

STRONG MEDICINE: PROCEDURAL LIMITATIONS AND THEIR EFFECT ON VACCINE INJURY CLAIMS

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The National Childhood Vaccine Injury Act of 1986 creates a no-fault administrative process for handling vaccine injury claims called the National Vaccine Injury Compensation Program (VICP). In a recent case before the Supreme Court, it was argued that the special procedural rules limiting discovery and evidence in claims adjudicated through the VICP hinder claimants' ability to prove causal connections between the use of vaccines and subsequent injuries. The Supreme Court did not address this argument. This Note empirically analyzes these claims by examining over 1,500 VICP decisions and concludes that the VICP's procedural rules do not significantly burden claimants' ability to establish causation.

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INTRODUCTION

Congress crafted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act)¹ in response to a spike in tort lawsuits for vaccine injuries in the 1980s²—a perceived national crisis that created a genuine threat of vaccine shortages.³ To ease the burden of tort litigation on vaccine manufacturers while simultaneously preserving injured victims’ rights to compensation, the Vaccine Act created the National Vaccine Injury Compensation Program (VICP).⁴ The VICP, in turn, established a special administrative court for vaccine-injured petitioners, overseen by special masters with statutory discretion to limit the evidence considered and discovery permitted.⁵ Under the VICP’s no-fault scheme, claimants seeking damages for vaccine-related injuries must first file a petition in an administrative division of the United States Court of Federal Claims.⁶ These VICP petitions are overseen by a handful of special masters whose duty is to conduct the proceedings in a “less-adversarial, expeditious, and informal” manner.⁷ Yet despite these procedural distinctions from an ordinary civil law suit, “vaccine-injured persons may obtain a full and fair award for their injuries even if the manufacturer has made as safe a vaccine as possible,”⁸ so long

1. 42 U.S.C. § 300aa-1 to -34 (2006).

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

3. *Id.* at 5 (“Current economic conditions have resulted in an unstable and unpredictable childhood vaccine market, making the threat of vaccine shortages a real possibility.”).

4. 42 U.S.C. § 300aa-10; see also H.R. REP. NO. 99-908, at 12 (“While the bill does not prohibit a vaccine-injured person who has completed compensation proceedings from going on to court, the system is intended to lessen the number of lawsuits against manufacturers.”).

5. 42 U.S.C. § 300aa-12(d)(3)(B) (“There may be no discovery in a proceeding on a petition other than the discovery required by the special master.”).

6. *Id.* § 300aa-11(a)(1).

7. *Id.* § 300aa-12(c)(1), (d)(2)(A).

8. H.R. REP. NO. 99-908, at 26.

as they prove by a preponderance of the evidence that their injuries were caused by the vaccine.⁹

Petitioners can establish causation in two ways. First, the Vaccine Act includes a Vaccine Injury Table, maintained by the Department of Health and Human Services (HHS), which lists various injuries associated with specific vaccines as well as time limits within which the onset of those injuries must occur.¹⁰ Having an “on-Table” injury establishes a rebuttable presumption of causation.¹¹ Alternatively, petitioners can proceed on a causation-in-fact (“off-Table”) theory, under which they have the burden to show a medical theory, logical sequence, and temporal relationship linking the vaccination and the alleged injury by a preponderance of the evidence.¹²

In short, the VICP was designed so that “the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system’s awards [would] divert a significant number of potential plaintiffs from litigation.”¹³ Nevertheless, claimants who are dissatisfied with their VICP outcomes may elect to withdraw from the administrative scheme and file a traditional tort suit in state or

9. 42 U.S.C. § 300aa-13(a)(1); *see also* H.R. REP. NO. 99-908, at 26 (“Petitioners are compensated because they suffered harm from the vaccine—even a ‘safe’ one—not because they demonstrated wrongdoing on the part of the manufacturer.”).

10. 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3 (2012); *National Childhood Vaccine Injury Act: Vaccine Injury Table*, U.S. DEP’T HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN. (July 22, 2011), <http://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>. HHS has the authority to amend the Table as it deems necessary, in collaboration with the Centers for Disease Control, the Institute of Medicine, and the Advisory Commission on Childhood Vaccines. *See* 42 U.S.C. § 300aa-14(c)(1) (“The Secretary may promulgate regulations to modify . . . the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.”). In pursuing the overarching goal of compensating injured victims, Congress recognized that the scientific linkage between an individual’s injury and a particular vaccine may not be ironclad, but HHS could amend the Table as scientific knowledge developed. *See* H.R. REP. NO. 99-908, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359 (noting that when “more definitive information about the incidence of vaccine injury . . . is available, the Secretary . . . may propose to revise the Table . . .”).

11. *Gruber ex rel. Gruber v. Sec’y of Health & Human Servs.*, 61 Fed. Cl. 674, 678 (2004).

12. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Specifically, petitioners must show:

by preponderant evidence that the vaccine brought about [the] 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.

Id.

13. H.R. REP. NO. 99-908, at 13.

federal court,¹⁴ but only after filing a VICP petition in the Court of Federal Claims.¹⁵

The VICP has not pleased everyone. Many petitioners are denied compensation altogether and seek review of their administrative outcome in federal court.¹⁶ For example, in *Bruesewitz v. Wyeth* the Supreme Court of the United States denied compensation for Hannah Bruesewitz's seizures and developmental delay by finding that the Vaccine Act categorically preempts state law design-defect claims against vaccine manufacturers.¹⁷ Hannah, who was at one time a normal, healthy baby,¹⁸ received a series of shots of the diphtheria, pertussis, and tetanus (DPT) vaccine when she was an infant.¹⁹ Thereafter, she suffered a number of debilitating seizures that left her with residual seizure disorder and severe developmental delays.²⁰ The Bruesewitzes failed to obtain compensation through the VICP because they were unable to prove causation.²¹ Unfortunately, they filed their VICP petition just one month after new regulations removed residual seizure disorder from the Vaccine Injury Table corresponding to the DPT vaccine.²² This forced the Bruesewitzes to proceed on the more daunting off-Table track.²³ Dr. Marcel Kinsbourne, a frequent expert witness in VICP cases, lamented that, because of the amendments:

seizures have been removed from the Table, *although that the pertussis vaccine can cause seizures is uncontested (and warned in the manufacturer's package insert)*, and although the [National Childhood Encephalopathy Study] found a significant association between a severe seizure and DPT administration in the preceding

14. 42 U.S.C. § 300aa-21(a).

15. *Id.* § 300aa-11(a)(2)(A).

16. *See, e.g.,* *Argueta v. Sec'y of Health & Human Servs.*, 102 Fed. Cl. 272, 280 (2011) (upholding Special Master's determination that DTP vaccine did not cause petitioner's acute encephalopathy).

17. 131 S. Ct. 1068, 1082 (2011).

18. Brief for Petitioners at 19, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (No. 09-152), 2010 WL 2130598, at *19 [hereinafter *Pet. Br.*].

19. *See Bruesewitz*, 131 S. Ct. at 1074.

20. *Id.* at 1075.

21. *See Bruesewitz ex rel. Bruesewitz v. Sec'y of Health & Human Servs.*, No. 95-0266V, 2002 WL 31965744, at *17 (Fed. Cl. Dec. 20, 2009) (denying recovery based on inadequately proven causation).

22. *Id.* at *1 n.1.

23. *See id.* at *12; *see also* Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 446 (2007) (discussing the adversarial nature and lower success rate of off-Table claims).

three days (a finding that was endorsed by the Institute of Medicine).²⁴

When their off-Table claim proved unfruitful, the Bruesewitzes pursued a design-defect claim in federal civil court, where the vaccine manufacturer, Wyeth, asserted a successful preemption defense.²⁵ Among the Bruesewitzes' many arguments before the Supreme Court on appeal was a claim that procedural limitations in the administrative compensation adjudication hindered their ability to prove causation-in-fact.²⁶ Indeed, the special procedural rules governing VICP cases dictate, *inter alia*, that "[t]here is no discovery as a matter of right. The informal and cooperative exchange of information is the ordinary and preferred practice."²⁷ The Bruesewitzes argued that extensive civil discovery was crucial to their demonstration of many key facts—for example, that Wyeth negligently ignored a known safer vaccine design.²⁸

Thus, the Bruesewitzes argued that Wyeth should not win on preemption grounds solely because the VICP exists—"precisely because the Vaccine Court process contains limits" and abridged procedures that negatively affect claimants' ability to prove causation, and thus obtain compensation.²⁹ However, this practical objection made no impact on the Supreme Court—it is mentioned nowhere in a mostly textualist opinion that focuses on the Vaccine Act's express preemption clause.³⁰ The Court likely disregarded the discovery question because

24. *Compensating Vaccine Injuries: Are Reforms Needed?: Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Res. of the H. Comm. on Gov't Reform*, 106th Cong. 60 (1999) [hereinafter *Hearings*] (statement of Marcel Kinshourne, Medical Expert, Tufts University) (emphasis added).

25. *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 435–36, 451 (E.D. Pa. 2007).

26. *See* Pet. Br., *supra* note 18, at 57 ("Without discovery, causation—which is extremely difficult in vaccine cases—would be nearly impossible to prove.").

27. Fed. Cl. Vaccine R. 7(a) (2012); *see also* 42 U.S.C. § 300aa-12(d)(2)(E) (2006). Congress, discussing the limited scope of VICP proceedings, explained that "neither party is given power to cross-examine witnesses, file interrogatories, or take depositions. In this regard, the Committee expects the Special Master to be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim." H.R. REP. NO. 99-908, at 17 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6358.

28. *See* Pet. Br., *supra* note 18, at 57.

29. *Id.* One of the Bruesewitzes' several amici strongly supported the notion that the limitations of the administrative recovery system militate in favor of keeping civil tort suits available. *See* Brief of Vaccine Injured Petitioners Bar Ass'n et al. as Amici Curiae in Support of Petitioners at 24, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (No. 09-152), 2010 WL 2208240, at *24 [hereinafter *VIPBA Br.*] (arguing against preemption of civil design-defect claims because "cases cannot be fully litigated given the restrictions built into the Program.").

30. 42 U.S.C. § 300aa-22(b)(2).

the record indicates that the Bruesewitzes were allowed “extensive discovery.”³¹ But the Court’s failure to address this argument head-on leaves important empirical questions unanswered.

This Note takes up the questions raised in *Bruesewitz* and ignored by the Supreme Court: does the limited evidentiary procedure contemplated by Congress and employed in VICP cases pose a significant obstacle for claimants attempting to prove “off-Table” causation? Do the special masters systematically deny access to crucial evidence? Is there a significant correlation between limited procedure and outcomes for VICP petitioners?

