
EMPIRICAL STUDY

WHEN SCIENCE IS SILENT: EXAMINING COMPENSATION OF VACCINE-RELATED INJURIES WHEN SCIENTIFIC EVIDENCE OF CAUSATION IS INCONCLUSIVE

I. INTRODUCTION

Vaccinations against infectious diseases have revolutionized American public health. The positive impacts of this medical development are resounding; so much so that we hardly even pause to think about the possibility that we might one day be struck by mumps, measles, or polio—a concern that plagued our ancestors only a century ago.¹ Because the benefits of vaccinations are so great, they have become a compulsory and routine task for every person wishing to participate in public life.² However, vaccines are not perfect, and sometimes adverse events resulting from their administration can cause injury or even death.

As explained below, Congress has created an alternative system to tort law that is intended to streamline the compensation process for those suffering from adverse events as a result of vaccination.³ A selected group of adverse events following vaccination merits automatic compensation under this system because they have been deemed a direct effect of the vaccine, while all other injured claimants must still prove actual causation to receive any compensation.⁴ Recently, an increasing number of Americans have begun to dedicate more attention to vaccine-related adverse events that are not automatically compensated, due to questions regarding a possible relationship between childhood vaccines and autism.⁵ This area is a particularly hot topic, since medical evidence is still

1. *See infra* note 94 and accompanying text.

2. *See infra* note 95 and accompanying text.

3. 42 U.S.C. § 300aa-10 (2000); *see infra* Part II.

4. *See infra* notes 16-18 and accompanying text.

5. *See* Centers for Disease Control and Prevention, Vaccines and Autism Theory, http://www.cdc.gov/od/science/iso/mmr_autism.htm (last visited Jan. 22, 2007).

inconclusive regarding a causal link.⁶ Similarly, a causal link between vaccines and demyelinating disorders, which have had a much longer and broader career in compensation determinations, has yet to be affirmed or dispelled by the scientific community.⁷

This Study will use compensation claims for demyelinating disorders to gain insight into how claimants fare in compensation determinations, absent a general scientific acceptance or rejection of a causal link between a vaccine and the particular disorder. To begin, this Study will discuss the history of the National Vaccine Injury Compensation Program ("Program") and compare the treatment of causation under the Program to its treatment under the traditional American tort system. It will then give a brief background of various demyelinating disorders and their potential relationships to vaccine administration as examined by an extra-judicial entity. This Study will then focus on judicial treatment of these demyelinating disorder cases under the Program, examining several variables which may explain why certain cases are compensated (or why in certain cases there is an inclination to compensate) in light of the general uncertainty that a causal link exists.

II. NATIONAL VACCINE INJURY COMPENSATION PROGRAM

On October 1, 1988, Congress established the National Vaccine Injury Compensation Program to address the increasingly apparent inadequacy and inefficiency of the traditional American civil tort system in providing compensation for vaccine-related injuries and deaths.⁸ As evidenced by the House Report discussing the Program, Congress noted that the vaccination of children against "deadly, disabling, but preventable diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken," but also recognized that mandatory immunization has had a negative impact upon the health of a "small but significant number" of individuals.⁹ These victims of vaccine-related injuries and their families had traditionally turned to the civil tort system,

6. *See id.* (stating that scientific evidence does not support a link between the MMR vaccine and autism). *But see, e.g.,* Kelly Patricia O Meara, *Vaccines May Fuel Autism Epidemic*, WORLDNETDAILY, June 9, 2003, http://www.worldnetdaily.com/news/article.asp?ARTICLE_ID=32988 (disputing the government's claim that there is no link between the measles-mumps-rubella ("MMR") vaccine and autism).

7. *See infra* notes 112-14 and accompanying text.

8. *See* 42 U.S.C. § 300aa-10 (2000); *see also* H.R. REP. No. 99-908, at 4-5 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345.

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

seeking compensation from vaccine manufacturers to cover medical and rehabilitative costs.¹⁰

By the early 1980s, the increase in litigation over vaccine-related injuries proved to be problematic for the victims of such injuries, the vaccine manufacturers, and the American public as a whole.¹¹ With regard to the victims of vaccine-related injuries, the opportunities for redress and restitution (under the traditional civil tort system) were “limited, time-consuming, expensive, and often unanswered.”¹² For manufacturers, the increase in litigation caused not only concerns about time and expense, but also increased the difficulty of obtaining adequate products liability insurance.¹³ As a result, vaccine manufacturers began to drop out of the industry, creating serious concerns about the unavailability of vaccines and, in turn, the possibility of a nationwide public health hazard due to the “resurgence of preventable diseases.”¹⁴

The National Childhood Vaccine Injury Act of 1986,¹⁵ which established the Program, was designed to address these problems by “providing a streamlined system for compensation in rare instances where an injury results from vaccination.”¹⁶ Essentially, the Program creates a “no-fault” compensation system, under which victims of *enumerated*¹⁷ vaccine-related injuries may enjoy the presumption of causation between the injury and the administration of the vaccine.¹⁸

A person who believes that she has been injured by the administration of a vaccine (“petitioner”) may sue the Department of Health and Human Services (“respondent”) in the Court of Federal Claims, where a special master will be assigned to hear the case.¹⁹ The petitioner (or her representative or family) must then establish her eligibility by demonstrating that she received a vaccine set forth in the Vaccine Injury Table (“Vaccine Table”),²⁰ that the vaccine was

10. *Id.*

11. *Id.* at 4-7, reprinted in 1986 U.S.C.C.A.N. 6344, 6345-48.

12. *Id.* at 6, reprinted in 1986 U.S.C.C.A.N. 6344, 6347.

13. *Id.* at 6-7, reprinted in 1986 U.S.C.C.A.N. 6344, 6347-48.

14. *Id.* at 7, reprinted in 1986 U.S.C.C.A.N. 6344, 6348.

15. 42 U.S.C. §§ 300aa-1 to -34 (2000).

16. U.S. Dep’t of Justice, *About the National Vaccine Injury Compensation Program*, <http://www.usdoj.gov/civil/torts/const/vicp/about.htm> (last visited Jan. 22, 2007).

17. Only certain vaccines and certain injuries are covered under the Program. These vaccines and corresponding injuries, as well as the time limitations for proving causation, are listed in the Vaccine Injury Table found in § 300aa-14(a).

18. *See* § 300aa-13(a)(1).

19. § 300aa-11.

20. § 300aa-14(a).

received in the United States,²¹ that she sustained an injury set forth in the Vaccine Table that is associated with the vaccine she claims caused the injury, that the injury began to manifest itself within the time period specified by the Vaccine Table,²² and that she suffered residual effects or complications from the injury for more than six months after administration of the vaccine.²³ If she can establish these facts by a preponderance of the evidence, the petitioner will enjoy the presumption of causation, and the government will have the burden of proving that the injury "is due to factors unrelated to the administration of the vaccine."²⁴ The petitioner may still bring a claim for an injury not listed on the Vaccine Table (an "off-table" injury) that she believes was caused by a vaccine listed in the Vaccine Table; however, in that case, she must bear the burden of proving traditional causation-in-fact.²⁵

Once the petitioner's burden has been satisfied, whether through the Vaccine Table or through traditional causation, she will be compensated with funds from the Vaccine Trust Fund for her medical and rehabilitative expenses, and in some instances, for pain and suffering and future lost earnings.²⁶ Even if the petitioner is unsuccessful, the Vaccine Trust Fund may cover her attorney's fees and costs as long as the claim was brought in good faith and there was a reasonable basis for the claim.²⁷ Only when the petitioner is unsatisfied with the system's compensation findings is she free to reject them and pursue the matter in court against the vaccine manufacturer.²⁸

The Vaccine Table's elimination of the burden of proving causation-in-fact makes the process of seeking compensation much more accessible to those who have suffered "on-table" vaccine-related injuries. So how do an injury and an associated vaccine obtain a coveted spot on the Vaccine Table? Any changes to the Vaccine Table are made by the Advisory Commission on Childhood Vaccines, which is composed of nine voting members including

21. There are some exceptions for individuals who received vaccinations while abroad. *See* § 300aa-11(c)(1)(B)(i).

22. § 300aa-14(a).

