William & Mary Law Review

Volume 52 (2010-2011)
Issue 4

Article 6

March 2011

What to do With Daubert: How to Bring Standards of Reliable Scientific Evidence to the National Vaccine Injury Compensation Program

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NOTES

WHAT TO DO WITH *DAUBERT*: HOW TO BRING STANDARDS OF RELIABLE SCIENTIFIC EVIDENCE TO THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

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INTRODUCTION

Whether a vaccine caused a person's injuries is a complex biological question. Yet every day, litigants ask judges and jurors who lack scientific sophistication to answer this and other difficult medical questions.[1] And as scientific knowledge advances, the number of science-based disputes reaching our country's courtrooms is exploding.[2]

Legal institutions must adapt to this dynamic medicolegal nexus by developing standards and procedures that enable courts to utilize the benefits of novel scientific truths while simultaneously avoiding the perils of junk science.[3] The legal system's response to scientific advancement, however, should not come at the expense of its own institutional goals of efficiently resolving conflicts and achieving justice.[4] Although "[s]cientific issues permeate the law,"[5] they should not swallow the legal decision-making process altogether. In

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1. SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 43 (1995).

2. *See* JUDICIAL CONFERENCE OF THE U.S., REPORT OF THE FEDERAL COURTS STUDY COMMITTEE 97 (1990), *available at* http://www.fjc.gov/public/pdf.nsf/lookup/repfcsc.pdf/$file/repfcsc.pdf; *see also* Adam J. Siegel, Note, *Setting Limits on Judicial Scientific, Technical, and Other Specialized Fact-Finding in the New Millennium*, 86 CORNELL L. REV. 167, 169 n.1 (2000) (providing examples of cases involving complex scientific and technological subject matters).

3. *See* Thomas J. Moyer & Stephen P. Anway, *Biotechnology and the Bar: A Response to the Growing Divide Between Science and the Legal Environment*, 22 BERKELEY TECH. L.J. 671, 673 (2007). The term "junk science" emerged in the 1980s and was made famous by Peter W. Huber's book, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991). Huber defined junk science as "a hodgepodge of biased data, spurious inference, and logical legerdemain." *Id.* at 3. This Note uses a more refined definition of the term, namely, to describe those "fallacious interpretations of scientific data or opinions that are not supported by scientific evidence." KENNETH R. FOSTER & PETER W. HUBER, JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS 17 (1997). For criticisms of Huber's scholarship and use of the term "junk science," see generally Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637 (1993), and Gary Edmond & David Mercer, *Trashing "Junk Science"*, 1998 STAN. TECH. L. REV. 3.

4. *See* CARL F. CRANOR, TOXIC TORTS: SCIENCE, LAW, AND THE POSSIBILITY OF JUSTICE 212 (2006); Howard T. Markey, *Jurisprudence or "Juriscience"?*, 25 WM. & MARY L. REV. 525, 525 (1984) ("No court ... should base a decision solely on science if doing so would exclude the transcendental ethical values of the law.").

5. Stephen Breyer, *The Interdependence of Science and Law*, 82 JUDICATURE 24, 25 (1998).

other words, "we must build legal foundations that are sound in science, as well as in law."[6]

Striking the appropriate medicolegal balance is not easy, but it is important—especially when litigants ask courts to resolve disputes involving alleged vaccine injuries.[7] If the legal system decides without a sufficient medical basis that a vaccine can or did cause a certain injury, it not only increases the divide between science and law,[8] it also risks decreasing the public's trust in vaccines and potentially destabilizing one of the most important public health institutions of the modern world.[9]

This Note explores the interaction among science, law, and justice within the context of our country's immunization policies. It argues that courts should protect the stability and integrity of our national immunization program by refusing to declare that a vaccine harmed someone without basing that finding on reliable science. Special masters[10] presiding over proceedings brought under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[11] should thus have clear, uniform standards by which to scrutinize the complex medical evidence presented in their cases. In particular, special masters should have the power to weigh and exclude evidence and testimony pursuant to the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[12] And they should have that power even though the Federal Rules of Evidence do not govern litigation brought under the Act.[13]

Part I of this Note outlines the importance of maintaining an appropriate balance between law and science within the context of

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6. *Id.* at 27.

7. *See infra* notes 42-44 and accompanying text.

8. Joseph Sanders, *Applying* Daubert *Inconsistently?: Proof of Individual Causation in Toxic Tort and Forensic Cases*, 75 BROOK. L. REV. 1367, 1370-74 (2010) (explaining that "[t]here is a disconnect between science and law .... [because] the law's search for causal information about a particular case often finds little or no help from science").

9. *See infra* notes 45-49 and accompanying text.

10. The Office of Special Masters consists of not more than eight judges whose sole responsibility is to decide vaccine injury cases. 42 U.S.C. § 300aa-12(a), (c) (2006). Judges from the United States Court of Federal Claims appoint the special masters to four-year terms. *Id.* § 300aa-12(c)(1), (4); *see also infra* notes 86-89 and accompanying text.

11. 42 U.S.C. §§ 300aa-1 to -34.

12. 509 U.S. 579, 594-98 (1993) (holding that Federal Rule of Evidence 702 requires federal judges to exclude irrelevant, unreliable, and scientifically invalid expert testimony).

13. 42 U.S.C. § 300aa-12(d)(2).

our national immunization policies and legal institutions. It also highlights the public's increased attention to vaccine injuries and discusses how misinformation about vaccine safety can create adverse public health consequences. Part II briefly reviews the legal procedures and evidentiary requirements for receiving compensation under the Vaccine Act. Part III details why the Vaccine Act and the Federal Circuit case law fail to provide sufficient guidance regarding the type and amount of scientific evidence plaintiffs must provide to receive compensation under the Act, and it explains how this void negatively affects the accuracy, consistency, and fairness of judicial decision making. Part IV then discusses how Vaccine Act jurisprudence has applied *Daubert*, details why the case law fails to provide a sufficient analytical framework for scrutinizing evidence, and highlights the special masters' continued need for uniform evidentiary standards. Finally, Part V argues that *Daubert*'s analytical framework should be binding precedent in all Vaccine Act litigation in order to maintain the Act's congressional purpose and ensure that decisions linking vaccines to injury are firmly rooted in reliable science.

I. THE LEGAL SYSTEM'S INTERACTION WITH NATIONAL IMMUNIZATION POLICIES

A. Benefits and Risks of Vaccination

Vaccines are one of the greatest medical achievements in human history.[14] In the 1950s, measles infected more than 500,000 children per year in the United States.[15] The disease caused a range of respiratory and neurological complications that resulted in more than 48,000 hospitalizations and 450 deaths every year in the

14. 131 CONG. REC. 7032 (1985) (statement of Sen. Hatch); *see also Vaccines—Finding the Balance Between Public Safety and Personal Choice: Hearing Before the H. Comm. on Gov't Reform*, 106th Cong. 14 (1999) [hereinafter *Vaccine Hearing*] (statement of Rep. Henry A. Waxman, Member, H. Comm. on Gov't Reform) ("[T]here are a few triumphs in the annals of medicine like vaccinations."); INST. OF MED., IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 2 (2004); Helen Bedford & David Elliman, *Concerns About Immunisation*, 320 BRIT. MED. J. 240, 240 (2000).

15. 48 CTRS. FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REPORT 246 (1999) [hereinafter CDC, MORBIDITY REPORT].

United States alone.[16] But after a measles vaccine was licensed in 1963,[17] the disease's morbidity plummeted: in 1998, measles infected fewer than 100 people.[18]

Vaccines have similarly reduced the morbidity of other diseases, including rubella, mumps, tetanus, diphtheria, and pertussis—each of which used to harm thousands of children every year.[19] Widespread vaccination against these diseases[20] reduced their morbidities by over 95 percent.[21] Perhaps the most notable vaccine accomplishment was the eradication of smallpox in the United States in 1977—a disease that caused an average of 1528 deaths per year from 1900 to 1904.[22] Put simply, vaccines prevent disease and save lives.[23]

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16. Walter A. Orenstein et al., *Measles Elimination in the United States*, 189 J. INFECTIOUS DISEASES S1, S1 (Supp. I 2004).

17. CDC, MORBIDITY REPORT, *supra* note 15, at 244 tbl.1.

18. *Id.* at 245 tbl.2. The measles vaccine has saved millions of human lives worldwide. *See* Orenstein, *supra* note 16, at S2; *see also* Bedford & Elliman, *supra* note 14, at 241 tbl.1 (showing a reduction in measles morbidity and mortality after the measles vaccine was introduced).

19. CDC, MORBIDITY REPORT, *supra* note 15, at 245 tbl.2; *see also id.* at 624. For an overview of routinely administered childhood vaccines and their historical impact on infectious disease prevention, see Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 370-79 (2004).

20. All fifty states have compulsory vaccination laws. *See* Calandrillo, *supra* note 19, at 381 & n.199. Indeed, requiring and obtaining wide-scale vaccination is an essential component of the national immunization program. *See infra* notes 31-32 and accompanying text.

21. CDC, MORBIDITY REPORT, *supra* note 15, at 245 tbl.2.

22. *Id.*

23. In addition to their public health benefit, vaccines are also an extremely cost-effective form of healthcare. *See* H.R. REP. NO. 99-908, at 4-5 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345-46; *see also* OFFICE OF TECH. ASSESSMENT, COST EFFECTIVENESS OF INFLUENZA VACCINATION 3 (1981); Michael A. Riddiough et al., *Influenza Vaccination: Cost-effectiveness and Public Policy*, 249 JAMA 3189, 3189 (1983); Craig C. White et al., *Benefits, Risks, and Costs of Immunization for Measles, Mumps, and Rubella*, 75 AM. J. PUB. HEALTH 739, 740-41 & tbls.2 & 3 (1985); Press Release, Ctrs. for Disease Control and Prevention, Most U.S. Parents Are Vaccinating According to New CDC Survey (Sept. 4, 2008), *available at* http://www.cdc.gov/media/pressrel/2008/r080904.htm ("[D]uring a given year .... [v]accination results in a total savings of $43.3 billion, including $9.9 billion in direct medical costs."). *But see* James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 844 n.88 (2001) ("Some recently licensed vaccines may have marginal benefit to cost ratios." (citing Letter from Dr. Neal A. Halsey (Apr. 3, 2000) (on file with authors))).

Yet no vaccine is perfect.[24] Many immunizations contain live or attenuated viruses[25] and a range of chemical ingredients that trigger adverse reactions in some members of the population.[26] Indeed, the Vaccine Act contains a "Vaccine Injury Table" that lists several post-immunization injuries that are presumptively causally related to vaccines.[27] Plaintiffs earn this presumption of causation if they prove onset of an injury listed in the Table within a specified time period.[28] Once Vaccine Act plaintiffs establish that they suffered an "on-Table" injury, "the burden shifts to the [government] to prove that a factor unrelated to the vaccination actually caused the illness, disability, injury, or condition."[29]

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24. *See, e.g.*, H.R. REP. NO. 99-908, at 5-6, 1986 U.S.C.C.A.N. at 6346-47; *see also* Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1306-07 (Fed. Cir. 1999) (describing the risks of immunization). Because the defendant in all Vaccine Act cases is the Secretary of Health and Human Services, *see infra* text accompanying note 86, "Health and Human Services" is abbreviated "HHS" hereinafter for convenience.

25. *See, e.g.*, PHYSICIANS' DESK REFERENCE: PRESCRIPTION DRUGS 2054 (63d ed. 2009) (measles, mumps, and rubella vaccine); *id.* at 2133 (varicella vaccine).

26. *See id.* at 1480-82 & tbls.1, 2, 3 & 4 (listing adverse events occurring within three days following receipt of Infanrix, a DTaP vaccination containing the diphtheria and tetanus toxoids and inactivated pertussis toxin); *id.* at 2075 & tbl.5 (describing adverse reactions to PedvaxHIB, a vaccination containing a meningococcal protein conjugate); *see also Terran*, 195 F.3d at 1306-07; Ctrs. for Disease Control and Prevention, Possible Side-effects from Vaccines, http://www.cdc.gov/vaccines/vac-gen/side-effects.htm (last visited Jan. 27, 2011); Ctrs. for Disease Control and Prevention, Vaccine Safety: What You Should Know, http://www.cdc.gov/Features/VaccineSafety/ (last visited Jan. 27, 2011).

27. 42 U.S.C. § 300aa-14(a) (2006); *see also* 42 C.F.R. § 100.3 (2010) (reporting the current version of the Vaccine Injury Table); Andreu v. Sec'y of HHS, 569 F.3d 1367, 1374 (Fed. Cir. 2009) ("[A] claimant who shows that he or she received a vaccination listed in the Vaccine Injury Table ... and suffered an injury listed in the table within a prescribed period is afforded a presumption of causation." (citing 42 U.S.C. § 300aa-11(c)(1)(C)(i) and Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006))). The Secretary of Health and Human Services has authority to modify the Vaccine Injury Table after a period for public comment. 42 U.S.C. § 300aa-14(c). The Secretary's ability to modify the Table does not violate the Presentment Clause of the U.S. Constitution because "the Vaccine Act does not authorize the Secretary to amend or repeal portions of the Act, but rather merely grants her the power to promulgate new regulations as contemplated in the Act." *Terran*, 195 F.3d at 1312; *cf.* U.S. CONST. art. I, § 7, cl. 2 ("Every Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a Law, be presented to the President of the United States.").

28. Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Some of the injuries presumptively caused by vaccines include brachial neuritis within 2-28 days of receiving a tetanus toxoid-containing vaccine, encephalopathy within 72 hours of receiving a pertussis antigen-containing vaccine, or chronic arthritis within 7-42 days of receiving a rubella virus-containing vaccine. 42 C.F.R. § 100.3.

29. *Pafford*, 451 F.3d at 1355 (citing 42 U.S.C. § 300aa-13(a)(1)(A)-(B)).

Despite their potential harmful effects, vaccines continue to be "one of the most spectacularly effective public health initiatives [the] country has ever undertaken."[30] For that reason, all fifty states have passed compulsory vaccination laws.[31] Governments recognize that the substantial benefits of widespread immunization and disease prevention outweigh the risk of injury that vaccines pose to some subpopulations.[32] Indeed, in upholding the constitutionality of these laws, the U.S. Supreme Court acknowledged that some children and adults "might not be fit subjects of vaccination,"[33] and that it may be "impossible ... to determine with absolute certainty whether a particular person could be safely vaccinated."[34] But according to the unanimous Court, these risks do not "strip the legislative department of its function to care for the public health and the public safety when endangered by epidemics of disease."[35]

B. Good Law Is Rooted in Good Science

National immunization policies, therefore, must balance the benefits of disease prevention with the risks of sporadic, idiosyncratic adverse reactions.[36] In many ways, this policy balance is a

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

31. Calandrillo, *supra* note 19, at 381 & n.199.

32. Compulsory vaccination laws help to achieve high immunization rates among the general population, which creates herd immunity, "the resistance of a group to attack by a disease to which a large proportion of the members are immune, thus lessening the likelihood of a patient with a disease coming into contact with a susceptible individual." John P. Fox et al., *Herd Immunity: Basic Concept and Relevance to Public Health Immunization Practices*, 94 AM. J. EPIDEMIOLOGY 179, 180 (1971) (quoting DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (WB Saunders Co. 1965)). In other words, the immunity of vaccinated children indirectly benefits unvaccinated children by reducing a virus's transmission. 57 CTRS. FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REPORT 699 (2008). *See generally* Paul E.M. Fine, *Herd Immunity: History, Theory, Practice*, 15 EPIDEMIOLOGIC REVS. 265 (1993). The vaccination rate required for herd immunity depends on the type of infectious disease, but generally ranges from 80 to 90 percent. *Id.* at 268 tbl.1.