I attempt to answer these questions in four parts. Part I looks for guidance in the few examples set by other no-fault compensation schemes.³² Although the Bruesewitzes elected not to draw analogies to these other funds, doing so sheds light on the merits and drawbacks of limited discovery and abridged procedures in the administrative vaccine recovery context. Part II takes a hard look at VICP cases in practice. Examining the record in over 1,500 VICP cases³³ provides insight into how much evidence the special masters typically weigh when disposing of individual cases. Categorizing the VICP decisions by the ostensible amount of procedure observed and whether compensation was granted illuminates the effect of the restrictive Vaccine Rules on compensation outcomes. Part III concludes by answering the Bruesewitzes’ disregarded questions. Finally, Part IV provides some suggestions for the future conduct of vaccine injury cases.

Ultimately, the argument that limited procedure in the VICP impedes recovery for injured claimants is attenuated at best. The bulk of VICP cases examined in this study drew from voluminous amounts of evidence and did not apparently foreclose requested avenues of discovery, regardless of their compensation outcomes.³⁴ Thus, for most

31. See *Bruesewitz ex rel. Bruesewitz v. Sec’y of Health & Human Servs.*, No. 95-0266V, 2002 WL 31965744, at *14 (Fed. Cl. Dec. 20, 2002) (noting that the case involved “extensive discovery that petitioners wanted and an extraordinary amount of delay while petitioners asked for repeated postponements of the hearing . . .”).

32. I examine three no-fault compensation funds: (1) the Federal Coal Mine Health and Safety Act of 1969 (Black Lung Benefits Program), 30 U.S.C. §§ 901–44 (2006); (2) the Florida Birth-Related Neurological Injury Compensation Act (Florida Birth Injury Program), FLA. STAT. ANN. § 766.301–.316 (West 2010); and (3) the Virginia Birth-Related Neurological Injury Compensation Act (Virginia Birth Injury Program), VA. CODE ANN. § 38.2-5000 (West 2011).

33. I categorized more than 1,500 VICP decisions according to the level of discovery they permitted and their corresponding outcomes. See *infra* Table II. Full lists of the cases considered in each category are on file with the *New York University Journal of Legislation and Public Policy*, and available at <http://www.nyuujpp.org/wp-content/uploads/2013/04/ROLLER.APPENDICES.pdf>.

34. See *infra* notes 120–132 and accompanying text.

claimants, the VICP provides a comprehensive and fair chance to prove causation and is not an unreasonable burden. For others, however, it does present a challenge, especially in cases involving new drugs about which scientific knowledge of their effects has not fully developed.³⁵

I.

A COMPARATIVE LOOK: PROCEDURE IN OTHER NO-FAULT COMPENSATION FUNDS

The VICP does not allow claimants to conduct discovery as of right.³⁶ This restriction is a sharp departure from ordinary civil practice, which broadly allows all relevant discovery unless it is duplicative or overly burdensome.³⁷ Congress's stated purpose for abridging claimants' right to discovery in VICP cases was simply to "expedite the proceedings" in light of what it contemplated would be rapidly resolved, narrow-issue cases.³⁸ The discovery limitation was imposed to keep VICP cases quick, efficient, and perhaps most importantly, affordable.³⁹

Concerns about the inefficiency and cost of tort law are not unique to the VICP. Other instances of no-fault compensation systems have been implemented partly in response to tort crises, as well as out of a general desire to facilitate and expedite victim compensation.⁴⁰ With this in mind, one would expect to find common characteristics regarding procedural rights in the statutory language of similar schemes. However, none of the schemes examined in this Note explicitly restrict the discovery rights of victims as severely as the VICP. These schemes—the Black Lung Benefits Program, the Florida Birth

35. See, e.g., *infra* notes 139–145 and accompanying text.

36. See 42 U.S.C. § 300aa-12(d) ("There may be no discovery in a proceeding on a petition other than the discovery required by the special master."); Fed. Cl. Vaccine R. 7(a) (2012).

37. See FED. R. CIV. P. 26(b)(1) ("Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense . . .").

38. See H.R. REP. NO. 99-908, at 16 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6357. ("Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues.")

39. See *id.* at 13 ("The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation."); see also *id.* at 36 (explaining that the costs of litigation in the VICP will be "significantly lower" with, *inter alia*, "prohibitions on traditional discovery . . .").

40. See *infra* notes 42–45, 61, 69 and accompanying text.

Injury Program, and the Virginia Birth Injury Program—do not contain procedurally restrictive language similar to that in the Vaccine Act.⁴¹ In this Part, I discuss each of these three programs in turn. I then conclude by explaining why the VICP's more restrictive limitations are a non-factor in light of my finding that the VICP works, in practice, in a thorough, comprehensive manner similar to comparable schemes.

A. *The Black Lung Benefits Program*

The Federal Coal Mine Health and Safety Act (Coal Act) was passed in the wake of a tragic mine explosion in Farmington, West Virginia that left seventy-eight coal miners dead.⁴² Thousands more were stricken with debilitating respiratory diseases, most commonly pneumoconiosis (a painful lung disease caused by inhalation of excessive amounts of coal dust).⁴³ The high visibility of these mine injuries sparked a public outcry, prompting Congress to intervene to compensate victims of “accidents that continue to make coal mining the most hazardous occupation in the United States.”⁴⁴ One of the most egregious effects of coal mining accidents was that victims and their families routinely went uncompensated in state courts for injuries or deaths.⁴⁵

41. I examine these schemes in particular because they responded to perceived tort crises and had a general purpose of streamlining compensation for victims while avoiding placing important industries in dire straits. In fact, Congress, hoping to create an efficient, cheap administrative compensation scheme in the Vaccine Act, drew parallels to the Black Lung Benefits Program examined in Part I.A. See H.R. REP. NO. 99-908, at 36 (discussing intent that “the costs of legal services will more closely approximate those incurred in such systems as the Black Lung benefits program . . .”). Thus, the framers of the VICP had these kinds of schemes in mind when they decided to impose the procedural limitations examined in this Note.

42. H.R. REP. NO. 91-563, at 1 (1969), reprinted in 1969 U.S.C.C.A.N. 2503, 2503. The explosion, which occurred in the early morning hours of November 20, 1968, could be felt for miles. *A Look Back at the Farmington Mine Disaster* (National Public Radio broadcast Jan. 5, 2006), available at <http://www.npr.org/templates/story/story.php?storyId=5131746>. There were ninety-nine miners underground at the time of the explosion and only twenty-one made it to the surface; the remaining seventy-eight died. *Id.*

43. See H.R. REP. NO. 91-563, at 1.

44. *Id.*

45. See *id.* at 12 (“State laws are generally remiss in providing compensation for individuals who suffer from an occupational disease as it is, and only one state—Pennsylvania—provides retroactive benefits to individuals disabled by pneumoconiosis.”).

The Black Lung Benefits Program⁴⁶ was Congress's no-fault administrative answer to the crises caused by coal mining accidents.⁴⁷ For injured miners to establish eligibility for compensation under the Program, they must prove (1) that they suffer from pneumoconiosis;⁴⁸ (2) that their pneumoconiosis "arose at least in part out of coal mine employment";⁴⁹ and (3) that they are "totally disabled due to pneumoconiosis."⁵⁰ Like the VICP and the Vaccine Injury Table, the Black Lung Benefits Program creates a rebuttable presumption that allows claimants to skip the causation inquiry. Specifically, a rebuttable presumption that a claimant's pneumoconiosis "arose out of" his employment is established if he "was employed for ten years or more in one or more coal mines"⁵¹

As for causation in practice, courts implementing the Black Lung Benefits Program have reached different results, but many have dramatically relaxed the burden on claimants who must show that their *total* disability is "due to" pneumoconiosis.⁵² For example, the Sixth Circuit only requires miners to show that their total disability is due "at least in part" to their pneumoconiosis.⁵³ The Seventh and Tenth Circuits have adopted similarly lenient standards, requiring pneumoconiosis to be at least a "contributing cause" of a miner's total disability.⁵⁴ By contrast, the Third, Fourth, and Eleventh Circuits require a claimant to show that pneumoconiosis was a "substantial" cause of his total disability.⁵⁵

In any case, claimants have ample opportunity under the statutory scheme to meet the Black Lung Benefits Program's requirements. Far from limiting procedure in any way, the Black Lung Benefits Program

46. 30 U.S.C. §§ 901–44 (2006).

47. H.R. REP. NO. 91-563, at 12 ("One of the compelling reasons the committee found it necessary to include this program in the bill was the failure of the States to assume compensation responsibilities for the miners covered by this program.").

48. 20 C.F.R. § 718.202 (2012).

49. *Id.* § 718.203(a).

50. *Id.* § 718.204(a).

51. *Id.* § 718.203(b).

52. *See, e.g., Adams v. Dir., Office of Workers' Comp. Programs*, 886 F.2d 818, 825 (6th Cir. 1989) (interpreting "due to" pneumoconiosis to mean due "at least in part" to pneumoconiosis, "consistent with the beneficial purposes of the [Black Lung Benefits Act]").

53. *Id.*

54. *See Shelton v. Dir., Office of Workers' Comp. Programs*, 899 F.2d 690, 693 (7th Cir. 1990); *Mangus v. Dir., Office of Workers' Comp. Programs*, 882 F.2d 1527, 1531 (10th Cir. 1989).

55. *See Williams Mountain Coal Co. v. Lucas*, 100 F. App'x 893, 897 n.6 (4th Cir. 2004); *Lollar v. Ala. By-Products Corp.*, 893 F.2d 1258, 1265 (11th Cir. 1990); *Bonessa v. U.S. Steel Corp.*, 884 F.2d 726, 734 (3d Cir. 1989).

provides claimants with a comprehensive opportunity to produce medical evidence and professional opinions. In fact, the regulations implementing the program require the Office of Workers' Compensation Programs (OWCP) to develop a host of medical evidence to substantiate an injured miner's claim.⁵⁶ Moreover, if the medical evidence is insufficient on its own to prove causation (e.g., where it is medically contraindicated), "total disability may nevertheless be found if a physician . . . concludes that a miner's respiratory or pulmonary condition prevents or prevented the miner from engaging in employment"⁵⁷ This evidentiary safety valve demonstrates Congress's solicitude for claimants who encounter struggles in proving causation under the Black Lung Benefits Program.⁵⁸ By providing mandatory evidentiary assistance, as well as presumptions to overcome difficult causation barriers, the Coal Act and its implementing regulations offer broad protection for victims of mining injuries.

At bottom, the Coal Act is a remedial law—"[i]n the absence of definitive medical conclusions there is a clear need to resolve doubts in favor of the disabled miner or his survivors."⁵⁹ The language of the Coal Act does not include anything close to the VICP's restrictive proclamation that discovery is not available as of right. The Black Lung Benefits Program thus provides a telling example of how an administrative compensation scheme can proceed without the limiting language that permeates the VICP.

B. *The Florida Birth Injury Fund*

In a similar vein, the Florida Birth-Related Neurological Injury Compensation Act, which authorized the Florida Birth Injury Fund, was a no-fault response by the state legislature to skyrocketing medical malpractice insurance premiums, as well as the waning availability

56. See 20 C.F.R. § 718.101(a) (2012). The medical evidence OWCP must develop includes, but is not limited to, chest X-rays, physical examinations, pulmonary function tests, and arterial blood-gas studies. *Id.*

57. *Id.* § 718.204(b)(2)(iv).