23. § 300aa-11(c)(1)(D)(i).

24. § 300aa-13(a)(1)(B).

25. § 300aa-11(c)(1)(C)(ii).

26. § 300aa-15(a)(1), (f)(4)(A).

27. § 300aa-15(e)(1).

28. § 300aa-11(a)(2)(A). The purpose of this requirement was to reduce litigation initiated against vaccine manufacturers and to stabilize the vaccine manufacturing market. *See* H.R. Rep. No. 99-908, at 12, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6353.

health professionals, members of the public, legal representatives of victims of vaccine-related injuries, and attorneys.²⁹

The Commission's functions include recommending changes to the Vaccine Table and "adv[is]ing] the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines."³⁰ The current system for collecting such data is known as the Vaccine Adverse Event Reporting System ("VAERS")³¹ and has been the subject of much criticism with regard to its accuracy.³² Given the inherent unreliability of this reporting system, it would appear likely that the Commission's consideration for inclusion in the Vaccine Table of any particular injury, illness, or condition related to the administration of a pediatric vaccine is largely based instead upon the recommendation of the Immunization Safety Review Committee ("Committee"). The Committee is part of the Institute of Medicine, which examines the possibility of a causal link between specific vaccines and adverse events as discussed below.

III. CAUSATION UNDER THE ACT AND TORT LIABILITY

Vaccine litigation and concern for vaccine safety became an issue of nationwide interest in the 1960s and 1970s, when lawsuits were filed by those injured by the polio and DPT vaccines.³³ Initially, and despite uncertain scientific evidence, most verdicts were rendered in favor of the children, and many vaccine manufacturers were found liable under strict liability, breach of implied warranty of merchantability, negligence, and failure to warn theories.³⁴ This torrent of litigation led vaccine manufacturers to threaten to stop producing vaccines unless the federal government

29. § 300aa-19(a).

30. § 300aa-19(f)(4).

31. See § 300aa-25; Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 409 (2004) (explaining that any injury arising from immunization must be reported to VAERS).

32. A major limitation on the accuracy of VAERS data is the underreporting of adverse events after the administration of a vaccine, either because that is an inherent flaw in a passive surveillance system or because the onset of the injury is delayed or not traditionally associated with the administration of a particular vaccine. See Steven Rosenthal & Robert Chen, *The Reporting Sensitivities of Two Passive Surveillance Systems for Vaccine Adverse Events*, 85 AM. J. PUB. HEALTH 1706, 1708 (1995).

33. See Calandrillo, *supra* note 31, at 406.

34. *Id.* at 406-07. Courts upheld jury verdicts for children, holding that negligence need not be proven since the products were sold under a guarantee of purity. Manufacturers were found liable for marketing unavoidably unsafe products and failing to warn parents of the possible dangers. *Id.*

guaranteed the manufacturers' indemnification.³⁵ Congress's response to the ensuing vaccine shortages and steep increase in the price of vaccines was the National Childhood Vaccine Injury Act of 1986 ("the Act").³⁶

As previously mentioned, the Act created a no-fault compensation system and accompanying presumption of causation for those who suffer on-table injuries.³⁷ If a petitioner suffers an off-table injury or if his injury or condition did not occur within the time period specified on the Vaccine Table, he bears the burden of proving that the vaccine was the cause-in-fact of his injury.³⁸ To recover Program compensation under this theory, a petitioner must prove by a preponderance of the evidence that the vaccination caused his injury by showing a "medical theory causally connecting the vaccination and the injury."³⁹ To demonstrate a persuasive medical theory, petitioner must show "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury."⁴⁰ This logical sequence must be supported by reputable medical or scientific explanation, specifically "evidence in the form of scientific studies or expert medical testimony."⁴¹

In evaluating causation-in-fact, courts today typically follow a standard clarified in *Althen v. Secretary of Health and Human Services*.⁴² The *Althen* court stated that a petitioner's burden is to demonstrate by a preponderance of the evidence that the vaccination caused "her injury by providing: (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."⁴³ If a petitioner satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine."⁴⁴

35. *Id.* at 407-08.

36. *Id.* at 408; see also Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 170 (2005) (reasoning that many vaccine manufacturers stopped producing vaccines because vaccine claims amounted to over \$3.5 billion between 1980 and 1986, with some vaccines only being produced by a single manufacturer).

37. See *supra* notes 17-18 and accompanying text.

38. See *supra* note 25 and accompanying text.

39. *Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

40. *Id.*

41. *Id.*

42. 418 F.3d 1274 (Fed. Cir. 2005).

43. *Id.* at 1278.

44. *Id.* (quoting *Knudsen v. Sec'y of Dep't of Health & Human Servs.*, 35

The Federal Circuit has held that, in order to prevail in a vaccine case, petitioners are not mandated to identify and prove precise biological mechanisms, recognizing that “the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.”⁴⁵ For this reason, both circumstantial evidence and medical opinions may be sufficient to prove the logical sequence of cause and effect showing that the vaccination was the reason for the injury.⁴⁶ Further, under the preponderance standard, petitioners are not required to show that the vaccination was the only cause or even the predominate cause of the injury or condition, but must instead show that the vaccination was a “substantial factor” and a “but for” cause in order to recover.⁴⁷

Despite the widespread uncertainty regarding vaccine-related injuries, petitioners suffering off-table effects must still overcome the traditional civil preponderance standard, a surmountable task when both the courts and the medical community appear pervasively incongruous on the issue of causation. The Supreme Court considers evidence of “poor quality—irrelevant, immaterial, unreliable, and non-probative—and of insufficient quantity” to be less than a preponderance.⁴⁸ Correspondingly, courts often explain the preponderance standard as “the greater weight of the evidence, evidence which is more convincing than the evidence which is offered in opposition to it.”⁴⁹ It arguably follows that if the “evidence appears to be equally balanced, or if it cannot be said upon which side it weighs heavier, then plaintiff has not met his or her burden of proof.”⁵⁰ Thus, with vaccine cases, where so much is unknown, it

F.3d 543, 547 (Fed. Cir. 1994)).

45. *Id.* at 1280.

46. *Scott v. Sec’y of Dep’t of Health & Human Servs.*, No. 03-2211V, 2006 WL 2559776, at *12 (Fed. Cl. Aug. 21, 2006).

47. *Id.*; *see also Pafford v. Sec’y of Dep’t of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (requiring plaintiff to prove both that her vaccinations were a substantial factor in causing her injury and that the injury would not have occurred in the absence of the vaccination); *Shyface v. Sec’y of Dep’t of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999) (adopting the Restatement (Second) of Torts rule that an action must be a substantial factor in bringing about the harm and that the harm would not have occurred but for the action in order for that action to be the legal cause of the harm).

48. *Scott-Sheppard v. Sec’y of Dep’t of Health & Human Servs.*, No. 97-449V, 2000 WL 1772472, at *9 (Fed. Cl. Nov. 16, 2000) (citing *Steadman v. SEC*, 450 U.S. 91, 102 (1981)).

49. *Id.* at *9 (citing *Hale v. Dep’t of Transp., Fed. Aviation Admin.*, 772 F.2d 882, 885 (1985)).

50. *Id.* (citing *Smith v. United States*, 557 F. Supp. 42, 51 (W.D. Ark. 1982), *aff’d*, 726 F.2d 428 (8th Cir. 1984)).

is extremely difficult to predict on which side the preponderance will fall.