33. Jacobson v. Massachusetts, 197 U.S. 11, 36 (1905).

34. *Id.* at 37.

35. *Id.*; *cf.* Zucht v. King, 260 U.S. 174, 177 (1922) (upholding mandatory vaccination as a precondition for public school attendance). For a discussion of the constitutionality of compulsory vaccination laws, including a discussion of *Jacobson*, see Hodge & Gostin, *supra* note 23, at 853-58.

36. Other controversial medicolegal issues complicate national vaccine policies, including the tensions between the government's interest in providing public health through mandatory vaccinations and an individual's right to refuse medical treatment. *See* PUBLIC HEALTH LAW

social compact: individuals assume a "tiny risk of harm for the greater good";[37] in return, the government ensures that those harmed by vaccines receive a fair and just legal process to compensate their injuries.[38] Accordingly, law and medicine cannot be analyzed in isolation—at least not when viewed within the context of vaccine policy. Their relationship is symbiotic: medical decisions impact legal institutions[39] and legal institutions impact medical decisions.[40]

Because of this relationship, courts deciding whether a particular vaccine caused an injury must root their decisions in reliable scientific evidence. Otherwise, the legal system risks unduly influencing public health based on junk science. Justice Breyer has made a similar observation:

> The importance of scientific accuracy ... reach[es] well beyond the case itself. A decision wrongly denying compensation in a toxic substance case, for example, can deprive not only the plaintiff, say a worker, of warranted compensation, but can discourage other, similarly situated workers from even trying to obtain compensation and encourage the continued use of a dangerous substance. On the other hand, a decision wrongly granting compensation, while of immediate benefit to the

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AND ETHICS: A READER 203-06, 215-16 (Lawrence O. Gostin ed., 2002). Parental rights, personal autonomy, and religious beliefs also complicate vaccine policies. *See* Comm. on Bioethics, Am. Acad. of Pediatrics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 PEDIATRICS 314, 314-17 (1995).

37. Transcript of Record at 12, Cedillo v. Sec'y of HHS, 2009 U.S. Claims LEXIS 146 (No. 98-916), *available at* ftp://autism.uscfc.uscourts.gov/autism/cedillo/transcripts/day01-cor.pdf [hereinafter *Cedillo* Transcript]; *cf. supra* notes 31-32 and accompanying text.

38. *See infra* note 75 and accompanying text; *cf. Cedillo* Transcript, *supra* note 37, at 11A-13A.

39. *See, e.g.*, MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 69-70 (1997) (discussing the "tidal wave of litigation" that arose in the aftermath of the U.S. Food and Drug Administration's ban on silicone breast implants).

40. *See, e.g.*, *id.* at 29-30 (discussing the disruptive effect that plaintiffs' attorneys can have on the scientific process); Edmond & Mercer, *supra* note 3, ¶¶ 46-48 (1998); Marilee M. Kapsa & Carl B. Meyer, *Scientific Experts: Making Their Testimony More Reliable*, 35 CAL. W. L. REV. 313, 321 (1999) ("Law, science, and medicine are interdependent."); Donald G. McNeil, Jr., *Court Finds No Link of Vaccine and Autism*, N.Y. TIMES, Feb. 13, 2009, at A16 (quoting a physician who predicted that, as a result of a Vaccine Act decision finding no link between childhood vaccines and autism, "pediatricians would meet less resistance from parents over vaccinating children").

> plaintiff worker, can ... improperly force abandonment of the substance. This, if the decision is wrong, will improperly deprive the public of what can be far more important benefits—say those surrounding a drug that cures many while subjecting to less serious risk a few.[41]

This risk of inaccurate decision making applies to any legal dispute involving toxic substances or pharmaceutical products. But Justice Breyer's insights apply to an even greater extent in cases where the outcome can have a considerable effect on one of the most important public health institutions of the modern world: vaccines.

C. Junk Science and the Risk to Public Health

Any legal decision involving an alleged vaccine injury has the potential to produce significant—and adverse—public health consequences. News that a vaccine caused harm can create public fear, which may decrease vaccination rates and ultimately increase the morbidity and mortality of preventable diseases.[42] Judges, therefore, must be careful not to overstate the dangerousness of vaccines. And when they do causally connect a vaccine to injury, judges must ensure that their reasoning is firmly rooted in reliable science. Put another way, "there is an increasingly important need for law to reflect sound science."[43] The stability of our country's immunization program is too important to be harmed by bad law created from bad science.

While ensuring that they do not *overstate* the dangerousness of vaccines, judges must also strive not to *understate* the dangerousness of vaccines. Failure to compensate legitimate claims of vaccine injury may frustrate public confidence in the justice system, or even erode the public's willingness to get vaccinated if the public feels that vaccine injuries are not fairly, promptly, and generously compensated.[44] As Chief Special Master Gary Golkiewicz explained, there is "a tension between [the] two objectives" of "protecting the

41. Breyer, *supra* note 5, at 25.

42. *See infra* notes 48-65 and accompanying text.

43. Breyer, *supra* note 5, at 26.

44. *Cf. supra* text accompanying notes 37-38 (describing the "social compact" of national vaccine policy).

vaccine's integrity" and "compensat[ing] those who suffer a vaccine-related injury."[45] The proper way to resolve this tension is to ensure that good science informs the judicial decision-making process.

The need for accurate science-based jurisprudence is especially strong today, as the historical success of immunizations has created a level of complacency in the general public.[46] "Because many of the diseases preventable by vaccines are now uncommon, parents have little experience of the disease and so potential, however tenuous, side effects take on a disproportionate importance."[47] News that a particular vaccine can cause injury—no matter how well-founded—creates public fear. Fueled by the modern-day twenty-four-hour news cycle and the Internet, this fear can spread at an alarming rate—often leaving public health officials with no opportunity to overcome the "persuasive power of personal tragedy"[48] with the empirical insights of reliable science. And as the public's fear of vaccines increases, its trust in vaccines decreases. In turn, immunization rates fall and the occurrence rates of preventable diseases rise.[49]

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45. Chief Special Master Gary J. Golkiewicz, Full Presentation to the Advisory Commission on Childhood Vaccines, U.S. Dep't of Health & Human Servs. (Mar. 6-7, 2008), *available at* http://www.hrsa.gov/vaccinecompensation/GolkewiczTranscript.htm.

46. *See, e.g.*, *Vaccine Hearing*, *supra* note 14, at 14 (statement of Rep. Henry A. Waxman, Member, H. Comm. on Gov't Reform) ("[T]oday we are becoming complacent about our success against infectious diseases. Unlike our parents and grandparents, we aren't terrorized every year by paralytic polio and whooping cough epidemics. This makes it easier to forget the value of vaccines and to focus on their potential risks. But, if children are frightened and parents discouraged about vaccines, we will quickly become vulnerable again to infectious diseases."); E.J. Gangarosa et al., *Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story*, 351 LANCET 356, 356 (1998); Ross D. Silverman, *No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions To Ensure Public Health Protection*, 12 ANNALS HEALTH L. 277, 278-79 (2003); Michael Specter, Comment, *Shots in the Dark*, NEW YORKER, Oct. 11, 1999, at 39.

47. Bedford & Elliman, *supra* note 14, at 241; *see also* Adam J. Ruben, *Why The Controversy? Vaccines Save Lives*, NPR, Nov. 17, 2010, http://www.npr.org/2010/11/17/131385344/why-the-controversy-vaccines-save-lives ("When 58,000 American children contracted polio in 1952, and a vaccine promised to curtail the misery, we were grateful. Now, having forgotten about pandemics, we're suspicious.").

48. Julie Marquis, *A Vocal Attack on Vaccines*, L.A. TIMES, Mar. 12, 1997, at A1.

49. In 1974, for example, a medical journal published preliminary research suggesting the whole-cell pertussis vaccine may cause neurological injuries. M. Kulenkampff et al., *Neurological Complications of Pertussis Inoculation*, 49 ARCHIVES DISEASE CHILDHOOD 46, 48-49 (1974). Within five years, the pertussis vaccination coverage in Sweden dropped from 90 percent to 12 percent, which caused a drastic increase in the incidence of pertussis disease among children 0-4 years old. Gangarosa et al., *supra* note 46, at 357. Japan experienced

Consider, for example, the public fear resulting from news surrounding the theory that the measles, mumps, and rubella (MMR) vaccine causes autism. The fear began in 1998 when Dr. Andrew Wakefield and twelve co-authors published an article in *The Lancet* suggesting that regressive autism was linked to a gastrointestinal disease caused by the measles vaccine.[50] Within a decade—a very short time period for medical research—the scientific community debunked this theoretical link[51] and ten of Dr. Wakefield's twelve co-authors published a retraction.[52] Some in the medical community went so far as to describe the study as "scientific fraud."[53] A panel of doctors for the British General Medical Council (GMC) ultimately agreed, finding that Dr. Wakefield had "abused his position of trust."[54] The panel also held that Dr. Wakefield was

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similar results; in 1974, no Japanese children died from pertussis. *Id.* But after immunization rates fell from 80 percent in 1974 to 10 percent in 1976, forty-one children died. *Id.* at 358. The United Kingdom, Russia, Ireland, and Australia also experienced pertussis epidemics. *Id.* at 358-59 figs.2 & 3.

50. A.J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637, 641 (1998).

51. *See, e.g.*, INST. OF MED., IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 152 (2004); World Health Org., *Global Advisory Committee on Vaccine Safety, 16-17 December 2002*, 78 WKLY. EPIDEMIOLOGICAL REC. 17, 18 (2003); *see also* F. DeStefano, *Vaccines and Autism: Evidence Does Not Support a Causal Association*, 82 NATURE 756, 756-58 (2007) (reviewing the scientific evidence rejecting a causal relationship between MMR vaccine and autism); *cf.* Cedillo v. Sec'y of HHS, No. 98-916, 2009 U.S. Claims LEXIS 146, at *459 (Fed. Cl. Feb. 12, 2009) ("The overall weight of the evidence is *overwhelmingly contrary* to the petitioners' causation theories [that MMR vaccine causes autism].").

52. Simon H. Murch et al., *Retraction of an Interpretation*, 363 LANCET 750, 750 (2004).

53. Transcript of Record at 504A-508A, Hazlehurst *ex rel.* Hazlehurst v. Sec'y of HHS, 2009 U.S. Claims LEXIS 183 (No. 03-654), *available at* ftp://autism.uscfc.uscourts.gov/autism/hazlehurst/transcripts/day03-cor.pdf; *see also* Snyder v. Sec'y of HHS, No. 01-162, 2009 U.S. Claims LEXIS 193, at *311-21 (Fed. Cl. Feb. 12, 2009) (reviewing expert testimony criticizing Dr. Wakefield's research methods and conclusions). As an example of Dr. Wakefield's fraudulent behavior, consider the testimony of Dr. Nicholas Chadwick, who worked in Dr. Wakefield's laboratory when it began testing gut biopsy materials from autistic children. *Cedillo* Transcript, *supra* note 37, at 2283, *available at* ftp://autism.uscfc.uscourts.gov/autism/cedillo/transcripts/day10-cor.pdf. Dr. Chadwick reported that every measles-positive sample from Dr. Wakefield's laboratory was sent to a second laboratory for verification, but "the data that came back showed that they were all false positive results." *Id.* at 2288. Dr. Chadwick told Dr. Wakefield about this contamination problem, *id.* at 2287, yet Dr. Wakefield submitted his paper for publication anyway. *Id.* at 2298A. Dr. Chadwick "specifically asked that [his] name not be on that paper because of [his] reservations about the data." *Id.* at 2290A.

54. *Doctor Who Sparked MMR Controversy 'Abused His Position of Trust'*, TELEGRAPH (U.K.), Jan. 28, 2010, http://www.telegraph.co.uk/health/healthnews/7093450/Doctor-who-sparked-MMR-controversy-abused-his-position-of-trust.html.

"guilty of serious professional misconduct,"[55] and erased his name from the United Kingdom Medical Register.[56] In 2010, *The Lancet* formally retracted Dr. Wakefield's paper, noting that many claims in the original paper "have been proven to be false."[57] And in early 2011, the *British Medical Journal* declared that Dr. Wakefield's research "was in fact an elaborate fraud" that "was fatally flawed both scientifically and ethically."[58]

Despite the scientific community's extraordinarily prompt response to Dr. Wakefield's article, it was too late. The media's widespread coverage of his theories caused many in the public to question the safety of government-recommended vaccines.[59] Vaccination rates plummeted.[60] The number of measles infections skyrocketed.[61] In the United Kingdom alone, cases of measles increased from 78 in 2005 to more than 1000 in 2008.[62] Health

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55. Gen. Med. Council, Dr. Andrew Jeremy Wakefield, Determination on Serious Professional Misconduct (SPM) and Sanction (May 24, 2010), at 7, *available at* http://www.gmc-uk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf.

56. *Id.* at 9.

57. Editors of the Lancet, *Retraction—Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 375 LANCET 445, 445 (2010).

58. Fiona Godlee, Jane Smith & Harvey Marcovitch, *Wakefield's Article Linking MMR Vaccine and Autism Was Fraudulent*, 342 BRIT. MED. J. 64, 64 (2011). *See generally* Brian Deer, *How the Case Against the MMR Vaccine Was Fixed*, 342 BRIT. MED. J. 77 (2011) (reporting that Dr. Wakefield falsified or misrepresented the medical histories of every patient in his 1998 study, and was involved with a lawsuit against manufactures of the MMR vaccine for more than two years before he published the paper); Richard Epstein, *Academic Fraud Today: Its Social Causes and Institutional Responses*, 21 STAN. L. & POL'Y REV. 135, 149-50 (2010) (discussing why the "Wakefield fraud" involved "the worst conflict of interest violations imaginable").

59. *See* Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing out of Vaccine Court*, 58 AM. U. L. REV. 459, 479 (2008); *see also* Sharon Begley, *Anatomy of a Scare*, NEWSWEEK, Mar. 2, 2009, at 43-44 (discussing the "hoopla" and "hysteria" following the publication of Dr. Wakefield's paper); Gardiner Harris, *Opening Statements in Case on Autism and Vaccinations*, N.Y. TIMES, June 12, 2007, http://www.nytimes.com/2007/06/12/us/12vaccine.html?_r=3 ("Every major study and scientific organization examining this issue has found no link between vaccination and autism, but the parents and their advocates have persisted.").

60. *See* John Carvel, *Warning of Measles Epidemic Risk as Cases Rise Sharply*, GUARDIAN (U.K.), Nov. 29, 2008, at 15.

61. *See id. See generally* Joëlle Anne Moreno, *It's Just a Shot Away: MMR Vaccines and Autism and the End of the* Daubertista *Revolution*, 35 WM. MITCHELL L. REV. 1511, 1520-22 (2009) (discussing the public's reaction to—and social impact of—Dr. Wakefield's study).