58. In passing a 1972 amendment to the Coal Act, Congress stated that because claimants were having trouble providing sufficient evidentiary proof of pneumoconiosis, "it has become glaringly apparent that the Act is not benefitting many of the nation's disabled coal miners who Congress intended to benefit." S. REP. NO. 92-473 (1972), reprinted in 1972 U.S.C.C.A.N. 2305, 2312. To ease this burden, Congress prohibited denial of a claim solely based on a negative X-ray, *id.* at 2315, created a rebuttable presumption that a claimant's pneumoconiosis was caused by coal mining if the claimant was employed in a mine for fifteen years, *id.* at 2316, and provided that "claims for benefits on the basis of pneumoconiosis may be established through one or more of a number of tests." *Id.* at 2317.

59. *Id.* at 2315.

of insurance in the wake of birth-injury tort lawsuits in the 1970s and 80s⁶⁰—in other words, another perceived tort crisis.⁶¹ To establish eligibility for compensation under the Florida Birth Injury Fund, claimants must show that the injury claimed (1) is a “birth-related neurological injury”;⁶² and (2) resulted from obstetrical services delivered by a participating physician or certified nurse midwife “in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital.”⁶³ Moreover, any remedy granted to a claimant in the program is exclusive—compensated claimants may not thereafter sue an obstetrician for malpractice.⁶⁴

Although administrative law judges (ALJs) have “full power and authority” to determine the compensability of birth-injury claims,⁶⁵ nothing in the statutory language approaches the restrictive nature of the VICP’s discovery rules. To the contrary, the Florida Birth Injury Fund provides that, “upon application to the administrative law judge setting forth the materiality of the evidence to be given, [claimants may] serve interrogatories or cause the depositions of witnesses residing within or without the state to be taken”⁶⁶ By contrast, procedural devices like interrogatories seeking information directly from vaccine manufacturers rarely make their way into VICP decisions.⁶⁷ Although the element of ALJ discretion is present in both the Florida

60. See FLA. STAT. ANN. § 766.301(1)(a) (West 2010) (“Physicians practicing obstetrics are high-risk medical specialists for whom malpractice insurance premiums are very costly, and recent increases in such premiums have been greater for such physicians than for other physicians.”).

61. See *id.*; see also Sandy Martin, Comment, *NICA-Florida Birth-Related Neurological Injury Compensation Act: Four Reasons Why this Malpractice Reform Must Be Eliminated*, 26 NOVA L. REV. 609, 609 (2002) (“During [the 1970s and 1980s], medical liability insurance had become so expensive that, although ‘technically available’, it was ‘functionally unavailable.’”).

62. “Birth-related neurological injury” has a very specific definition:

[I]njury to the brain or spinal cord of a live infant weighing at least 2,500 grams for a single gestation or, in the case of a multiple gestation, a live infant weighing at least 2,000 grams at birth caused by oxygen deprivation or mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate postdelivery period in a hospital, which renders the infant permanently and substantially mentally and physically impaired.

FLA. STAT. ANN. § 766.302(2).

63. *Id.* § 766.309(1).

64. *Id.* § 766.303(2).

65. *Id.* § 766.304.

66. *Id.* § 766.307(3). *Contra* Fed. Cl. Vaccine R. 7(a) (2012) (“There is no discovery as a matter of right.”).

67. They are often denied. See, e.g., *Berger v. Sec’y of Health & Human Servs.*, No. 05-1120V, 2008 WL 269524, at *5 (Fed. Cl. Jan. 14, 2008) (denying petitioner’s served interrogatories); see also *infra* note 112 and accompanying text.

Birth Injury Fund and the VICP, only the latter takes the extra step of providing language that explicitly restricts discovery in both the statute and the accompanying administrative rules.

In practice, ALJ findings in the Florida Birth Injury Fund draw upon multiple sources of evidence, including expert and witness testimonies. One reviewing court noted that the ALJ had “carefully considered” the medical records and physician and witness testimonies offered by the parties.⁶⁸ Thus, the Florida Birth Injury Fund provides another example of a more permissive regime, in which claimants have a wider opportunity (one more analogous to their rights under the Federal Rules of Civil Procedure) than under the VICP to collect evidence to prove their claim.

C. *The Virginia Birth Injury Fund*

A close sister to the Florida Birth Injury Fund is the Virginia Birth-Related Neurological Injury Compensation Act, which created the Virginia Birth Injury Fund—Virginia’s 1988 response to an “obstetric malpractice crisis” similar to Florida’s.⁶⁹ The Virginia Birth Injury Fund is akin to the Florida scheme in that it provides a detailed statutory definition of “birth-related neurological injury,”⁷⁰ its remedy is exclusive,⁷¹ and it contains explicit provisions for the production of supporting evidence.⁷² The Virginia scheme is also, through its construction, a more claimant- and discovery-friendly system than the VICP.

The Virginia Workers Compensation Commission hears all claims brought under the Virginia Birth Injury Fund.⁷³ Among the items reviewed by the Commission in birth injury claims are “[a]ll available relevant medical records,” as well as “[a]ppropriate assessments, evaluations, and prognoses and such other records and docu-

68. *Orlando Reg'l Healthcare Sys., Inc. v. Alexander*, 909 So. 2d 582, 586 (Fla. Dist. Ct. App. 2005); *see also St. Vincent's Med. Ctr. v. Bennett*, 27 So. 3d 65, 67 (Fla. Dist. Ct. App. 2009) (“At the administrative hearing, extensive medical records were introduced into evidence, although only two witnesses gave live testimony . . .”).

69. *See Elizabeth S. Falker, The Medical Malpractice Crisis in Obstetrics: A Gestalt Approach to Reform*, 4 *CARDOZO WOMEN'S L.J.* 1, 20 (1997) (“Not only had Virginia experienced high jury awards, record numbers of malpractice claims and high premiums, but two of the state’s major malpractice insurance carriers had refused to issue any new policies for obstetricians.”).

70. VA. CODE ANN. § 38.2-5001 (West 2012).

71. *Id.* § 38.2-5002(B).

72. *Id.* § 38.2-5004.

73. *Id.* § 38.2-5003.

ments as are reasonably necessary”⁷⁴ Moreover, upon application to the Commission, parties may serve interrogatories or depose witnesses.⁷⁵ The statute even allows for the confrontation and cross-examination of witnesses at hearings.⁷⁶ In addition to creating a rebuttable presumption of birth-related neurological injury for claimants,⁷⁷ the statute requires all claims to be reviewed by local medical school deans, who must submit a report to the Commission containing a detailed statement of their opinion regarding whether the infant’s injury sufficiently meets the criteria of a birth-related neurological injury.⁷⁸

Whereas the Vaccine Act speaks in terms of “limitations” placed on claimants, the Virginia Birth Injury Fund’s language is more permissive and claimant-protective.⁷⁹ As a result, in practice, the breadth of evidence weighed in Virginia birth injury cases is substantial.⁸⁰ The Commission has sole discretion to decide the “probative weight” to be given to conflicting medical evidence.⁸¹ More importantly, claimants have ample opportunity under the statute to *provide* conflicting evidence.⁸² In one case, for example, the Commission gave more probative weight to one set of medical experts than to another because the former was “the most qualified to evaluate the timing of the injury

74. *Id.* § 38.2-5004(A)(1)(h).

75. *Id.* § 38.2-5007.

76. *Id.* § 38.2-5008.1.

77. *Id.* § 38.2-5008(A)(1)(a) (“A rebuttable presumption shall arise that the injury alleged is a birth-related neurological injury where it has been demonstrated, to the satisfaction of the Virginia Workers’ Compensation Commission, that the infant has sustained a brain or spinal cord injury caused by oxygen deprivation or mechanical injury, and that the infant was thereby rendered permanently motorically disabled and (i) developmentally disabled or (ii) for infants sufficiently developed to be cognitively evaluated, cognitively disabled.”).

78. *Id.* § 38.2-5008(B), (C).

79. Compare 42 U.S.C. § 300aa-12(d)(2)(E) (2006) (permitting rules that “provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.”), with VA. CODE ANN. § 38.2-5007 (“Any party to a proceeding under this chapter may, upon application to the Commission setting forth the materiality of the information requested, serve interrogatories or cause the depositions of witnesses residing within or without the Commonwealth to be taken”), and VA. CODE ANN. § 38.2-5008.1 (“Upon a timely motion, all parties to a claim under this chapter shall have the right to confront and cross-examine witnesses.”).

80. See, e.g., *Virginia v. Bakke*, 620 S.E.2d 107, 109 (Va. Ct. App. 2005) (noting that the medical records in the case were “extensive” and that the record included “extensive testimony, reports, and other documents from physicians regarding the infant’s condition at birth and later”).

81. See *C.D.S. Constr. Servs. v. Petrock*, 243 S.E.2d 236, 241 (Va. 1978).

82. VA. CODE ANN. § 38.2-5004.

causing [the infant's] cerebral palsy."⁸³ In another, *six* different medical experts provided their opinions on an infant's injury and were ultimately unable to definitively show developmental disability stemming from obstetrical malpractice.⁸⁴ Thus, the statutory lenience enjoyed by claimants under the Virginia Birth Injury Fund is amply borne out in practice.

D. Are the VICP's Procedural Limitations Justified in Light of Other No-Fault Examples?

The comparable no-fault compensation schemes examined in this Note demonstrate that remedial schemes can and do operate in a comprehensive manner without the strict procedural limitations that are written into the VICP.⁸⁵ In light of this fact, prior to examining the VICP empirically, I anticipated the Bruesewitzes' argument to be correct—that any lower success rate among claimants in the VICP must be attributable to the fact that the scheme restricts the level of admissible evidentiary proof as compared to analogous schemes. In practice, however, VICP cases operate similarly to cases in the black lung and birth injury schemes, handling myriad evidence and exploring seemingly all avenues of proof offered by claimants.⁸⁶ So are the VICP's textual procedural limitations justified?

There are a number of arguments in favor of a higher evidentiary proof burden in VICP claims. Indeed, the VICP is unique in both its subject matter and its construction, thereby making it somewhat incommensurable with sister acts. For one, the birth injury funds operate on an opt-in basis, i.e., no-fault compensation is an option for claimants if and only if the physician who injured their infant previously elected to participate in the program by paying annual assessment fees.⁸⁷ The VICP, by contrast, is a mandatory scheme for all vaccine-injured claimants.⁸⁸ It is funded by a seventy-five cent excise tax on

83. *Bakke*, 620 S.E.2d at 112 .

84. *See* Cent. Va. Obstetrics & Gynecology Assocs., P.C. v. Whitfield, 590 S.E.2d 631, 639 (Va. Ct. App. 2004) (“Of the six physicians that reviewed the file, four stated that they could not ‘determine that the infant was developmentally or cognitively disabled’ at the time of his death.”).

85. *See supra* notes 56, 66, and 79 and accompanying text.

86. *See infra* notes 123–132 and accompanying text.