The Act channels vaccine-related litigation through the Court of Federal Claims,⁵¹ but victims may still pursue alternate remedial avenues once they have exhausted all available remedies under the Program. The Act expressly prohibits any person from bringing a civil action for damages in an amount exceeding \$1000 against a vaccine manufacturer or administrator in state or federal court until he has first filed a petition for relief under the Act.⁵² If a petitioner is unsatisfied with the compensation provided under the Act, if the Court did not award compensation, or if her petition is dismissed, she may elect to file a civil suit against vaccine manufacturers or administrators in state or federal court.⁵³ Because compensation under the Act is limited to \$250,000 in damages for pain and suffering or emotional distress, in addition to reasonable attorney's fees, actual unreimbursable medical and rehabilitative expenses, and damages for lost wages or reduced earning capacity,⁵⁴ claimants might understandably be tempted to abandon their program award to pursue a claim against the deep-pocketed vaccine manufacturers. However, in doing so, claimants will not benefit from any of the Act's lessened burdens of proof and will instead be subject to the more stringent traditional civil standards of causation.

Although injured vaccinees may potentially recover more for pain and suffering and emotional distress in a separate civil suit against drug manufacturers or administrators, these claimants face additional hurdles imposed by the Vaccine Act. The Act provides that no vaccine manufacturer shall be held liable in a civil action for damages "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."⁵⁵ The Act further asserts that no vaccine manufacturer shall be found liable "solely due to the manufacturer's failure to provide direct warnings to the injured party . . . of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer."⁵⁶ Also, the Act's time limitations, requiring injured vaccinees to file claims within a specified time following vaccination, can preclude claimants from succeeding in separate civil actions even if the

51. 42 U.S.C. § 300aa-11(a)(1) (2000).

52. § 300aa-11(a)(2)(A).

53. § 300aa-21(a).

54. Craig P. Sanders, *A Roadmap for Vaccine Injury Litigation in Tennessee*, TENN. B.J., May 2006, at 22, 23 (citing 42 U.S.C. § 300aa-15 (2000)).

55. § 300aa-22(b)(1).

56. § 300aa-22(c).

causal link between the vaccine and the injury is not discovered within the allowed timeframe.⁵⁷

IV. OFF-TABLE EFFECTS

Under the Program, injuries resulting from diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenza* type b, varicella, rotavirus, pneumococcal conjugate, and *trivalent influenza* vaccinations may be compensated⁵⁸ provided that the statutory requirements are met.⁵⁹ The “on-table” vaccine-related injuries currently compensated, dependent on vaccine, include anaphylaxis or anaphylactic shock, encephalopathy, brachial neuritis, chronic arthritis, thrombocytopenic purpura, vaccine-strain measles, viral infection in an immunodeficient recipient, paralytic polio, vaccine-strain polio viral infection, and any acute complication or sequela (including death) of a listed event.⁶⁰ Although this list includes many of the most frequently experienced adverse vaccine-related effects, it is not exhaustive and omits several debilitating and often life-threatening illnesses suffered by vaccinees, many of which are considered by medical professionals and courts to have been a direct result of on-table vaccines.

This Study will discuss the off-table adverse events experienced by vaccinees who filed suit under the Act alleging injury as a direct result of a vaccination included on the Vaccine Table. The injuries studied primarily include demyelinating diseases, conditions resulting in damage to the myelin sheath, the protective covering that surrounds nerves in the brain and spinal cord, and cause a wide range of motor, sensory, and cognitive dysfunctions.⁶¹

Central nervous system demyelinating disease has for some time been acknowledged to follow viral and certain bacterial infections as well as the receipt of live attenuated and inactivated

57. § 300aa-11(a)(2)(B); *see also* Brent M. Rosenthal et al., *Toxic Torts and Mass Torts*, 58 SMU L. REV. 1183, 1199 (2005) (citing *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 655-58 (S.D. Tex. 2004)) (rejecting the argument that the fact that the Vaccine Act lacked a provision allowing claims to be filed within a reasonable time following discovery of a causal relationship between the injury and the vaccine violated constitutional due process, equal protection, and trial by jury rights)).

58. § 300aa-14(a).

59. *See* § 300aa-11(a)(2)(A).

60. § 300aa-14(a).

61. J. William Lindsey & Jerry S. Wolinsky, *Demyelinating Diseases*, ACP MEDICINE (Sept. 2005), <http://www.acpmedicine.com/acpmedicine/pdf/med1109.pdf>.

antiviral vaccines.⁶² First noted in the 1880s after the administration of the rabies vaccine grown in an animal brain or spinal cord,⁶³ demyelinating complications following vaccination examined in this Study include multiple sclerosis (“MS”), acute disseminated encephalomyelitis (“ADEM”), optic neuritis, transverse myelitis, Guillain-Barré syndrome, and chronic inflammatory demyelinating polyradiculoneuropathy (“CIDP”).

The most common of these disorders, MS, is considered a chronic demyelinating disease and can feasibly be related to vaccine administration in patients who are predisposed to develop the disease or in persons with already established disease.⁶⁴ While there is no precise causal relation between any vaccine or virus and MS, reports indicating a relation between MS and vaccination have principally been associated with the hepatitis B vaccine,⁶⁵ and MS is also the alleged result of several on-table vaccinations.⁶⁶ Symptoms of MS include problems with urinary and bowel function, pain and changes in sensation and dizziness, tiredness, depression and cognitive memory impairment, mobility problems, speech and eating difficulties, and problems with eyesight and hearing.⁶⁷

ADEM, also known as postvaccinal encephalomyelitis or postinfectious encephalomyelitis, is an acute monophasic central nervous system disease⁶⁸ associated with the tetanus-diphtheria, tetanus toxoid, and measles-mumps-rubella (“MMR”) vaccines.⁶⁹

62. KATHLEEN R. STRATTON ET AL., ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY 83 (1994).

63. *Id.*

64. *Id.* at 36.

65. *Id.*

66. Incidents of MS were reported in recipients of diphtheria-tetanus-pertussis, tetanus toxoid, hepatitis B, and MMR vaccinations. *See* Scott v. Sec’y of Dep’t of Health & Human Servs., No. 03-2211V, 2006 WL 2559776, at *1 (Fed. Cl. Aug. 21, 2006); Werderitsh v. Sec’y of Dep’t of Health & Human Servs., No. 99-310V, 2006 WL 1672884, at *1 (Fed. Cl. May 26, 2006); Bubb v. Sec’y of Dep’t of Health & Human Servs., No. 01-721V, 2005 WL 1025707 (Fed. Cl. Apr. 29, 2005); Scott-Sheppard v. Sec’y of Dep’t of Health & Human Servs., No. 97-449V, 2000 WL 1772472, at *1 (Fed. Cl. Nov. 16, 2000); Rogers v. Sec’y of Dep’t of Health & Human Servs., No. 94-0089V, 2000 WL 1337185, at *1 (Fed. Cl. June 6, 2000); Williams v. Sec’y of Dep’t of Health & Human Servs., No. 90-3091V, 1998 WL 156967, at *1 (Fed. Cl. Mar. 18, 1998).

67. IAN ROBINSON ET AL., MULTIPLE SCLEROSIS 11 (2000).

68. STRATTON ET AL., *supra* note 62, at 34.

69. *See, e.g.*, De Bazan v. Sec’y of Dep’t of Health & Human Servs., 70 Fed. Cl. 687, 695-96 (2006); Kuperus v. Sec’y of Dep’t Health & Human Servs., No. 01-0060V, 2003 WL 22912885, at *9 (Fed. Cl. Oct. 23, 2003); Tufo v. Sec’y of Dep’t of Health & Human Servs., No. 98-108V, 2001 WL 286911, at *10 (Fed. Cl. Mar. 2, 2001); Johnson v. Sec’y of Dep’t of Health & Human Servs., No. 99-0219V, 2000 WL 1141582, at *11 (Fed. Cl. July 27, 2000); Lodge v. Sec’y of Dep’t

Incidents of ADEM have also occurred after natural infections with varicella, mumps, rubella, measles, and other viruses.⁷⁰ Characterized by multifocal neurological findings and acute depression of consciousness usually occurring a few days or weeks following virus-like disease or vaccination, ADEM is widely considered to be the human equivalent of experimental allergic encephalomyelitis.⁷¹

Represented by a lesion in the optic nerve, optic neuritis is a demyelinating disease that comes in the form of retrobulbar neuritis, occurring when the lesion is central to the orbit, and papillitis, occurring when the lesion or inflammation is very near the orbit.⁷² Commonly an early symptom of MS, optic neuritis can also occur as a solitary unexplained monophasic disease or may accompany ADEM⁷³ and is linked to tetanus toxoid and diphtheria-pertussis-tetanus vaccinations.⁷⁴ Optic neuritis patients experience unilateral or bilateral impairment of vision and either temporary or permanent loss of sight.⁷⁵

As its name implies, transverse myelitis is a demyelinating disorder associated with several vaccines, including hepatitis B, diphtheria-pertussis-tetanus, polio, MMR, and tetanus toxoid.⁷⁶ As myelitis is inflammation of the spinal cord, transverse myelitis

of Health & Human Servs., No. 92-697V, 1994 WL 34609, at *9 (Fed. Cl. Jan. 25, 1994).