62. Carvel, *supra* note 60; *see also Emergency £1.8m Fund Launched To Halt Measles Epidemic in UK*, DAILY MAIL ONLINE (U.K.), Aug. 7, 2008, http://www.dailymail.co.uk/health/article-1042624/Emergency-1-8m-fund-launched-halt-measles-epidemic-UK.html; *How the*

officials in the United States also reported several measles outbreaks among unvaccinated populations.[63] And to this day, many parents still believe in the validity of Dr. Wakefield's research;[64] a crowd of people even heckled the GMC panel's chairman when he announced that Dr. Wakefield's medical license was revoked.[65]

A related example, which stemmed directly from a Vaccine Act lawsuit, was the government's widely reported concession in early 2008 that childhood vaccines worsened a rare genetic mitochondrial disorder in a nineteen-month-old girl named Hannah Poling.[66] Although the case never went to trial—and thus no court reached the merits of the claim—the media reported that a federal "vaccine court" had ruled that Poling's immunizations caused her autism.[67]

MMR Scare Led to the Return of Measles, SUNDAY TIMES (U.K.), Feb. 8, 2009, http://www.timesonline.co.uk/tol/life_and_style/health/article5683687.ece; Tim Moynihan, *Measles 'Epidemic' Fears After Low MMR Take-Up*, INDEPENDENT (U.K.), Nov. 28, 2008, http://www.independent.co.uk/life-style/health-and-families/health-news/measles-epidemic-fears-after-low-mmr-takeup-1039562.html.

63. *See* Steven Reinberg, *Measles Outbreak Rises to 64 Cases, Most Since 2001*, WASH. POST, May 1, 2008, http://www.washingtonpost.com/wp-dyn/content/article/2008/05/01/AR2008050102633.html (reporting measles outbreaks in Arizona, Michigan, New York, and Wisconsin, among other states); *Minn. Working To Prevent a Measles Outbreak*, MINN. PUB. RADIO NEWS, May 5, 2008, http://minnesota.publicradio.org/display/web/2008/05/05/measles (reporting on the concern over a possible measles outbreak in Minnesota).

64. *See, e.g.*, Dana Kennedy, *Autism Activists Defend Embattled Dr. Wakefield*, AOL NEWS, Jan. 6, 2011, http://www.aolnews.com/2011/01/06/autism-activists-defend-embattled-dr-andrew-wakefield/ ("Despite a new report that a 1998 study linking childhood vaccines to autism was based on 'bogus data,' many autism activists are standing by their man [Wakefield]."); *Will Autism Fraud Report Be a Vaccine Booster?*, FOX NEWS, Jan. 6, 2011, http://www.foxnews.com/us/2011/01/06/autism-fraud-report-vaccine-booster/ ("[A]t least some advocacy groups continue to take Wakefield's side. And though the latest report [finding that Wakefield committed fraud] may ease the doubts of some parents, experts said they'd be surprised if the latest news changes views overall."); *cf.* Wendy E. Parmet, *Pandemic Vaccines—The Legal Landscape*, 362 NEW ENG. J. MED. 1949, 1950 (2010) ("Despite overwhelming scientific evidence to the contrary, many parents still believe that thimerosal [in vaccines] causes autism.").

65. Sarah Boseley, *Andrew Wakefield Found 'Irresponsible' by GMC over MMR Vaccine Scare*, GUARDIAN (U.K.), Jan. 28, 2010, at 4.

66. Claudia Wallis, *Case Study: Autism and Vaccines*, TIME, Mar. 10, 2008, http://www.time.com/time/health/article/0,8599,1721109,00.html.

67. *Court Rules Vaccine Contributed to Autism Symptoms*, ABC7 (Chi.), Mar. 7, 2008, http://abclocal.go.com/wls/story?section=news/local&id=6003909; *see also* Heather Warlick, *A Piece to the Puzzle?—Vaccine Court Finding Stirs Possible Autism Link Controversy*, OKLAHOMAN, Mar. 11, 2008, at 1E. Like the media, some scholars have misinterpreted the facts of the Poling case and concluded that a court actually reached the merits of her claim. *See, e.g.*, Daniela Caruso, *Autism in the US: Social Movement and Legal Change*, 36 AM. J.L. & MED. 483, 538 (2010) (stating that Poling was an "individually tried" case); Bruce Patsner,

Public health officials scrambled to produce a coherent response to quell the public's fear.[68] But despite these officials' careful description of the Poling case as a "very special situation" involving the unique nature of Poling's preexisting condition,[69] every major news outlet covered the story—from Larry King Live[70] to Fox News[71]—with headlines suggesting that the case called into question vaccine safety.[72]

Whether immunization rates fall as a result of the Poling case will be unknown for several years.[73] What *is* known, however, is

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Riegel v. Medtronic, Inc.*: Revisiting Pre-emption for Medical Devices*, 37 J.L. MED. & ETHICS 305, 313 (2009) (referring to the Poling case as "the recent Special Master determination [involving] the autism-like condition of a child with a rare mitochondrial disease").

68. *Cf.* Caruso, *supra* note 67, at 33 ("The [Poling] case spurred a renewal of interest in the vaccine-autism theory."); *id.* at 80 (stating that the Poling case helps to "keep alive the hypothesis of a connection between autism and vaccination").

69. Debra Cassens Weiss, *Autism Settlement Based on Special Circumstances*, A.B.A. J., Mar. 7, 2008, http://www.abajournal.com/news/article/autism_settlement_based_on_special_circumstances/. In response to the media's coverage of the Poling case, Dr. Julie L. Gerberding, Director of the U.S. Centers for Disease Control and Prevention, stated: "Let me be very clear that the government has made absolutely no statement indicating that vaccines are a cause of autism.... That is a complete mischaracterization of the findings of the [Poling] case and a complete mischaracterization of any of the science that we have at our disposal today." Gardiner Harris, *Deal in an Autism Case Fuels Debate on Vaccine*, N.Y. TIMES, Mar. 8, 2008, at A9 (quoting Dr. Gerberding).

70. For a transcript of Larry King's interview with the Poling family, see Transcript of Interview, *Larry King Live* (CNN television broadcast Mar. 6, 2008), *available at* http://transcripts.cnn.com/TRANSCRIPTS/0803/06/lkl.01.html.

71. *Georgia Girl, 9, Helps Link Vaccines to Autism Cause*, FOX NEWS, Mar. 6, 2008, http://www.foxnews.com/story/0,2933,335451,00.html.

72. *See, e.g.*, Claudia Kalb, *Mysteries and Complications*, NEWSWEEK, Mar. 24, 2008, at 64; David Kirby, Editorial, *Give Us Answers on Vaccines*, ATLANTA J. CONST., Mar. 20, 2008, at A19. *But cf.* Editorial, *The Healthy Choice; Vaccines Protect Us All. We Can't Allow the Fears of a Few Parents To Endanger Society*, L.A. TIMES, Apr. 29, 2008, at A16; Phil Doherty, *Court Links MMR to Autism*, SUNDAY SUN (U.K.), Mar. 9, 2008, http://www.sundaysun.co.uk/news/tm_headline=court-links-mmr-to-autism&method=full&objectid=20587416&siteid=50081-name_page.html; *Georgia Girl*, *supra* note 71.

73. One recent report, however, indicates that the immunization rates of DTaP, Hepatitis B, and MMR vaccines declined between 2008 and 2009 for children with commercial health insurance policies. NAT'L COMM. FOR QUALITY ASSURANCE, THE STATE OF HEALTH CARE QUALITY 74-75 (2010), *available at* http://www.ncqa.org/Portals/0/State%20of%20Health%20Care/2010/SOHC%202010%20-%20Full2.pdf. The authors of this study stated that "[o]ne plausible reason" for the decline in vaccination rates is "parents in commercial plans refusing or delaying use of vaccines for their children based on the popular but discredited notion that vaccines cause autism spectrum disorders." *Id.* at 13; *see also* Jeffrey Kluger, *Vaccination Rates Drop in Wealthier Kids: The Autism Rumors Take a Toll*, TIME, Nov. 4, 2010, http://healthland.time.com/2010/11/04/vaccination-rates-drop-in-wealthier-kids-the-autism-rumors-take-a-toll/ (suggesting that the vaccination rates have declined "due mostly to fears about the

that the media and the public are paying close attention to the reported adverse effects of immunizations.

II. A DELICATE MEDICOLEGAL BALANCE: THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

Our country's vaccine policy rests at a crucial breaking point in the public health system: the intersection of law and science. Because maintaining stability at this intersection is so important, Congress passed the National Childhood Vaccine Injury Act of 1986.[74] The Act seeks to encourage and improve the country's immunization program, while simultaneously providing a legal process to compensate victims of adverse vaccine reactions.[75]

A. Unfettered Litigation and a Public Health Emergency

Before 1986, persons believing they were harmed by an immunization could receive compensatory damages only by suing a pharmaceutical company.[76] And sue they did. Due in part to the public's increased awareness of the inherent risks of immunization,[77] the number of lawsuits against pharmaceutical companies dramatically increased during the early 1980s.[78] Between 1980 and 1986 alone, plaintiffs filed more than $3.5 billion in damage claims against vaccine manufacturers.[79] This potential liability caused many companies to stop—or threaten to stop—vaccine production.[80]

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widely disproven link between vaccines and autism"); Robin Nixon, *Myths Fuel Dangerous Decisions To Not Vaccinate Children*, LIVESCIENCE, Nov. 14, 2010, *available at* http://www.livescience.com/8948myths-fuel-dangerous-decisions-vaccinate-children.html (blaming fear that immunizations "can make children autistic" for the decreased vaccination rates in 2009).

74. Pub. L. No. 99-660, 100 Stat. 3755 (1986) (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2006)).

75. Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 62 (1999).

76. *See* H.R. REP. NO. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

77. *See* Shemin, *supra* note 59, at 469 n.45.

78. *See* Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 315-16 & n.53 (1999).

79. Ridgway, *supra* note 75, at 60-61.

80. *See* George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1567 & n.179 (1987); *see also* H.R. REP. NO. 99-908, at 4, 1986 U.S.C.C.A.N. at 6345; Rachel F. Ochs, *Pharmaceuticals: The Battle for Control in the 21st Century*, 10 J.L. & HEALTH 297, 318 & n.130 (1995-96); Daniel A. Cantor, Comment, *Striking a Balance Between Product*

As a result, vaccines became more expensive, immunization rates declined, and the prevalence of preventable diseases and deaths increased.[81] The traditional legal remedies for vaccine injuries had created a public health emergency.

In response to this emerging crisis, Congress passed the Vaccine Act. According to then-Judge Stephen Breyer:

> Congress passed the law after hearing testimony 1) describing the critical need for vaccines to protect children from disease, 2) pointing out that vaccines inevitably harm a very small number of the many millions of people who are vaccinated, and 3) expressing dissatisfaction with traditional tort law as a way of compensating those few victims.[82]

The purpose of the Act is accordingly straightforward: stabilize the vaccine supply and fairly compensate those injured by vaccines.[83]

B. The Vaccine Act's Basic Statutory Scheme

The Vaccine Act established the National Vaccine Injury Compensation Program (Vaccine Program).[84] This program is essentially a tort shield: it prevents individuals who believe they were injured by a vaccine from suing a vaccine administrator or manufacturer if the claim exceeds one thousand dollars.[85] Such plaintiffs

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Availability and Product Safety: Lessons from the Vaccine Act, 44 AM. U. L. REV. 1853, 1858-59 (1995) (discussing the instability of the vaccine market in the early 1980s); David J. Damiani, Comment, *Proposals for Reform in the Evaluation of Expert Testimony in Pharmaceutical Mass Tort Cases*, 13 ALB. L.J. SCI. & TECH. 517, 524 (2003).

81. *See* H.R. REP. NO. 99-908, at 4, 1986 U.S.C.C.A.N. at 6345; *see also* Hodge & Gostin, *supra* note 23, at 881; Ridgway, *supra* note 75, at 61.

82. Schafer *ex rel.* Schafer v. Am. Cyanamid Co., 20 F.3d 1, 2 (1st Cir. 1994).

83. *See* H.R. REP. NO. 99-908, at 5, 1986 U.S.C.C.A.N. at 6346; *see also* Cantor, *supra* note 80, at 1902 ("The National Childhood Vaccine Injury Compensation Act of 1986 represents a much needed legislative response to the civil tort system's inability to achieve a proper balance between vaccine safety and vaccine availability."). For a discussion of the circumstances, politics, and policies surrounding the passage of the Vaccine Act, see generally 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, 688-702 (2007).

84. 42 U.S.C. §§ 300aa-10 to -17 (2006).

85. § 300aa-11(a)(2)(A). The Vaccine Act thus preempts state law remedies for vaccine-related injuries, including design-defect tort claims. *See* Bruesewitz v. Wyeth, Inc., No. 09-152, 2011 U.S. LEXIS 1085 (U.S. Feb. 22, 2011) (clarifying the scope of the Act's preemption

must instead file suit against the Secretary of Health and Human Services in the U.S. Court of Federal Claims.[86] There, a division of judges called "special masters"[87] determines whether plaintiffs have established causation by a preponderance of the evidence,[88] and, if so, awards money damages.[89] The Vaccine Program is a "no-fault" compensation system; petitioners may prevail without establishing a vaccine's defect or a manufacturer's negligence.[90]

Special master decisions are appealable to the Court of Federal Claims,[91] which reverses if the decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[92] The next level of appeal is to the U.S. Court of Appeals for the Federal Circuit, which conducts a de novo review to determine whether the special master acted arbitrarily or capriciously.[93] A party may then appeal to the U.S. Supreme Court.[94]

Vaccine Act plaintiffs establish entitlement to compensation in one of two ways: (1) proving they suffered an injury listed on the Vaccine Injury Table within the requisite time frame or (2) proceed-

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provision). *See generally* Nitin Shah, Note, *When Injury Is Unavoidable: The Vaccine Act's Limited Preemption of Design Defect Claims*, 96 VA. L. REV. 199 (2010) (discussing the constitutionality of the Vaccine Act's broad preemption provision).

86. § 300aa-11(a)(1).

87. § 300aa-12(a), (c); *see also supra* note 10.

88. § 300aa-13(a)(1)(A); *see also* Bunting *ex rel.* Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991). The standard of proof for "causation" in off-Table cases is the same as "legal cause" in civil tort cases. Shyface *ex rel.* Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Congress hoped this easier path to compensation would reduce the number of civil actions filed against vaccine manufacturers in state court. *See* H.R. REP. NO. 99-908, at 12, 1986 U.S.C.C.A.N. at 6353.

89. § 300aa-12(a). Since 1989, special masters have awarded plaintiffs over $1.8 billion in compensatory damages. HEALTH RES. & SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL VACCINE INJURY COMPENSATION PROGRAM POST-1988 STATISTICS REPORT 2 tbl.3 (2010), *available at* http://www.hrsa.gov/vaccinecompensation/DOCS/statisticsreport.pdf.

90. *See* Lowry *ex rel.* Lowry v. Sec'y of HHS, 189 F.3d 1378, 1381 (Fed. Cir. 1999).

91. § 300aa-12(e).

92. § 300aa-12(e)(2)(B).

