁷ *Althen III*, 418 F.3d at 1280 (vaccine injury field is “bereft of complete and direct proof of how vaccines affect the human body”).

⁴⁵⁸ Bernstein, *supra* note 1, at 70. Practically speaking, scientists will accept that there is no effect when well-designed studies produce null results. See Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301 (1992) (describing Bendectin cases).

⁴⁵⁹ See PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 435 (Kenneth R. Foster et al. eds., 1993).

⁴⁶⁰ See Richard A. Epstein, *It Did Happen Here: Fear and Loathing on the Vaccine Trail*, 24 HEALTH AFF. 740, 741 (2005) (“The false attribution of harm to a vaccine not only results in a miscarriage of justice in the individual case, but it also alters for the worse the incentives of key players throughout the system, thereby aggravating the public-goods problem [to increase levels of vaccination].”); Sabovich & Mayhew, *supra* note 205, at 385 (describing long term public health effects of the now debunked vaccine-autism theory due to families rejecting vaccines, including resurgence of diseases such as measles in Britain and the United States).

⁴⁶¹ Cf. Apolinsky & Van Detta, *supra* note 11, at 576–77 (“[S]ome specter of liability should remain to maintain vaccine manufacturers’ consistent production of safe, effective vaccines” but currently, manufacturers “feel no sting of liability.”).

trality to the scheme.⁴⁶² The more significant question with regard to this approach is “how low is too low?”

In the toxic tort context, Professor Michael Green has advocated using a sliding scale for proof of causation generally based on available evidence.⁴⁶³ Thus, if the epidemiological record is substantial, then other types of evidence that are considered weaker, such as animal studies, would be given less weight. But if the epidemiological evidence, taken as a whole, is weak or nonexistent, he argues that other types of toxicological evidence should be given more weight.⁴⁶⁴ In this way, “[p]laintiffs should be required to prove causation by a preponderance of the available evidence, not by some predetermined standard that may require nonexistent studies.”⁴⁶⁵

This is an appealing argument because it acknowledges the reality of a field like vaccines, “bereft” of evidence due to no one’s fault.⁴⁶⁶ It recognizes that petitioners are forced to litigate long before epidemiologic or other research is available and allows a flexible approach to sufficiency of proof in the face of this lack of evidence. And, as noted above, scientific validity is a question of degree. It may not make sense to reject all research merely because it does not meet a somewhat arbitrary threshold of .05 significance.⁴⁶⁷ The challenge is how to synthesize less than ironclad evidence in law. As Professor Mnookin points out, the key questions are: “How do you aggregate the variety of imperfect evidence into a conclusion about general causation? How do you assess the disparate items and make a judgment about the probability that the substance is capable of causing the harm at issue?”⁴⁶⁸

Evidence synthesis is a particularly difficult enterprise,⁴⁶⁹ especially in a context like the vaccine compensation program where so little reliable empirical data exists. Ideally, evidence synthesis should consider what evidence is missing as well as what is present to maximize the chances of reaching a correct result; otherwise, claimants could recover based on thin and practi-

⁴⁶² See Gregory C. Keating, *Rawlsian Fairness and Regime Choice in the Law of Accidents*, 72 *FORDHAM L. REV.* 1857, 1897 (2004) (“Fairness favors dispersing the costs of blameless accidents among all those who create similar risks of such accidents” so that both blameless accidents and accidents caused by wrongdoers should be “pooled.”).

⁴⁶³ Green, *supra* note 176, at 316. A related approach to relaxing causal standards would be to award damages proportionately based on the quality of the evidence proffered by the petitioner. Research has not revealed any court decision following such an approach. Cf. Richard Delgado, *Beyond Sindell: Relaxation of Cause-in-fact Rules for Indeterminate Plaintiffs*, 70 *CALIF. L. REV.* 881, 892 (1982) (arguing for proportional recovery in the mass tort context). Similarly, compensation could be awarded based on the health risk borne by each individual as a result of exposure to a toxin. See Lin, *supra* note 161, at 1443 (proposing a risk-based administrative system of liability and compensation for exposure to environmental pollutants).

⁴⁶⁴ Green et al., *supra* note 176, at 316.

⁴⁶⁵ *Id.*

⁴⁶⁶ See *Althen III*, 418 F.3d 1274, 1280 (Fed. Cir. 2005) (“[T]he purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.”).

⁴⁶⁷ FAIGMAN ET AL., *supra* note 1, § 25:38.

⁴⁶⁸ Mnookin, *supra* note 218, at 1023.

