

NOTE

BALANCING POLICY TENSIONS OF THE VACCINE ACT IN LIGHT OF THE OMNIBUS AUTISM PROCEEDING: ARE PETITIONERS GETTING A FAIR SHOT AT COMPENSATION?

I. INTRODUCTION

Her life has been marked with sadness and suffering, but when Michelle Cedillo was born in 1994 she was a happy, healthy baby.¹ She shifted into her toddler years meeting all key developmental milestones.² Then at fifteen months of age she received the measles-mumps-rubella (“MMR”) vaccine³ and her life was changed forever. Michelle’s development began to regress as she became increasingly less interactive and affectionate, lost motor skills and the ability to verbalize, and began engaging in repetitive behavior patterns.⁴ Her condition continued to

1. Theresa Cedillo, *Gone in Seven Days: A Brief Story of Our Daughter Michelle’s Vaccine Injury and Subsequent Landmark Court Case*, 33 THE AUTISM FILE 46, 46 (2009).

2. See Cedillo, *supra* note 1, at 46; *Learn the Signs — Milestones*, AUTISM SPEAKS, <http://www.autismspeaks.org/whatisit/milestones.php> (last visited July 4, 2011) (describing typical developmental milestones for children. For example, a child at three to four months of age “[w]atches faces with interest and follows moving objects . . . [b]egins to develop a social smile[,] and [t]urns [her] head toward sounds.” At seven months, a child typically “[r]esponds to other people’s emotions[,] [e]njoys face-to-face play . . . [and] [r]esponds to [her] own name.” A one-year old child generally “[e]njoys imitating people; tries to imitate sounds . . . uses simple gestures[,] such as pointing to an object, [and] [b]abbles with changes in tone[] [or] may use single words.” By two years of age, a child “[u]nderstands several words[,] . . . [b]egins to sort by shapes and colors [and] . . . [c]ombines two words to communicate with others.” At three years old, a child “[e]xpresses affection openly and has a wide range of emotions[,] . . . [f]ollows a 2- or 3- part command[,] [and] uses simple phrases to communicate with others.”).

3. Cedillo, *supra* note 1, at 46; see also Michael E. Horwin, Comment, *Ensuring Safe, Effective and Necessary Vaccines for Children*, 37 CAL. W. L. REV. 321, 326 (2001) (noting that children today receive twenty-four injections, including “five doses of DPT, four doses of polio vaccine, two doses of measles, mumps and rubella, three injections of hepatitis B, one shot of varicella (chicken pox), . . . four injections of a pneumococcal conjugate vaccine, and, depending on where the child lives, . . . one shot of hepatitis A”). In addition, twenty of these injections are administered before the child reaches eighteen months old. *Id.*

4. See Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of February 12, 2009 at 20, *Cedillo v. Sec’y of HHS*, 89 Fed. Cl. 158 (2009) (No. 98-916V), available at <http://www.whale.to/vaccine/michellesappeal03162009.pdf> (“Mr. and Mrs. Cedillo noticed a change in Michelle’s behavior beginning a few weeks after her illness following the MMR vaccination. Michelle became less interactive and affectionate with her family, and

decline, and, eventually Michelle was diagnosed with autism.⁵

Michelle, now a teenager, spends most of her life confined to her bed or a wheelchair instead of attending football games and dances with friends.⁶ In addition, she is under the care of seven pediatric specialists, must use a feeding tube for meals and medication, cannot speak, and requires constant supervision from her parents.⁷ Unfortunately, Michelle's story is not unique. Michelle Cedillo is just one of thousands of children who allege that the administration of a childhood vaccine caused them to develop autism.⁸

Autism is loosely defined as a complex and life-long neurological disorder.⁹ Although the modern study of autism began in 1943 by the Austrian psychiatrist Leo Kanner,¹⁰ there is still little known about the condition's exact etiology.¹¹ Characterized as a developmental disorder, autism typically manifests during early childhood and adversely affects the individual's ability to develop normally.¹² The symptoms of autism range from mild to severe brain dysfunction that may cause impairments in verbal and physical communication, difficulty with social interaction, and decreased physical health.¹³ These symptoms serve to isolate the autistic from the world around them and cause numerous hardships for

stopped using words and communicative behavior she previously produced.”).

5. Cedillo, *supra* note 1, at 46. “Autism is a complex developmental disability that typically appears during the first three years of life and affects a person’s ability to communicate and interact with others. Autism is defined by a certain set of behaviors and is a ‘spectrum disorder’ that affects individuals differently and to varying degrees.” *About Autism*, AUTISM SOC’Y, <http://www.autism-society.org/about-autism/> (last updated Jan. 21, 2008).

6. See Cedillo, *supra* note 1, at 47.

7. *Id.* at 46. In addition to autism, Michelle suffers from “Crohn’s disease, arthritis, spondyloarthritis, osteoporosis, uveitis, open angle glaucoma, and intractable grand mal epilepsy.” *Id.*

8. As of August 2010, over 5,600 petitions for compensation have been filed alleging that certain childhood vaccines caused or contributed to autism. Dep’t of Health & Human Servs., *About the Omnibus Autism Proceeding*, HEALTH RESOURCES & SERV. ADMIN., <http://www.hrsa.gov/vaccinecompensation/omnibusproceeding.htm> (last updated Dec. 21, 2010) [hereinafter *Omnibus Autism Proceeding*].

9. Helia Garrido Hull, *Induced Autism: The Legal and Ethical Implications of Inoculating Vaccine Manufacturers from Liability*, 34 CAP. U. L. REV. 1, 4 (2005).

10. See generally Leo Kanner, *Autistic Disturbances of Affective Contact*, 2 NERV. CHILD 217 (1943) (describing Kanner’s breakthrough observations and evaluations on the behavior of eleven autistic children).

11. Hull, *supra* note 9, at 3-4.

12. Katherine Marie Bulfer, *Childhood Vaccines and Autism: Does the National Childhood Vaccine Injury Act Leave Parents of Children with Autism Out in the Cold with Nowhere to Go?*, 27 CAMPBELL L. REV. 91, 92 (2004).

13. Hull, *supra* note 9, at 4; Joëlle Anne Moreno, *It’s Just a Shot Away: MMR Vaccines and Autism and the End of the Daubertista Revolution*, 35 WM. MITCHELL L. REV. 1511, 1518 (2009); see also Cedillo, *supra* note 1, at 46 (discussing the decline in physical health for a recently diagnosed autism patient).

their caretakers.¹⁴ Although autism generally affects an individual for her entire life, the condition generally has no effect on the individual's life span.¹⁵

Documented cases of autism around the world have experienced a marked increase in recent history.¹⁶ In fact, the most recent data from the Centers for Disease Control suggests that one in every 110 children in the United States is diagnosed with an autism spectrum disorder ("ASD").¹⁷ That figure represents a huge increase from studies conducted in the 1960s that indicated only four or five cases of autism in every 10,000 people.¹⁸ The growing prevalence of the disorder has led many researchers and advocacy groups to refer to the increase as the "autism 'epidemic.'"¹⁹

Several theories are posited to explain the rise in instances of autism.²⁰ Some researchers contend that the escalation in cases does not represent a true increase but is instead a reflection of the broadened definition of ASD and heightened recognition of autism.²¹ Still others believe that autism is created by certain "[g]enetic predisposition[s], metabolic abnormalities, and abnormalities of the gastrointestinal, hepatic, [or] immune system[]." ²² Advocates of the theory linking autism to vaccines assert that vaccines can either exacerbate the above abnormalities and ultimately result in autism, or that vaccines can cause autism independent of other preexisting factors.²³

14. Bulfer, *supra* note 12, at 92-93 (noting that in addition to the characteristic difficulties of physical and verbal communication, some individuals with autism never learn to speak).

15. Holly Bortfeld, *Health Insurance Coverage for Biomedical & Traditional Treatments*, TALK ABOUT CURING AUTISM (Sept. 1, 2008), <http://www.talkaboutcuringautism.org/resources/autism-insurance/insurance-coverage-for-biomedical-traditional-treatments.htm>.