93. Hines *ex rel.* Sevier v. Sec'y of HHS, 940 F.2d 1518, 1524 (Fed. Cir. 1991).

94. The Supreme Court has granted certiorari in only two Vaccine Act cases, neither of which concern the evidentiary standards of Vaccine Act litigation. *See* Bruesewitz v. Wyeth, Inc., No. 09-152, 2011 U.S. LEXIS 1085 (U.S. Feb. 22, 2011) (involving whether the Act preempts design defect claims); Shalala v. Whitecotton, 514 U.S. 268 (1995) (involving how the Secretary of Health and Human Services may rebut a plaintiff's establishment of a prima facie case).

ing "off-Table."[95] Off-Table cases receive no presumption of causation; plaintiffs must prove causation-in-fact under the same preponderance standard used in the general torts context.[96] This Note is concerned with the evidence plaintiffs use in establishing off-Table claims, which is the way that nearly all Vaccine Act cases proceed today.[97]

C. Rules of Discovery, Evidence, and Procedure in the Vaccine Program

Congress provided remarkably little guidance to the special masters who oversee Vaccine Act litigation. Indeed, because Congress intended the Vaccine Program to be "expeditious,"[98] it removed many of the civil tort system's procedural and evidentiary requirements that can delay the speed at which cases move to decision.[99] Instead of abiding by the rules of traditional civil litigation, Congress charged the Court of Federal Claims with promulgating "flexible and informal standards of admissibility of evidence" to govern Vaccine Act litigation.[100] Accordingly, the Court of Federal

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95. *See* Walther v. Sec'y of HHS, 485 F.3d 1146, 1149 (Fed. Cir. 2007); *see also supra* notes 27-28 and accompanying text.

96. De Bazan v. Sec'y of HHS, 539 F.3d 1347, 1351 (Fed. Cir. 2008).

97. Stevens v. Sec'y of HHS, No. 99-594, 2001 U.S. Claims LEXIS 67, at *25 (Fed. Cl. Mar. 30, 2001). Most cases now proceed off-Table because the Secretary of Health and Human Services has added new vaccines to the Table without also including corresponding vaccine injuries. *See, e.g.*, National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II, 62 Fed. Reg. 7685, 7686, 7688-89 (Feb. 20, 1997) (adding the haemophilus influenzae vaccine and varicella vaccine to the Table and listing "No Condition Specified" as the injury covered). Thus, plaintiffs can prevail only by proving actual causation without the benefit of a presumptive Table injury. *See generally Stevens*, 2001 U.S. Claims LEXIS 67, at *24-25 (stating anecdotally that amendments to the Table in the 1990s, which added new vaccines without adding corresponding injuries, have changed the proportion of off-Table cases in the Program from 10 percent to 90 percent of total petitions filed).

98. H.R. REP. NO. 99-908, at 12 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6353.

99. *See Whitecotton*, 514 U.S. at 269-70. One may question whether Congress achieved this goal. *See, e.g.*, Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 358 (2001). Although the Vaccine Act requires special masters to issue their decisions within 240 days of a petitioner's filing, 42 U.S.C. § 300aa-12(d)(3)(A)(ii) (2006), the average case adjudication time for the five years preceding 2007 was approximately 1000 days (2.8 years). Advisory Comm'n on Childhood Vaccines, Meeting and Conference Call Minutes 18 (Mar. 7-8, 2007), ftp://ftp.hrsa.gov/vaccinecompensation/ACCVMinutesMar7-8-07.pdf.

100. § 300aa-12(d)(2).

Claims created the Vaccine Rules of the United States Court of Federal Claims (Vaccine Rules).[101]

The Vaccine Rules regulate all proceedings brought under the Act.[102] They detail what must be included in a petition for relief,[103] require the government to file a written report within ninety days of the action's commencement,[104] and outline procedures for entering judgments and appeals.[105] Most importantly for the purposes of this Note, the Vaccine Rules specifically state that special masters "will *not* be bound by common law or statutory rules of evidence."[106] Thus, because the Federal Rules of Evidence are statutory rules of evidence,[107] they do not apply to Vaccine Act litigation.[108]

III. DEFICIENT EVIDENTIARY STANDARDS: THE PROBLEM AND ITS JURISPRUDENTIAL CONSEQUENCES

A. The "Overwhelming Discretion" of Special Masters

Because the Federal Rules of Evidence do not control Vaccine Act litigation, special masters have great freedom to admit and weigh evidence. The Act's only constraint on this freedom is that special masters cannot award compensation in the absence of *some* medical and scientific evidence: "The special master or court may not [award compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."[109] But even when

101. *See* VACCINE R. FED. CL., *available at* http://www.uscfc.uscourts.gov/sites/default/files/court_info/rules_071309_v8.pdf (Appendix B); *cf.* 28 U.S.C. § 2071(a).

102. VACCINE R. FED. CL. 1(a).

103. VACCINE R. FED. CL. 2(c).

104. VACCINE R. FED. CL. 4(c).

105. VACCINE R. FED. CL. 11, 23.

106. VACCINE R. FED. CL. 8(b)(1) (emphasis added).

107. Congress adopted the Federal Rules of Evidence in 1975. Act of Jan. 2, 1975, Pub. L. No. 93-595, 88 Stat. 1926. This statute gave the Supreme Court the power to modify the rules. *Id.* § 2076, 88 Stat. at 1948; *see also* 28 U.S.C. § 2072(a) (2006).

108. *See, e.g.*, Hazlehurst *ex rel.* Hazlehurst v. Sec'y of HHS, 604 F.3d 1343, 1349 (Fed. Cir. 2010); Andreu *ex rel.* Andreu v. Sec'y of HHS, 569 F.3d 1367, 1383 (Fed. Cir. 2009); Munn *ex rel.* Vukelich v. Sec'y of HHS, 970 F.2d 863, 873 (Fed. Cir. 1992); Hines *ex rel.* Sevier v. Sec'y of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Corder *ex rel.* Corder v. Sec'y of HHS, No. 97-125, 1999 U.S. Claims LEXIS 158, at *19 n.15 (Fed. Cl. May 28, 1999); Isom *ex rel.* Isom v. Sec'y of HHS, No. 94-770, 1998 U.S. Claims LEXIS 280, at *18 (Fed. Cl. Nov. 3, 1998); Dickerson *ex rel.* Dickerson v. Sec'y of HHS, 35 Fed. Cl. 593, 601 (1996).

109. 42 U.S.C. § 300aa-13(a)(1) (2006).

plaintiffs do provide records to support their claims, special masters are not bound by the conclusions contained in those documents, and must instead "consider the entire record."[110] The *evidentiary standards* by which special masters evaluate the entire record of evidence, however, are left entirely to their judgment.[111]

Special masters thus possess "overwhelming discretion" to control Vaccine Act litigation, including the weight they assign to evidence and the merits of each petition for relief.[112] This lack of evidentiary guidance would be troubling in any litigation context, but it is especially worrisome in the Vaccine Program, where disputes involve "extremely difficult"[113] questions of medical causation that science has rarely definitively answered.[114] In *Hargrove v. Secretary of Health & Human Services*, for example, the plaintiffs' theory of causation included principles of anamnesis, molecular mimicry, and agent rechallenge.[115] Without evidentiary standards by which to evaluate and decide the merits of such difficult cases, special masters risk relying on bad science, producing bad law,[116] and

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110. § 300aa-13(b)(1).

111. *See generally* Erica A. Little, Note, *The Role of Special Masters in Off-Table Vaccination Compensation Cases: Assuring Flexibility over Certainty*, 16 FED. CIR. B.J. 355, 364-65 (2007) (reviewing Federal Circuit case law regarding the special master's authority to make evidentiary determinations).

112. Breen, *supra* note 78, at 321 (arguing that special master discretion "represents one of the flaws inherent in the [Vaccine] Act"); *see also* Whitecotton *ex rel.* Whitecotton v. Sec'y of HHS, 81 F.3d 1099, 1108 (Fed. Cir. 1996) ("Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence."); Burns *ex rel.* Burns v. Sec'y of HHS, 3 F.3d 415, 417 (Fed. Cir. 1993); Davis v. Sec'y of HHS, No. 07-451, 2010 U.S. Claims LEXIS 525, at *29 (Fed. Cl. July 12, 2010) ("It is axiomatic that special masters in vaccine cases have great leeway in building a record for decision."); Kimberly J. Garde, Note, *This Will Only Hurt for … Ever: Compulsory Vaccine Laws, Injured Children, and No Redress*, 3 PHOENIX L. REV. 509, 544 (2010) (noting that special masters' "immense discretion" makes case adjudication "very arbitrary"); Little, *supra* note 111, at 361-63.

113. Miller *ex rel.* Miller v. Sec'y of HHS, No. 89-75, 1991 U.S. Cl. Ct. LEXIS 336, at *8 n.5 (Cl. Ct. July 17, 1991).

114. *Cf.* Althen v. Sec'y of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005) (stating that the Vaccine Act occupies "a field bereft of complete and direct proof of how vaccines affect the human body"); Doe *ex rel.* Doe v. Sec'y of HHS, 2010 U.S. Claims LEXIS 581, at *28 (Fed. Cl. July 26, 2010) ("Assessing the reliability of expert opinion in Vaccine Act cases can be challenging because often there is little confirmatory evidence for the expert's opinion.").

115. No. 05-0694, 2009 U.S. Claims LEXIS 171, at *20-24 (Fed. Cl. Apr. 14, 2009).

116. Moreno, *supra* note 61, at 1540-41 ("[G]ood law will continue to depend on good science.").

"undermin[ing] the ultimate function of courts—to seek the truth."[117]

This risk of relying on bad science may already be the reality of Vaccine Act jurisprudence. Numerous special master decisions, for example, have causally linked multiple sclerosis with receipt of hepatitis B vaccine.[118] This body of law has developed despite the tomes of scientific literature refuting such a link, including articles published in leading medical journals, such as *The New England Journal of Medicine*[119] and *The Lancet*.[120] Moreover, in 2002, the Immunization Safety Review Committee of the Institute of Medicine reviewed the evidence of a possible connection between hepatitis B vaccine and multiple sclerosis, and concluded that the scientific evidence "favors rejection of a causal relationship."[121] This broad scientific consensus, however, has not prevented special masters from finding a causal relationship between the hepatitis B vaccine and multiple sclerosis. Indeed, there is a recent trend *toward* compensating such claims.[122]

B. Why Have No Uniform Standards Emerged?

The special masters have openly expressed their frustration with the lack of uniform standards by which they reach entitlement decisions.[123] At times, this frustration and the need for uniformity

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117. Victor E. Schwartz & Cary Silverman, *The Draining of* Daubert *and the Recidivism of Junk Science in Federal and State Courts*, 35 HOFSTRA L. REV. 217, 226 (2006).

118. *See, e.g.*, Fisher v. Sec'y of HHS, No. 99-432, 2009 U.S. Claims LEXIS 470, at *55 (Fed. Cl. July 13, 2009); Doe v. Sec'y of HHS, No. 07-360, 2009 U.S. Claims LEXIS 452, at *9-10 (Fed. Cl. June 8, 2009); Borrero v. Sec'y of HHS, No. 01-417, 2008 U.S. Claims LEXIS 451, at *70-71 (Fed. Cl. Sept. 24, 2008); Doe v. Sec'y of HHS, 2008 U.S. Claims LEXIS 99, at *31 (Fed. Cl. Mar. 31, 2008); Werderitsh v. Sec'y of HHS, No. 99-319, 2006 U.S. Claims LEXIS 156, at *76 (Fed. Cl. May 26, 2006).

119. *See* Alberto Ascherio et al., *Hepatitis B Vaccination and the Risk of Multiple Sclerosis*, 344 NEW ENG. J. MED. 327, 327 (2001).

120. A. Dessa Sadovnick & David W. Scheifele, *School-Based Hepatitis B Vaccination Programme and Adolescent Multiple Sclerosis*, 355 LANCET 549, 549 (2000).

121. IMMUNIZATION SAFETY REVIEW COMM., INST. OF MED., IMMUNIZATION SAFETY REVIEW: HEPATITIS B VACCINE AND DEMYELINATING NEUROLOGICAL DISORDERS 1 (2002), *available at* http://www.nap.edu/catalog/10393.html.

122. 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, 324-25 (2007).

123. *See infra* notes 139-43 and accompanying text.

have caused the special masters to construct their own evidentiary guidelines.[124] But the Federal Circuit consistently rejects this self-guidance, reasoning that "[c]ausation in fact under the Vaccine Act is ... based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules."[125] In keeping with this view, the Federal Circuit has refused to promulgate evidentiary standards that would restrain special master discretion.[126] The result is case-by-case jurisprudence that is void of any cohesive explanation of what it takes to prevail within the Vaccine Program.

One explanation for the Federal Circuit's failure to promulgate evidentiary guidelines is the court's "highly deferential standard of review" of special master decisions,[127] namely, whether the decision was arbitrary and capricious.[128] The Federal Circuit "may not second-guess the special master's fact-intensive conclusions, particularly where the medical evidence of causation is in dispute."[129] In other words, the circuit court does not substitute its own unifying judgment simply because it disagrees with a special master's analysis.[130] For that reason, conflicting special master decisions may each survive the deferential appellate review process; special masters may reasonably disagree about what evidence is required

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124. *See infra* notes 132-38 and accompanying text.

125. Knudsen *ex rel.* Knudsen v. Sec'y of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); *cf.* Althen v. Sec'y of HHS, 418 F.3d 1274, 1281 (Fed. Cir. 2005).

126. Liable *ex rel.* Liable v. Sec'y of HHS, No. 98-120, 2000 U.S. Claims LEXIS 209, at *39 (Fed. Cl. Sept. 7, 2000) ("[T]he courts *reviewing* [Vaccine Act] special master decisions ... have *not* attempted to impose any particular analysis."); *see also* Doe *ex rel.* Doe v. Sec'y of HHS, 601 F.3d 1349, 1358 (Fed. Cir. 2010) ("As for what the special master may do, neither [the Vaccine Act] nor our cases limit what evidence the special master may consider in deciding whether a prima facie case has been established.").

127. Hines *ex rel.* Sevier v. Sec'y of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

128. *See supra* notes 91-94 and accompanying text.

129. Hazlehurst *ex rel.* Hazlehurst v. Sec'y of HHS, 604 F.3d 1343, 1349 (Fed. Cir. 2010); *see also* Cedillo v. Sec'y of HHS, 617 F.3d 1328, 1338 (Fed. Cir. 2010) ("Our role is not to second guess the Special Master's fact-intensive conclusions, particularly in cases in which the medical evidence of causation is in dispute." (quotations and citation omitted)); *Doe*, 601 F.3d at 1356 ("It is not our role to reweigh the factual evidence or assess whether the special master correctly evaluated the evidence."); Munn v. Sec'y of HHS, 970 F.2d 863, 871 (1992) ("Clearly it is not ... the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence.").