70. STRATTON, *supra* note 62, at 35.

71. *Id.* at 36, 45.

72. *Id.* at 37.

73. *Id.*

74. *See, e.g.*, Althen v. Sec'y of Dep't of Health & Human Servs., 58 Fed. Cl. 270, 285-86 (2003); Williams v. Sec'y of Dep't of Health & Human Servs., No. 09-3091V, 1998 WL 156967, at *12 (Fed. Cl. Mar. 18, 1998).

75. STRATTON, *supra* note 62, at 147.

76. *See, e.g.*, Rodriguez v. Sec'y of Dep't of Health & Human Servs., 67 Fed. Cl. 409, 409 (2005); Camerlin v. Sec'y of Dep't of Health & Human Servs., No. 99-615V, 2003 WL 22853070, at *13 (Fed. Cl. Oct. 29, 2003); Morris v. Sec'y of Dep't of Health & Human Servs., 57 Fed. Cl. 383, 386 (2003); Bisson v. Sec'y of Dep't of Health & Human Servs., No. 98-121V, 2003 WL 21730914, at *12 (Fed. Cl. June 30, 2003); Guillory v. U.S. 59 Fed. Cl. 121, 123 (2003); Anthony v. Sec'y of Dep't of Health & Human Servs., No. 01-594V, 2002 WL 1906527, at *14-15 (Fed. Cl. July 22, 2002); Harris v. Sec'y of Dep't of Health & Human Servs., No. 93-333V, 2001 WL 530644, at *12 (Fed. Cl. May 2, 2001); Hekert v. Sec'y of Dep't of Health & Human Servs., No. 97-518V, 2000 WL 141263, at *11 (Fed. Cl. Jan. 19, 2000); Huston v. Sec'y of Dep't of Health & Human Servs., 39 Fed. Cl. 632, 634 (1997); Yergert v. Sec'y of Dep't of Health & Human Servs., No. 90-2228V, 1995 WL 108673, at *5 (Fed. Cl. Feb. 24, 1995); Lodge v. Sec'y of Dep't of Health & Human Servs., No. 92-697V, 1994 WL 34609, at *5, *9 (Fed. Cl. Jan. 25, 1994); McCummings v. Sec'y of Dep't of Health & Human Servs., 27 Fed. Cl. 417, 418 (1992).

involves inflammation of one or more spinal cord segments, exhibiting transverse cord lesions.⁷⁷ It is distinguished by the acute onset of signs of spinal cord disease, typically including ascending sensory fibers and descending motor tracts that indicate a lesion at one level of the spinal cord.⁷⁸ Like optic neuritis, transverse myelitis involves focal demyelinating lesions that may occur either in isolation or as components of diffuse demyelinating diseases like ADEM and MS.⁷⁹ Early symptoms of the disease involve sphincter paralysis related to a partial or total loss of sensation underneath the level of the lesion.⁸⁰

Documented since the early nineteenth century but medically identified in 1916, Guillain-Barré Syndrome (“GBS”) is mediated by the immune system and targets peripheral nerves.⁸¹ More than half of all GBS patients have a history of a preceding acute infectious illness one to four weeks before symptoms appear, and several infectious agents are associated with the disease, including measles, mumps, and hepatitis B.⁸² Likewise, the disease has been connected to the tetanus toxoid, MMR, diphtheria-pertussis-tetanus, and polio vaccinations,⁸³ as well as several others not covered under the Vaccine Table. The major symptom of GBS, also known as acute inflammatory demyelinating polyneuritis, is weakness, generally

77. STRATTON ET AL., *supra* note 62, at 241.

78. *Id.* at 37.

79. *Id.* at 83.

80. *Id.* at 241.

81. *Id.* at 37.

82. *Id.* at 39.

83. *See, e.g.*, *Brown v. Sec’y of Dep’t of Health & Human Servs.*, No. 01-0060V, 2005 WL 2659073, at *1 (Fed. Cl. Sept. 21, 2005) (GBS from tetanus toxoid vaccine); *Watson v. Sec’y of Dep’t of Health & Human Servs.*, No. 96-639V, 2001 WL 1682537, at *1 (Fed. Cl. Dec. 18, 2001) (GBS from tetanus vaccine); *Tufo v. Sec’y of Dep’t of Health & Human Servs.*, No. 98-108V, 2001 WL 286911, at *1 (Fed. Cl. Mar. 2, 2001) (GBS from MMR vaccine); *Fadelalla v. Sec’y of Dep’t of Health & Human Servs.*, No. 97-0573V, 1999 WL 270423, at *1 (Fed. Cl. Apr. 15, 1999) (GBS from rubella vaccine); *Domeny v. Sec’y of Dep’t of Health & Human Servs.*, No. 94-1086V, 1999 WL 199059, at *1 (Fed. Cl. Mar. 15, 1999) (GBS from tetanus vaccine); *Tyson v. Sec’y of Dep’t of Health & Human Servs.*, No. 90-3379V, 1997 WL 702562, at *1 (Fed. Cl. Sept. 30, 1997) (GBS from tetanus toxoid); *Housand v. Sec’y of Dep’t of Health & Human Servs.*, No. 94-441V, 1996 WL 282882, at *1 (Fed. Cl. May 13, 1996) (GBS from tetanus-diphtheria vaccine); *Sepulveda v. Sec’y of Dep’t of Health & Human Servs.*, No. 92-349V, 1995 WL 502887, at *1 (Fed. Cl. Aug. 10, 1995) (GBS from polio vaccine); *Alberding v. Sec’y of Dep’t of Health & Human Servs.*, No. 90-3177V, 1994 WL 110736, at *1 (Fed. Cl. Mar. 18, 1994) (GBS from diphtheria-pertussis-tetanus vaccine); *Robinson v. Sec’y of Dep’t of Health & Human Servs.*, 91-01V, 1991 WL 268650, at *1 (Cl. Ct. Nov. 27, 1991) (GBS from diphtheria-pertussis-tetanus vaccine).

symmetrical and usually affecting the legs more than the arms, characterized by an uneven stance and gait, a decrease in reflexes, and weakness of the tongue, swallowing, and facial muscles.⁸⁴ Major sensory deficits are infrequent, but a majority of patients experience paresthesias and pain, and around thirty percent require respiratory support at some point in the illness.⁸⁵

Like GBS, chronic inflammatory demyelinating polyneuropathy (“CIDP”) is an immune-mediated disorder⁸⁶ that is often misdiagnosed as GBS.⁸⁷ Because GBS and CIDP are both inflammatory neuropathies, have clinically similar symptoms, and have similar pathogenesis, it has been argued that they can be analogized for causation purposes.⁸⁸ Notably, at least one petitioner has made a successful claim under the Act for encephalomyeloneuritis,⁸⁹ a rare disorder able to mimic GBS and also often confused with that disease.⁹⁰ Recipients of the hepatitis B, tetanus toxoid, polio, and diphtheria-pertussis-tetanus vaccines have been subsequently diagnosed with CIDP,⁹¹ which is characterized by the gradual progression of autoimmune muscle weakness in legs and arms caused by myelin sheath inflammation covering peripheral nerve axons.⁹² The fact that CIDP, like most demyelinating disorders, is often confused with and misdiagnosed as

84. STRATTON ET AL., *supra* note 62, at 31, 38.

85. *Id.* at 38.