16. See Hull, *supra* note 9, at 4-5 (discussing the prevalence of autism).

17. Ctrs. for Disease Control & Prevention, *Prevalence of Autism Spectrum Disorders - Autism and Developmental Disabilities Monitoring Network, United States, 2006*, 58 MORBIDITY & MORTALITY WKLY. REP. 1, 14 (2009), available at <http://www.cdc.gov/mmwr/pdf/ss/ss5810.pdf> [hereinafter *Prevalence of Autism Spectrum Disorders*]. Autism spectrum disorders ("ASD") are a range of developmental disorders "characterized by atypical development in socialization, communication, and behavior." *Id.* at 2. See also Bradley J. Andrus, *In the Courts: Autism Proceedings in the Vaccine Court*, 28 CHILD. LEGAL RTS. J. 56, 57 (2008) (explaining that the three main types of ASD are autism, Asperger's syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)).

18. Bulfer, *supra* note 12, at 93.

19. *Id.*; Jeffrey P. Baker, *Mercury, Vaccines, and Autism: One Controversy, Three Histories*, 98 AM. J. PUB. HEALTH 244, 250 (2008).

20. See Andrus, *supra* note 17, at 60; Bulfer, *supra* note 12, at 93-94; Moreno, *supra* note 13, at 1520-21.

21. Moreno, *supra* note 13, at 1519.

22. Bulfer, *supra* note 12, at 93.

23. See *The Autism Proceedings: Background Information*, U.S. CT. OF FED. CLAIMS, http://www.uscfc.uscourts.gov/sites/default/files/autism.background.2010_0.pdf (last updated Mar. 12,

Over the past decade, the fear of a causal link between vaccines and autism has garnered an anti-vaccination movement comprised of a large group of skeptics who maintain that vaccines are dangerous and should not be used.²⁴ Though it was already years in the making, the vaccine-autism controversy really began to heat up in 1998 when a study published in the *Lancet*²⁵ by British doctor Andrew Wakefield²⁶ indicated a link between the MMR vaccine and autism.²⁷ Then in 1999, the U.S. Public Health Service and the American Academy of Pediatrics recommended that vaccine manufacturers remove thimerosal²⁸ from vaccines as soon as possible.²⁹ Finally, in 2008, the U.S. Department of Health and Human Services conceded that a vaccine had irritated a preexisting mitochondrial condition in ten-year old Hannah Poling that

2010 1:38PM) (listing the three theories of general causation under which autism petitions have been filed).

24. Chris Mooney, *Why Does the Vaccine/Autism Controversy Live On?*, DISCOVER, June 2009, at 58, 59 (“The idea that there is something wrong with our vaccines—that they have poisoned a generation of kids, driving an ‘epidemic’ of autism—continues to be everywhere: on cable news, in celebrity magazines, on blogs, and in health news stories. It has had a particularly strong life on the Internet, including the heavily trafficked *Huffington Post*, and in pop culture . . . [d]espite repeated rejection by the scientific community, it has spawned a movement, led to thousands of legal claims, and even triggered occasional harassment and threats against scientists whose research appears to discredit it.”).

25. See A.J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637 (1998). It should be noted that this article was later retracted because “it has become clear that several elements . . . are incorrect, [and] contrary to the findings of an earlier investigation.” Editors of the *Lancet*, *Retraction—Ileal-lymphoid-nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children* (Feb. 2, 2010), <http://press.thelancet.com/wakefieldretraction.pdf>.

26. Andrew Wakefield, a British former gastrointestinal surgeon, was the lead author of the controversial 1998 article first linking vaccines to autism. See *Profile: Andrew Wakefield, the Man at the Centre of the MMR Scare*, THE TIMES (May 24, 2010), <http://www.timesonline.co.uk/tol/news/uk/article7135099.ece>. Dr. Wakefield’s findings resulted in a frenzied fear of vaccines, causing immunization levels to plunge to record lows. *Id.* In the aftermath of the article, Dr. Wakefield was accused of fraud and his study was eventually discredited. *Id.* In 2010, Dr. Wakefield’s British medical license was revoked. *Id.* He currently lives in Texas where he continues to research autism. *Id.*

27. See generally Wakefield et al., *supra* note 25 (describing a study of twelve previously normal autistic children who had developed inflammatory bowel disease after receipt of the MMR vaccine); but see Kevin B. O’Reilly, *Regaining Trust After Vaccine Threat Debunked*, AM. MED. NEWS (Jan. 24, 2011), <http://www.ama-assn.org/amednews/2011/01/24/prl20124.htm> (noting that the *Lancet* retracted Dr. Wakefield’s article in January 2010. In addition, Dr. Wakefield’s study has been met with countless allegations of fraud, conflicts of interest, and ethics violations after the *British Medical Journal* concluded that Wakefield had “‘altered numerous facts about the patients’ medical histories in order to support his claim to have identified a new syndrome’ and ‘sought to exploit the ensuing MMR scare for financial gain.’”).

28. Andrus, *supra* note 17, at 57. Thimerosal is a preservative composed of 49.6% ethyl mercury by weight that was used in over thirty childhood vaccines before it was completely phased out in 2001. *Id.* at 57; Moreno, *supra* note 13, at 1514 n.13.

29. Andrus, *supra* note 17, at 57.

resulted in her developing autism.³⁰ Although research is ongoing, numerous medical and scientific reports, as well as the U.S. Court of Appeals for the Federal Circuit, expressly deny a vaccine-autism link.³¹

In 1986, Congress established the Vaccine Injury Compensation Program (“VICP”) to guarantee the continued stability of the vaccine market and to ensure compensation for individuals who had been injured by a vaccine.³² Vaccine injury claims are overseen by the Office of Special Masters (“OSM”) of the Court of Federal Claims,³³ informally referred to as “Vaccine Court.”³⁴ In 2002, as a response to the growing vaccine-autism controversy, the OSM coordinated the “Omnibus Autism Proceeding” (“OAP”)³⁵ to consolidate and adjudicate the significant number of anticipated claims alleging a causal relationship between vaccines and autism.³⁶

The OAP is significant for several reasons. For one, there are currently 5636 petitioners in the OAP searching for answers to their illness and anxiously waiting to find out whether they will receive

30. See *Poling ex rel. Poling v. Sec’y of HHS*, No. 02-1466V, 2008 WL 1883059, at *3 (Fed. Cl. Apr. 10, 2008); Michael J. Donovan, *The Impact of “Hurricane” Hannah: The Government’s Decision to Compensate in One Girl’s Vaccine Injury Case Could Drastically Alter the Face of Public Health*, 50 JURIMETRICS J. 229, 233, 249 (2010) (describing the government’s decision to award compensation to Hannah Poling despite the fact that causation was not demonstrated and noting that no rationale has been published for the Court’s conclusion).

31. See, e.g., *Cedillo v. Sec’y of HHS*, 617 F.3d 1328, 1337 (Fed. Cir. 2010); *Hazlehurst v. Sec’y of HHS*, 604 F.3d 1343, 1354 (Fed. Cir. 2010); *Snyder ex rel. Snyder v. Sec’y of HHS*, 88 Fed. Cl. 706, 748 (2009); IMMUNIZATION SAFETY REVIEW COMM. BD. ON HEALTH PROMOTION & DISEASE PREVENTION, IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 7 (2004) (detailing a 2004 study conducted by the Institute of Medicine (IOM) that conclusively rejects a causal relationship between vaccines and autism). There has also been an inability to recreate the initial findings of Dr. Wakefield’s study, leading to numerous retractions on the part of Dr. Wakefield and criticisms of his study. See Mady Hornig et al., *Lack of Association Between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study*, PLOS ONE, Sept. 2008, at 1, 5, available at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0003140>.