130. *See Hazlehurst*, 604 F.3d at 1349 ("If the special master has considered the relevant evidence of record, drawn plausible inferences, and articulated a rational basis for the decision, 'reversible error will be extremely difficult to demonstrate.'" (quoting *Hines*, 940 F.2d at 1528)); *see also Liable*, 2000 U.S. Claims LEXIS 209, at *31-32.

to award petitioners damages, and neither decision may be so capricious that it warrants reversal. Indeed, the Act's legislative history makes clear that Congress intended review of a special master's decision to be an "extraordinary event."[131]

C. Inconsistent and Unpredictable Case Law

Regardless of the reason for the Federal Circuit's unwillingness to promulgate uniform evidentiary standards for Vaccine Act cases, the lack of such guidance produces troubling consequences: nothing binds special masters to use the same evidentiary standards from case to case. "For the most part, case outcome is determined by the weighing of the substantive evidence presented against the *particular* evidentiary standard employed—*this standard frequently varies between the individual special masters and even between decisions by the same special master*."[132] Because the Federal Circuit has not promulgated a uniform evidentiary framework, special masters are free to continue this practice.[133]

As one example of the Vaccine Program's case-by-case jurisprudence, consider *Cucuras v. Secretary of Health & Human Services*.[134] In *Cucuras*, the court affirmed a special master's finding that the diphtheria, tetanus, and pertussis vaccine cannot—and did not—cause chronic encephalopathies.[135] In reaching that decision, the special master found that an Institute of Medicine (IOM) report was more persuasive than the conflicting expert testimony of Dr. Mark R. Geier.[136] One year later, *the same special master* reached the exact opposite conclusion, finding Dr. Geier's testimony to be more persuasive than the IOM report.[137] *Both* decisions were affirmed on appeal.[138]

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131. Piper *ex rel.* Piper v. Sec'y of HHS, 29 Fed. Cl. 628, 632 (1993).

132. Stevens v. Sec'y of HHS, No. 99-594, 2001 U.S. Claims LEXIS 67, at *35 (Fed. Cl. Mar. 30, 2001).

133. *See id.* at *41. The *Stevens* decision was particularly concerned with the special masters' inconsistent approaches to circumstantial evidence. *See, e.g.*, *id.* at *43-50 & n.25 (epidemiologic studies); *id.* at *53-54 (animal studies); *id.* at *53 & n.32 (case reports).

134. 26 Cl. Ct. 537 (1992).

135. *See id.* at 543.

136. *See id.* at 545-46.

137. Estep *ex rel.* Estep v. Sec'y of HHS, 28 Fed. Cl. 664, 668-69 (2003).

138. *Id.* at 669 ("[T]he variety of conclusions reflects the complexities of fact finding in vaccine cases ... and differences in proof offered in each case.").

Put simply, Vaccine Act jurisprudence lacks a clear statement regarding what amount, type, or quality of evidence plaintiffs must provide to satisfy the preponderance standard.[139] This void has produced unpredictable—and even contradictory—case law.[140] In *Stevens v. Secretary of Health & Human Services*, the chief special master correctly described such inconsistencies as an "inequity" stemming from a variety of legal standards that "special masters employ *in the absence of clear causation criteria*."[141] He continued:

> The special masters' efforts to create standards for evaluating circumstantial evidence have not fared well. The difficulties stem largely from the less scientific, more clinical, nature of the evidence submitted. *The special masters want petitioners to present a claim rooted in scientific or medical principles*, ... but the court is not wholly convinced of *how* that is successfully effected when petitioners can only rely on circumstantial evidence. *There simply exists no consensus about what circumstantial evidence, if any, sufficiently supports petitioner's claim*. The result is confusing and inconsistent standards.[142]

In other words, because the special masters lack uniform standards by which to interpret, analyze, and weigh complex scientific evidence, their decision making is unpredictable, inconsistent, and unjust—three words that should never be affiliated with the American legal system.[143]

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139. Stevens v. Sec'y of HHS, No. 99-594, 2001 U.S. Claims LEXIS 67, at *89 (Fed. Cl. Mar. 30, 2001); *see also* Little, *supra* note 111, at 373.

140. *See* James B. Currier, *Too Sick, Too Soon?: The Causation Burden Under the National Vaccine Injury Compensation Program Following* De Bazan v. Secretary of Health & Human Services, 19 FED. CIR. B.J. 229, 238 (2009) ("[T]he variance displayed by the special masters generates tension within the compensation program by reducing consistency across cases." (citing Little, *supra* note 111, at 361)); *see also Stevens*, 2001 U.S. Claims LEXIS 67, at *41, *46.

141. *Stevens*, 2001 U.S. Claims LEXIS 67, at *49; *see also id.* at *51 ("Not surprisingly, the petitioners' use of [circumstantial] evidence is met with varying success *depending on the particular evaluative standard the special master utilizes*.") (emphasis added).

142. *Id.* at *72 (emphasis added).

143. *See id.* at *41.

D. A Unique Need for Evidentiary Guidance

The lack of substantive evidentiary standards for achieving compensation within the Vaccine Program is particularly troublesome because of the nature of evidence that special masters must weigh. In a single case, they may have to scrutinize clinical evaluations, lab reports, and expert opinions that span numerous scientific disciplines.[144] As one extreme example, consider the general causation hearing on the allegation that the MMR vaccine causes childhood autism. Three special masters presided over three trials in which evidence used by one plaintiff could be used by the other two.[145] According to one presiding special master:

> The record contains about 7,700 pages of Michelle Cedillo's medical records alone. The parties filed a total of 23 expert reports in this *Cedillo* case alone, and a total of 50 expert reports including the *Hazlehurst* and *Snyder* cases. During the evidentiary hearings, 16 expert witnesses testified in *Cedillo*, four in *Hazlehurst*, and eight in *Snyder*. The hearing transcripts totaled 2,917 pages in *Cedillo*, 1,049 pages in *Snyder*, and 570 pages in *Hazlehurst*. The parties filed six post-hearing briefs in this *Cedillo* case alone, totaling 462 pages.[146]

The expert witnesses in these three cases came from fields such as molecular biology,[147] medical toxicology,[148] pediatric immunology,[149]

144. *See* Moreno, *supra* note 61, at 1532 ("Federal Vaccine Court cases involve thorough and detailed judicial explorations of complex scientific evidence."); Ridgway, *supra* note 75, at 68 ("Except in the most straightforward cases, [Vaccine Program] claims are routinely accompanied by offers of expert testimony in support of the claimed causation."); Waldenberg & Wallace, *supra* note 122, at 324 (reporting that 59 percent of plaintiffs filed medical literature to support their claims, and stating that "[u]nquestionably, expert testimony plays an enormous role in vaccine cases, and almost all petitioners offer some form of expert testimony").

145. The plaintiffs litigated this causation theory in three different cases; the evidence submitted in any one case could be used by either party in the other two cases. *See* Cedillo *ex rel.* Cedillo v. Sec'y of HHS, No. 98-916, 2009 U.S. Claims LEXIS 146 (Fed. Cl. Feb. 12, 2009); Hazlehurst *ex rel.* Hazlehurst v. Sec'y of HHS, No. 03-654, 2009 U.S. Claims LEXIS 183 (Fed. Cl. Feb. 12, 2009); Snyder *ex rel.* Snyder v. Sec'y of HHS, No. 01-162, 2009 U.S. Claims LEXIS 193 (Fed. Cl. Feb. 12, 2009).

146. *Cedillo*, 2009 U.S. Claims LEXIS 146, at *46-47.

147. *Id.* at *58.

148. *Id.* at *60.

149. *Id.* at *90.

microbiology,[150] virology,[151] pediatric neurology,[152] and gastroenterology.[153] The three presiding special masters each had to weigh and scrutinize *all* of this evidence in reaching their decisions.

In sum, Vaccine Program cases involve a unique level of complex —and often novel—medical evidence and expert testimony. Without uniform guidance for how to examine this evidence, special masters use varying legal standards to decide cases, and issue inconsistent opinions about the merits of similar claims.[154] In other words, a plaintiff's success within the Vaccine Program does not fully depend upon the strength or reliability of her evidence. Instead, her success depends upon which evidentiary standard a special master chooses to apply in her case.

IV. *DAUBERT*'S TREATMENT IN VACCINE ACT LITIGATION

Because the Vaccine Act, Vaccine Rules, and Federal Circuit precedents all fail to provide a clear legal calculus for special masters to use when evaluating evidence, many special masters have turned for guidance to the U.S. Supreme Court's seminal decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[155] This reliance, however, has been problematic because *Daubert* interpreted Federal Rule of Evidence 702. That rule does not apply to the Vaccine Program.[156]

Nonetheless, Part V of this Note argues that *Daubert* or *Daubert*'s analytical framework should be binding precedent on Vaccine Act litigation—whether expressly adopted by an appellate court or legislated by Congress. The *Daubert* line of cases provides a well-developed body of law that includes clear guidelines for how judges should evaluate scientific evidence.[157] *Daubert* is thus a readily accessible judicial tool that can fill a problematic void in the Vaccine Program.

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150. *Id.* at *99.
151. *Id.* at *287.
152. *Id.* at *223.
153. *Id.* at *360-66.
154. *See id.* at *41-42.
155. 509 U.S. 579 (1993).
156. *See infra* Part IV.B.
157. *See infra* note 161 and accompanying text.

A. The Supreme Court's Focus on Reliable Science

The question presented in *Daubert* was whether Federal Rule of Evidence 702 superseded the *Frye* test and thus governed the admissibility of expert evidence in federal courts.[158] After answering affirmatively, the Court reasoned that Federal Rule of Evidence 702 obligated federal trial court judges to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."[159] As a threshold matter, trial judges should exclude expert testimony that is not based on reliable science or will not assist the jury with determining a fact in issue.[160]

To assist judges in making these exclusionary determinations, the Court outlined components of "good science": (1) whether the theory or technique can be or has been tested; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) the technique's known or potential error rate; and (4) the level of the theory or technique's acceptance within the relevant discipline.[161] These four factors are a flexible framework. *Daubert* did not "hand judges a step-by-step guide to applying scientific principles."[162] It did, however, make clear that junk science has no place in the courtroom.[163]

The Court's *Daubert* jurisprudence has clarified that expert opinion testimony must be connected to reliable science by more

158. Before Congress enacted the Federal Rules of Evidence, many federal courts followed *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), and determined the admissibility of scientific evidence by looking exclusively at its "general acceptance" within the scientific community.

159. *Daubert*, 509 U.S. at 589.

160. *Id.* at 592-93; *see also Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481, 1556 (1995).

161. *Daubert*, 509 U.S. at 593-94; *cf.* HUBER, *supra* note 3, at 228 (arguing that the "best test of certainty" in "good science" is "the science of publication, replication, ... verification, ... consensus[,] and peer review"). *Daubert* thus relegated *Frye*'s "general acceptance" inquiry into just one of several factors that determine admissibility. *See Daubert*, 509 U.S. at 589 ("*Frye* made 'general acceptance' the exclusive test for admitting expert scientific testimony. That austere standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials."); *cf. supra* note 158.

162. *Confronting the New Challenges of Scientific Evidence*, *supra* note 160, at 1556-57.

163. Notably, Congress amended Federal Rule of Evidence 702 in 2000 to codify the *Daubert* framework. FED. R. EVID. 702 advisory committee's note ("Rule 702 has been amended in response to *Daubert*.").

than "the *ipse dixit* of the expert."[164] Trial courts should thus focus on the evidence itself, not merely the witness's conclusions derived from that evidence:[165] "Evaluation of the reliability of an expert's opinion ... depends in part on the size of the gap between the scientific data and the opinion proffered."[166] In other words, reliable expert *testimony* is rooted in reliable scientific *evidence*. If an expert's opinion strays too far from the legitimate science on which it relies, trial courts should exclude the testimony accordingly.[167]

B. Daubert *Without the Federal Rules of Evidence?*

"The facts at issue and the issue presented in *Daubert* dealt specifically with the Federal Rules of Evidence,"[168] which are not germane to Vaccine Act litigation.[169] For that reason, *Daubert*'s applicability could be limited to only court proceedings that follow the Federal Rules of Evidence.[170] Indeed, some Vaccine Act plaintiffs' attorneys have expressly adopted such a position, and argued that special masters should "explicitly dismiss[]" the notion that *Daubert*'s substantive criteria apply to the Vaccine Program.[171]

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164. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997); *see also* Liquid Dynamics Corp. v. Vaughan Co., 449 F.3d 1209, 1220 (Fed. Cir. 2006); Margaret A. Berger, *Expert Testimony: The Supreme Court's Rules*, ISSUES SCI. & TECH., Summer 2000, at 57.

165. ERICA BEECHER-MONAS, EVALUATING SCIENTIFIC EVIDENCE 11 (2007).

166. Doe *ex rel.* Doe v. Sec'y of HHS, 2010 U.S. Claims LEXIS 581, at *29 (Fed. Cl. July 26, 2010).

167. *See Joiner*, 522 U.S. at 146-47.

168. Garcia v. Sec'y of HHS, No. 05-0720, 2010 U.S. Claims LEXIS 390, at *31-32 (Fed. Cl. May 19, 2010). *Daubert* involved whether the Federal Rules of Evidence superseded *Frye*; *Joiner* involved what standard of review applied to evidence excluded under Rule 702; and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), involved what types of experts Federal Rule of Evidence 702 encompassed. *See also* Libas, Ltd. v. United States, 193 F.3d 1361, 1366 (Fed. Cir. 1999) ("*Daubert* and *Kumho* were decided in the context of determining standards for the admissibility of expert testimony under the Federal Rules of Evidence.").

169. *See infra* notes 170-71, 176, 184-85 and accompanying text.

170. The Court has come close to limiting its holding in *Daubert* this way. *See Joiner*, 522 U.S. at 149 (Breyer, J., concurring); *cf.* Estep *ex rel.* Estep v. Sec'y of HHS, 28 Fed. Cl. 664, 668 n.2 (1993).

171. PSC Reply Brief Regarding General Causation Hearing at 7, *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder, or a Similar Neurodevelopmental Disorder (Fed. Cl. Feb. 26, 2007), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/psc%20reply%202%2026%2007.pdf; *see also* Cedillo v. Sec'y of HHS, 617 F.3d 1328, 1338 (Fed. Cir. 2010) ("Petitioners assert that the Special Master used an incorrect legal standard to determine causation, in particular, they assert that the Special Master erred in using the *Daubert* standard to judge the reliability of the expert testimony."); *cf.* Sanders, *supra* note

But the evidentiary and public policy concerns of *Daubert*—and indeed the Federal Rules of Evidence—exist with incredible force within the Vaccine Program. Every case involves a question of complex medical causation, and the perils of relying on junk science in answering these questions are nascent and severe.[172] Few court proceedings have a more pressing need to ensure that their legal decisions are "justly determined"[173] and based on reliable science.[174] If *Daubert*'s evidentiary principles should apply to *any* science-based court proceedings, it should be those within the Vaccine Program.[175]

C. Federal Circuit Inconsistency

The Federal Circuit has never adopted *Daubert* as a binding precedent within the Vaccine Program. Indeed, much of the circuit's jurisprudence actually contradicts *Daubert*'s admonition that courts should objectively evaluate the reliability of proposed scientific theories.[176]

The first Federal Circuit opinion to mention *Daubert* in the context of the Vaccine Act was the dissent in *Hodges v. Secretary of Health & Human Services*.[177] In *Hodges*, the majority affirmed a special master's finding that a diphtheria-pertussis-tetanus vaccination did not cause a child's death, even though she died less than four hours after receiving the shot.[178] Judge Newman's dissent argued that the special master's opinion did not comply with the "principles and methodology" delineated in *Daubert*, and that it

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8, at 1394 n.116 (2010) (describing a discussion at a Court of Federal Claims conference in 2008 where "[a] number of attorneys from the petitioners' bar argued for a relaxed standard of causation").