86. Pieter A. van Doorn, *Treatment of Guillain-Barré Syndrome and CIDP*, 10 J. PERIPHERAL NERVOUS SYS. 113, 113 (2005).

87. *See, e.g.*, Kelley v. Sec’y of Dep’t of Health & Human Servs., 68 Fed. Cl. 84, 86 (2005).

88. Trojanowicz v. Sec’y of Dep’t of Health & Human Servs., No. 95-215V, 1998 WL 774338, at *2 (Fed. Cl. July 1, 1998) (reissued for publication Oct. 16, 1998).

89. *See* Casey v. Sec’y of Dep’t of Health & Human Servs., No. 97-612V, 2005 WL 3597263, at *18 (Fed. Cl. Dec. 12, 2005).

90. H. Rauschka et al., *Guillain-Barré Syndrome with Marked Pleocytosis or a Significant Proportion of Polymorphonuclear Granulocytes in the Cerebrospinal Fluid: Neuropathological Investigation of Five Cases and Review of Differential Diagnoses*, 10 EUR. J. OF NEUROLOGY 479, 483 (2003).

91. *See* Kelley, 68 Fed. Cl. at 85 (CIDP from tetanus toxoid vaccine); *see also* Gilbert v. Sec’y of Dep’t of Health & Human Servs., No. 04-455V, 2006 WL 1006612, at *1 (Fed. Cl. Mar. 30, 2006) (CIDP from hepatitis B vaccine); Ashe-Robinson v. Sec’y of Dep’t of Health & Human Servs., No. 94-1096V, 1998 WL 994191, at *1 (Fed. Cl. Dec. 22, 1998) (reissued for publication Feb 5, 1999) (CIDP from polio vaccine); Trojanowicz, 1998 WL 774338 at *1 (CIDP caused by diphtheria-pertussis-tetanus vaccine); O’Leary v. Sec’y of Dep’t of Health & Human Servs., No. 90-1729V, 1997 WL 254217, at *1 (Fed. Cl. Apr. 4, 1997) (CIDP from a diphtheria-tetanus vaccine); Sepulveda v. Sec’y of Dep’t of Health & Human Servs., No. 92-349V, 1995 WL 502887, at *1 (Fed. Cl. Aug. 10, 1995) (CIDP from polio vaccine).

92. *See* Kelley, 68 Fed. Cl. at 86 n.2.

one of its demyelinating counterparts, increases the difficulty of conclusively proving a vaccine-related injury and augments the extensive irresoluteness present in most vaccine cases.⁹³

V. EXTRA-JUDICIAL EXAMINATIONS OF CAUSAL LINKS

Although we may only think about it when we feel the needle's prick, vaccines have revolutionized public health in the United States. The development of vaccines has nearly erased our concern about the spread of infectious diseases such as mumps, smallpox, and polio, which plagued our ancestors at the turn of the century.⁹⁴ To ensure widespread use of vaccines, every state has made the receipt of such vaccines mandatory, a decision that was upheld by the United States Supreme Court.⁹⁵ Because these vaccines are now compulsory, good policy suggests that anyone injured as a direct effect of the administration of a vaccine should be compensated by the government. The problem, as previously discussed, is establishing the causal link between the injection and the injury.

Kathleen Stratton, Cynthia Howe, and Richard Johnston provide an excellent description of how the Immunization Safety Review Committee, part of the Institute of Medicine, examines the possibility of a causal link between specific vaccines and adverse events before making recommendations to policymakers as to whether a vaccine and accompanying effect might be a candidate for the Vaccine Table.⁹⁶ The question of causality can be addressed by three different inquiries: (1) *Can it?* (potential causality), (2) *Did it?* (retrodictive causality), and (3) *Will it?* (predictive causality).⁹⁷

The Committee is charged with examining the possibility of *Can it?*, which is based mainly on the evaluation of epidemiological studies conducted in controlled groups of human subjects, biological theory, and experimental evidence of a biological mechanism.⁹⁸

Can it? is generally answered in the affirmative if the relative risk (the ratio of the rate of occurrence of the adverse event in vaccinated persons to the rate in otherwise comparable

93. *See id.* at 89-90.

94. For a general history of the development of vaccines in the United States, see Calandrillo, *supra* note 31, at 363-68.

95. *See Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905) (holding that the local government had the right to require that all citizens receive a smallpox vaccination); *see also* Calandrillo, *supra* note 31, at 358.

96. STRATTON ET AL., *supra* note 62, at 3. This section of the Study attempts only to summarize what is a very complex process. For a detailed explanation of all considerations regarding causality, the reader should refer to the above-cited book.

97. *Id.* at 20.

98. *See id.* at 20-23.

unvaccinated persons) is greater than 1 In other words, if a statistically significant relative risk has been obtained in an epidemiological study . . . and is unlikely to be due to systematic bias, *Can it?* causality can be accepted.⁹⁹

Although the Committee is not charged with evaluating the *Did it?* question, which focuses mainly on causation in individual vaccinee cases, it has found that using such evidence can be helpful in determining the *Can it?* question of causality.¹⁰⁰ More simply put, if the vaccine was proven to cause an adverse event in one individual case, there is evidence that the vaccine *can* cause the adverse event.¹⁰¹ Obviously, this is where the problem of intervening causes comes into play, and evidence of a causal link is subject to a number of inquiries.

The Committee adopted a Bayesian approach to examine the causal link in individual cases, calculating the posterior probability of causation from estimates of prior possibility and “a series of likelihood ratios for each pertinent element of the observed case” (each likelihood ratio is calculated by dividing the probability that the adverse event was vaccine-caused by the probability that the effect would have happened had no vaccine been administered).¹⁰² The elements of this approach include “the individual’s medical history, the timing of onset of the adverse event following vaccine administration, specific characteristics of the adverse event, and follow-up information concerning its evolution.”¹⁰³

The *Will it?* inquiry, which refers to the frequency of vaccine-related adverse events, “is best estimated by the magnitude of the *risk difference (attributable risk)*: the incidence of the adverse event among vaccine recipients minus the incidence of the adverse event among other otherwise similar nonrecipients.”¹⁰⁴ This is perhaps the most helpful inquiry in evaluating whether a vaccine and associated adverse event may be a candidate for placement on the Vaccine Table, as “the risk difference expresses the probability of the risk of an adverse event caused by the vaccine.”¹⁰⁵ Although the Committee is not charged with conducting a *Will it?* inquiry, members have identified it as essential to the risk-benefit evaluation of any vaccine under examination.¹⁰⁶

99. *Id.* at 20-21.

100. *Id.* at 23.

101. *Id.*

102. *Id.* at 25.

103. *Id.*

104. *Id.* at 27.

105. *Id.*

106. *See id.*

Once the Committee has evaluated the causality evidence available for the vaccine and the associated adverse event through the three inquiries described above, it will summarize its findings by placing the relationship in one of five categories: (1) no evidence bearing on a causal relation, (2) the evidence is inadequate to accept or reject a causal relation, (3) the evidence favors rejection of a causal relation, (4) the evidence favors acceptance of a causal relation, or (5) the evidence establishes a causal relation.¹⁰⁷ Two of these categories were utilized in a 2002 report furnished by the Committee regarding the hepatitis B vaccine and demyelinating disorders.¹⁰⁸

The report examined the causal relationship between the hepatitis B vaccine and MS, the first instance of a central nervous system demyelinating disorder (which is sometimes associated with MS), optic neuritis, ADEM, transverse myelitis, GBS, and brachial neuritis.¹⁰⁹ The Committee explained, "Assessments begin from a position of neutrality regarding the specific vaccine safety hypothesis under review. . . . The weight of the available clinical and epidemiological evidence determines whether it is possible to shift from that neutral position to a finding for causality . . . or away from causality . . ." ¹¹⁰ If there was not enough evidence to support or reject causality, the Committee would maintain a neutral position and recommend neither an acceptance nor a rejection.¹¹¹

Using the epidemiological evidence available, the Committee specifically concluded "that the evidence favors rejection of a causal relationship between hepatitis B vaccine" and the incidence of MS in adults (category 3).¹¹² However, based on case reports, the Committee concluded "that the evidence is inadequate to [either] accept or reject a causal relationship between hepatitis B vaccine" and the other demyelinating disorders (category 2).¹¹³ Their conclusion was based largely on the fact that not many studies have been conducted regarding such causal relationships.¹¹⁴

As set forth below, this Study attempts to examine the factors relevant or even crucial to the determination of causation in a given demyelinating disorder case in light of the medical community's

107. *Id.* at 32-33.