⁴⁶⁹ *Id.* at 1023–24 (“Evidence synthesis is an especially difficult and methodologically fraught area.”).

cally non-existent evidence, inviting subjective judgments.⁴⁷⁰ Such weakly supported legal victories would ultimately defeat the purpose of the causation requirement, which seeks a strong degree of accuracy to justify shifting the loss from the plaintiff to the defendant or fund and to avoid awarding damages based merely on the fact of injury.

A final approach, which could be used in conjunction with the others, is to expand the use of educated scientific bodies, such as the IOM, experts appointed by the special masters, or science panels, to provide independent scientific input on causation. Using such independent scientific bodies should increase consistency in findings of general causation. The IOM and the CDC already provide this role in the context of recommending Table revisions, but increasing the number and frequency of Table reviews by the IOM presumably would increase the use of the Table (assuming HHS adopted the suggestions of these bodies), which would return the program to the original congressional intent of having the vast majority of claims decided as Table claims.⁴⁷¹

The special masters can also make greater use of independent experts. This is permitted by the statute but rarely exercised.⁴⁷² Expanding use of independent experts draws on a proposal that has been around for over twenty years, advanced by Professor Troyen Brennan and others, for the use of expert panels of scientists to advise courts on toxic causation problems.⁴⁷³ Expert panels are best used in large mass tort cases, such as the breast implant litigation, where the panel can review a body of information and propose causal findings based on averages.⁴⁷⁴ This system is already in place in other areas.⁴⁷⁵

⁴⁷⁰ See *id.* at 1024 (“Engaging in evidence synthesis . . . is as much an art as a science.”); Douglas L. Weed, *Truth, Epidemiology and General Causation*, 73 BROOK. L. REV. 943, 953 (2008) (“A central purpose of a systematic review is to determine if the available evidence sufficiently supports and/or warrants a claim of causation.”).

⁴⁷¹ See *supra* notes 71–100 and accompanying text.

⁴⁷² See MOLLY TREADWAY JOHNSON ET AL., USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 32–33 (Fed. Jud. Ctr. 1998) (reporting that the special masters said they had never used an independent expert for a number of reasons, including that the mechanisms for doing so were unclear and that they did not find it necessary).

⁴⁷³ Troyen A. Brennan, *Helping Courts with Toxic Torts: Some Proposals Regarding Alternative Methods for Presenting and Assessing Scientific Evidence in Common Law Courts*, 51 U. PITT. L. REV. 1, 11 (1989).

⁴⁷⁴ Howard M. Erichson, *Mass Tort Litigation and Inquisitorial Justice*, 87 GEO. L.J. 1983, 1994–95 (1999) (describing use of expert panels in breast implant, asbestos, and Bendectin litigation: “where the stakes are high, the scientific dispute central, and the public interest great—as in much mass tort litigation—it is difficult to justify the failure to employ independent experts”). See generally Brennan, *supra* note 473.

⁴⁷⁵ For example, the Department of Veterans Affairs does not restrict its hearings on whether to compensate Vietnam veterans who were exposed to Agent Orange to experts professed by both sides. Instead, it consults a bi-annual report on causal claims associated with Agent Orange exposure produced by an independent panel of scientists retained by the Institute of Medicine. See COMM. TO REVIEW THE HEALTH EFFECTS IN VIETNAM VETERANS ON EXPOSURE TO HERBICIDE, INST. OF MED., VETERANS AND AGENT ORANGE UPDATE 2004 (2005).

Independent experts could report to the court on the state of scientific knowledge regarding primary vaccines and injuries.⁴⁷⁶ From this information, special masters could develop consistent responses to various categories of cases (a kind of “off-Table Table”), so that as they saw repeated instances of the same injury, allegedly caused by the same vaccine, with the same sorts of evidence proffered, a “common law rule” could be developed on general causation. This “rule” could be challenged on appeal to the Court of Federal Claims and the Federal Circuit, which would affirm or revise it.⁴⁷⁷ This approach would help address the issue of inconsistency that plagues the off-Table claims, bringing more coherence and efficiency to the vaccine program, and increasing confidence in it.