32. See National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986) (codified at 42 U.S.C. § 300aa-1–34 (2006)). The compensation provision is located at § 330aa-10(a) of the Act. 42 U.S.C. § 300aa-10(a) (2006).

33. Vaccine injury claims are governed under the National Childhood Vaccine Injury Compensation Act (“Vaccine Act” or “Act”). 42 U.S.C. § 300aa-10–11 (2006). The Act further establishes the Office of Special Masters. 42 U.S.C. § 300aa-12(c)(1) (2006).

34. The mainstream media commonly refers to the OSM as the “Vaccine Court.” See, e.g., Miranda Hitti, *Vaccine Court Rejects Autism Claims*, WEBMD (Feb. 12, 2009), <http://www.webmd.com/brain/autism/news/20090212/vaccine-court-rejects-autismclaims>.

35. See Autism General Order # 1, 2002 WL 31696785, at *3 (Fed. Cl. July 3, 2002).

36. *Id.* at *1. The OAP adopted a two-step procedure for handling autism claims. First, the OSM designated eight individual special masters to explore into the general causation issues involved in the case (specifically, whether there exists a causal link between vaccines and autism). In the second step of the framework, the designated special masters were to apply the findings of the general causation inquiry to the individual cases. *Id.* at *3.

compensation.³⁷ In addition, the claims of a vaccine-autism link have created tremendous anxiety in the hearts and minds of many parents who struggle with the question of whether they should have their children vaccinated.³⁸ Vaccine proponents who emphasize the health benefits of vaccines are optimistic that the OAP will reassure worried parents by conclusively establishing that there is no link between vaccines and autism.³⁹

The OAP is also significant for revealing the fundamentally competing policy tensions that exist between compensating injured petitioners and upholding the public confidence in vaccines and their use.⁴⁰ This Note contends that these unresolved policy conflicts have created a tension that burdens special masters during the fact-finding process. The high-publicity case *Cedillo v. Secretary of Health and Human Services*⁴¹ will be applied as an example of how the tension special masters feel may influence their ultimate conclusions. Although it will highlight scientific evidence from *Cedillo* and analyze the Special Master's findings, this Note is not an attempt to draw any conclusions regarding the safety of vaccines or the existence of a vaccine-autism link.

This Note will proceed as follows. Part II will review the general history of vaccines, the current use of vaccines in the United States, and the events immediately preceding the creation of the Vaccine Act. The discussion will then shift to a detailed description of the Vaccine Act's statutory framework and relevant Vaccine Court precedent. This Part will conclude by tracing the formation of the OAP and providing a brief account of the OAP test case *Cedillo*.

Part III will commence with an outline of the legislative intent of the Vaccine Act and the emergence of the competing policy concern. Next, this Part will articulate how the task of balancing the incompatible policies has fallen on the shoulders of the special masters rather than being resolved by Congress or the Federal Circuit. Part III will also

37. Dep't of Health & Human Servs., *National Vaccine Injury Compensation Program: Statistics Report*, HEALTH RESOURCES & SERV. ADMIN. (June 2, 2011), http://www.hrsa.gov/vaccinecompensation/statistics_report.htm [hereinafter *VICP Statistics Report*].

38. Erin Andersen, *Parents Remain Skeptical Over Newest Autism Report*, LINCOLN J. STAR (Jan. 8, 2011, 6:00 AM), http://journalstar.com/news/local/article_91aae8b3-82d9-5716-ac5c-3c4a4bbc7000.html; see also Roy Richard Grinker, Op-Ed., *Science on Trial*, WALL ST. J., June 30-July 1, 2007, at A6 (noting that the "anti-vaccine movement may be evidence that the public confidence in science is eroding, which means that public health is at risk too").

39. See Arthur Allen, *In Your Eye, Jenny McCarthy: A Special Court Rejects Autism-Vaccine Theories*, SLATE (Feb. 12, 2009, 3:35 PM ET), <http://www.slate.com/id/2211156>.

40. See discussion *infra* Part III.A-B.

41. 617 F.3d 1328 (Fed. Cir. 2010).

examine the impact and consequences that the conflicting policy concerns may have on the OAP. Part IV will provide a detailed illustration of how *Cedillo* highlights the issue of fundamental policy clashes and how special masters have been left to strike the balance between them.

Part V proposes a process solution to improve the OAP cases to ensure that the original intent of Congress is upheld. Specifically, Part V will recommend that the Federal Circuit give more guidance to the special masters on how to strike a balance between the competing policies. Finally, this Part will conclude with a discussion of how clarifying previous Federal Circuit precedent and providing more guidance will be the fairest and most efficient way to balance the policy tensions.

II. FROM SHARP POINTS TO PUNCTURE WOUNDS: THE IMPACT OF VACCINES AND THEIR USE IN THE PAST, PRESENT, AND FUTURE

Vaccines are commonly celebrated as a great victory for modern medicine and public health.⁴² The use of vaccines has been instrumental in the near to complete eradication of diseases which have historically claimed millions of lives.⁴³ Today, vaccines are considered to be so effective that every state has made immunization a condition precedent to enrollment in public or private school or licensed day care facilities.⁴⁴ Several vaccines are presently mandated in the United States to prevent diseases such as “polio, diphtheria, pertussis, tetanus, measles, mumps, rubella, congenital rubella syndrome, smallpox, influenza, hepatitis B,

42. Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241, 247 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056803.htm> [hereinafter *Ten Great Public Health Achievements*]; see also H.R. REP. NO. 99-908, at 4 (1986), reprinted in 1986 U.S.C.A.N. 6344, 6345 (stating that “[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken”).

43. See *Ten Great Public Health Achievements*, *supra* note 42, at 243-44 (explaining that prior to the advent of vaccines, diseases and viruses such as smallpox, polio, diphtheria, measles, mumps, and rubella were rampant); Rob Henson, Comment, *Inoculated Against Recovery: A Comparative Analysis of Vaccine Injury Compensation in the United States and Great Britain*, 15 TULSA J. COMP. & INT’L L. 61, 61 (2007) (noting that at the dawn of the twentieth century, infectious disease was so prevalent that 160 of every 1000 children born in the United States never reached their fifth birthday).

44. See James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 868-69 (2002) (noting that most existing vaccination laws were enacted as a precautionary measure in response to the measles outbreak in schools during the 1960s and 1970s).

varicella (chicken pox), *Haemophilus influenzae* type b . . . , and pneumococcal disease.”⁴⁵

A. Vaccines: Past and Present

The science behind vaccines is groundbreaking and dates back to the ancient Indian practice of “variolaion,” or direct, intentional exposure to a virus in order to create immunity.⁴⁶ A contemporary vaccination is essentially the introduction of a weakened strain of a particular disease or virus into the body in order to create antibodies.⁴⁷ The weakened strain of antigens is typically not strong enough to create full-blown symptoms of the virus or disease but *is* strong enough for the immune system to create antibodies against them.⁴⁸ In turn, these antibodies respond by attacking and defeating the intruding organism that was introduced into the body by the vaccine.⁴⁹ The cells involved in the antibody production create “memory cells” to remember the antigen and defend the body if it encounters the virus or disease again.⁵⁰

In 1796, Dr. Edward Jenner created the first contemporary vaccine.⁵¹ Dr. Jenner obtained cowpox matter from the arm of a dairymaid who was previously infected with smallpox and introduced the sample into the arm of a healthy young boy.⁵² The boy became immune to smallpox, and modern vaccines were born.⁵³ Dr. Jenner’s discovery marked the beginning of the recognition that introducing a weakened strain of a virus (rather than a full-blown attack as in variolaion) was a much safer and effective approach to creating mass immunity.⁵⁴

45. Henson, *supra* note 43, at 61.

46. See Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 363 (2004) (explaining variolaion and how the theories supporting it eventually led to the creation of contemporary vaccines).

47. *Id.* at 362-63.

48. Ctrs. for Disease Control & Prevention, *How Vaccines Prevent Disease*, DEP’T OF HEALTH & HUMAN SERVS., <http://www.cdc.gov/vaccines/vac-gen/howvpd.htm> (last updated Aug. 7, 2009) [hereinafter *How Vaccines Prevent Disease*].