108. *See generally* IMMUNIZATION SAFETY REV. COMM., IMMUNIZATION SAFETY REVIEW: HEPATITIS B VACCINE AND DEMYELINATING NEUROLOGICAL DISORDERS (Stratton et al. eds., 2002).

109. *Id.* at 4.

110. *Id.* at 3.

111. *Id.*

112. *Id.* at 8.

113. *Id.*

114. *Id.*

general uncertainty. This area is particularly interesting given the Committee's conclusion that there is simply inadequate evidence to either confirm or reject the likelihood of a causal link between vaccines and demyelinating disorders. In other words, this Study attempts to shed some light on hidden indicators of why some cases are compensated and others not.

VI. METHODOLOGY UTILIZED FOR EXAMINING COMPENSATION

The data available to examine the determination of compensation claims for off-table demyelinating disorders are inherently limited by the private nature of the medical information involved and the limited number of written decisions. Also, any collectable data provided through the VAERS database reveal no information regarding the compensability of demyelinating disorder claims. In response to a Freedom of Information Act request, the Department of Health and Human Services stated that statistics on the number of claims brought seeking compensation for demyelinating disorders and the corresponding instances of compensation have never been compiled or recorded by the government.

In light of these limitations, the cases collected for examination are those reduced to written opinions available through an online legal research database.¹¹⁵ These cases are an incomplete representation of how and why demyelinating disorder claims are compensated. However, through an inspection of different variables that could possibly affect the outcome of compensation determinations within this specific class of cases, this Study reveals some factors that may have a bearing on a petitioner's chances of success generally. While we do not claim that these variables are universally indicative of the outcome of all demyelinating disorder claims, there are some interesting trends.

Specifically, this Study examines six variables in the written opinions collected: (1) the disorder itself, (2) the years of the determinations, (3) the level of examination and discussion of medical literature presented by the petitioner, (4) the petitioner's expert witness, (5) the petitioner's attorney, and (6) the special master deciding the case.¹¹⁶ As explained below, some of these variables have an intense relationship with the outcome of these

115. For example, a Westlaw search of all federal cases containing the terms "demyel!" and "vaccin!" revealed 129 cases, which were then reduced to the forty-four cases relevant to this Study.

116. For the purpose of this Study, we chose to replace the personal names of any attorneys, expert witnesses, and special masters with alphabetical letters.

compensation determinations, while others appear to have little or no impact at all.

A. *Adverse Events and Compensation*

The crux of our initial inquiry into demyelinating disorders and vaccinations was to discern whether certain demyelinating disorders following vaccination should be added to the Compensation Table. The Immunization Safety Review Committee claimed that the data were either inconclusive or that there was no correlation between demyelinating disorders and vaccination,¹¹⁷ and we sought to either prove or disprove this through our analysis. Perhaps most noteworthy is that an arguable majority of the medical community asserts that there is no positive relationship between vaccinations and demyelinating disorders,¹¹⁸ yet special masters compensate many of these claims each year upon finding a causal link.¹¹⁹

Of the forty-four cases we examined, the distribution of demyelinating disorders alleged is reflected on Table 1 below. As noted, ADEM is the adverse event most frequently compensated, with seventy-one percent of all ADEM cases studied being granted compensation. This could be attributed to a number of factors, one being that it is often confused with other demyelinating disorders, possibly leading to misdiagnosis. Transverse myelitis is the demyelinating disorder for which the most cases were reported, and like GBS and Optic Neuritis claims, nearly half of the transverse myelitis cases were compensated. MS and CIDP fell at the lower end of those cases compensated for, with only thirty-three percent of each of those claims receiving compensation.

Overall, our data reflect what the Committee concluded regarding demyelinating disorders and vaccinations. Specifically, the Committee found that MS was not a medical effect of the Hepatitis B vaccination, a finding which is supported in our data. The Committee owes a duty to those harmed by vaccines to make sure that any absolutely positive correlations are included on the Compensation Table, but it also owes a duty to the government, taxpayers, and the medical community to ensure that only those effects actually caused by vaccinations receive Program compensation.

117. See IMMUNIZATION SAFETY REV. COMM., *supra* note 108, at 8.

118. See *id.* at 40-69 (discussing the results of scientific investigations into relationships between vaccinations and demyelinating disorders).

119. See *infra* Part VI.B.

Table 1

Adverse Event	Cases Reported	Compensated (Y/N)	Percentage Compensated
Optic Neuritis	2	1/1	50%
ADEM	7	5/2	71%
Transverse Myelitis	15	8/7	53%
GBS	12	6/6	50%
MS	6	2/4	33%
CIDP	6	2/4	33%

B. Time and Compensation

Perhaps the most telling variable that speaks to the outcomes of these vaccine injury compensation cases is the passage of time. While the information we have is inherently imperfect because of limited access to all cases and varying volumes of written opinions each year, there is a noticeable trend favoring compensation.

Below are two linear graphs. The first demonstrates the raw number of cases compensated for each year in which written opinions were made available. It is imperative that this graph be read in conjunction with the second, which depicts the volume of written decisions compiled for each year. For example, in 1991 and 2001, 100% of written opinions ordered compensation for vaccine injuries. However, there is only one written opinion from 1991, whereas there are five written opinions from 2001. Therefore, while the compensatory trend may not be patently obvious through a simple temporal representation, the volume of written opinions gives the first graph some depth.

The number of cases compensated from 1991 through 1994 may not be a good indicator of any trend (toward compensation or otherwise) simply because very few written opinions from that period are available. Therefore, while the drastic drops and increases during those years could be an indicator that special masters were uncertain about the possibility of a scientific link between vaccines and injuries (compensating approximately fifty percent of the time), there are simply not enough written opinions to serve as a basis for that hypothesis.

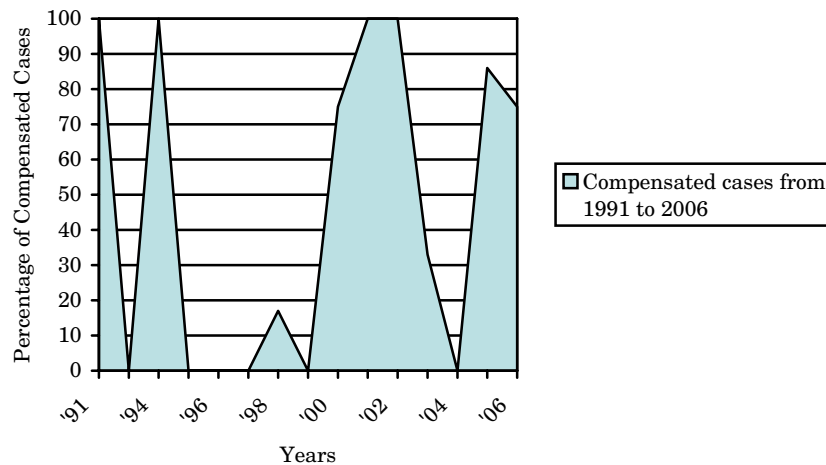
However, starting in 1995, as more written opinions became available, it is readily apparent that there is a definite judicial trend in denying compensation for these demyelinating disorders until the year 2000. Over this five year period, only one out of fifteen were compensated—that is, only six percent of all available written

opinions found a causal link between the vaccine and the disorder.