Aside from the sheer expense of studying all novel claims,⁴⁷⁸ however, this proposal has limits for other reasons. One concern is that the data reviewed by science panels may become stale over time. Another limitation is that panels would be of less help with regard to determining specific causation where the evidence is more contentious. A third limitation is that science and law require different levels of certainty to determine the validity of a proposition.⁴⁷⁹ As noted above, the law often needs to reach a conclusion before the scientific community is willing (if ever) to pronounce a proposition proven.⁴⁸⁰ These are perennial concerns with regulatory systems in general, and tort cases are sometimes justified on these bases—they fill in the cracks of the regulatory system until the system and the scientific record have time to catch up with one another.⁴⁸¹ In the vaccine area, the off-Table claim mechanism serves this purpose, allowing individuals to propose novel theories of harm before the regulatory body has had time or sufficient data to

⁴⁷⁶ Cf. Apolinsky & Van Detta, *supra* note 11, at 626 (advocating giving stakeholders the ability to designate a scientific expert willing to serve as arbitrator on a vaccine panel to deliberate with special master); Michael J. Donovan, *The Impact of “Hurricane” Hannah: The Government’s Decision to Compensate in One Girl’s Vaccine Injury Case Could Drastically Alter the Face of Public Health*, 50 JURIMETRICS J. 229, 255–56 (2010) (advocating use of panel of scientific experts in autism cases).

⁴⁷⁷ This Article saves for another day the question whether discretion should be removed from the courts completely by making this an exclusively administrative program, as is done in other areas. See, e.g., Public Readiness and Emergency Preparedness (“PREP”) Act, 42 U.S.C. § 247d-6d (2006). The PREP Act authorizes the Secretary of HHS to establish the Injury Compensation Program (“CICP”) to provide benefits to persons who sustain serious injury or death as a result of the use or administration of countermeasures taken under the PREP Act, such as H1N1 vaccinations. *Id.* The final rule to establish the CICP proposes that final decisionmaking authority rests with the Secretary, including for off-Table claims, with no judicial review. See 42 C.F.R. § 110.92 (2010).

⁴⁷⁸ Presumably, monies from the fund itself could be used to support this system, but the statute does not authorize such a diversion of funds. Congress could also change the system of amending the Table to rely more heavily on independent experts and less heavily on the regulatory function of HHS, both to satisfy the public’s need for independent review and to keep the Table current and accurate.

⁴⁷⁹ See FAIGMAN ET AL., *supra* note 1, § 1:4.

⁴⁸⁰ See Cranor & Eastmond, *supra* note 161, at 7–8 (2001) (discussing how courts respond to slow accumulation of scientific knowledge).

⁴⁸¹ See generally DAN B. DOBBS, THE LAW OF TORTS § 5 (2000).

study it adequately. This function may be critical where the concern, as already noted, is that the public will mobilize around a novel theory before the regulatory body or science has had time to adequately assess it. If the vaccine courts are required to provide a “safety valve” against public overreaction, they must be given the tools to deal with new causal claims; science panels may be too impractical to serve the individualistic nature of the specific causation inquiry.⁴⁸²

Reviewing all of these approaches, the best approach may well be the one the vaccine courts have already hit upon (at least until *Moberly*): to lower the sufficiency of evidence standard. But there is nothing in the current language in the Act that justifies this approach. As discussed below, the Act should be amended to make explicit that petitioners do not need to provide the level of evidence required in a toxic tort case to meet the statutory preponderance standard. Rather, a lower showing of causation is sufficient to meet the statutory purposes of the Act. Further, Congress must explicitly acknowledge that the overriding goal of the program is to protect the vaccine market by ensuring that most claims are resolved through that system, regardless of whether they are Table or off-Table claims.

B. Proposed Model

Currently, the Vaccine Act requires that claimants prove “causation” in order to recover for off-Table injuries.⁴⁸³ Congress should amend the Act to replace the requirement of “causation” in off-Table claims with a term such as “association,”⁴⁸⁴ which is less demanding and less laden with tort meaning. Under this new regime, petitioners would not be required to provide the same level of causal evidence demanded in traditional toxic tort pharmaceutical drug cases. In amending the statute, Congress should give clear direction that the paramount purpose of the program is to protect the vaccine market by shielding manufacturers from tort liability through a broadened domain of compensable petitioners under the off-Table claims program. At

⁴⁸² See Brennan, *supra* note 473, at 37 (suggesting that science panels may be too expensive to convene in individual causal uncertainty cases before they have reached mass tort stature).

⁴⁸³ 42 U.S.C. § 300aa-11(c)(1)(C)(ii) (2006).

⁴⁸⁴ This borrows from the standard used in the Agent Orange Veterans Settlement Fund, which uses a “positive association” standard to determine which diseases will be compensated after possible exposure to Agent Orange. See 38 U.S.C. § 1116(a)(1)(A) (2006) (stating that “the Secretary determines in regulations [which diseases] . . . warrant[] a presumption of service-connection by reason of having positive association with exposure to an herbicide agent”); 38 C.F.R. § 3.307(a)(6) (2010).