172. *See supra* Part I.C.

173. *Joiner*, 522 U.S. at 149 (Breyer, J., concurring) (quoting FED. R. EVID. 102).

174. *See* CRANOR, *supra* note 4, at 49-51 (discussing the policy considerations underlying *Daubert*).

175. For a discussion of *Daubert*'s applicability to federal regulatory proceedings—another legal process not governed by the Federal Rules of Evidence—see generally Paul S. Miller & Bert W. Rein, *"Gatekeeping" Agency Reliance on Scientific and Technical Materials After* Daubert*: Ensuring Relevance and Reliability in the Administrative Process*, 17 TOURO L. REV. 297 (2000). *Cf.* Niam v. Ashcroft, 354 F.3d 652, 660 (7th Cir. 2004).

176. *See supra* note 111 and accompanying text.

177. 9 F.3d 958, 962 *passim* (Fed. Cir. 1993) (Newman, J., dissenting).

178. *Id.* at 959 (majority opinion).

should be reversed accordingly.[179] To Judge Newman, *Daubert* was on point and controlling.[180] Not only was *Daubert* applicable to Vaccine Act cases, it was *binding precedent*.

No majority Federal Circuit opinion has followed Judge Newman's dissent and held that *Daubert* controls the evidentiary analyses of Vaccine Act litigation. The only case to come close was *Terran v. Secretary of Health & Human Services*.[181] There, the court rejected the plaintiff's argument that the special master erred by analyzing proffered expert testimony according to the *Daubert* framework.[182] Because "the Special Master's application of the *Daubert* factors [was] reasonable," the court refused to reverse the trial court decision for abuse of discretion.[183]

Terran never expressly stated that *Daubert* was binding precedent within the Vaccine Program. Nor did it authorize special masters to exclude unreliable evidence. The Federal Circuit went no further than to hold that the special master's use of *Daubert* was "reasonable."[184] *Daubert* was helpful, but it was neither binding nor determinative.[185]

Terran thus did little to solidify *Daubert* as the framework for evaluating scientific evidence and expert testimony within the Vaccine Program. But *even if* the decision is interpreted as establishing *Daubert* as binding precedent, the special masters are still

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179. *Id.* at 966 (Newman, J., dissenting).

180. *See, e.g.*, *id.* ("That it was incorrect to ignore the Hodges' medical experts' testimony and documentary evidence has been reinforced in *Daubert*."); *id.* at 968 ("The special master erred in failing to consider the epidemiologic evidence ... and in failing to exercise independent judgment upon the entirety of the evidence, applying the correct standard of proof."). *See generally* Bert Black, *The Supreme Court's View of Science: Has* Daubert *Exorcised the Certainty Demon?*, 15 CARDOZO L. REV. 2129, 2136-37 (1994) (discussing Judge Newman's dissent and her use of *Daubert*).

181. 195 F.3d 1302 (Fed. Cir. 1999).

182. *Id.* at 1316.

183. *Id.*; *see also* Hager v. Sec'y of HHS, No. 01-307, 2008 U.S. Claims LEXIS 421, at *43 (Fed. Cl. Oct. 15, 2008) ("Pursuant to *Terran*, which affirmed using *Daubert* in vaccine cases to evaluate an expert's theory, special masters are not required to accept an expert's theory merely because an expert himself said it.").

184. *Terran*, 195 F.3d at 1316.

185. *See* Cedillo v. Sec'y of HHS, 617 F.3d 1328, 1339 (Fed. Cir. 2010) ("It it thus quite clear that the *Daubert* factors *may* be used in vaccine cases.") (emphasis added); Moberly *ex rel.* Moberly v. Sec'y of HHS, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *cf.* David S. Caudill & Richard E. Redding, *Junk* Philosophy *of Science?: The Paradox of Expertise and Interdisciplinarity in Federal Courts*, 57 WASH. & LEE L. REV. 685, 711 (2000).

without guidance as to *how* they are to apply *Daubert*.[186] Can special masters exclude testimony? Can they apply *Daubert* to the testimony of a treating physician?[187] As the chief special master once commented: "Whatever guidance can be garnered from *Daubert*, without some additional direction on *how to evaluate* petitioner's clinical evidence from a legal perspective and *weigh* that evidence against the scientific evidence routinely offered by respondent, *the special masters are left to their own devices*."[188]

In *Stevens*, the chief special master attempted to provide such direction by adopting portions of *Daubert*'s analytical framework into a five-part test for determining what scientific evidence Vaccine Act plaintiffs must provide to receive compensation.[189] But the *Stevens* decision was never controlling law: no other special masters were bound to follow it and the case was never appealed. Regardless, in 2005, the Federal Circuit issued *Althen v. Secretary of Health & Human Services*, which held that "the *Stevens* test was contrary to law."[190]

D. What About Althen*?*

Althen never mentioned *Daubert*. Nor did it "address the Chief Special Master's overarching concern [in *Stevens*] that there are no evidentiary standards for the Special Masters to follow when

186. *Cf.* Stevens v. Sec'y of HHS, 2001 U.S. Claims LEXIS 67, at *63-64 (Fed. Cl. Mar. 30, 2001).

187. *Cf. id.* at *65-68.

188. *Id.* at *68 (emphasis added).

189. Under *Stevens*, plaintiffs must prove (1) medical plausibility, (2) "confirmation of medical plausibility from the medical community and literature," (3) "an injury recognized by the medical plausibility evidence and literature," (4) "a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury," and (5) "the elimination of other causes." *Id.* at *91-108.

190. 418 F.3d 1274, 1281 (Fed. Cir. 2005); *see also* Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (stating that the *Stevens* test "impermissibly raise[d] a claimant's burden under the Vaccine Act"). This Note does not mean to suggest that this limited holding—that *Stevens* was contrary to law—is erroneous. *Althen* correctly held that the role of special masters is "not to craft a new legal standard." *Althen*, 418 F.3d at 1281. The point is simply that the chief special master felt compelled to create the test in the first place because he—and the other special masters—lacked sufficient statutory and jurisprudential guidance for how to determine whether petitioners should receive compensation under the Vaccine Act. Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 450 & n.182 (2007).

evaluating circumstantial evidence in causation-in-fact cases."[191] Instead, the Federal Circuit outlined the current three-part test for determining whether plaintiffs satisfied the Vaccine Act's preponderance standard. According to *Althen*, plaintiffs must provide: "(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."[192]

A few things about the *Althen* test are worth highlighting. First, it does not resolve any of the uncertainty regarding the Vaccine Program's evidentiary standards that the chief special master attempted to address in *Stevens*.[193] The *Althen* test is simply a way to interpret what "preponderance of the evidence" means—it does not explain the nature or quality of evidence plaintiffs must provide to satisfy their burden.[194]

Second, the *Althen* test specifically rejects *Stevens*'s requirement —adopted from *Daubert*—that plaintiffs provide "*objective confirmation*" that a vaccine is associated with an alleged injury.[195] *Althen* does not require plaintiffs to submit published medical articles, evidence of general acceptance, or scientific testing.[196] Indeed, the *Althen* plaintiff alleged that her tetanus toxoid vaccine caused a loss of vision, which the Federal Circuit acknowledged was "a [causal] sequence *hitherto unproven in medicine*."[197] Nonetheless, the Federal Circuit upheld the lower court's decision awarding compensation.[198]

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191. Strong, *supra* note 190, at 450.

192. *Althen*, 418 F.3d at 1278.

193. Strong, *supra* note 190, at 450-51; *cf.* Garcia v. Sec'y of HHS, No. 05-0720, 2010 U.S. Claims LEXIS 390, at *32 (Fed. Cl. May 19, 2010) ("[T]he Federal Circuit's opinions in *Althen*, *De Bazan*, *Pafford*, and *Shyface* do not primarily discuss threshold determinations of reliability.").

194. *See* Strong, *supra* note 190, at 451 (suggesting that the *Althen* test is "contrary to the plain language of the statute and to the court's own precedent") (footnote omitted).

195. *Althen*, 418 F.3d at 1279 (emphasis added).

196. *See id.* at 1279-80.

197. *Id.* at 1280 (emphasis added); *cf.* Knudsen *ex rel.* Knudsen v. Sec'y of HHS, 35 F.3d 543, 550 (Fed. Cir. 1994) (awarding compensation to a plaintiff although the epidemiological evidence suggested that a virus unrelated to the vaccine was the more likely cause of the child's encephalitis).

198. *Althen*, 418 F.3d at 1282.

Finally, the *Althen* test invites plaintiffs to bring suit based on tautological theories of causation. The first prong requires plaintiffs to present a medical *theory*.[199] To satisfy the second prong, plaintiffs must prove that their *theory* is logical.[200] And under the third prong, plaintiffs must show that their injury occurred within the appropriate time frame, *which their theory provides*.[201] In other words, plaintiffs can craft their causation theories based on their own medical histories without having to demonstrate objective support for those theories.[202] So long as the proposed theory is "logical," the plaintiff prevails.

The *Althen* test, therefore, does not resolve the Vaccine Program's need for uniform evidentiary guidelines. In fact, it moved the case law *away* from a standard that embraces reliable science.[203] At bottom, the test requires plaintiffs to prove only that they have a logical theory—a "proposed explanation"[204]—of causation. Plaintiffs do not have to prove that their theory is based on reliable science or that it is generally accepted in the relevant medical communities.[205] Nor do plaintiffs have to provide epidemiologic studies, pathological markers, or any other empirical medical basis to prove causation.[206]

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199. *Id.* at 1278. In subsequent cases, the Federal Circuit refers to this prong as requiring a "biologically plausible" theory of causation. *See, e.g.*, Andreu *ex rel.* Andreu v. Sec'y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009). Notably, "plausible" is defined as "*[s]eemingly* or apparently valid, likely, or acceptable; credible" or "[g]iving a *deceptive impression* of truth or reliability." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1346 (4th ed. 2000) (emphasis added).

200. *Althen*, 418 F.3d at 1278; *see* Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

201. *Althen*, 418 F.3d at 1278.

202. The Federal Circuit essentially conceded this point when it later held that the same evidence could establish multiple *Althen* prongs. *Capizzano*, 440 F.3d at 1326.

203. *Cf.* Currier, *supra* note 140, at 238 (stating that *Althen* "decreased the amount of specialized medical knowledge necessary to prevail on a claim"); Wendy N. Davis, *The Immune Response*, A.B.A. J., Oct. 2010, at 48, 52 ("[I]n a move that seemed to give vaccine court plaintiffs a considerable boost, the Federal Circuit relaxed the causation standard in 2005 in [*Althen*].").

204. Broekelschen v. Sec'y of HHS, No. 07-137, 2009 U.S. Claims LEXIS 137, at *60 (Fed. Cl. Feb. 4, 2009); *see also* Pecorella v. Sec'y of HHS, No. 04-1781, 2008 U.S. Claims LEXIS 407, at *11 (Fed. Cl. Sept. 17, 2008).

205. *See Capizzano*, 440 F.3d at 1325; *see also* Andreu *ex rel.* Andreu v. Sec'y of HHS, 569 F.3d 1367, 1379 (Fed. Cir. 2006) ("[A] paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery.").

206. *See Capizzano*, 440 F.3d at 1325; *cf. Andreu*, 569 F.3d at 1379 ("[A] claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act.").

Indeed, Vaccine Act plaintiffs can prevail without providing *any* objective scientific or medical evidence.[207]

In short, the Federal Circuit's *Althen* decision not only failed to address the Vaccine Program's evidentiary problems, it made them worse.[208] Special masters still lack an analytical framework within which to weigh scientific evidence, and they still lack a clear answer as to whether—and how—*Daubert* applies to Vaccine Act litigation.

E. A Final Example

As an example of the continued lack of evidentiary clarity within—and *Daubert*'s applicability to—the Vaccine Program, consider *Cedillo v. Secretary of Health & Human Services*.[209] There, the government filed four motions *in limine* to exclude the opinions of four of the plaintiff's expert witnesses.[210] These motions argued that the special master should evaluate the reliability of the experts' testimony within the *Daubert* analytical framework.[211]

The special master denied the government's motions and issued an order that cited only two cases: *Daubert* and *Terran*.[212] According to the special master, *Terran* "made quite clear" that *Daubert* "does have application to Vaccine Act cases."[213] But other than *Terran*, the

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207. *See* Waldenberg & Wallace, *supra* note 122, at 325 tbl.2 (reporting that plaintiffs who alleged that a vaccine caused a demyelinating disease were successful 35 percent of the time when they did not provide *any* medical literature as evidence to bolster their claims); *id.* at 324 ("[It is a] fact that neither an expert nor medical literature is a definite prerequisite to a successful vaccine claim.").

208. After *Althen*, the Federal Circuit clarified that a plaintiff's theory of causation "must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (quoting Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Other than stating that plaintiffs may use "relevant scientific data" to establish their causal theories as reputable, the court has never clarified what "reputable" means. *Id.* at 1380. Regardless, it is difficult to synthesize this "reputable" requirement with the Federal Circuit's other precedent, which specifically held that requiring general acceptance in the medical or scientific community—one way of determining whether a theory is reputable—"impermissibly raises a claimant's burden under the Vaccine Act." *Capizzano*, 440 F.3d at 1325-26.

209. No. 98-916, 2009 U.S. Claims LEXIS 146 (Fed. Cl. Feb. 12, 2009).

210. *See* Order Denying Motions for Exclusion of Expert Testimony at 1, *Cedillo*, 2009 U.S. Claims LEXIS 146 (No. 98-916), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Order%20Denying%20Untitled.pdf [hereinafter *Cedillo* Order].

211. *See id.* at 1.

212. *Id.*

213. *Id.*

special master was without guidance. He *could* apply *Daubert*, but it was unclear how.

Because he lacked direction from the Federal Circuit, the special master resolved his confusion based entirely on his own reasoning.[214] He initially noted that, "in [his] view, application of the [*Daubert*] reliability test can be procedurally different in jury vs. non-jury proceedings."[215] In a jury trial, the judge is obligated to prevent unreliable science from reaching the jury.[216] A bench trial, however, is different.[217] According to the special master:

> In a non-jury context ... I can see two different reasonable procedures by which to test scientific testimony for reliability. First, the judicial factfinder—such as a special master in a Vaccine Act case—could elect, as in a jury case, to decide an exclusion motion *prior* to any trial. However, in my view the judicial factfinder may, alternatively, elect to hear the challenged expert testimony at the trial in the case, and, *then* apply the reliability test in deciding whether to *accord that testimony any weight*.[218]

Ultimately, the special master adopted the latter of these two approaches and denied the government's motions *in limine*.[219]

The *Cedillo* order provides an example of the continued confusion surrounding *Daubert*'s applicability to the Vaccine Program. Indeed, the special master's decision to *admit* the challenged expert testimony and *then* perform a *Daubert* analysis is contrary to subsequent Federal Circuit precedent. In *De Bazan v. Secretary of*

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214. *See id.* at 1-2. In this regard, the special master's decision is remarkably similar to the self-guidance described by the chief special master in *Stevens*. *See supra* notes 141-44 and accompanying text.