49. Lisa J. Steel, Note, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?*, 63 GEO. WASH. L. REV. 144, 147 (1994).

50. *How Vaccines Prevent Disease*, *supra* note 48.

51. Calandrillo, *supra* note 46, at 364.

52. *Id.*

53. *Id.*

54. *Id.*

After Dr. Jenner's breakthrough, the use of vaccines spread quickly in several developed countries throughout the world.⁵⁵ In the early 1800s, many members of the United States government began to recognize the valuable contributions of vaccines to public health.⁵⁶ In 1905, the Supreme Court held that compulsory vaccination laws by states and municipalities were constitutional.⁵⁷ By the mid-twentieth century, elimination and control of diseases such as smallpox and polio led to wide scale efforts towards mass immunity through the use of compulsory vaccinations.⁵⁸ To date, vaccines are credited with safeguarding humans from over twenty once-deadly diseases.⁵⁹ In addition to saving lives, the use of vaccines has served to save billions of dollars in resources.⁶⁰ Due to the many successes of vaccines, it is nearly impossible to question their utility.⁶¹

Perhaps the most notable characteristic of vaccines is that they are effective only when administered to the masses.⁶² This characteristic caused compulsory vaccination to become standard or highly recommended in most well developed countries.⁶³ The need for "herd immunity"⁶⁴ resulted in controversy when numerous individuals began reporting adverse reactions subsequent to a vaccination.⁶⁵ This issue is underscored by the fact that the risk of an adverse reaction is nearly

55. *Id.*

56. *Id.* at 365.

57. *See Jacobson v. Massachusetts*, 197 U.S. 11, 12, 39 (1905).

58. Calandrillo, *supra* note 46, at 365-68.

59. *Id.* at 369 (stating that modern day vaccines "protect against over twenty deadly diseases, including smallpox, measles, mumps, rubella, diphtheria, tetanus, pertussis (whooping cough), polio, hepatitis A and B, some forms of influenza, pneumococcal disease, *Haemophilus influenzae* type b, and varicella (chicken pox)").

60. *Id.* at 380 ("Vaccine-preventable diseases cost 16 times more in medical-related costs than do the vaccines that prevent those diseases.").

61. *See* Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 432 (2007) ("According to the U.S. General Accountability Office ("GAO") vaccination in the United States has resulted in a ninety-five percent reduction in the number of people who contract 'vaccine-preventable diseases.'").

62. *Id.* (explaining that anyone who is not vaccinated may still catch the disease and spread it to others). Strong references one instance in which vaccination rates dropped in the former Soviet Union, and a diphtheria epidemic emerged that resulted in an increase of the disease from 839 cases in 1989 to nearly 50,000 cases in 1994. *Id.*

63. *See* Calandrillo, *supra* note 46, at 381-83 (discussing the history of compulsory vaccination laws in the U.S.); *see also* Strong, *supra* note 61, at 433 (noting that today most U.S. children are vaccinated at a rate of about 57,000 children per week).

64. Strong, *supra* note 61, at 432 (describing the term "herd immunity" to mean that the success of vaccines is dependent upon "virtually everyone getting vaccinated").

65. *Id.* at 433 (explaining that reported reactions ranged from "local reactions at the injection sight [sic], such as redness or swelling, to more severe systemic reactions such as convulsions or very high fevers").

unavoidable because it is impossible to know prior to administration of the vaccine whether a person will suffer a negative reaction to it.⁶⁶

B. *Civil Lawsuits on the Rise*

In the 1980s, pharmaceutical manufacturers came under fire when countless individuals initiated lawsuits against them in civil court claiming an adverse reaction to a vaccine.⁶⁷ These lawsuits were costly to the vaccine manufacturers, with damage claims climbing to approximately 3.5 billion dollars between 1980 and 1986.⁶⁸ In response to the high damage awards and fear of limitless liability in future lawsuits, many pharmaceutical manufacturers began to seriously limit or cease the production of vaccines.⁶⁹

With the increase in litigation, reports of adverse reactions quickly spread to the general public, resulting in fear and lack of confidence in vaccines.⁷⁰ Faith in vaccines also began to dwindle due to the fact that many of the diseases that vaccines were meant to protect had been all but eradicated.⁷¹ As a result, parents were considerably more concerned with the potential risk of adverse reaction presented by vaccines than by the diseases that vaccines had already eliminated.⁷²

C. *The National Childhood Vaccine Injury Act of 1986*

By 1985, the mass exodus of manufacturers from the vaccine market left just four companies still producing the vaccines that states had mandated for childhood immunizations.⁷³ As a result, vaccine

66. See H.R. REP. NO. 99-908, at 6 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347 (“There is today no ‘perfect’ or reaction-free childhood vaccine on the market . . . it is not always possible to predict” who will have reactions or what the reactions will be.).

67. See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL’Y & L. 59, 60 (1999) (citing relevant case law); see generally S. A. Sturges, Comment, *Vaccine-Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U. L.J. 919 (1986) (describing the historical background of vaccine manufacturer tort liability and how it gave rise to several claims including products liability, breach of warranty, and duty to warn). Several courts even imposed strict liability upon the vaccine manufacturers). *Id.*

68. Strong, *supra* note 61, at 434.

69. Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J.L. & PUB. POL’Y 537, 550 (2010).

70. Calandrillo, *supra* note 46, at 388.

71. Apolinsky & Van Detta, *supra* note 69, at 550.

72. *Id.*

73. H.R. REP. NO. 99-908, at 7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6348 (noting that, at the time, there was “only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine”).

production was limited and vaccine prices increased significantly.⁷⁴ The Centers for Disease Control stated that local shortages of vaccines had been reported and indicated that certain vaccines in the vaccine stockpiles were at below safe levels.⁷⁵ The reduction of vaccine supply and increase in prices created concern for the state immunization programs.⁷⁶ Disruption to the vaccine supply and immunization programs caused concern for a potential “vaccine crisis” and the consequent increase of public susceptibility to diseases that had long been under control or wiped out altogether.⁷⁷

Before the vaccine crisis could fully come to fruition, Congress intervened by passing the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act” or “Act”).⁷⁸ The Vaccine Act legislation was enacted in order to provide liability protection to vaccine manufacturers and to compensate vaccine recipients who had been harmed by a vaccine.⁷⁹ The Vaccine Act itself contains two parts. Part One established the National Vaccine Program that mandates continued research of vaccines, their possible side effects, and methods for improving vaccines.⁸⁰ Part Two of the Act instituted VICP.⁸¹ The VICP provides a means for individuals who were potentially injured by a vaccine to receive compensation.⁸²

1. Objectives and Strictures of the Vaccine Injury Compensation Program

The principle objective of the VICP was to establish a federal no-fault compensation system in which compensation would be awarded to vaccine-injured individuals “quickly, easily, and with certainty and generosity.”⁸³ The Congressional intent behind the VICP was to ensure continued production and adequate supply of vaccines by reducing tort litigation against physicians and manufacturers while simultaneously

74. Ridgway, *supra* note 67, at 61.

75. *Id.*

76. Strong, *supra* note 61, at 434.

77. *Id.*

78. 42 U.S.C. § 300aa-1–34 (2006).

79. H.R. REP. NO. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348 (“[T]wo overriding concerns have led to the development of this legislation: (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine-manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market.”).

80. 42 U.S.C. § 300aa-2(a)(1)–(2), (7).

81. *Id.* § 300aa-10–34.

82. *Id.* § 300aa-10.