87. *See* FLA. STAT. ANN. § 766.302(7) (West 2010); VA. CODE ANN. § 38.2-5020(A).

88. 42 U.S.C. § 300aa-11(a)(2)(A) (2006). A vaccine-injured claimant can elect to pursue remedies outside the VICP only once they have either received a decision from the Court of Federal Claims, or upon the failure of the special master to timely act upon the petition. *Id.* § 300aa-21(a)–(b).

all taxable vaccines sold in the United States.⁸⁹ Additionally, manufacturers must meet strict recordkeeping and reporting requirements, including reporting of specific adverse events associated with their vaccines to the Vaccine Adverse Event Reporting System (VAERS).⁹⁰ In light of the mandatory nature of the VICP and the program's strict reporting requirements, the procedural limitations written into the statute may be justifiable. Because the vaccine industry is highly regulated ex ante and all vaccine injury claims must be channeled through the VICP, it is at least understandable that Congress scaled back full evidentiary procedure.

The sheer breadth of the possible injuries covered by the vaccine compensation scheme also militates in favor of a higher causation barrier, unlike narrower schemes focusing solely on pneumoconiosis or neurological birth injuries. VICP petitioners assert a dizzying array of claimed injuries, ranging from the common⁹¹ to the far-fetched.⁹² Additionally, because of the rapidly changing landscape of toxic tort causation and ever-increasing knowledge about the side effects of vaccines, Congress left HHS with the discretion to amend the Vaccine Injury Table as necessary when new scientific evidence comes to light.⁹³

On the other hand, there are a number of reasons why the VICP's procedural limitations are arguably unjustified (aside from the fact that sister schemes operate without them). The most salient for injured claimants is that off-Table vaccine injury claims are difficult to prove for a number of practical reasons. For one, "[m]ost are handled on a contingency basis, limiting the available resources that can be devoted

89. 26 U.S.C. § 4131(b) (2006). For a list of taxable vaccines, see 26 U.S.C. § 4132(a)(1).

90. See 42 U.S.C. § 300aa-25(b)(1)(A); 21 C.F.R. § 600.80(c); see also *Vaccine Adverse Event Reporting System*, DEP'T OF HEALTH & HUMAN SERVS., <http://vaers.hhs.gov/index> (last visited Nov. 21, 2011).

91. See, e.g., *Jane Doe/69 v. Sec'y of Health & Human Servs.*, No. Redacted, 2010 WL 2507789 (Fed. Cl. June 17, 2010) (rheumatoid arthritis); *Van Uum v. Sec'y of Health & Human Servs.*, No. 05-1024V, 2007 WL 2296025 (Fed. Cl. July 24, 2007) (encephalopathy); *Werderitsh v. Sec'y of Health & Human Servs. (Werderitsh II)*, No. 99-310V, 2006 WL 1672884 (Fed. Cl. May 26, 2006) (multiple sclerosis); *Stevens v. Sec'y of Health & Human Servs.*, No. 99-594V, 2006 WL 659525 (Fed. Cl. Feb. 24, 2006) (transverse myelitis); *Brown v. Sec'y of Health & Human Servs.*, No. 00-0182V, 2005 WL 2659073 (Fed. Cl. Sept. 21, 2005) (Guillain-Barré syndrome).

92. See, e.g., *Jakymowych v. Sec'y of Health & Human Servs.*, No. 05-0518V, 2009 WL 2905607 (Fed. Cl. July 28, 2009) (attention deficit disorder); *Barron v. Sec'y of Health & Human Servs.*, No. 06-0855V, 2007 WL 5172406 (Fed. Cl. Nov. 5, 2007) (blindness); *Doe v. Sec'y of Health & Human Servs.*, No. Redacted, 2007 WL 5188011 (Fed. Cl. 2007) (obesity and depression); *Doe v. Sec'y of Health & Human Servs.*, No. 04-273V, 2005 WL 6117660 (Fed. Cl. Oct. 7, 2005) (depression).

93. See 42 U.S.C. § 300aa-14(c).

to any one individual case.”⁹⁴ Moreover, not only do physicians’ opinions frequently differ as to causation,⁹⁵ but medical records are often “many years old and were not made with the intent of satisfying the requisite specificity required to establish causation-in-fact under the [Vaccine Act].”⁹⁶ In light of these already-existing practical difficulties, additional restrictions on claimants’ abilities to uncover evidence compounds the challenges facing off-Table petitioners.⁹⁷

Furthermore, claimants might argue that the VICP’s procedural limitations are unjustified in light of the fact that HHS has, without adequate explanation, forced them to proceed with more off-Table claims. Recall that HHS’ 1995 amendment to the Vaccine Injury Table removing residual seizure disorder from the list of injuries caused by DPT vaccines forced the Bruesewitzes to pursue the more challenging off-Table claim.⁹⁸ Many commentators found this development troubling.⁹⁹

In sum, there are colorable arguments both for and against the VICP’s procedural restrictions. Especially since comparable schemes operate without such restrictions, one may legitimately argue that the VICP presents a particularly odious uphill climb for claimants. Yet whether these procedural limitations are justified or not is a moot question if they do not actually impede VICP claimants’ ability to press their claims. Part II considers this empirical question by examining over 1,500 VICP cases.

94. *John Doe 21 v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 178, 181 (2009). One notable VICP litigator remarked that his specialty firm had represented “thousands” of VICP claimants. Telephone Interview with Kevin Conway, Partner, Conway, Homer & Chin-Caplan, P.C. (Nov. 17, 2011) (on file with author).

95. *John Doe 21*, 88 Fed. Cl. at 181.

96. *Id.*

97. This is especially true in light of the fact that one of Congress’s chief goals underlying the VICP was victim compensation. See H.R. REP. NO. 99-908, at 12 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6353 (noting that the VICP was “intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective.”).

98. See Strong, *supra* note 23, at 443–44 (highlighting amendments in 1995 and 1997 that removed extremely common injuries from the Vaccine Injury Table).

99. See Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480, 481 (2011) (“[B]y the mid-1990’s, HHS had reduced the grounds for presumptive causation, and thus recovery, for vaccine injuries in ways that many observers found troubling.”).

II.

AN EMPIRICAL LOOK: VICP CASES AND TRENDS

The best way to uncover a link between procedural limitations and compensation is to delve into the VICP cases themselves. I focus my inquiry only on off-Table, causation-in-fact cases (since the on-Table presumption of causation removes much of the evidentiary burden claimants would otherwise have). Moreover, this survey does not examine cases claiming autism as a vaccine-related injury. Although there are thousands of autism-related vaccine injury cases pending in the VICP, they are uniquely grouped together in an “Omnibus Autism Proceeding” and would skew the results I intend to uncover given their numerosity, complexity, and special procedural handling by the VICP.¹⁰⁰ Within these parameters,¹⁰¹ a meaningful survey of causation-in-fact vaccine injury cases is possible.

A. *Scope of the Survey*

The year 2005 is an apt starting point for a survey of off-Table VICP cases, following the Federal Circuit’s decision in *Althen v. Secretary of Health and Human Services*.¹⁰² In *Althen*, the Federal Circuit rejected the off-Table causation test advocated by then-Chief Special Master Golkiewicz in *Stevens v. Secretary of Health and Human Services*¹⁰³ as overly restrictive, favoring a more lenient standard.¹⁰⁴ The *Althen* court struck two of the five prongs of the *Stevens* test—those requiring “confirmation of medical plausibility from the medical community and literature” and proof of “an injury recognized by the medi-

100. In 2011, there were over 5,000 petitions pending in the VICP alleging a causal link between vaccination and autism. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1100 n.25 (2011) (Sotomayor, J., dissenting). Even the government separates autism claims from other off-Table claims when tabulating statistics on Vaccine Program compensation. See *Statistics Reports*, HEALTH RES. & SERVS. ADMIN. (June 2, 2011), <http://www.hrsa.gov/nvicp/statisticsreports.html#Stats>.

101. I used the following Westlaw limiters, which returned over 1,500 post-*Althen* final decisions: “vaccine & injury & (preponderance or off-Table or *Althen* or prove or cause or causation) % autism.”

102. 418 F.3d 1274 (Fed. Cir. 2005).

103. The *Stevens* off-Table test required petitioners to meet five prongs: (1) proof of medical plausibility; (2) proof of confirmation of medical plausibility from the medical community and literature; (3) proof of an injury recognized by the medical plausibility evidence and literature; (4) proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) proof of the elimination of other causes. *Stevens v. Sec’y of Health & Human Servs.*, No. 99-594V, 2001 WL 387418, at *23–26 (Fed. Cl. Mar. 30, 2001).

104. See *Althen*, 418 F.3d at 1278. The *Althen* court took particular issue with the second and third prongs of the *Stevens* test. See *id.* at 1281 (“[T]he Vaccine Act does not require *Althen* to provide medical documentation of plausibility . . .”).

cal plausibility evidence and literature.”¹⁰⁵ The court held that these requirements contravened the plain language of the Vaccine Act, which only requires proof of causation by a preponderance of the evidence, either “by medical records *or* medical opinion”¹⁰⁶ One commentator suggests that this “may have triggered a noticeable trend toward increased compensation of off-Table claims.”¹⁰⁷

Is the Vaccine Act’s limited procedural regime truly outcome-determinative when the relaxed standard adopted in *Althen* ensures that “close calls regarding causation are resolved in favor of injured claimants”?¹⁰⁸ If the special masters dutifully apply this presumption in favor of claimants, one would expect an empirical study to turn up few cases like *Bruesewitz*, where petitioners are denied recovery in the administrative program and forced to pursue civil tort litigation. HHS statistics indicate that the pre-*Althen* (1989-2005) success rate for VICP claims is quite low—only 32% (1,887 out of 5,891) of non-autism related vaccine injury cases were deemed compensable before *Althen* relaxed the causation standard.¹⁰⁹ From 2005 to 2011, however, far more claims (798 out of 1,269, or 63%) were compensated than dismissed,¹¹⁰ demonstrating the real impact of *Althen*’s relaxed causation standard. In any event, to prevent cases decided based on an obsolete harsher standard from skewing the results (and to cabin the vast universe of VICP claims to a manageable sample), this study focuses on post-*Althen* cases.

B. Definitions and Categories of Cases

Since this study aims to uncover whether a link exists between procedural limitations and compensation decisions, it draws on hints gleaned from the enormous mass of VICP opinions regarding the level of discovery that special masters allow and the amount of evidence they consider. Cases that I categorize under “thorough procedure” include those, like *Bruesewitz*, where the special master exercised his or

105. *Id.* at 1279, 1281.

106. *Id.* at 1279.

107. Betsy J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 HARV. J. ON LEGIS. 343, 394 (2011) (citing a 2007 empirical study); *see also infra* note 182.

108. *Althen*, 418 F.3d at 1280 (citing *Knudsen ex rel. Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)).