215. *Cedillo* Order, *supra* note 210, at 1 (emphasis omitted).

216. *Id.*

217. *Id.*

218. *Id.* at 1-2 (some emphasis omitted).

219. *Id.* at 2. The special master's decision to admit the challenged testimony and then weigh its probative value is consistent with the approach embraced by other judges overseeing bench trials in conventional civil litigation. *See infra* notes 282-88 and accompanying text. But the approach also has significant setbacks, such as inefficiency. *See* G. Michael Fenner, *The* Daubert *Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 CREIGHTON L. REV. 939, 985-86 (1996); *cf.* Bradley v. Brown, 42 F.3d 434, 438-39 (7th Cir. 1994) (providing an example of the extensive examinations courts may complete to comply with the *Daubert* framework).

Health & Human Services, the court concluded that *Daubert* applied to Vaccine Act cases only when the special master *excludes* expert evidence.[220] Thus, because the special master in *De Bazan* had admitted and then weighed expert evidence, *Daubert* did not apply.[221] The *De Bazan* court provided no reasoning to support this conclusion.

Other special masters have taken a different evidentiary approach than the special master did in *Cedillo*. In *Veryzer v. Secretary of Health & Human Services*, for example, the government moved *in limine* to exclude two expert witness reports, arguing that they could not survive *Daubert* scrutiny.[222] The special master analyzed the reports, found them to be unreliable, and excluded them from the case.[223] But he did not rely upon *Daubert* to justify this exclusionary decision.[224] Instead, the special master relied upon his *discretion*: "the statutory language [of the Vaccine Act] grants a degree of discretionary latitude—bounded by right reason—in deciding whether to exclude evidence."[225] This discretion, he reasoned, means that all evidence is presumptively admissible, but may be barred if a special master finds "good cause" for exclusion.[226] Put another way, special masters "*qua* legal arbiter[s]" may use their expansive discretion to act as gatekeepers of expert testimony.[227] That gatekeeping power derives from—and is informed by—the Vaccine Act itself.[228] *Daubert* might be a helpful precedent,

220. 539 F.3d 1347, 1352 n.4 (Fed. Cir. 2008).

221. *Id.*

222. No. 06-0522, 2010 U.S. Claims LEXIS 375, at *1-2 (Fed. Cl. June 15, 2010).

223. *Id.* at *90-91 ("Neither [expert] should be permitted to waste the Court's (or counsel's) time at a hearing held merely to endure testimony that is patently unreliable.").

224. *Id.* at *65.

225. *Id.* at *64.

226. *Id.* at *65; *see also id.* at *66 ("Whereas, under the Federal Rules of Evidence, evidence is excluded until it is specifically admitted for consideration by the factfinder, practice in the Vaccine Program is inclusive, such that materials filed are presumed admitted unless grounds are presented by specific motion to exclude them." (citing 42 U.S.C. § 300aa-13(b) to (c) (2006))).

227. *Id.* at *65.

228. *See id.* at *69 ("[G]iven the fact that the Court must eschew unreliable evidence, and given that the Court has been granted by statutory provision the authority to exclude unreliable evidence, the Court states the conclusion that it may exclude unreliable evidence where the Court is persuaded to a preponderance that it is unreliable.").

but it does not directly affect the role, responsibility, or power of special masters.[229]

In sum, it is not clear whether—and how—*Daubert* applies to the Vaccine Program. The Federal Circuit's lack of guidance on this point is especially remarkable because it has held that the Court of International Trade, which also does not use the Federal Rules of Evidence, committed *reversible error* when it failed to perform a *Daubert* analysis in determining the proper classification of a fabric.[230] If *Daubert*'s principles should apply in a case involving imported textiles, the Federal Circuit should be equally demanding in cases involving the much more significant public health issue of whether a vaccine caused harm.

V. APPLYING *DAUBERT* TO THE VACCINE PROGRAM

The *Daubert* line of cases provides a well-developed legal framework within which judges scrutinize complex medical evidence and expert testimony. Such evidentiary guidance is missing from—but greatly needed in—the Vaccine Program. It is time to stop the "[l]et-it-all-in"[231] evidentiary approach of Vaccine Act litigation, which allows junk science to influence special master decision making and threatens the stability of our country's immunization policies. It is time to apply *Daubert* to the Vaccine Program.

The easiest way to accomplish this objective is for the Federal Circuit or the U.S. Supreme Court to declare unequivocally that *Daubert* is binding precedent on Vaccine Act litigation, thereby giving special masters guided authority to exclude unreliable evidence and testimony from their courtrooms. But such a declara-

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229. In a prior case, the *Garcia* special master reasoned that *Daubert* "in the strictest sense" was inapplicable because the Federal Rules of Evidence do not apply to the Vaccine Program. Garcia v. Sec'y of HHS, No. 05-0720, 2010 U.S. Claims LEXIS 390, at *24 n.10 (Fed. Cl. May 19, 2010). At best, he reasoned, *Daubert* is a precedent from which it was "appropriate to extrapolate and analogize, through the operation of inductive and deductive logic ... but that is not the same as applying a specific holding that is mandatory authority." *Id.*

230. Libas, Ltd. v. United States, 193 F.3d 1361, 1366, 1369 (Fed. Cir. 1999). *See generally* Miller & Rein, *supra* note 175, at 308-11 (discussing *Libas*'s interpretation of *Daubert* within the context of administrative law).

231. HUBER, *supra* note 3, at 3 (stating that "'[l]et-it-all-in' legal theory creates the opportunity" for junk science to enter the court system).

tion may require these appellate courts to act outside the strict limits of their constitutionally defined powers. After all, *Daubert* resolved a specific question about Federal Rule of Evidence 702,[232] so applying its evidentiary framework to litigation that is *not* governed by the Federal Rules would require an ambitious extension of precedent that may violate core principles of judicial restraint. This concern, however, has not stopped the Federal Circuit from treating *Daubert* as binding precedent in other litigation not governed by the Federal Rules.[233]

Regardless, the better alternative is for Congress to amend section 12(d) of the Vaccine Act and make *Daubert*'s evidentiary framework binding upon special masters. For ease of draftsmanship, this statutory fix could closely parallel the current version of Federal Rule of Evidence 702, which essentially codifies *Daubert*'s multifactor analysis[234]:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[235]

By changing the words "trier of fact" to "special master" and inserting this text into section 12(d) of the Vaccine Act, Congress will provide special masters with "a specific, judicially manageable standard for assessing reliability."[236] Moreover, the special masters could use nearly twenty years of *Daubert* jurisprudence as persuasive authority.[237] The statutory amendment, therefore, would give

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232. *See supra* notes 158-60 and accompanying text; *see also supra* notes 168-74 and accompanying text.

233. *See supra* note 230 and accompanying text.

234. *See supra* note 163.

235. FED. R. EVID. 702.

236. Paul A. Rodrigues, *Toward a New Standard for the Admission of Expert Evidence in Illinois: A Critique of the* Frye *General Acceptance Test and an Argument for the Adoption of* Daubert, 34 S. ILL. U. L.J. 289, 310 (2010).

237. *Cf.* Mark R. Nash, *Are We There Yet?: Gatekeepers,* Daubert*, and an Analysis of* State v. White, 61 S.C. L. REV. 897, 911-12 (2010) (arguing that South Carolina should amend its

special masters both the practical *legal tools* to improve the reliability of evidence admitted in Vaccine Program cases and also an informative *support system* of precedent to use when special masters are uncertain about how to use these new tools.[238]

No matter which branch of government implements *Daubert* or its principles, the result would be the same: special masters and reviewing courts will finally have uniform evidentiary standards by which to decide Vaccine Act cases. This guidance will restrain judicial discretion, produce more consistent case law, and, most importantly, ensure that reliable science underlies all decisions causally connecting immunizations with harm. Put another way, *Daubert* will help the Vaccine Program do what it was designed to do: stabilize the intersection of law and science, and safeguard the country's immunization policies.

A. Special Master Expertise

Because they preside over only vaccine injury cases, special masters are uniquely equipped to perform *Daubert*'s gatekeeping function. Special masters possess an exceptional familiarity with scientific and medical evidence that few judges can equal—especially if that evidence involves vaccines. One survey of state trial court judges, for example, found that only 6 percent properly understood the scientific meaning of falsifiability—a key principle used to assess the merits of scientific evidence and testimony.[239] The

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rules of evidence and civil procedure to adopt *Daubert*'s admissibility standards because doing so "would open up a significant body of case law for litigants to apply in state courts .... [and] provide insight on facts and circumstances that are important in determining the admissibility of an expert").

238. Another option for incorporating *Daubert*'s framework into Vaccine Act jurisprudence is for the Court of Federal Claims, in conjunction with the Office of Special Masters, to add Federal Rule of Evidence 702 to the Vaccine Rules. *See supra* notes 100-01 and accompanying text. After all, the Act does not place defined limits on the Court of Federal Claims' ability to promulgate or amend the Vaccine Rules. *See supra* notes 100-01 and accompanying text. Reason suggests, however, that the Court of Federal Claims cannot simply amend the Vaccine Rules in a way that overrules—or circumvents—Federal Circuit precedent. Thus, because the Federal Circuit refuses to accept encumbrances on special master discretion, such an amendment to the Vaccine Rules likely would be invalid. *See supra* notes 125-27 and accompanying text.

239. Sophia I. Gatowski et al., *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-*Daubert *World*, 25 LAW & HUM. BEHAV. 433, 444-45, 445 fig.1 (2001).

authors of that study questioned whether judges could properly administer the *Daubert* criteria, given their "lack of sophistication" regarding important principles of scientific validity.[240]

In contrast to the typical generalist trial court judge, special masters preside over only Vaccine Act claims. They are a "group of specialists"[241] who have the "unique ability"[242] to decide vaccine injury cases in light of their experience and "expertise."[243] As such, their judgments on the reliability—and admissibility—of scientific evidence are more refined than those of the typical trial judge.[244] Special masters wrestle with principles of immunology, neurology, and toxicology every day;[245] they possess a sophisticated understanding of what is and is not good science—and, therefore, what should and should not be let into the courtroom.

For this reason, many of the typical criticisms of *Daubert* gatekeeping are inapplicable to Vaccine Act litigation. For example, some judges in traditional civil contexts may possess an incorrect understanding of how scientists reach reliable conclusions[246] and thus prevent experts from testifying for erroneous reasons.[247] In other words, poor implementation of *Daubert* can create improperly "high barriers for plaintiffs seeking access to trials."[248] The special masters' unique judicial skill set, however, significantly reduces the likelihood that they will implement the *Daubert* framework poorly.

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240. *Id.* at 453; *see also* Brandon L. Boxler, *Judicial Gatekeeping and the Seventh Amendment: How* Daubert *Infringes on the Constitutional Right to a Civil Jury Trial*, 14 RICH. J.L. & PUB. INT. (forthcoming 2011) (manuscript at 23-25), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1712832 (explaining why trial judges' *legal* sophistication does not necessarily equip them with sufficient *scientific* sophistication to administer the *Daubert* criteria properly).

241. Hodges *ex rel.* Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993).

242. Sword *ex rel.* Sword v. United States, 44 Fed. Cl. 183, 188 (1999) (stating that, "even more than ordinary fact-finders," the special masters have the "unique ability ... to adjudge cases in the light of their own acquired specialized knowledge and expertise").

243. *Id.*; *see also* Marks-Smith v. Sec'y of HHS, No. 08-723, 2009 U.S. Claims LEXIS 598, at *5 ("Special masters may use expertise accumulated from other cases.").

244. *See Hodges*, 9 F.3d at 961; *see also* JASANOFF, *supra* note 1, at 5.

245. *See supra* notes 147-53 and accompanying text.

246. *Cf.* NEIL VIDMAR & VALERIE P. HANS, AMERICAN JURIES 188 (2007) ("[M]ost judges are laypeople when it comes to understanding scientific procedures and interpreting statistical evidence.").

247. CRANOR, *supra* note 4, at 16. *See generally* Gatowski, *supra* note 239, at 452-55 (discussing the potential harms resulting from judges' misapplication of the *Daubert* guidelines).

248. CRANOR, *supra* note 4, at 17.

If the power of *Daubert*'s gatekeeping function can be safely placed in the hands of any judge, it is those of a special master.

B. Using Daubert *To Buttress Congressional Goals*

Congress intended the Vaccine Program to be an "expeditious and fair"[249] legal process that produced "swift, uncomplicated compensation"[250] for those injured by vaccines.[251] To further these goals, Congress provided that the traditional rules of discovery in federal civil actions would not apply to Vaccine Act proceedings.[252] Instead, Congress let principles of flexibility, expediency, and efficiency guide its creation of the Vaccine Program.[253]

It may seem that giving special masters the power to exclude evidence as *Daubert* gatekeepers would run contrary to these congressional goals. Admittedly, *Daubert* evidentiary battles have the potential to increase costs, cause delays, and create procedural hurdles to bringing cases to trial.[254] These pretrial evidentiary obstacles may create some inefficiencies, but they are no more inefficient than the *carte blanche* of modern day Vaccine Act evidentiary practice—not to mention the "score of other concerns associated with experts who lack a reliable basis for their opinion."[255] When special masters admit all scientific and expert testimony, regardless of its reliability, they prolong litigation, waste the judicial system's time and resources, and increase the likelihood of

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249. H.R. REP. NO. 99-908, at 12 (1986), 1986 U.S.C.C.A.N. 6344, 6353; *see also id.* at 4-7, 1986 U.S.C.C.A.N. at 6345-48.

250. *Id.* at 16, 1986 U.S.C.C.A.N. at 6357.

251. *Cf.* Hazlehurst *ex rel.* Hazlehurst v. Sec'y of HHS, 604 F.3d 1343, 1350 (Fed. Cir. 2010) ("Congress intended for the Vaccine Act to establish a compensation system that is 'fair, simple, and easy to administer.'" (quoting Knudsen *ex rel.* Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994))).

252. *See* Part II.C; *see also* H.R. REP. NO. 99-908, at 16, 1986 U.S.C.C.A.N. at 6357 ("In order to expedite the proceedings, the power of the Special Master is intended to replace the usual rules of discovery in civil actions in Federal courts.").

253. *See supra* notes 249-55 and accompanying text.

254. CRANOR, *supra* note 4, at 6-7. Even if applying *Daubert* to the Vaccine Program does increase costs, such an increase would not affect whether a plaintiff—or her attorney—brings suit to seek redress for her injuries. The Vaccine Act provides that special masters shall award reasonable attorneys' fees and other costs to plaintiffs, regardless of whether they ultimately prevail, provided that the lawsuit was brought in good faith. 42 U.S.C. § 300aa-15(e)(1) (2006).

255. David L. Faigman et al., *How Good Is Good Enough?: Expert Evidence Under* Daubert *and* Kumho, 50 CASE W. RES. L. REV. 645, 648-49 (2000).

issuing a scientifically erroneous decision.[256] Special masters currently have no formal legal mechanism for excluding unreliable junk science from their courtrooms: it all comes in.[257] That is the true inefficiency.[258]

Holding pretrial *Daubert* hearings will also "reduce[ ] the risk of evidentiary ambush arising from the late disclosure or nondisclosure of experts."[259] In one Vaccine Act case, for example, a special master accepted into evidence expert reports that were filed just four days before trial.[260] *Daubert* hearings would end such last-minute document dumps and "provide[ ] litigants with a preview of the strength of their opponents' cases, which may encourage settlement or support a motion to dismiss a weak case on summary judgment."[261]

1. A Move Toward Traditional Civil Litigation?

The lack of evidentiary standards within Vaccine Act jurisprudence also affects litigants, who lack guidance—even before the same special master[262]—regarding what evidence is necessary to

256. *Id.*

257. Indeed, one commentator has suggested that a "pseudo-science of 'vaccine-ology' has arisen" within the Vaccine Program. Scott, *supra* note 99, at 362 & n.114.