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

providing injured claimants with an opportunity for redress.⁸⁴ The Vaccine Act does not eliminate a petitioner's ability to file a civil action.⁸⁵ However, civil suits are limited in two ways. First, the Act imposes a requirement that parties first file a petition and exhaust available remedies in Vaccine Court prior to initiation of a civil lawsuit.⁸⁶ Second, the Act places modifications upon the tort theories under which the action may be filed.⁸⁷

2. Filing and Deadlines

The Vaccine Act requires that individuals wishing to assert a vaccine-related injury must file a petition in the United States Court of Federal Claims.⁸⁸ The petition must also be served upon the Secretary of Health and Human Services, the named respondent in Vaccine Court cases.⁸⁹ The petition must include an affidavit and documentation that indicates that the individual received a vaccination covered by the VICP and that the vaccine was administered to the individual in the United States or its trust territories.⁹⁰ The Vaccine Act set forth a thirty-six

84. *See id.* at 13, *reprinted in* 1986 U.S.C.C.A.N. at 6354 (stating 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* DIV. OF VACCINE INJURY COMP., NATIONAL VACCINE INJURY COMPENSATION PROGRAM STRATEGIC PLAN 4 (2006), *available at* http://www.hrsa.gov/vaccinecompensation/strategic_plan.htm (explaining that the mission of the VICP is "[t]o process . . . claims expeditiously and fairly utilizing current vaccine safety research to determine injuries thought to be caused by vaccines, and raise awareness about the existence of the VICP").

85. *See* 42 U.S.C. § 300aa-11(a)(2)(A).

86. *Id.* ("No person may bring a civil action for damages in an amount greater than \$1,000 . . . against a vaccine administrator or manufacturer in State or Federal court for damages arising from a vaccine-related injury or death . . . unless a petition has been filed . . . for compensation under the Program for such injury or death . . .").

87. *Id.* § 300aa-22. For example, a vaccine manufacturer typically cannot be held liable under claims of duty to warn or design defects. Victor E. Schwartz & Liberty Mahshagian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 393 (1987). In addition, vaccine manufacturers are insulated from punitive damages provided that the vaccine complied with the requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. *Id.* at 393.

88. 42 U.S.C. § 300aa-11(a)(1).

89. *Id.*; *see also id.* § 300aa-12(b)(1) (noting that the Secretary of Health and Human Services is to be the named respondent).

90. *Id.* § 300aa-11(c)(1)(A)–(B)(i)(I); *see also* *National Childhood Vaccine Injury Act: Vaccine Injury Table*, HEALTH RESOURCES & SERV. ADMIN., (Nov. 10, 2008), <http://www.hrsa.gov/vaccinecompensation/table.htm> (listing the vaccines currently covered under the VICP, including tetanus toxoid-containing vaccines, pertussis antigen-containing vaccines, MMR virus-containing vaccines in any combination, rubella virus-containing vaccines, measles virus-containing vaccines, polio live virus-containing vaccines, polio inactivated-virus containing vaccines, hepatitis B antigen-containing vaccines, *hemophilus influenzae* type b, varicella vaccine, rotavirus vaccine, pneumococcal conjugate vaccines, and any new vaccines recommended by the Centers for Disease

month statute of limitations from the onset of injury in vaccine-related cases.⁹¹ In instances of death, the individual's estate must file within twenty-four months of the date of death.⁹²

3. The Role of Special Masters

The Vaccine Act created the Vaccine Court, to adjudicate all vaccine claims.⁹³ The Vaccine Court is composed of one chief special master and seven associate special masters.⁹⁴ Special masters are appointed by the U. S. Court of Federal Claims and serve four-year terms.⁹⁵ Special masters are delegated with the authority to make all findings of fact and conclusions of law in "Vaccine Court" cases.⁹⁶ Thus, the special master appointed to a case has jurisdiction over all proceedings, including medical records, evidence, hearings, testimony, and all aspects of discovery.⁹⁷ The Vaccine Act requires the special master to reach a determination "as expeditiously as practicable, but not later than 240 days" from the filing of the petition.⁹⁸ If either party needs to suspend proceedings, or if the special master is unable to render a

Control).

91. 42 U.S.C. § 300aa-16(a)(2). In May 2010, *Cloer v. Secretary of Health and Human Services*, which was later vacated by the Federal Circuit, provided a more generous interpretation of the statute of limitations, holding that "for the purposes of § 300aa-16(a)(2), to be 'vaccine-related[.]' the 'first symptom or manifestation of onset or of the significant aggravation of such injury' cannot occur until the medical community at large objectively realizes a link between the vaccine and the injury." 603 F.3d 1341, 1346 (Fed. Cir. 2010), *vacated*, 399 Fed. App'x 577 (Fed. Cir. Oct. 25, 2010); *see also* Kent Heckenlively, *The Cloer Decision - When Does the Statute of Limitations Begin to Run for Vaccine-Induced Autism?*, AGE OF AUTISM (June 10, 2010, 5:45 AM), <http://www.ageofautism.com/2010/06/the-cloer-decision-when-does-the-statute-of-limitations-begin-to-run-for-vaccine-induced-autism.html> (explaining that "in plain English, *Cloer* is saying that the statute of limitations cannot begin to run on a claimed vaccine injury until the medical community at large accepts that a certain vaccine can cause that particular injury").

92. 42 U.S.C. § 300aa-16(a)(3).

93. *See* U.S. Court of Fed. Claims Office of Special Masters, *Vaccine Program Background*, U.S. CT. OF FED. CLAIMS, http://www.uscfc.uscourts.gov/sites/default/files/vaccine.background.2010_0.pdf (last visited July 4, 2011) (noting that "[t]he Special Masters function in all respects as the trial judges in the vaccine cases, including having final decision authority").

94. U.S. Court of Federal Claims, *Vaccine Program/Office of Special Masters*, U.S. CT. OF FED. CLAIMS, <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited July 4, 2011).

95. *Id.*

96. *See* H.R. REP. NO. 99-908, at 16 (1986), *reprinted in* 1986 U.S.C.A.N. 6344, 6357; *see also* *Hodges v. Sec'y of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993) ("Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of individual claims.").

97. Strong, *supra* note 61, at 438.

98. 42 U.S.C. § 300aa-12(d)(3)(A)(ii) (2006). If the special master has not reached a decision within the 240-day period, the petitioner may elect to remain in the VICP or withdraw the petition. *Id.* § 300aa-12(g).

decision within 240 days, the Act provides for an extension period not to exceed 150 days.⁹⁹

The Federal Circuit sets the laws that are binding on special masters.¹⁰⁰ In addition, they are not bound by the Federal Rules of Civil Procedure or the Federal Rules of Evidence.¹⁰¹ Instead, the Vaccine Rules of the Office of Special Masters¹⁰² were created to enable the use of more informal procedures in vaccine cases.¹⁰³ The conclusions of the special masters are generally afforded great deference by reviewing courts.¹⁰⁴

4. Acceptance, Rejection, Appeals, and Compensation

After the special master has rendered his decision, the petitioner has ninety days to file an acceptance or rejection of the judgment.¹⁰⁵ Upon acceptance of the judgment, the petitioner is precluded from filing a civil lawsuit against the vaccine manufacturer.¹⁰⁶ A petitioner may also choose to appeal the special master's decision to the U.S. Court of Federal Claims¹⁰⁷ and may appeal to the Court of Appeals for the Federal Circuit and finally, the Supreme Court of the United States.¹⁰⁸

99. *Id.* § 300aa-12(d)(3)(C).

100. Gary Golkiewicz, Chief Special Master, Office of Special Masters, Omnibus Autism Proceedings Update and Implications of Causation Standard in the Program (Mar. 6, 2008) (transcript available at <http://www.hrsa.gov/vaccinecompensation/GolkiewiczTranscript.htm>).

101. VACCINE RULES OF THE U.S. COURT OF FED. CLAIMS tit. II, r. 8(b)(1) (2010) (providing that “[i]n receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties”); Strong, *supra* note 61, at 438.