This denial trend halted dramatically in 2000, where seventy-five percent of the available written opinions found adequate indices of causation. As depicted below, during the period from 2000 to 2002, an incredible nine out of ten cases, or ninety percent, were compensated. Compensation during 2003 and 2004 took a brief dip, but the trend appears to hold its course through 2005 and 2006, during which period nine out of eleven, or eighty-one percent, were compensated.

With this information, one can only speculate as to why these claims are increasingly compensated over time. Perhaps it is the availability of new medical evidence regarding the causal relationship between these vaccines and demyelinating disorders, or perhaps it is simply the increased experience and expertise of those adjudicating this narrow class of cases that is responsible for these changes. One important factor that has undoubtedly had an impact in recent years, and that will continue to influence compensation determination in coming years, is the Court of Appeals ruling in *Althen*,¹²⁰ which effectively relaxed the petitioner's burden by eliminating the need for peer-reviewed literature to establish actual causation.¹²¹

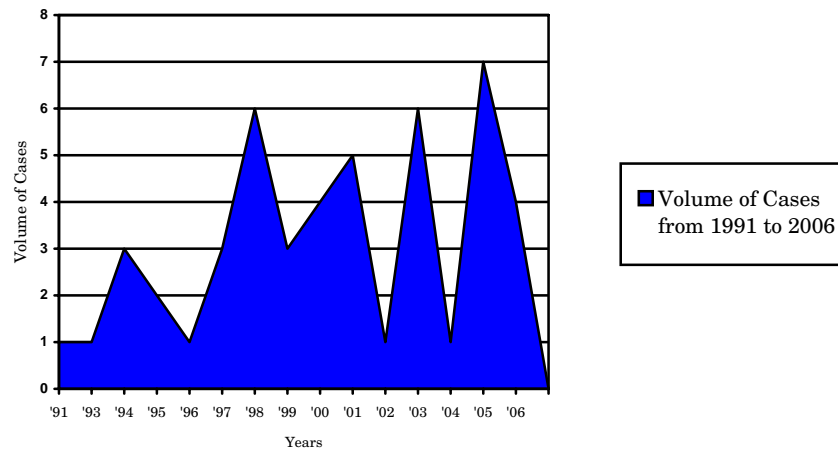
Graph 1



120. 418 F.3d. 1274 (Fed. Cir. 2005).

121. *Id.* at 1279-81 (explaining that the preponderance standard set forth by the Act does not have an “objective confirmation” requirement and that by requiring petitioners to present peer-reviewed medical literature as support for causation makes the petitioner’s burden exceedingly more difficult than the statute requires).

Graph 2



C. Medical Literature and Expert Testimony

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,¹²² federal courts are bound by Federal Rule of Evidence 702¹²³ with respect to establishing the admissibility of scientific evidence. Though the Federal Rules of Evidence are not binding on the Court of Federal Claims, Rule 702 and *Daubert* provide special masters with a helpful analytical framework for assessing the reliability of the evidence presented in vaccine cases.¹²⁴ *Daubert* set out four factors to be considered when evaluating the reliability of scientific testimony, namely whether the proposed theory has been tested, was subject to peer review and publication, is generally accepted within the relevant scientific community, and the known or potential rate of error and the existence or maintenance of standards controlling the technique's operation.¹²⁵ The *Daubert* factors are non-exclusive and to some extent inapplicable to vaccine

122. 509 U.S. 579, 585-97 (1993).

123. Federal Rule of Evidence 702 states:

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 form of 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.

FED. R. EVID. 702.

124. *Trojanowicz v. Sec'y of Dep't of Health & Human Servs.*, No. 95-215V, 1998 WL 774338, at *3 (Fed. Cl. July 1, 1998).

125. *Daubert*, 509 U.S. at 593-94.

cases, as special masters admit most evidence consistent with the legislative intent in creating the Program.¹²⁶

Unquestionably, expert testimony plays an enormous role in vaccine cases, and almost all petitioners offer some form of expert testimony. While it is not an absolute requirement that petitioners also provide evidence from medical literature supporting their claims, if no medical literature is provided, a petitioner must supply the medical opinion of a qualified expert.¹²⁷ In certain cases, “circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee’s medical records,”¹²⁸ may suffice to provide the requisite “logical sequence of cause and effect showing that the vaccination was the reason for the injury.”¹²⁹ Notwithstanding the fact that neither an expert nor medical literature is a definite prerequisite to a successful vaccine claim, the testimony of an expert, especially a qualified expert, and the presentation of medical literature in support of a petitioner’s claim, do bear heavily on the final outcome of a compensation determination.

1. *Medical Literature and Compensation*

Our results, depicted in the Table below, show that the presentation of medical literature to reinforce a petitioner’s claim does have an effect on the outcome of each case. Of the cases studied, 59% significantly relied on medical literature while 40.5% did not. Those petitioners that did present medical literature experienced a 64% success rate, suggesting that presentation of medical literature is inherently beneficial to a successful claim under the Vaccine Act. Petitioners who did not present medical literature were successful in 35.3% of the cases studied, confirming that offering medical literature is not absolutely essential to establishing a compensable claim under the Act.

As mentioned before, time seems to be a significant factor regarding whether a case will be compensated, as the evidence gathered unequivocally establishes that recently filed cases are compensated more frequently than those filed closer to the Act’s inception. This recent compensation trend could be due to the fact

126. See *Herkert v. Sec’y of Dep’t of Health & Human Servs.*, No. 97-518V, 2000 WL 141263, at *10 (Fed. Cl. Jan. 19, 2000). *But see Domyen v. Sec’y of Dep’t of Health & Human Servs.*, 1999 WL 199059, No. 94-1086V, at *14 (Fed. Cl. Mar. 15, 1999).

127. See *Althen v. Sec’y of Dep’t of Health & Human Servs.*, 418 F.3d. 1274, 1279-80 (Fed Cir. 2005).

128. *Bowes v. Sec’y of Dep’t of Health & Human Servs.*, No. 01-481V, 2006 WL 2849816, at *2 (Fed. Cl. Sept. 8, 2006).

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

that the standards were relaxed through *Althen*, or it could also be that, as time goes on, more medical literature is published on the subject of demyelinating disorders and vaccination, giving petitioners more credible evidence on which to base their claims. However, it must also be noted that just as medical literature is published supporting the proposition that vaccinations can cause demyelinating disorders, at least an equal quantity of reputable medical literature is presented refuting that proposition.

In the realm of tort law, it is widely known that as more information becomes available, claims are decided with more accuracy because experts and adjudicators have more information on which to base their decisions. While the passage of time and the availability of medical literature definitely have some correlation, our Study reveals that whether a case was filed last year or ten years ago, reliance on medical literature has been fairly constant. More plainly stated, petitioners relied on medical literature with the same frequency fifteen years ago as they do today. The fact that medical literature has not only been available and utilized since the Program was enacted, but also clearly influences a case in favor of compensation, begs the question—why wouldn't a petitioner use medical literature to bolster her claim?

Table 2

Total Cases	44
Compensated (Y/N)	23/21
Presentation of Medical Literature (Y/N)	25/19
Percentage of Successful Cases Relying on Medical Literature	64% (16 of 25)
Percentage of Unsuccessful Cases Relying on Medical Literature	36% (9 of 25)
Percentage of Successful Cases Without Medical Literature	35.3% (6 of 17)
Percentage of Unsuccessful Cases Without Medical Literature	64.7% (11 of 17)

2. *Expert Testimony and Compensation*

A claimant's selection of expert witness appears to have a significant bearing on his success under the Vaccine Act. Because these data only reflect a small portion of the overall cases filed, it is impossible to determine how many total cases each expert witness

has testified in and whether all cases filed received compensation. Of the cases reported, the evidence shows that, on the whole, experienced experts have a higher rate of success than those experts who have only testified in one of the cases studied.