109. *See Statistics Reports*, HEALTH RES. & SERVS. ADMIN. (June 2, 2011), <http://www.hrsa.gov/nvicp/statisticsreports.html#Stats>. If autism cases are included, the percentage drops to 31% (1,887 out of 6,031). *See id.*

110. HRSA reports that from 2005–2011, 798 non-autism cases were compensated, while just 471 claims were dismissed. *Id.* Compare this to the overall tally of 2,685 compensated cases to 4,475 dismissed cases. *Id.*

her discretion permissively and seemed to allow everything the claimant needed or requested (e.g., subpoenas, medical records, and expert testimony).¹¹¹ This means that the opinion makes no reference to any avenue of proof denied along the way. By contrast, “restricted procedure” cases are those in which language from the opinion indicates that certain items requested by the petitioners were denied, or certain avenues of proof were explicitly and purposely left undeveloped.¹¹²

I must acknowledge the imperfect nature of these definitions, including the fact that they do not permit a more nuanced data set. Moreover, it is quite possible that the language of the opinions does not adequately address which avenues of proof were unexplored (one might not expect a special master to litter an opinion with references about the “what ifs” that went unanswered). However, the virtue of these hard distinctions is that they allow for a more orderly categorization of VICP cases, as well as the identification of any correlation between limited procedure and recovery.

I also acknowledge the reality that the particular evidence denied in “restricted procedure” cases has no guarantee of admission in the civil tort context.¹¹³ However, the amount of gate-keeping discretion vested in the special masters is far more substantial than that vested in civil judges.¹¹⁴ This was confirmed in *DeLoatch ex rel. Estate of Roberts v. Secretary of Health and Human Services*, for example, where the “reasonable and necessary” standard of the Vaccine Rules was interpreted by Special Master Hastings to mean that:

[D]iscovery is appropriate when the master concludes that, given the overall context of the factual issues to be decided by the master,

111. See, e.g., *Lerwick v. Sec’y of Health & Human Servs.*, No. 06-847V, 2011 WL 4537874, at *2 (Fed. Cl. Sept. 8, 2011) (considering medical records, medical literature, and expert testimony and finding that the claimant’s neurological disorder was caused by the DTP vaccine).

112. See, e.g., *DeLoatch ex rel. Estate of Roberts v. Sec’y of Health & Human Servs.*, No. 09-171V, 2010 WL 5558349, at *2 (Fed. Cl. July 28, 2010) (“[T]he standard for ordering discovery is high. Consistent with this elevated showing, special masters have refrained from ordering discovery in a variety of contexts.”). In *DeLoatch*, the special master denied the petitioner’s request to Merck for (1) “[a]ny reports of sudden death temporally related to Gardasil vaccination . . .” and (2) “[a]ny papers, reports, or memoranda discussing a possible biological mechanism by which the Gardasil vaccine could cause or trigger sudden death.” *Id.* at *1 n.1.

113. I expected that the kind of evidence requested by claimants like Ms. DeLoatch—internal documents related to the manufacture and health risks of particular vaccines—might be allowed in a civil tort case, yet denied in restricted procedure VICP cases. See *id.* But it is not entirely clear that this evidence would necessarily be allowed in the civil tort context. See FED. R. CIV. P. 26(b)(1) (allowing a judge to limit discovery by court order, and limiting the scope of discovery as to nonprivileged matters).

114. See *supra* notes 37–38 and accompanying text.

he or she could not make a fair and well-informed ruling on those factual issues without the requested material. Requiring the requested testimony or document production must also be ‘reasonable’ under all the circumstances, which means that the special master must consider the burden on the party who would be required to testify or produce documents.¹¹⁵

The heightened level of discretion awarded to the special masters in the VICP justifies to some degree the “restricted procedure” classification, since it makes it easier for the special masters to deny requested discovery. This mitigates the potential for inaccuracy, as the avenues of proof denied to a petitioner in the administrative context would likely be allowed in civil court. Therefore, I categorize the cases into the following four-box table:

TABLE I: CATEGORIES OF VICP CASES

	Thorough Procedure	Restricted Procedure
Compensation Awarded	Box I	Box II
Compensation Denied	Box III	Box IV

Many cases fall outside of these neatly-drawn boxes. For example, a number of cases were dismissed based on the statute of limitations,¹¹⁶ or because the parties agreed to settle.¹¹⁷ These outlier cases are discussed below in Part II.C.5.

C. Results

Of the more than 1,800 post-*Althen* cases surveyed, 1,536 were final decisions either granting or denying compensation. There were 114 Box I claims, in which compensation was granted and procedure was thorough. There was just one Box II claim, in which compensation was granted despite the special master’s denial of some discovery. There were 1,068 Box III claims, in which compensation was denied

115. *DeLoatch*, 2010 WL 5558349, at *2 (quoting *In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder*, 2004 WL 1660351, at *9 (Fed. Cl. July 16, 2004)).

116. *See, e.g., Armstrong ex rel. Armstrong v. Sec’y of Health & Human Servs.*, No. 03-1280V, 2006 WL 337507, at *1 (Fed. Cl. Jan. 27, 2006) (holding that the action was barred by the statute of limitations).

117. *See, e.g., Miller v. Sec’y of Health & Human Servs.*, No. 99-551V, 2008 WL 1883307 (Fed. Cl. Mar. 11, 2008) (adopting the parties’ settlement agreement despite causation dispute).

even though the special masters exercised discretion to allow thorough procedure. No decisions made it into Box IV, where procedure would have been restricted and compensation denied. Finally, 353 decisions did not fit neatly into any of the defined categories.

TABLE II: PERCENTAGE OF VICP CASES BY CATEGORY¹¹⁸

	Thorough Procedure	Restricted Procedure
Compensation Awarded	114 (7%)	1 (0%)
Compensation Denied	1,068 (69%)	0 (0%)
Others	353 (23%)	

1. Box I Claims

Of the 442 cases in this survey in which claimants received compensation, just 114 came after an extensive hearing on the merits and a causation-in-fact determination by the special masters. The other 328 decisions resulted from settlement, before the special masters ever had the chance to make a finding with respect to causation, yet in spite of the fact that the parties maintained a dispute about the cause of injury.

There are two striking features about the Box I decisions. First, they represent only 7% of all post-*Althen* VICP claims. Very few claimants, therefore, will ever survive a proceeding on the merits in the vaccine compensation program and have their evidence adjudged sufficient to warrant compensation. The more likely outcome is that a claim will either be settled or dismissed as unsupported by sufficient evidence.¹¹⁹ Second, and more surprising, is the sheer breadth of evidence admitted and considered by the special masters. Much like judges implementing the Black Lung Benefits and Florida and Virginia's Birth Injury Programs, the VICP special masters consider mountains of medical records, treating physicians' opinions, testimony from claimants, family, and friends, medical literature and articles, and expert testimony.¹²⁰ Therefore, the restrictive statutory language

118. Full lists of the cases considered in each category are on file with the *New York University Journal of Legislation and Public Policy*, and available at <http://www.nyu.jp.org/wp-content/uploads/2013/04/ROLLER.APPENDICES.pdf>.

119. 1,068 of the cases studied in this Note were dismissed on the merits. *See supra* Table II.

120. *See, e.g.*, Fowler *ex rel.* Fowler v. Sec'y of Health & Human Servs., No. 03-1974V, 2011 WL 693746, at *1 (Fed. Cl. Jan. 31, 2011) (considering, in a forty-two page opinion, medical records, medical literature, and multiple expert reports); Van Uum v. Sec'y of Health & Human Servs., No. 05-1024V, 2007 WL 2296025, at *1

of the Vaccine Act (relative to other no-fault compensation funds) does not seem to have an empirically negative effect on the breadth of avenues of proof considered by the special masters, at least as far as one can glean from VICP opinions themselves. When claimants' medical records are inconclusive, special masters typically look to expert opinions to substantiate the underlying medical theory for the claimed injury.¹²¹ Petitioners are not required to present certain types of evidence, like epidemiological studies, but special masters are expected to examine the credibility of an expert's opinion.¹²² This is a strong indication that the special masters generally act in good faith, striving to make compensation decisions based on a full and complete record.

One particular decision is illustrative of the fair, open, and broad exercise of the special masters' evidentiary discretion. In *Schrum v. Secretary of Health and Human Services*,¹²³ Special Master Millman delivered a twenty-two page decision awarding Patricia Schrum compensation for her hepatitis-B vaccine-induced polyarteris nodosa.¹²⁴ To establish eligibility for compensation, Schrum first provided reams of medical records spanning four years of doctor's visits, detailing everything from kidney examinations and MRIs to treatment for simple nasal stuffiness.¹²⁵ Next, she submitted three unsworn statements—two from close friends and one from her husband—commenting on their perceptions of her deteriorating condition and general “decline in energy and mobility.”¹²⁶ Third, Schrum submitted dozens of pieces of medical literature, including articles, case studies, and textbook excerpts.¹²⁷ Fourth, she offered notes and pathology reports from her treating rheumatologist and otolaryngologist.¹²⁸ Finally, and most importantly, Schrum provided an expert opinion that

(Fed. Cl. July 24, 2007) (considering, in a sixteen-page opinion, medical records, treating physicians' statements, and expert reports).

121. See *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (“Although a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999))).

122. See *id.* at 1324, 1326.

123. No. 04-210V, 2006 WL 1073012 (Fed. Cl. Mar. 31, 2006).

124. *Id.* at *1. Polyarteris nodosa is a painful and “serious blood vessel disease in which small and medium-sized arteries become swollen and damaged.” *Polyarteris nodosa*, PUBMED HEALTH, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002410/> (last visited July 8, 2012).

125. *Schrum*, 2006 WL 1073012, at *1–4.

126. *Id.* at *5.

127. *Id.* at *5–10.

128. *Id.* at *7–10.

proved crucial to discrediting the government expert's alternate theory of causation.¹²⁹ Moreover, the procedure was by no means one-sided. The government also had the opportunity to offer up expert witnesses and medical literature.¹³⁰

After the testimony and cross-examination of experts from both parties, Special Master Millman ultimately decided that “hepatitis B vaccine was a substantial factor in causing [Schrum’s polyarteris nodosa] and, but for hepatitis B vaccine, she would not have had [polyarteris nodosa].”¹³¹ Special Master Millman paid particular heed to the fact that, in close cases, “[t]he Federal Circuit has enjoined the special masters to rule in favor of petitioners”¹³²

The *Schrum* decision represents just one of many lengthy, well-reasoned decisions—both granting and denying compensation—that demonstrate the special masters’ careful attention to detail, as well as their even-handed use of statutorily-granted discretion. *Schrum* follows the pattern of most VICP cases: a significant amount of material is considered by the special master, yet there is no indication that the petitioner ever sought information from the government or vaccine manufacturers themselves. When parties put forth the effort, special masters will routinely and openly review all testimony (expert and non-expert), medical records, and literature offered to them. Thus, VICP claims, as far as the opinions of the special masters can exemplify, operate as permissively as black lung or birth injury claims in other schemes.