102. VACCINE RULES OF THE U.S. COURT OF FED. CLAIMS tit. I-VI.

103. For example, Vaccine Rule 7(a) provides that “[t]here is no discovery as a matter of right. The informal and cooperative exchange of information is the ordinary and preferred practice.” VACCINE RULES OF THE U.S. COURT OF FED. CLAIMS tit. II, r. 7(a). Vaccine Rule 7(b)(1) provides that a party who believes informal discovery is insufficient could file a formal motion to compel discovery. *Id.* tit. II, r. 7(b)(1).

104. *See* Bradley v. Sec’y of HHS, 991 F.2d 1570, 1577 (Fed. Cir. 1993) (explaining Congress’s orders to afford a “highly deferential legal standard to the review of special masters’ fact determinations . . . [W]ith regard to fact-based determinations, we defer absent a clear showing that something went badly awry.”); *but see* Andreu *ex rel.* Andreu v. Sec’y of HHS, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (“While considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review.”) (citation omitted).

105. 42 U.S.C. § 300aa-21(a).

106. *Id.* (noting that should a petitioner elect to receive compensation from the Vaccine Court, “such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered”).

107. *Id.* § 300aa-12(e).

108. U.S. Court of Fed. Claims Office of Special Masters, *supra* note 93.

Injured individuals are to be compensated out of the Vaccine Injury Compensation Trust Fund (“Trust Fund”), which is overseen by the Treasury Department.¹⁰⁹ The Trust Fund revenues are generated by a \$0.75 excise tax on each dose of vaccine that is purchased.¹¹⁰ As of February 28, 2011 the Trust Fund was reported to contain approximately \$3.3 billion.¹¹¹

The Vaccine Act provides that an injured petitioner is entitled to recovery for medical expenses, lost wages, cost of future medical care, and up to \$250,000 for pain and suffering.¹¹² Recovery for injuries that result in death is statutorily set at \$250,000.¹¹³ The Act does not provide for punitive or exemplary damages.¹¹⁴

Attorneys may not charge fees while representing a petitioner in the VICP.¹¹⁵ However, attorneys may usually recover reasonable attorneys’ fees and costs,¹¹⁶ regardless of whether the petitioner is awarded compensation.¹¹⁷ In addition, the Vaccine Court will reimburse petitioners for the reasonable costs of scientific experts.¹¹⁸ Many petitioners alleging injuries other than an ASDs have enjoyed success in Vaccine Court, with 2,678 petitioners being granted compensation totaling approximately \$2.07 billion as of June 2011.¹¹⁹

109. See 26 U.S.C. § 9510(a) (2006).

110. Dep’t of Health & Human Servs., *Vaccine Injury Compensation Trust Fund*, HEALTH RESOURCES & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm (last visited July 4, 2011) [hereinafter *VICP Trust Fund*] (explaining the excise tax on a vaccine that prevents one disease is \$0.75, whereas the tax on vaccines that prevent three diseases, such as the MMR vaccine, is \$2.25).

111. Dep’t of Treasury, *Vaccine Injury Compensation Trust Fund: 75X8175*, TREASURY DIRECT, 5 (Feb. 28, 2011), <ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0211.pdf>.

112. 42 U.S.C. § 300aa-15(a)(1)(A), (a)(4) (2006).

113. *Id.* § 300aa-15(a)(2).

114. *Id.* § 300aa-15(d)(1).

115. *Id.* § 300aa-15(e)(3).

116. As of June 2, 2011, the VICP has awarded \$80,252,649.98 in attorneys’ fees and costs. *VICP Statistics Report*, *supra* note 37.

117. 42 U.S.C. § 300aa-15(e)(1) (providing that attorneys may recover reasonable fees and costs provided “that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought”).

118. See Kathleen Seidel, *A Brief Introduction to Vaccine Court*, NEURODIVERSITY WEBLOG (Jan. 30, 2008, 14:00 PM), <http://neurodiversity.com/weblog/article/142/> (quoting Chief Special Master Gary Golkiewicz that “[t]he expert is not given a blank check for his services and the special masters will not sanction inflated hourly rates and limitless hours spent investigating potential medical or scientific theories of causation”).

119. *VICP Statistics Report*, *supra* note 37.

D. "Table" Versus "Off Table" Claims

There are two avenues by which an individual can file a petition for compensation. First, the petitioner may assert a claim listed under the Vaccine Injury Table ("Table").¹²⁰ The Table provides a list of vaccines covered by the VICP, specific injuries known to have been the result of a vaccine, and time constraints for the manifestation of injury symptoms.¹²¹ Congress entrusted the Secretary of Health and Human Services with the authority to amend the Table at its discretion.¹²² In a Table claim, proof by a preponderance of the evidence that the petitioner received a vaccine listed on the Table and subsequently manifested symptoms within the given time frame creates a rebuttable presumption that the vaccine caused the injury.¹²³

The second option for petitioners is to assert an "off-table" or "causation-in-fact" claim for injuries not listed on the Table.¹²⁴ This type of claim requires proof by preponderance of the evidence that the vaccine was the actual cause of the petitioner's injury.¹²⁵ The vaccine need not be the sole reason for the injury, but must be at least a "substantial factor."¹²⁶ In addition, conclusions as to causation-in-fact are to be determined under a "legally probable, not medically or scientifically certain" standard.¹²⁷ Since the Table does not currently list

120. 42 C.F.R. § 100.3(a) (2010).

121. *Id.* For example, the Table lists rubella virus-containing vaccines as potentially causing chronic arthritis, with symptoms manifesting seven to forty-two days after vaccination. *Id.*

122. 42 U.S.C. § 300aa-14(c)(1) (2006).

123. *See* Grant v. Sec'y of HHS, 956 F.2d 1144, 1147 (Fed. Cir. 1992) ("The Vaccine Table, in effect, determines by law that the temporal association of certain injuries with the vaccination suffices to show causation."); Strong, *supra* note 61, at 437 (explaining that the rebuttable presumption may be defeated if the Secretary of Health and Human Services proves that the petitioner's injury was caused by "factors unrelated" to the vaccine).

124. Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 475-76 (2008).

125. 42 U.S.C. § 300aa-13(a)(1); *see also* Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (setting forth a three-prong test for proving causation-in-fact in an off-Table injury claim: "(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 the vaccination and injury").

126. *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999); *see also* Walther v. Sec'y of HHS, 485 F.3d 1146, 1150 (Fed. Cir. 2007) (holding that the "Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case").

127. *See* Knudsen *ex rel.* Knudsen v. Sec'y of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994) (explaining that "[c]ausation in fact . . . is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules . . . [t]he determination of causation in fact . . . involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain").

any autism spectrum disorders or vaccines at issue in the OAP,¹²⁸ ASD claims must be asserted under the “causation-in-fact” approach.¹²⁹

It is notable that over two-thirds of off-Table claims that come before the Vaccine Court are dismissed.¹³⁰ This statistic is likely due to the fact that it is considerably more difficult to prove a causation-in-fact injury than a Table injury for several reasons.¹³¹ For one, this approach does not contain the presumption of causation that is available to on-Table petitioners.¹³² In addition, the government has not already conceded the vaccine caused the injury as they have with Table injuries.¹³³ Thus, the proceeding becomes more adversarial as the government defends against these claims.¹³⁴ Moreover, statistics show that petitioners who present testimony of an experienced medical expert and are represented by an experienced attorney are significantly more likely to prevail.¹³⁵ However, many potential petitioners do not have access to the time, funds, and resources necessary to secure seasoned experts and attorneys.¹³⁶

1. Federal Circuit Precedent Interpreting Causation-in-Fact Claims

There have been several noteworthy attempts by the Federal Circuit to interpret causation-in-fact claims.¹³⁷ *Grant v. Secretary of Health and*

128. 42 C.F.R. § 100.3(a) (2010).

129. Shemin, *supra* note 124, at 476.

130. James B. Currier, *Too Sick, Too Soon?: The Causation Burden Under the National Vaccine Injury Compensation Program Following De Bazan v. Secretary of Health & Human Services*, 19 FED. CIR. B.J. 229, 246-47 (2009).