As illustrated in the Table below, most experts in the claims examined only testified in one case. Of the fifty-nine experts involved,¹³⁰ only seven, or 11.8%, had testified in more than one case. Where an expert has only testified in one reported case, the success rate is hit-or-miss, because his success will be reported as a 100% win or loss, a statistic that is necessarily lacking in probative value.¹³¹ It is futile to evaluate an expert's effectiveness based on his success in one case due to all the other variables that exist and bear on the outcome. Thus, only where an expert has testified in two or more cases reported can his overall results be realistically considered in our analysis.

Even where an expert is more "experienced," his success rate varies. Experienced experts—those who participated in two or more cases—testified in twenty-four of the forty-five case studied, which represents slightly over 50% of the total claims evaluated. The success rate of those experts who testified in two or more cases is 58.3%, while the success rate of "inexperienced" experts is 39.5%. Keeping in mind the incomplete nature of the data available, this indicates that an expert with more experience testifying in vaccine cases possibly yields a greater chance of prevailing.

Also telling is the fact that Expert C, who has testified in the highest volume of cases, has a much higher rate of achieving compensation than any of the other experienced experts. Expert C has been an expert witness in six cases, five of which were compensated, making his success rate 83.3%. Even more interesting is the fact that in each of the cases in which Expert C was a witness, Attorney F represented the claimant. This suggests that it is possibly the attorney, and not the plaintiff, who selects the expert witness for each case. The foregoing theory is further confirmed by the fact that Expert A and Attorney A have worked together in three cases and Expert G and Attorney G have successfully joined forces in two cases.

Like the attorneys who might choose to be selective in deciding which vaccine cases to litigate based on the chance of success, experts might also base their decision to testify on whether they

130. In several cases, more than one expert offered testimony on the claimant's behalf.

131. For this reason, rather than listing each of the thirty-eight experts who had only testified in one case, we combined their total and identified these experts collectively as Expert X.

think the plaintiff has a valid claim. Also, in several cases, the testifying expert is the claimant's actual treating physician and may not have prior experience with the Vaccine Act or with testifying in the compensation hearings. However, as little is known about how both attorneys and expert witnesses are ultimately selected by claimants, this is only speculative.

Table 3

Expert	Cases Testified	Compensated (%)	Uncompensated (%)
A	3	2 (66.6%)	1 (33.3%)
B	3	2 (66.6%)	1 (33.3%)
C	6	5 (83.3%)	1 (16.7%)
D	2	1 (50%)	1 (50%)
E	3	1 (33.3%)	2 (66.6%)
F	2	1 (50%)	1 (50%)
G	2	2 (100%)	0 (0%)
X	1 (each) 38 (total)	15 (39.5%)	23(60.5%)

D. Petitioners' Attorney and Compensation

Another variable examined to try to explain the outcome of these limited number of cases is which attorney handled the petitioner's case. When evaluating which cases were compensated, we noticed that attorneys who handled several cases had relatively notable success in getting their clients compensation. As illustrated in the Table below, Attorney A has handled seven cases, and three were compensated, resulting in a 43% success rate; Attorney F has also handled seven cases, and six were compensated, resulting in an 86% rate; Attorney G has handled five cases, three of which were compensated, resulting in a 60% success rate.

Compare these results to those attorneys who have handled only one or two cases. These cases, on average, are only compensated 43% of the time. If a petitioner chooses an attorney who has experience with five or more cases, the average success rate is 63%. In other words, according to this limited number of cases that are available, the likelihood of success for petitioner might increase 20% if she chooses an attorney with more experience.¹³²

Moreover, experience may not even be indicative of success. Of the available opinions we have, Attorney A—with the experience of seven cases—has the same rate of success as the collectively

132. Once again, this figure may be speculative considering the limited information available.

inexperienced attorneys, 43%. Instead, it may just be that Attorney F and Attorney G, who have had consistent success, are truly exceptional attorneys. Or, alternatively, it may be that Attorney F and Attorney G are simply more selective about the cases that they take on.¹³³ In other words, the identity of the petitioner's attorney and his or her experience may have some effect on the outcome of her case, but it may be totally unrelated to that attorney's experience. It would, however, be safe to say that should a potential petitioner decide to seek compensation for what she believes to be a vaccine-related injury, her chances of success will undoubtedly increase if either Attorney F or Attorney G agrees to take her case, whatever the reason for that increase in success may be.

133. However, attorney's fees in these vaccine injury compensation cases are not awarded on a contingent basis. Therefore, attorneys will be awarded the same amount regardless of whether the petitioner is compensated or how large the award may be. 42 U.S.C. § 300aa-15(e) (2000).

Table 4

Petitioners Attorney	Compensated (Y/N)	Percentage Compensated
Attorney A	3/4	43%
Attorney B	0/1	0%
Attorney C	0/1	0%
Attorney D	1/0	100%
Attorney E	0/1	0%
Attorney F	6/1	86%
Attorney G	3/2	60%
Attorney H	1/0	100%
Attorney I	1/0	100%
Attorney J	0/1	0%
Attorney K	0/1	0%
Attorney L	1/0	100%
Attorney M	1/0	100%
Attorney N	1/0	100%
Attorney O	1/0	100%
Attorney P	0/1	0%
Attorney Q	0/1	0%
Attorney R	0/1	0%
Attorney S	0/1	0%
Attorney T	1/1	100%
Attorney U	0/2	0%
Attorney V	0/1	0%
Attorney W	0/1	0%
Attorney X	0/1	0%
Attorney Y	1/0	100%
Attorney Z	1/0	100%

E. Special Masters and Compensation

Nine different special masters authored the written opinions available, and we chose to examine authorship as a variable in studying the outcomes of these cases. What the data indicate, however, is that the identity of the special master handling the compensation claim is generally not an indicator of how the cases are decided. In fact, the volume of compensated and uncompensated cases decided by each special master is split roughly down the middle. As the Table below indicates, four of the special masters—B, D, E, and F—have found that a causal link exists between the administration of a vaccine and a demyelinating disorder roughly fifty percent of the time. Special masters A's and H's results may or

may not be explained by the variable of time, whereas special masters C's and I's results are not indicators of any bias simply because we only have one written opinion by each available to us.

Those special masters handling a larger volume of cases appear to have little or no bias for or against a finding of causation. In fact, these results vaguely echo the Committee's finding that there is simply not enough evidence to either establish or dispute a causal link between a vaccine and most demyelinating disorders. These special masters have neither affirmed nor discounted a definite causal link; they simply look at each case on an individual basis. The outcomes of these cases may nevertheless be attributed to combinations of other variables—such as the year of the decision or the expert witnesses—despite the special masters' general neutrality.

Table 5

Special Master	Compensated (Y/N)	Percentage Compensated
Special Master A	4/7	36%
Special Master B	3/3	50%
Special Master C	0/1	0%
Special Master D	8/5	62%
Special Master E	2/2	50%
Special Master F	1/1	50%
Special Master G	2/0	100%
Special Master H	0/2	0%
Special Master I	0/1	0%

VII. CONCLUSION

Based on all the variables we examined, there appears to be no guaranteed means to assure success in a vaccine case. However, certain factors—such as presentation of medical literature and the choice of a “winning” attorney—do seem to strengthen a petitioner's chance of prevailing. Also, our results reveal an increasing trend toward granting compensation. Considering these data, a petitioner would be well-advised to seek counsel with both experience and success litigating vaccine claims and to bolster her position with as much supporting documentation as possible. Perhaps most encouraging, our results indicate that the particular special master involved does not seem to have any genuine bearing on whether a claim will receive compensation. Ultimately, while we did find certain trends and positive correlations, the end result of our Study

revealed that, due to the widespread uncertainty involving demyelinating disorders and vaccination, these claims should be dealt with on a case-by-case basis and do not warrant a position on the schedule of on-table effects.

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