2. *Box II Claims*

The one Box II claim, *Werderitsh v. Secretary of Health and Human Services*,¹³³ provides the antithesis to the permissive discretion evinced in Box I. In *Werderitsh*, the petitioner sought access to thousands of entries in VAERS for examination by a medical expert.¹³⁴ She was denied, however, because certain information in

129. *See id.* at *10–11. The government expert attempted to show that a pre-existing condition, Wegener’s granulomatosis, was the true cause of Schrum’s polyarteris nodosa. *Id.* at *10. Schrum’s expert countered by arguing that, while polyarteris nodosa and Wegener’s can overlap, “the presence of aneurysms in petitioner overwhelmingly points to [polyarteris nodosa].” *Id.* at *11.

130. *Id.* at *10–13.

131. *Id.* at *22.

132. *Id.* (citing *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005)).

133. *Werderitsh v. Sec’y of Health & Human Servs. (Werderitsh I)*, No. 99-319V, 2005 WL 3320041 (Fed. Cl. Nov. 10, 2005).

134. *Id.* at *2.

VAERS (specifically, underlying medical records) is protected by statute,¹³⁵ and the information was found to be “not reasonable and necessary” for the special master’s decision.¹³⁶ This all proved inconsequential, however, as Ms. Werderitsh was eventually awarded compensation for her multiple sclerosis in a long and thorough opinion by Special Master Millman.¹³⁷

The *DeLoatch* case is another example of a special master denying discovery, although the case has not yet reached final adjudication.¹³⁸ There, Special Master Moran held that Ms. DeLoatch failed to satisfy the high standard for discovery in VICP cases.¹³⁹ By arguing that information from Merck (the manufacturer of Gardasil) “would be *of use* to the medical review,” Ms. DeLoatch did not meet the statutory threshold of “reasonable and *necessary*.”¹⁴⁰ Ms. DeLoatch also argued that more discovery should be allowed because the Gardasil vaccine is relatively new and little is known about its side effects, making meaningful expert review impossible.¹⁴¹ Special Master Moran balked at this idea, pointing to the availability, for instance, of Gardasil’s package insert as a sufficient source of information for experts.¹⁴²

The *DeLoatch* petitioners’ wholehearted disagreement with the special master’s determination prompted their support as amici of the anti-preemption arguments made in *Bruesewitz*. They argued that “most of the data regarding adverse effects of the Gardasil vaccine is held by its manufacturer, which is, understandably, not keen on releasing such data.”¹⁴³ The data they sought included the facts underlying all Gardasil entries into VAERS, as well as an “ongoing and overdue safety study of 44,000 young women vaccinated with

135. 42 U.S.C. § 300aa-25(c) (2006).

136. *Werderitsh I*, 2005 WL 3320041, at *11.

137. *See Werderitsh II*, No. 99-310V, 2006 WL 1672884, at *27 (Fed. Cl. May 26, 2006) (finding that medical records, medical literature, and expert reports established that hepatitis-B vaccine caused Ms. Wederitsh’s multiple sclerosis).

138. After being denied the discovery she requested, Ms. DeLoatch sought interlocutory mandamus relief from the Court of Federal Claims. The court denied the mandamus relief, noting that Ms. DeLoatch “cited no reason why she cannot obtain adequate and meaningful relief on the special master’s discovery order on appeal, after a final decision.” *Phillips-DeLoatch v. Sec’y of Health & Human Servs.*, 104 Fed. Cl. 223, 226 (2012).

139. *DeLoatch ex rel. Estate of Roberts v. Sec’y of Health & Human Servs.*, No. 09-171V, 2010 WL 5558349, at *1 (Fed. Cl. July 28, 2010).

140. *Id.* at *5 (emphasis added).

141. *See id.* (“The newness of the vaccine does not modify the standard for approving discovery.”).

142. *See id.* at *4–5.

143. *VIPBA Br.*, *supra* note 29, at 18.

Gardasil”¹⁴⁴ Without this information, Ms. DeLoatch and claimants like her¹⁴⁵ argued that their ability to prove causation-in-fact was hamstrung.¹⁴⁶

3. *Box III Claims*

Box III claims—claims with permissive discretion where petitioners were denied compensation—were by far the most common post-*Althen* fixtures in the VICP. Interestingly, of the 1,068 Box III claims, over 800 (most from 2010 and 2011) were dismissed on a motion by the *petitioners*, who were routinely noted as acknowledging “that insufficient evidence exists to demonstrate entitlement to compensation.”¹⁴⁷ These numbers are incongruent with the statistics reported by the Health Resources and Services Administration (HRSA), which show that only 471 non-autism cases have been dismissed as non-compensable since 2005.¹⁴⁸

There are several possible explanations for this statistical contrast. These cases may follow the pattern of voluntarily dismissed claims in civil court after settlements off the record,¹⁴⁹ which the HRSA may not report in its official statistics. A more likely possibility is that some autism-related cases, of which 182 were dismissed as non-compensable in 2011 alone,¹⁵⁰ seeped into this Note’s study. However, none of the more than 800 cases dismissed on the petitioners’ motions mentions either autism or the Omnibus Autism Proceeding. These 800 claims notwithstanding, this study encountered over 250 examples of detailed decisions, weighing all sorts of evidence, which ultimately denied compensation.

There are three notable features of the Box III claims. First, they are rife with examples of special masters giving claimants abundant

144. *Id.*

145. One prominent VICP litigator lamented the difficulties of proving causation in the Gardasil context, expressing his opinion that the special masters are protective of pharmaceutical companies and noting an ongoing effort to stay Gardasil claims until more appropriate medical studies are available. Telephone Interview with Kevin Conway, *supra* note 94; *see also infra* notes 209–210 and accompanying text.

146. *See* VIPBA Br., *supra* note 29, at 16 (“Lacking medical literature and completed safety studies, Mrs. DeLoatch’s vaccine proceeding has stalled.”).

147. *E.g.*, *Maslans v. Sec’y of Health & Human Servs.*, No. 02-0362V, 2011 WL 830729, at *1 (Fed. Cl. Feb. 10, 2011). Hundreds of other Box III cases make this same concession.

148. *Statistics Reports*, HEALTH RES. & SERVS. ADMIN. (June 2, 2011), <http://www.hrsa.gov/nvicp/statisticsreports.html#Stats>.

149. *See* FED. R. CIV. P. 41(a) (permitting voluntary dismissal by a plaintiff without a court order).

150. *Statistics Reports*, HEALTH RES. & SERVS. ADMIN. (June 2, 2011), <http://www.hrsa.gov/nvicp/statisticsreports.html#Stats>.

opportunities to provide the necessary evidence to prove causation-in-fact. Often, when petitioners were unable to provide expert testimony, it was not the fault of the special master.¹⁵¹ To the contrary, multiple special masters took care to ensure that “adequate opportunity” was given.¹⁵² This generally meant that petitioners were given several extensions of time while they sought out favorable medical expert opinions.¹⁵³ In one instance, a claim was filed on May 11, 2006, but the petitioner did not offer the expert report of Dr. Marcel Kinsbourne until more than three years later, “[a]fter several requests for extensions of time”¹⁵⁴ The special masters also made frequent use of “orders to show cause” why a petition should not be dismissed when it was clear that a petitioner’s case was lacking.¹⁵⁵ Given that extensions of time are entirely at the discretion of the special masters,¹⁵⁶ these examples demonstrate that the special masters are not hasty with the dismissal trigger.

A second notable feature of Box III claims is that petitioners have difficulty getting experts to support certain medical theories. Even though the special masters exercise restraint, many cases are nevertheless dismissed because it is difficult to find experts to testify in support of attenuated medical theories.¹⁵⁷ The clearest examples are the

151. *E.g.*, *Born v. Sec’y of Health & Human Servs.*, No. 06-392V, 2010 WL 2473576 (Fed. Cl. May 10, 2010) (stating that petitioner delayed presentation of medical expert testimony); *Avera ex rel. Avera v. Sec’y of Health & Human Servs.*, No. 04-1385V, 2005 WL 6117662 (Fed. Cl. Dec. 21, 2005) (noting that petitioner could not obtain medical expert).

152. *See, e.g.*, *Avera*, 2005 WL 6117662, at *1 (“[D]espite adequate opportunity to adduce medical expert opinion, the Averas cannot obtain medical expert opinion that supports the petition.”).

153. *E.g.*, *Born*, 2010 WL 2473576, at *1 (highlighting the petitioner’s “many delays”).

154. *See id.* *But see Barnes v. Sec’y of Health & Human Servs.*, No. 09-603V, 2010 WL 4791638, at *4 (Fed. Cl. Oct. 19, 2010) (denying petitioner’s motion to stay proceedings indefinitely in order to wait for more advanced studies on the Gardasil vaccine and allowing just two extra months for petitioner to provide an expert report).

155. *See, e.g.*, *Lovett v. Sec’y of Health & Human Servs.*, No. 98-749V, 2006 WL 5626486, at *2 (Fed. Cl. June 21, 2006) (issuing an order allowing petitioner more than a month to show cause why the petition should not be dismissed even after expressing doubt that petitioner could find an expert to support her attenuated medical theory, given that the onset of the decedent’s fatal condition was three months after vaccination).

156. Fed. Cl. Vaccine R. 19(b)(1) (2012) (“The special master or the court *may* grant a motion for an enlargement of time for good cause shown”) (emphasis added), available at http://www.uscfc.uscourts.gov/sites/default/files/court_info/11.07.15finalversionofvaccinerules.pdf.

157. *See, e.g.*, *Alzheimer v. Sec’y of Health & Human Servs.*, No. 03-1708V, 2010 WL 3582454, at *1 (Fed. Cl. Aug. 17, 2010) (dismissing petition alleging that vaccine caused diabetes for lack of a “reliable medical opinion”); *Veryzer v. Sec’y of*

numerous petitions alleging that vaccines caused Type-I diabetes. In *Alsheimer v. Secretary of Health and Human Services*, for instance, the petitioner alleged that the hepatitis-B vaccine caused his Type-I diabetes, but provided no expert opinion to support his medical theory.¹⁵⁸ The petitioner recognized that, based on a vaccine-diabetes test case finding no causal link between vaccines and diabetes,¹⁵⁹ he was unlikely to be able to retain a favorable medical expert.¹⁶⁰ These evidentiary deficiencies abound in other contexts as well. For example, in *Veryzer v. Secretary of Health and Human Services*, the petitioner was unable to prove that the hepatitis-A vaccine caused neurological and vascular injuries, “primarily due to trouble finding an expert to opine in support of Petitioner’s claim”¹⁶¹ Therefore, the sheer difficulty of mounting all the necessary evidence to support novel causation theories operates as a formidable obstacle for many off-Table claimants.

Finally, the many Box III cases dismissed on *petitioners’* motions are bare of references to how much evidence—if any—was examined prior to the motions.¹⁶² All of the decisions occupy one page and they each contain the same form language: “the petitioners moved for a decision on the merits of the petition, acknowledging that insufficient evidence exists to demonstrate entitlement to compensation.”¹⁶³ Often, several cases were dismissed in this perfunctory manner on the same day.¹⁶⁴ The skeletal nature of these more than 800 final deci-

Health & Human Servs., No. 06-0522V, 2010 WL 5185485 (Fed. Cl. Aug. 9, 2010) (denying compensation for neurological and vascular injuries because petition was not supported by either medical records or medical expert opinion).