131. See *Hodges v. Sec’y of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993) (noting the differences in bringing Table versus off-Table claims: “[o]ne route is easy, as far as evidentiary proof goes . . . [b]ring the case within the timetable and specifications of a Table Injury and the statute does the heavy lifting—causation is conclusively presumed . . . [f]ailing that, the heavy lifting must be done by the petitioner, and it is heavy indeed . . . [g]iven the statutory burden of persuasion placed upon the petitioner, 42 U.S.C. § 300aa-13(a)(1), and the general state of medical knowledge about the causes of infant illness and death, it is not surprising that petitioners have a difficult time proving cases such as this”).

132. 42 U.S.C. § 300aa-13(a)(1) (2006).

133. See *supra* note 121 and accompanying text.

134. See Shemin, *supra* note 124, at 476 (citing several examples of the adversarial nature of off-Table claims).

135. Currier, *supra* note 130, at 247-48 (noting that use of an experienced medical expert and experienced attorney resulted in a 20% increase in the likelihood of compensation).

136. *Id.* at 248; see Brittani Scott Miller, *The National Childhood Vaccine Injury Compensation Program: The Unavailability of Experienced Attorneys Places Petitioners at an Institutional Disadvantage*, 19 FED. CIR. B.J. 253, 265 (2009) (discussing the need for more experienced attorneys to represent VICP petitioners).

137. See *Moberly ex rel. Moberly v. Sec’y of HHS*, 592 F.3d 1315, 1318 (Fed. Cir. 2010); *Andreu ex rel. Andreu v. Sec’y of HHS*, 569 F.3d 1367, 1374 (Fed. Cir. 2009); *De Bazan v. Sec’y of HHS*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *Walther v. Sec’y of HHS*, 485 F.3d 1146, 1149

Human Services,¹³⁸ a very early Vaccine Court case, determined that the preponderance standard is met in vaccine cases by showing “a medical theory causally connecting the vaccination and the injury.”¹³⁹ In *Knudsen ex rel. Knudsen v. Secretary of Health and Human Services*,¹⁴⁰ the Federal Circuit held that petitioners who have shown actual causation by a preponderance of the evidence are entitled to compensation unless the government can show by a preponderance of the evidence that “the injury was in fact caused by factors unrelated to the vaccine.”¹⁴¹ *Shyface v. Secretary of Health and Human Services*¹⁴² is significant for applying the Restatement (Second) of Torts¹⁴³ to causation-in-fact cases.¹⁴⁴ Specifically, *Shyface* determined that a petitioner is entitled to recovery upon a showing that the vaccine was a “but for” cause of the harm and a “substantial factor” in bringing about the injury.¹⁴⁵ The decision in *Walther v. Secretary of Health and Human Services*¹⁴⁶ noted that in instances where there are multiple potential etiologies of the harm, the government must prove, by a preponderance of the evidence,¹⁴⁷ that the vaccine did not cause the harm *and* must establish alternative causation.¹⁴⁸ Finally, the recent Vaccine Court case *Andreu ex rel. Andreu v. Secretary of Health and Human Services*¹⁴⁹ confirmed that the Vaccine Rules, not the Federal Rules of Evidence, are applicable in Vaccine Court cases.¹⁵⁰

(Fed. Cir. 2007); *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1328 (Fed. Cir. 2006); *Pafford v. Sec’y of HHS*, 451 F.3d 1352, 1353, 1355 (Fed. Cir. 2006); *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1279 (Fed. Cir. 2005); *Shyface v. Sec’y of HHS*, 165 F.3d 1344, 1348 (Fed. Cir. 1999); *Terran ex rel. Terran v. Sec’y of HHS*, 195 F.3d 1302, 1308 (Fed. Cir. 1999); *Knudsen ex rel. Knudsen v. Sec’y of HHS*, 35 F.3d 543, 547 (Fed. Cir. 1994).

138. 956 F.2d 1144 (Fed. Cir. 1992).

139. *Id.* at 1148 (noting that a medical theory may be established by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury”). This proof may be derived from “evidence in the form of scientific studies or expert medical testimony.” *Id.*

140. 35 F.3d 543 (Fed. Cir. 1994).

141. *Id.* at 547.

142. 165 F.3d 1344 (Fed. Cir. 1999).

143. *See* RESTATEMENT (SECOND) OF TORTS §§ 430-432 (1965).

144. 165 F.3d at 1351-52.

145. *Id.* at 1352; *see also* RESTATEMENT (SECOND) OF TORTS § 431(a) (stating that “[t]he actor’s negligent conduct is a legal cause of harm to another if his conduct is a substantial factor in bringing about the harm”).

146. 485 F.3d 1146 (Fed. Cir. 2007).

147. *Id.* at 1151.

148. *Id.* (“[A]pplying the Restatement to the Vaccine Act context, the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm.”).

149. 569 F.3d 1367 (Fed. Cir. 2009).

150. *See id.* at 1383 (noting the Vaccine Rule 8(b) provision that “[i]n receiving evidence, the special master will not be bound by the common law or statutory rules of evidence”).

2. *Althen* and “Close Calls”

One of the most remarkable interpretations of the Vaccine Act was set forth in *Althen v. Secretary of Health and Human Services*.¹⁵¹ *Althen* postulated a three-prong test consistent with the Vaccine Act’s lowered standard of proof for causation-in-fact petitioners.¹⁵² According to the test, a petitioner may prevail by providing preponderant evidence that: “(1) a medical theory causally connect[s] the vaccination and the injury; (2) a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury; and (3) . . . [there is] a proximate temporal relationship between [the] vaccination and [the] injury.”¹⁵³ The *Althen* Court appreciated that in an area “bereft” of direct proof as to how vaccines affect the human body, a requirement of anything more than circumstantial evidence from the petitioner would impermissibly raise the standard set forth by the Vaccine Act.¹⁵⁴ It is also of great significance that *Althen* interpreted the Congressional intent of the Vaccine Act to be one in which “close calls” on the issue of causation are to be “resolved in favor of injured claimants.”¹⁵⁵

E. The “Autism Epidemic” Explodes into the Courts

In 2002, the OSM released Autism General Order #1 (“Autism Order”)¹⁵⁶ to address the seemingly exponential increase in the amount of petitions asserting a causal link between vaccines and the diagnoses of ASD.¹⁵⁷ The first ASD petition was filed in Vaccine Court in 1998.¹⁵⁸ By the time the Autism Order was issued, the number of ASD petitions had increased to slightly over 400.¹⁵⁹ In 2003, the number of petitions had expanded to 2437.¹⁶⁰ As of June 2011, 5636 petitions have been filed and over 5000 petitions are pending.¹⁶¹

151. 418 F.3d 1274 (Fed. Cir. 2005).

152. *Id.* at 1278.

153. *Id.*

154. *Id.* at 1280; see also Currier, *supra* note 130, at 238 (noting that “the Vaccine Act never intended an ‘off-table’ claim to ‘act as a presumption against the petitioner’ . . . [b]ringing an ‘off-table’ claim just deprives the plaintiff of the automatic presumption of causation”).

155. Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1324 (Fed. Cir. 2006); *Althen*, 418 F.3d at 1280.

156. See Autism General Order # 1, 2002 WL 31696785, at *1 (Fed. Cl. July 3, 2002).

157. *Id.* (noting the “influx of [VICP] claims and the potential for many more such claims”).

158. Andrus, *supra* note 17, at 60.

159. Bulfer, *supra* note 12, at 103 (noting that the 400 claims generally alleged a causal connection between vaccines—specifically the MMR vaccine, thimerosal-containing vaccines, or a combination of the two—and diagnosis autism spectrum disorder).

160. Andrus, *supra* note 17, at 60.

161. *Omnibus Autism Proceeding*, *supra* note 8; *VICP Statistics Report*, *supra* note 37.