258. One recent Court of Federal Claims decision explained the allocation of evidentiary burden in the Vaccine Program as follows: "[U]nder the Federal Rules of Evidence, evidence is out unless and until it is brought in, whereas in the Vaccine Program, evidence is in unless and until it is put out." Veryzer v. Sec'y of HHS, No. 06-0522, 2010 U.S. Claims LEXIS 375, at *66 (Fed. Cl. June 15, 2010). Despite this presumption of admissibility, the *Veryzer* court reasoned that a special master may "act in a gatekeeping capacity," *id.* at *65, and "exclude unreliable evidence where the Court is persuaded to a preponderance that it is unreliable." *Id.* at *69. Giving special masters unguided gatekeeping authority, however, is not a complete solution to the problems described in Parts III.C and III.D. Although *Veryzer* authorizes special masters to exclude evidence, it does not explain *what standards* special masters must apply when making these exclusionary determinations. In other words, *Veryzer* gave special masters a gatekeeping power without providing binding, uniform guidelines for exercising that power. The court simply held that special masters may exclude "unreliable evidence," but did not explain what standards inform this reliability analysis. To some extent, then, *Veryzer* actually moved the Vaccine Act case law in the wrong direction: it increased special masters' already "overwhelming discretion" without remedying the Vaccine Program's troublesome lack of evidentiary guidelines to encumber this discretion. *See supra* Part III.A.

259. Schwartz & Silverman, *supra* note 117, at 259; *see also* Nash, *supra* note 237, at 913.

260. Cedillo *ex rel.* Cedillo v. Sec'y of HHS, 2009 U.S. Claims LEXIS 146, at *206-07 (Fed. Cl. Feb. 12, 2009).

261. Schwartz & Silverman, *supra* note 117, at 259.

262. *See supra* notes 134-38 and accompanying text.

prevail.[263] As a result, they strategically err on the side of submitting too much evidence, or resort to the better-defined evidentiary practices of traditional civil torts litigation. According to Chief Special Master Golkiewicz: "In the absence of clear guidance as to what proof is sufficient to establish a causation case, each case proceeds as a traditionally litigated case—that is, full blown litigation."[264] In other words, the lack of uniform evidentiary standards within the Vaccine Program directly undermines Congress's intent.[265] Indeed, within just three years of passing the Vaccine Act, Congress acknowledged that the compensation scheme was more formal and adversarial than originally intended.[266] As Representative Dan Burton stated in 2004, the Vaccine Program "was supposed to be nonadversarial[, but] it's become very adversarial."[267]

Daubert hearings and motions *in limine* may move the Vaccine Program closer to traditional civil litigation, which Congress sought to avoid,[268] but they will also move the Vaccine Program toward more certain evidentiary standards, more consistent case law, and, ultimately, more reliance on good science. To promote flexibility and informality, the Vaccine Program has sacrificed certainty and

263. *Cf.* Waldenberg & Wallace, *supra* note 122, at 309-10 ("Thus, with vaccine cases, where so much is unknown, it is extremely difficult to predict on which side the preponderance [of the evidence] will fall.").

264. Stevens v. Sec'y of HHS, No. 99-594, 2001 U.S. Claims LEXIS 67, at *25 (Fed. Cl. Mar. 30, 2001); *see also* Myron Levin, *Vaccine Injury Claims Face Grueling Fight; Victims Increasingly View U.S. Compensation Program as Adversarial and Tightfisted*, L.A. TIMES, Nov. 29, 2004, at A1.

265. *See Stevens*, 2001 U.S. Claims LEXIS 67, at *120-21; *see also* Strong, *supra* note 190, at 451.

266. H.R. REP. NO. 101-247, at 510 (1989), *reprinted in* 1989 U.S.C.C.A.N. 1906, 2236. *See generally* Scott, *supra* note 99, at 362 (describing the "contentious and even stingy" adversarial nature of modern Vaccine Act litigation).

267. Levin, *supra* note 264, at A20; *see also* Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J.L. & PUB. POL'Y 537, 578-79 (2010) (arguing that Vaccine Act litigation "has become increasingly adversarial" such that the goal of providing "fair and efficient adjudication of claims" has been brought into question).

268. *See* Knudsen *ex rel.* Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994) ("The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims.").

consistency—both of which are cornerstones of the American justice system.[269] Applying *Daubert* will put an end to those sacrifices.[270]

Indeed, other courts that apply *Daubert* have "successfully kept junk science out of federal product liability" and other types of cases where such evidence may otherwise have been admitted.[271] Post-*Daubert* judicial gatekeeping has helped to streamline the trial process and dismiss frivolous suits that lack reliable scientific support.[272] The Vaccine Program needs access to these institutional benefits. And giving special masters the power to dismiss a case before it goes to trial because the suit is based upon junk science will certainly be more efficient than giving every plaintiff her day in court with a handful of tautological medical theories and unreliable evidence.[273]

2. An Example of Inefficiency

The recent decision in *Snyder v. Secretary of Health & Human Services* provides a good example of the inefficiency that results from the open gate of the Vaccine Program's current evidentiary procedures.[274] There, plaintiffs introduced into evidence six expert reports and the expert testimony of Dr. Jeffrey Bradstreet on the theory that vaccines cause autism.[275] But according to the special master, Dr. Bradstreet's credentials were "less robust than [those of] most expert witnesses."[276] Even more troubling was the fact that "*two courts* [had] refused, based on *Daubert*, to permit him to testify as an expert witness in cases alleging that vaccines cause or contribute to [autism spectrum disorders]."[277]

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269. *See* Little, *supra* note 111, at 372; *cf. id.* at 373 ("The cost of achieving flexibility ... has been a lack of certainty.").

270. *Cf. id.* at 372 ("Uniform guidelines for evaluating evidence when determining causation in fact would foster more consistent results.").

271. Schwartz & Silverman, *supra* note 117, at 228.

272. *See* Mark Hansen, *Admissions Tests: Fewer Post-*Daubert *Federal Judges Allow Experts To Testify Without Limitation in Civil Trials, Study Finds*, 87 A.B.A. J. 28, 28 (2001); Peter Huber, *Fact Versus Quack*, FORBES, July 4, 1994, at 132.

273. *See supra* notes 199-207 and accompanying text.

274. 2009 U.S. Claims LEXIS 193 (Fed. Cl. Feb. 12, 2009).

275. *Id.* at *87.

276. *Id.* at *88; *cf. id.* at *669 ("Three well-qualified specialists examined Dr. Bradstreet's opinions ... and all disagreed with his ... conclusions.").

277. *Id.* at *88 (emphasis added); *see also* Redfoot *ex rel.* Redfoot v. B.F. Ascher & Co., No. C 05-2045 PJH, 2007 U.S. Dist. LEXIS 40002, at *39-40 (N.D. Cal. June 1, 2007) (excluding

So at least two traditional civil cases and one Vaccine Program case have addressed the theory that vaccines cause autism with plaintiffs submitting the proposed testimony of Dr. Bradstreet. The two courts that followed the Federal Rules of Evidence dismissed their cases on *Daubert* grounds *before* reaching trial.[278] The Vaccine Program case, however, admitted Dr. Bradstreet's reports and heard his testimony at trial.[279] Ultimately, all three courts reached the same conclusion: the Dr. Bradstreet evidence was unreliable. But only the special master had to sit through an entire trial before rendering her opinion; the two district court judges dismissed the complaint and moved on to the next case.

C. Daubert *Without Judicial Gatekeeping*

Many policy arguments underlying *Daubert* concern distrust of juries and the need for trial judges to prevent the jury from becoming confused with unreliable evidence.[280] This motivation for exclusion may not be as strong within the Vaccine Program, where all cases proceed as bench trials.[281] But "a court sitting as a finder of fact may not abandon its duty to scrutinize expert testimony under *Daubert*."[282] As the Seventh Circuit recently stated:

> It is not that evidence may be less reliable during a bench trial; it is that the court's gatekeeping role is necessarily different. Where the gatekeeper and the factfinder are one and the same—that is, the judge—the need to make such decisions prior to hearing the testimony is lessened. That is not to say that the

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Dr. Bradstreet's testimony because he was "not [a] percipient witness[ ]" about vaccines causing autism); Easter v. Aventis Pasteur, Inc., 358 F. Supp. 2d 574, 576-77 (E.D. Tex. 2005) (agreeing with the defendant and quoting its argument that "there is no scientifically recognized methodology by which Dr. Bradstreet could reliably [reach his conclusions]").

278. *See supra* note 277 and accompanying text.

279. *Snyder*, 2009 U.S. Claims LEXIS 193, at *89.

280. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993); *see also* Loeffel Steel Prods. v. Delta Brands, 372 F. Supp. 2d 1104, 1122 (N.D. Ill. 2005) ("[T]he Supreme Court's overriding concern in *Daubert* was with the problem of jury exposure to confusing and unreliable expert testimony.").

281. *See* 42 U.S.C. § 300aa-12(d)(3) (2006); *see also* Doe 93 v. Sec'y of HHS, 2010 U.S. Claims LEXIS 818, at *23 (Fed. Cl. Oct. 8, 2010) (explaining that, in the Vaccine Program, "special masters decide the case[s] without a jury").

282. Lyondell Chem. Co. v. Albemarle Corp., Nos. 1:01-CV-890, 1:02-CV-003 & 1:03-CV-225, 2007 U.S. Dist. LEXIS 97833, at *13 (E.D. Tex. June 8, 2007).

> scientific reliability requirement is lessened in such situations; the point is only that the court can hear the evidence and make its reliability determination during, rather than in advance of, trial. Thus, where the factfinder and the gatekeeper are the same, the court does not err in admitting the evidence subject to the ability later to exclude it or disregard it if it turns out not to meet the standard of reliability established by Rule 702.[283]

Put another way, although bench trials present less risk that bad science will mislead the ultimate factfinder,[284] *Daubert* still applies.

The Federal Circuit has similarly concluded that *Daubert* applies to bench trials, albeit not within the context of the Vaccine Program. In a breach of contract case, it reasoned that: "While [*Daubert*'s] concerns are of lesser import in a bench trial, where no screening of the factfinder can take place, the *Daubert* standards of relevance and reliability for scientific evidence *must nevertheless be met*."[285] Here again, if the Federal Circuit is concerned about whether an expert's calculation of breach of contract damages is sufficiently reliable under *Daubert*, that same reasoning should apply with even greater force when the expert testifies about whether a vaccination caused harm—a legal determination that could have a tremendous adverse impact on public health.[286]

Thus, even if the special masters do not—or cannot—*exclude* expert testimony after performing a *Daubert* gatekeeping analysis, a clear adoption of *Daubert*'s analytical framework for purposes of *weighing* evidence would nonetheless provide much-needed guidance. In other words, if the Vaccine Program's lenient approach toward admitting evidence[287] outweighs the benefits of excluding unreliable evidence, *Daubert* should still be the uniform framework

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283. *In re* Salem, 465 F.3d 767, 777 (7th Cir. 2006) (citation omitted).

284. *See, e.g.*, Volk v. United States, 57 F. Supp. 2d 888, 896 n.5 (N.D. Cal. 1999) ("[T]he *Daubert* gatekeeping obligation is less pressing in connection with a bench trial."); *In re* Bay Area Material Handling, Inc., No. C-95-1163-VRW, 1995 U.S. Dist. LEXIS 18241, at *16 (N.D. Cal. Dec. 4, 1995) ("Given the flexible nature of FRE 702 ... and given the fact that the trier of fact in this case was a judge ... there thus was little risk that the expert testimony would be given undue weight.").

285. Seaboard Lumber Co. v. United States, 308 F.3d 1283, 1302 (Fed. Cir. 2002) (emphasis added); *cf.* Gibbs v. Gen. Am. Life Ins., 210 F.3d 491, 500 (5th Cir. 2000).

286. *See supra* Part I.C.

287. *See* Horner *ex rel.* Horner v. Sec'y of HHS, 35 Fed. Cl. 23, 26-27 (1996) (discussing the "lenient standard" for admitting evidence in Vaccine Act litigation and reversing the special master's decision to exclude a piece of evidence).

within which special masters assess the merits of Vaccine Act claims.[288]

Finally, it is worth noting that adopting *Daubert* would not transform the Vaccine Program into full-blown traditional tort litigation. Many other statutory streamlining measures will remain in effect to ensure that vaccine petitions move quickly through the legal system.[289] *Daubert*'s adoption would simply return the Vaccine Program's focus to good science.[290] If that change moves the compensation program toward traditional civil litigation, then it is a move that needs to occur.

CONCLUSION

Vaccine Act litigation is uniquely complex. In most cases, the parties submit substantial amounts of medical, scientific, and expert evidence in an effort to prove or disprove novel theories of medical causation. Special masters have lacked sufficient guidance for how to evaluate this evidence since the Act's inception.[291] As a result, Vaccine Act jurisprudence is unpredictable, inconsistent, and, at times, unjust.[292] The Supreme Court's *Daubert* line of cases and the *Daubert*-inspired Federal Rule of Evidence 702 provide a readily accessible and well-developed analytical framework to remedy these problems.

This Note does not mean to suggest that applying *Daubert*'s evidentiary standards to the Vaccine Act will suddenly ease the tension between science and law that exists in every science-based

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288. For example, much like the Vaccine Act, the Armed Services Board of Contract Appeals is governed by evidentiary rules that are "more flexible than the Federal Rules when it comes to the admissibility of evidence." Universal Yacht Servs., Inc., No. 53951, 2004-2 B.C.A. (CCH) 32,648 (A.S.B.C.A. May 24, 2004). Nonetheless, it uses *Daubert*'s evidentiary framework to weigh the credibility of expert opinions. *Id.* at *35-36.

289. *See, e.g.*, 42 U.S.C. § 300aa-21(b) (2006) (detailing a procedure for plaintiffs to exit the Vaccine Program and pursue a civil action if a special master fails to enter judgment on their petitions within 240 days); VACCINE R. FED. CL. 4(a) (requiring the government to review all petitions for compensation within 30 days of their filing); *id.* 4(c) (requiring the government to "file a report setting forth a full and complete statement of its position" within 90 days of a petition's filing).

290. For a discussion about how applying *Daubert* to an area of law can change scientifically incorrect verdicts into scientifically correct verdicts, see Schwartz & Silverman, *supra* note 117, at 226-31.

291. *See supra* Part III.

292. *See supra* note 143 and accompanying text.

legal dispute. But *Daubert* will inject *some* reliability and predictability into a body of case law that lacks clear evidentiary guidelines for special masters and litigants alike. And most importantly, *Daubert* will focus special master decision making on reliable science. Junk science does not belong in any courtroom—and it certainly does not belong in the Vaccine Program.

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