158. *Alsheimer*, 2010 WL 3582454, at *1 (“[T]he record does not contain a medical expert’s opinion or any other persuasive evidence indicating that petitioner’s alleged injury was vaccine-caused.”).

159. *Hennessey v. Sec’y of Health & Human Servs.*, No. 01-190V, 2009 WL 1709053 (Fed. Cl. May 29, 2009), *aff’d*, 91 Fed. Cl. 126 (2010) (considering multiple expert reports and pieces of literature, and ultimately denying a causal link between vaccines and diabetes).

160. *Alsheimer*, 2010 WL 3582454, at *1.

161. *Veryzer*, 2010 WL 5185485, at *1.

162. *E.g.*, *Weiser v. Sec’y of Health & Human Servs.*, No. 03-1784V, 2011 WL 846101, at *1 (Fed. Cl. Feb. 18, 2011) (discussing acknowledgement by petitioners of insufficient evidence to prove causation); *Schmidt ex rel. Schmidt v. Sec’y of Health & Human Servs.*, No. 04-0689V, 2011 WL 760350, at *1 (Fed. Cl. Feb. 10, 2011) (same).

163. *E.g.*, *Schmidt*, 2011 WL 760350, at *1.

164. *See, e.g.*, *Miller v. Sec’y of Health & Human Servs.*, No. 03-2758V, 2011 WL 976387, at *1 (Fed. Cl. Feb. 24, 2011) (dismissing case after petitioners acknowledged lack of sufficient evidence to prove causation); *Swindell v. Sec’y of Health & Human Servs.*, No. 03-1638V, 2011 WL 971681, at *1 (Fed. Cl. Feb. 24, 2011) (same); *Torres v. Sec’y of Health & Human Servs.*, No. 03-1782V, 2011 WL 976382, at *1 (Fed. Cl. Feb. 24, 2011) (same).

sions makes it difficult to draw helpful conclusions about the link between VICE procedure and denied compensation.¹⁶⁵

4. *Box IV Claims*

No decisions fit neatly into Box IV, representing claims with limited procedure *and* denied compensation. However, one outrageous example of a special master overstepping her bounds warrants discussion here. In *Campbell ex rel. Campbell v. Secretary of Health and Human Services*, the petitioners alleged that the DPT vaccine administered to their infant daughter caused her seizure disorder.¹⁶⁶ However, Special Master Millman dubbed the petitioners' expert report "erroneous," and stated categorically that she had "never accepted that either whole cell or acellular DPT causes afebrile seizures."¹⁶⁷ On appeal, however, the Court of Federal Claims vacated the decision.¹⁶⁸ Judge Allegra held that the special master unjustifiably discredited the petitioners' evidence.¹⁶⁹ He then chided the special master for introducing, *sua sponte*, nine exhibits regarding seizure disorders and fevers that "apparently had been found by the Special Master while exploring the Internet."¹⁷⁰ One of the special master's exhibits "indicates that its information was drawn from Wikipedia.com, a website that allows virtually anyone to upload an article into what is essentially a free, online encyclopedia."¹⁷¹ The court found this abuse of discretion more indefensible in light of the fact that the special master rejected two affidavits from the petitioner's mother, as well as two reports from the petitioner's expert, "essentially on weak credibility grounds . . ."¹⁷²

165. Note, however, that even though many cases in this study went uncompensated, most of the petitioners were nevertheless awarded attorneys' fees and costs. See, e.g., *Schmidt*, 2011 WL 760350, at *1 (awarding petitioners \$8,633.50 in attorneys' fees and costs, despite their losing the claim); see also 42 U.S.C. § 300aa-15(e)(1). In fact, attorneys' fees are denied only in egregious and frivolous cases, such as where medical records do not even show that the claimant ever received a vaccine. See *Rydzewski v. Sec'y of Health & Human Servs.*, No. 99-571V, 2007 WL 949759, at *9 (Fed. Cl. Mar. 12, 2007) ("After weighing all the evidence, the Court finds as a fact that Ms. Rydzewski did not receive the hepatitis B vaccine. Ms. Rydzewski's assertion that she received the hepatitis B vaccine borders the line—if not actually crosses the line—marking frivolous petitions."). No attorneys' fees were awarded in Ms. Rydzewski's case. *Rydzewski v. Sec'y of Health & Human Servs.*, No. 99-571V, 2008 WL 382930, at *8 (Fed. Cl. Jan. 29, 2008).

166. *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, No. 02-554V, 2005 WL 6117483, at *1 (Fed. Cl. June 30, 2005), *vacated*, 69 Fed. Cl. 775 (2006).

167. *Campbell*, 2005 WL 6117483, at *6.

168. *Campbell*, 69 Fed. Cl. at 784.

169. *Id.* at 780.

170. *Id.* at 775, 777.

171. *Id.* at 781.

172. *Id.* at 779.

In granting broad discretion to the special masters, Congress probably did not anticipate the unchecked admission of questionably reliable sources into evidence. Nor would it have intended for the petitioners' affidavits to be denied at the same time. Fortunately, however, VICP decisions reversed on appeal for abuses of discretion (like *Campbell*) are the exception, not the rule. By and large, the special masters consider all reasonable evidence proffered by the petitioners and the government.¹⁷³ The same goes for Special Master Millman, whose thorough and well-reasoned opinion in *Schrum*¹⁷⁴ demonstrates that she is quite capable of thoughtful decision making, despite her errors in *Campbell*.

5. Other Claims

Finally, 353 post-*Althen* VICP decisions did not neatly fit into any of the four boxes. Many of them were dismissed because the claims were filed after the Vaccine Act's three-year statute of limitations.¹⁷⁵ Others were dismissed because counsel could no longer maintain contact with the petitioner, i.e., "failure to prosecute."¹⁷⁶ Still others were dismissed because the suspect vaccine was not listed on the Vaccine Injury Table as compensable, regardless of whether causation was presumed or not.¹⁷⁷ However, the most common "other" VICP claims are those that end in settlement before a decision on the merits and causation-in-fact is rendered.

The more than 300 decisions that ended in settlement explicitly state that the parties still maintained a dispute about causation, yet simply decided along the way that it would be more worthwhile to end the matter.¹⁷⁸ Indeed, almost all of the settlement agreements appended to the VICP decisions contain clauses that say something simi-

173. See *supra* notes 123–130 and accompanying text.

174. No. 04-210V, 2006 WL 1073012, at *1 (2006).

175. *E.g.*, *Kay ex rel. Kay v. Sec'y of Health & Human Servs.*, No. 05-0393V, 2007 WL 5161781, at *4 (Fed. Cl. Mar. 26, 2007) (holding claim barred by statute of limitations).

176. *E.g.*, *Durham ex rel. Durham v. Sec'y of Health & Human Servs.*, No. 99-648V, 2007 WL 5185471, at *2 (Fed. Cl. May 2, 2007).

177. *E.g.*, *Gearin v. Sec'y of Health & Human Servs.*, No. 07-0737V, 2008 WL 2009736, at *2 (Fed. Cl. Jan. 31, 2008) (dismissing case because pneumococcal conjugate vaccine was not covered by the Vaccine Injury Table). Pneumococcal conjugate vaccines have since been added to the Vaccine Injury Table. See *National Childhood Vaccine Injury Act: Vaccine Injury Table*, U.S. DEP'T HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN. (July 22, 2011), <http://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>.

178. See, *e.g.*, *Bubar v. Sec'y of Health & Human Servs.*, No. 03-2837V, 2008 WL 2275567, at *1 (Fed. Cl. May 14, 2008) (noting that claim settled despite causation dispute).

lar to: “Maintaining their [contrary] positions, the parties nevertheless now agree that the issues between them shall be settled and that a decision should be entered awarding . . . compensation”¹⁷⁹ Therefore, although the opinions do not provide insight into what evidence was considered leading up to the settlements, the evidence was significant enough in the *Althen* causation context to convince the government to settle the claims. This settlement trend is significant for injured claimants—awards ranged from the modest¹⁸⁰ to the substantial,¹⁸¹ and everywhere in between.¹⁸²

III.

ANALYSIS

I now turn to the disregarded question raised by the Bruesewitzes and their amici. Are VICP claimants systematically disadvantaged by the limited procedure contemplated by the Vaccine Act? For the majority of claimants, my answer is no. Since the *Althen* decision relaxed the causation standard, petitioners have had an easier time meeting their preponderance burden. Moreover, most VICP decisions demonstrate the even-handed approach of the special masters, as well as the consideration of an enormous amount of medical records and testimony.¹⁸³

The overwhelming majority (all but one) of the 1,183 Box I–IV cases examined in this study could only be fairly characterized as in-

179. *Id.*

180. *See, e.g.,* Garcia v. Sec’y of Health & Human Servs., No. 07-0767V, 2008 WL 2275563, at *2 (Fed. Cl. May 13, 2008) (granting compensation of \$25,000).

181. *See, e.g.,* Romano v. Sec’y of Health & Human Servs., No. 09-447V, 2010 WL 2287038, at *2 (Fed. Cl. Apr. 28, 2010) (granting compensation of \$405,000).

182. The trend toward significant settlements post-*Althen* began in earnest in 2008. *See, e.g.,* Miller v. Sec’y of Health & Human Servs, No. 99-551V, 2008 WL 1883307, at *1 (Fed. Cl. Mar. 11, 2008) (settling the claim for \$128,000, despite disagreement between the parties as to whether the petitioner’s injuries were caused by the hepatitis-B vaccine). A list of cases corroborating the settlement trend’s genesis in 2008 is on file with the author and the *New York University Journal of Legislation & Public Policy*. A 2007 empirical study suggested that the relaxed causation standard of *Althen* “has undoubtedly had an impact in recent years, and . . . will continue to influence compensation determination in coming years” 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, 322 (2007). The 2007 study also noted that certain attorneys have a higher success rate than others, often because they have cultivated relationships with “winning” medical experts. *Id.* at 325–27. One such successful attorney, Kevin Conway (whose firm litigated and won the *Althen* case at the Federal Circuit), argues that *Althen* “turned the tide” in favor of VICP claimants and has played a role in the government’s increased tendency to settle. Telephone Interview with Kevin Conway, *supra* note 94.