HHS has recently gone to the other extreme, proposing a more demanding causal standard for the compensation program for injuries from countermeasures taken under the PREP Act. See *supra* note 477. In its final rule, the Secretary proposes that causal evidence be based on “compelling, reliable, valid, medical and scientific evidence.” 42 C.F.R. 110.20(c) (2010). Although use of such a standard may achieve a more accurate result in terms of causation, it would not achieve the goals of the vaccine program.

the same time, the vaccine program would not leave vaccine victims uncompensated by stifling claims due to lack of scientific evidence, even if doing so means allowing compensation of claims that are false positives.

This statutory change would conform the words of the Act to the practice now largely followed by HHS and the vaccine courts, which have allowed recovery without the standard of proof typically required to prove causation in product liability cases.⁴⁸⁵ Upon this statutory change, the Federal Circuit would then have the opportunity to develop proof standards that could clear the muddle that the jurisprudence has become.

In particular, in interpreting this statutory change, this Article proposes that the Federal Circuit develop a model requiring petitioners to meet a two-part burden, each with two subparts, which would align closely with the traditional tort divisions of general and specific causation. To satisfy the element aligning with general causation, the petitioner must demonstrate both that the association between the vaccine and the injury is plausible and that the theory has not been *rejected* by the scientific or medical community. Under this prong, the petitioner would first demonstrate, with sound medical or scientific evidence, that a link between the vaccine and the injury is theoretically possible or “biologically plausible.” Next, the petitioner must demonstrate, by a preponderance of evidence, that the scientific data do not disprove a link between the disease and the vaccine. Thus, the lack of scientific data is not a bar to petitioner’s claim as long as there is reliable medical support for a possible association coupled with insufficient evidence that contradicts the claim. This lowered burden recognizes the difficulty (or, in many cases, impossibility) of proving general causation in the absence of generally accepted studies establishing a strong correlation between receiving a vaccine and a specific medical condition. The government could defeat this element of general association by persuasively demonstrating that the link is not scientifically plausible or has been rejected by the scientific community.

If the threshold for general causation is lowered to one of general association, the main focus of the claim falls under the element aligned with the traditional specific causation inquiry—testing whether this individual suffered harm from the vaccine at issue. Under this part, the petitioner would first demonstrate that the temporal relationship between the vaccination and the onset of the first symptoms is consistent with a link. This would require a showing that the time lapse between the vaccine and the petitioner’s injury was within a period of time that is medically and biologically appropriate. The respondent could defeat this claim with persuasive evidence to the contrary. Second, the petitioner would have to demonstrate that he had no pre-existing medical history of the disease at issue. Placing this burden on the petitioner recognizes that the petitioner likely has better access to this per-

⁴⁸⁵ See *supra* notes 277–280 and accompanying text (describing vaccine courts’ reliance on weak circumstantial evidence to support causation).

sonal information. The importance of this element is to move the claim from the realm of coincidence to a plausible imputation of the petitioner's damage based on receiving the vaccine.

If the petitioner could meet his or her burden on these two elements, the burden would switch to the respondents to prove by a preponderance of the evidence that a factor unrelated to the vaccine was more likely associated with the injury. This would include demonstrating other possible causes of the disease in this petitioner, such as exposure to other toxins or genetic predisposition. Because the diseases at issue often have no known etiology or identified genetic predispositions, in practice, this may prove to be a very high burden.

The proposed model clarifies that causation, in either the scientific or legal sense, is no longer the benchmark in the context of this program. Instead, the vaccine courts must look to an intermediate standard, an association between the vaccination and the petitioner's injury. Thus, the vaccine courts would condition the awarding of compensation on a lower level of certainty. This balances the overriding policy objectives of the program with the recognition that the overwhelming difficulty in this area is simply finding the evidence—which generally does not exist for non-Table-recognized injuries—to prove a causal link between the vaccine and the disease.

A critical question is the extent to which the *Daubert* jurisprudence should play a role in the vaccine courts' evaluation of expert testimony and literature used to support the claim. As explained above, the *Daubert* holding is not binding on the vaccine courts, given the inquisitorial model of the court (without a jury) and the fact that the Federal Rules of Evidence do not apply to the program.

Changing the model from causation to a lower intermediate level of association lessens the importance of the *Daubert* tests in the vaccine courts. Instead of using *Daubert* as a benchmark—along with all of the academic and judicial baggage it has accumulated—the proposed model would require vaccine judges to rely on sound scientific evidence to the extent it is available. Experts will have to demonstrate familiarity with the scientific literature so that they can testify that the association between the harm and the vaccine has not been ruled out by the scientific community. Significantly, however, experts will not have to demonstrate a theory of causation that survives more rigorous testing than biological or medical plausibility. This model recognizes that strict application of traditional tort analysis, including importation of the *Daubert* tests, would result in little possibility of succeeding in an off-Table claim, which would defeat the vaccine compensation program's primary purpose of capturing as many claims as possible through the administrative system instead of the courts. At the same time, it allows vaccine judges to reject some expert evidence as scientifically unsound.

This model also lessens the significance of the testimony of treating physicians on the ultimate issue of causation. For the reasons explained

above,⁴⁸⁶ the vaccine courts currently place too much weight on a treating physician's suspicion of causation. The treating physician is a key fact witness, but is not necessarily qualified to testify as an expert on causation. Lowering the causation element to an intermediate, theoretical standard would militate away from using this evidence. Instead, testimony by experts familiar with the medical and scientific literature would become the paramount evidence used in testing the association between the vaccine and the claimed injury.

While recognizing that placing so much weight on subjective evidence, such as a treating physician's suspicions of a link between the vaccine and the alleged harm, is a misguided standard, this model recognizes as well that requiring full-fledged epidemiological studies would be an insurmountable barrier to off-Table claimants. Assuming that Congress intended some of these claims to succeed, since it created the mechanism in the first place, the model sets the sufficiency standard at an appropriate intermediate level. Accepting that Congress's paramount goal is to ensure the protection of the integrity of the vaccine industry does not mean that the goal of protecting the integrity of the vaccine and the public's perception of vaccine safety can be ignored. Accordingly, although the claims should not be denied because they fail to meet the causal standards found in toxic tort cases, they also should not succeed because a treating physician cannot identify another cause of an injury.

Further, although they do not need to adopt toxic tort standards or abandon their focus on the idiosyncratic nature of each claim, the vaccine courts would do well to shape their decisions in terms similar to the traditional toxic tort concepts of general and specific causation, separating the two concepts more clearly. Lowering the sufficiency standard does not change what elements must be proved. In addition, the complexity of the experts' testimony in this area requires that courts have some reliable and fully-considered mechanism for evaluating the testimony, even if it does not meet *Daubert* standards. Although defining that mechanism is beyond the scope of this Article, it should include requiring demonstrable evidence based on reliable scientific methods.

VI. CONCLUSION

The plague of causation in the vaccine compensation program could be cured were Congress to speak clearly on the level of proof sufficient to meet the causation standard. The uncertainty on this issue derives from Congress's use of the word "causation" in the first place. Although that word points in the direction of the traditional tort system, proof relied upon under the program for off-Table claims is not susceptible to causal proof standards in the traditional sense. The original Act never anticipated the large number of

⁴⁸⁶ See *supra* notes 220–221.

cause-in-fact-cases outside of the Table. The increase in off-Table cases has caused the Act to lose its original policy bearings, and the off-Table program has failed to meet the goal of delivering compensation through a speedy, efficient system without the hindrance of courts and their evidentiary standards.

Assuming Congress wanted to create a safety valve to deal with novel theories of harms caused by vaccines through the off-Table mechanism, the vaccine program and compensation system has become the front line to handle these claims. The vaccine courts appropriately lowered the amount of proof required to establish off-Table causation-in-fact, comporting with the goal of ensuring adequate vaccine supplies and compensating likely victims of vaccine injury. But insuring victims against risks from vaccines does not remove the need to prove connection to the vaccine. And it still remains critical to avoid the devastating impact that compensation driven by poor information could create. Not “every child with epilepsy who had a seizure in time relationship to [a vaccine] would have to be considered to have [the vaccine] as the etiology.”⁴⁸⁷ The stakes are high in the vaccine area, calling for a greater degree of accuracy in determining causation.

This need for accuracy must be balanced against the dearth of scientific evidence with regard to general causation in the vaccine area. Given this lack of evidence, one would predict that the verdicts generally would be against the petitioner if the special masters demanded the type of scientific support usually required in toxic tort cases. On closer examination, the decisions do not reflect this result.⁴⁸⁸ Other standards are in play, and what would be considered insufficient in a common law toxic tort case is at times considered sufficient in the vaccine program context. The Act should now be amended to reflect and codify this difference. Instead of causation, Congress should think in terms of “validating” a claim through sufficient correlative links. This method recognizes that the science may not always be available without denying every claim for want of sufficient causal proof.

⁴⁸⁷ *Moberly ex rel. Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1320 (Fed. Cir. 2010).

⁴⁸⁸ See *supra* Part IV.