183. *See supra* Parts II.C.1, II.C.3.

volving “thorough procedure.”¹⁸⁴ The remaining cases were outliers and could not be easily categorized because they were disposed of on grounds unrelated to the merits (e.g., statute of limitations).¹⁸⁵ In practice, then, the VICP mimics the Black Lung Benefits and Florida and Virginia’s Birth Injury Programs examined in Part I, notwithstanding its more restrictive statutory language. Moreover, medical records, one of the most accessible and important portions of a claimant’s causation-in-fact evidence, are given special weight by the special masters.¹⁸⁶ This special weight is important for claimants, as every single VICP claimant must provide medical records.¹⁸⁷ Special masters presume the trustworthiness of medical records, since they are created by medical professionals and are “generally contemporaneous to the medical events.”¹⁸⁸

For other claims, however, where science is not yet developed enough to prove causation by a preponderance of the evidence, limited discovery may indeed have a negative impact on compensation outcomes. Recall that, unlike the black lung or birth injury compensation schemes, which focus solely on pneumoconiosis and birth injury, respectively, the VICP handles claims of all kinds of alleged vaccine injuries.¹⁸⁹ Moreover, vaccine injury claims must be filed within three years of “the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury”¹⁹⁰ Because the science underlying novel claims under the VICP is often undeveloped, claimants might run up against the statute’s three-year statute of limitations before they are able to provide expert testimony or obtain sufficient medical evidence of causation.¹⁹¹ This is the predicament of Ms. DeLoatch and all Gardasil claimants. With no advanced medical studies, Gardasil-injured claimants object that they cannot retain legitimate medical opinions and that, forced to file within the three-year period, their claims will be summarily dismissed. One amicus brief in *Bruesewitz* inquired: “With no medical literature

184. See *supra* Table II.

185. See *supra* notes 175–177 and accompanying text.

186. See *Gonzalez v. Sec’y of Health & Human Servs.*, No. 99-656V, 2006 WL 5668214, at *13 (Fed. Cl. Oct. 17, 2006) (“Medical records, in general, warrant consideration as trustworthy evidence.”).

187. 42 U.S.C. § 300aa-13(a)(1) (2006) (“The special master or court may not make [a finding of vaccine-related injury] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.”).

188. *Curacas v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (“Medical records, in general, warrant consideration as trustworthy evidence.”).

189. See *supra* notes 91–92 and accompanying text.

190. 42 U.S.C. § 300aa-16(a)(2).

191. *Id.*

discussing the mechanisms by which Gardasil could cause an adverse vaccine reaction, where could the pathologist begin to look?”¹⁹²

IV.

POSSIBLE REFORMS

In this Part I propose and discuss three possible reforms to the VICP that could ease the burden on claimants asserting novel theories or pursuing compensation for injuries allegedly caused by new vaccines such as Gardasil. However, in light of the empirical findings described above, it is unclear that altering the VICP’s procedural framework would significantly increase claimants’ ability to demonstrate causation. Moreover, any change to the existing VICP framework must be carefully weighed against the stated purposes of the law—namely to create a less formal, more nimble system for adjudicating vaccine injury claims. The proposals may, however, provide some relief for the few claimants pressing novel theories of injury.

First, the Vaccine Act and Vaccine Rules of the Court of Federal Claims could be amended to open up more discovery. Second, the process for amending the Vaccine Injury Table could be made more transparent, and the Table could be amended to make more claims “on-Table.” And third, the statute of limitations for VICP claims could be extended. While they all have disadvantages, they do get at the heart of the complaints lodged by the Gardasil claimants.

A. *More Discovery?*

First, it is possible to amend the Vaccine Act and Vaccine Rules to remove the VICP’s explicit restrictions on discovery. This would be accomplished by striking the restrictive portion of the Vaccine Act that gives the United States Court of Federal Claims the power to “provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.”¹⁹³ Rule 7 of the Vaccine Rules could be changed by striking the “no discovery as a matter of right” language and replacing it with something more permissive and more akin to Federal Rule of Civil Procedure 26.¹⁹⁴ These changes would have the advantage of putting VICP claimants nearer to the baseline level of

192. VIPBA Br., *supra* note 29, at 18.

193. 42 U.S.C. § 300aa-12(d)(2)(E).

194. *Compare* Fed. Cl. Vaccine R. 7(a) (2012) (“There is no discovery as a matter of right.”), with FED. R. CIV. P. 26(b)(1) (“Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense—including the existence, description, nature, custody, condition, and location of any documents or

ability to gather evidence that they would have in civil court.¹⁹⁵ At the same time, however, these changes would undercut Congress's purpose of providing both expedited procedures for claimants as well as a shield for vaccine manufacturers.¹⁹⁶ It is also important to note that the argument for abridged procedures is that they work to prevent "exactly the crisis that precipitated the Act, namely withdrawals of vaccines or vaccine manufacturers from the market"¹⁹⁷ Moreover, since so few claimants have been negatively impacted by the VICP's restrictive discovery rules, this proposal's benefits would reach only a very small subset of all VICP petitioners.

B. Overhauling the Vaccine Injury Table Amendment Process?

The process for amending the Vaccine Injury Table would benefit from more transparency. Recall that HHS has been criticized in the past for its opacity when it comes to Vaccine Injury Table amendments.¹⁹⁸ The Secretary should be more forthcoming with the reasoning and science underlying why certain vaccine injury claimants get the benefit of presumed causation and others do not. This would help mollify the concerns of the Gardasil claimants and others pressing novel vaccine injury claims.

Moreover, some have further suggested that HHS should also amend the Vaccine Injury Table to create more "on-Table" injuries. This would ease the burden on claimants, like the Bruesewitzes, who likely would have obtained compensation but for HHS' ill-explained removal of presumed causation for DPT vaccine-induced encephalopathy.¹⁹⁹ One prominent VICP litigator, Clifford Shoemaker, suggested a complete roll-back of the Vaccine Injury Table's amendments: "Reinstate the table of injuries originally created by Congress (as to the vaccines originally included) and remove the Secretary's power to change the table in such a way as to make it more difficult to

other tangible things and the identity and location of persons who know of any discoverable matter.").

195. In the *DeLoatch* case, for example, the special master recognized that in civil court, where the standard for producing discovery is less strict, Ms. DeLoatch's requests for information from Merck might be successful. *DeLoatch ex rel. Estate of Roberts v. Sec'y of Health & Human Servs.*, No. 09-171V, 2010 WL 5558349, at *6 (Fed. Cl. July 28, 2010).

196. See H.R. REP. NO. 99-908, at 12 (1986), reprinted in 1986 U.S.C.A.N. 6344, 6353 (noting that the VICP is "intended to be expeditious and fair" and "to lessen the number of lawsuits against manufacturers.").

197. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1085 (2011) (internal quotation marks omitted).

198. See *supra* note 99.

199. See *supra* note 22 and accompanying text.

receive compensation.”²⁰⁰ Providing for more on-Table injuries has the advantage of removing the often-insurmountable causation-in-fact burden that trips up so many off-Table claimants, like the Bruesewitzes.

But Mr. Shoemaker’s suggestions might be too far-reaching. For one, while the Vaccine Act indeed authorizes the Secretary of HHS to amend the Vaccine Injury Table as necessary, he or she can only do so after providing “for notice and opportunity for a public hearing and at least 180 days of public comment.”²⁰¹ The Center for Disease Control can suggest amendments to the Vaccine Injury Table,²⁰² and the Secretary is also monitored by a separate agency created by the Vaccine Act, the Advisory Commission on Childhood Vaccines (ACCV).²⁰³ The nine-member ACCV includes three health professionals (at least two of whom must be pediatricians), three attorneys (one of whom specializes in plaintiff-side vaccine litigation), and three members of the general public (at least two of whom are the legal representatives of vaccine-injured children).²⁰⁴ These extra administrative checks on the Secretary’s discretion weaken the case for completely removing his or her power to amend the Vaccine Injury Table.

Moreover, because the science underlying vaccine injuries is constantly evolving, there must be *some* mechanism for keeping the Vaccine Injury Table up-to-date. Congress, recognizing this changing landscape,²⁰⁵ did not mean to carve the 1986 version of the Vaccine Injury Table into stone. Similarly, the effects of some vaccines (e.g., Gardasil) simply may not yet be concrete enough to warrant a presumption of causation. However, this does not mean that HHS should not adequately explain why its research does not support presuming causation in Gardasil cases.²⁰⁶ Perhaps at the very least this important authority would be better vested in a representative body like the ACCV.

200. *Hearings, supra* note 24, at 90 (statement of Clifford J. Shoemaker, Attorney, Shoemaker & Horn).

201. 42 U.S.C. § 300aa-14(c) (2006).

202. *Id.* § 300aa-14(e).

203. *Id.* § 300aa-19(f). The ACCV advises the Secretary on the implementation of the VICP, recommends changes to the Vaccine Injury Table, surveys federal, state, and local reporting of adverse vaccine reactions, advises the Secretary on the gathering, compilation, publication, and use of data on adverse reactions, and recommends research related to vaccine injuries that should be conducted. *Id.*

204. *Id.* § 300aa-19(a).

205. See H.R. REP. NO. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 (“Previously unrecognized injuries associated with vaccines have become more widely known.”).

206. See *supra* note 99 and accompanying text.

C. *A Lengthened Statute of Limitations?*

Finally, it would serve the interests of all claimants to lengthen the Vaccine Act's three-year statute of limitations.²⁰⁷ Mr. Shoemaker suggested this change in his testimony before Congress, noting that an extension of the limit from three to six years would be a "modest" start.²⁰⁸ The issue plaguing many claimants is that, by the time the nascent scientific literature supporting their claim matures into something credible and accepted in the field, the Vaccine Act's statute of limitations has run. At that point, claimants are left only with civil tort law for recourse. This is the problem dogging Ms. DeLoatch and other Gardasil claimants.²⁰⁹ Attorney Kevin Conway noted ongoing efforts to obtain indefinite stays of Gardasil proceedings for his clients until more solid information about the vaccine's effects could be obtained.²¹⁰ Extending the statute of limitations, while perhaps subjecting the government to more liability, would go a long way toward easing the fears of potential claimants who would otherwise be unable to obtain sufficient information to lodge a complete complaint.

CONCLUSION

What remains after this empirical look at VICP claims is an answer to the question the Supreme Court disregarded in *Bruesewitz*. For most claimants, the administrative compensation program offers a comprehensive, well-considered, and good faith effort by the special masters to decide complex causation-in-fact issues. In most cases, this means that an extensive record and heaps of evidence factor into the ultimate decision. For a few, however, the challenge of undeveloped scientific knowledge is exacerbated by procedural limitations to which the special masters are bound under the Vaccine Act. Relaxing these procedural limitations, while not without its own danger, could provide some relief while new medical theories of causation are developed. Because VICP procedures work so permissively and comprehensively for the vast majority of claimants, however, none of these reforms seems necessary.

207. 42 U.S.C. § 300aa-16.

208. *Hearings*, *supra* note 24, at 86 (statement of Clifford J. Shoemaker, Attorney, Shoemaker & Horn).

209. *See Barnes v. Sec'y of Health & Human Servs.*, No. 09-603V, 2010 WL 4791638, at *4 (Fed. Cl. Oct. 19, 2010) (discussing petitioner's argument that "unless she obtains an indefinite stay of proceedings, she will not be able to prove Prong 1 of *Althen*, i.e., that Gardasil can cause fibromyalgia").

210. Telephone Interview with Kevin Conway, *supra* note 94.