1. The Omnibus Autism Proceeding

The Autism Order adopted the OAP,¹⁶² a special procedure, in an attempt to process the extreme influx of autism petitions being filed.¹⁶³ The OSM authorized a team of attorneys called the “Petitioner’s Steering Committee” (“PSC”) to represent VICP petitioners.¹⁶⁴ All five thousand pending cases are divided between three presiding special masters.¹⁶⁵ The OAP provides an inquiry into the “general causation issues” alleged in the autism petitions.¹⁶⁶ The three original theories of causation for establishing an association between vaccines and autism are: (1) MMR vaccine and vaccines containing thimerosal cause autism; (2) vaccines containing thimerosal cause autism; and (3) MMR vaccine alone causes autism.¹⁶⁷ On June 11, 2007, five years after the Autism Order was issued, the Vaccine Court commenced the hearings of the OAP test cases.¹⁶⁸

162. See generally Autism General Order # 1, 2002 WL 31696785, at *3-4 (providing the framework for the OAP, designating Special Master Hastings to preside over the OAP, and amending the adjudication time-frame from the original 240/420 period set forth in the Vaccine Act to a two-year timeline in which to complete a discovery period, evidentiary hearings, and decision on the general causation inquiry).

163. *Id.* at *3.

164. *Id.* On January 12, 2011, the OSM issued a notice that the PSC had disbanded at the end of the OAP test case appeals. See Autism Update on Omnibus Autism Proceeding, *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder (Fed. Cl. Jan. 12, 2011), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism%20Update%201%2012%2011.pdf>. The remaining OAP cases are to be handled on a firm-by-firm or individual basis with no participation from the OAP. *Id.*

165. *Omnibus Autism Proceeding*, *supra* note 8; see also *Cedillo v. Sec’y of HHS*, 89 Fed. Cl. 158, 166 (2009) (noting the Chief Special Master designated the OAP proceedings to Special Master Hastings, Special Master Vowell, and Special Master Campbell-Smith).

166. Autism General Order # 1, 2002 WL 31696785, at *3.

167. *The Autism Proceedings: Background Information*, *supra* note 23 (explaining the theories of causation and noting that the third theory of causation was eventually merged with the first theory).

168. On Theory #1 of causation, see *Hazlehurst v. Sec’y of HHS*, 604 F.3d 1343, 1345 (Fed. Cir. 2010); *Cedillo v. Sec’y of HHS*, No. 98-916V, 2009 WL 331968, at *1, *60 (Fed. Cl. Feb. 12, 2009), *aff’d*, *Cedillo v. Sec’y of HHS*, 89 Fed. Cl. 158 (2009), *aff’d*, *Cedillo v. Sec’y of HHS*, 617 F.3d 1328 (Fed. Cir. 2010); *Snyder v. Sec’y of HHS*, 88 Fed. Cl. 706, 708 (2009). On Theory #2 of causation, see *Dwyer ex rel. Dwyer v. Sec’y of HHS*, No. 03-1202V, 2010 WL 892250, at *1 (Fed. Cl. Mar. 12, 2010); *King ex rel. King v. Sec’y of HHS*, No. 03-584V, 2010 WL 892296, at *1 (Fed. Cl. Mar. 12, 2010); *Mead ex rel. Mead v. Sec’y of HHS*, No. 03-215V, 2010 WL 892248, at *1 (Fed. Cl. Mar. 12, 2010); see also Dep’t of Health & Human Servs., *Advisory Commission on Childhood Vaccines*, DEP’T OF HEALTH & HUMAN SERVS., 44 (June 10, 2010), <http://www.hrsa.gov/vaccinecompensation/ACCVTranscript-6-10-10.pdf> [hereinafter *Advisory Commission on Childhood Vaccines*] (explaining that the “idea behind the test cases was to give some guidance as to what theories had merit, what theories didn’t have merit, whether there was any merit to any theories at all”).

2. Diagnosis: Autism

Cedillo was elected by the PSC to be the first test case tried in the OAP.¹⁶⁹ The petitioners in *Cedillo* were Theresa and Michael Cedillo, the parents of Michelle Cedillo.¹⁷⁰ Michelle's parents reported that she was developing normally up until sixteen months of age.¹⁷¹ One week after receiving the MMR vaccine Michelle developed a persistent rash and fever.¹⁷² Over the following months and years, Michelle's condition began to deteriorate further, and in 1997, Michelle was formally diagnosed with "severe autism and profound mental retardation."¹⁷³ In addition to autism, Michelle suffers from gastrointestinal issues, arthritis, glaucoma, pancreatitis, and feeding issues that require a feeding tube.¹⁷⁴

3. Michelle's Prima Facie Case

The Cedillos filed for compensation under the Vaccine Act in December 1998.¹⁷⁵ Michelle's case was later consolidated into the OAP under the theory that the MMR vaccine, along with certain thimerosal-containing vaccines, had damaged her immune system.¹⁷⁶ It was Michelle Cedillo's understanding that her burden of proof would be met when she presented a prima facie case¹⁷⁷ that her injuries were a result of the MMR vaccine that was administered to her at the age of fifteen months.¹⁷⁸ To that end, Michelle's team of attorneys presented evidence to support the medical theory that:

"(1) she was born healthy; (2) had normal development and met all

169. See Andrus, *supra* note 17, at 60 (noting that the PSC was permitted to present three test cases for each of the three general theories of causation).

170. *Id.*

171. *Cedillo*, 89 Fed. Cl. at 164 (citation omitted) ("At one year, she spoke a few words, crawled on her knees, and pulled herself to stand. She began walking at sixteen to eighteen months.").

172. *Id.* (noting that the fever came and went until January 6, 1996 and was recorded at 105.7 degrees at home by her parents and 100.3 degrees by her doctor).

173. *Id.* at 165.

174. *Id.*; see also Andrus, *supra* note 17, at 61 (commenting that "[s]ome have criticized the PSC's selection of the *Cedillo* case because of the distinctiveness of Michelle's condition, which many view as uncharacteristic of, and typically more severe, than that of other ASD Vaccine Court petitioners").

175. *Cedillo*, 89 Fed. Cl. at 165. The Cedillos originally asserted that Michelle suffered from encephalopathy, a Table Injury. *Id.* (internal quotation marks omitted).

176. *Id.* at 163, 165.

177. See Reply Brief for Petitioners-Appellants at 4-5, *Cedillo v. Sec'y of HHS*, 617 F.3d 1328 (Fed. Cir. 2010) (No. 2010-5004) (explaining that Michelle had presented a prima facie case by providing "a reliable medical theory, a logical sequence of cause and effect between her MMR vaccine and her injuries, an appropriate temporal relationship between her vaccine and the onset of symptoms, and the absence of an alternative cause").

178. See Petitioners' Memorandum in Support of Motion for Review of the Special Master's Decision of February 12, 2009, *supra* note 4, at 33.

milestones; (3) received the recommended childhood vaccinations, many of which contained thimerosal []; (4) received an MMR vaccine; (5) experienced fevers in excess of 105 degrees due to the MMR vaccine; and, (6) was unable to clear the measles virus [] contained in the MMR vaccine from her body.”¹⁷⁹

The Cedillos asserted that the MMR vaccine weakened Michelle’s immune system, causing the measles virus to persist and replicate in her body.¹⁸⁰ Finally, Michelle supplied evidence that the persisting measles virus resulted in “irritable bowel disease [], inflammation in her brain, and ultimately, autism.”¹⁸¹

4. The Special Master’s Conclusions

There is no doubt that Special Master Hastings, who presided over the *Cedillo* hearings, based his findings of fact on hard evidence.¹⁸² In making his determinations, Hastings considered a three-week evidentiary hearing that took place in June of 2007¹⁸³ and reviewed approximately 7700 pages of Michelle’s medical reports, hearing transcripts totaling 2917 pages, 658 medical journal articles, and post-hearing briefs totaling 462 pages.¹⁸⁴ Special Master Hastings found the respondent to be more persuasive,¹⁸⁵ concluding that the “evidence was overwhelmingly contrary to the petitioners’ contentions.”¹⁸⁶ However convincing the respondent’s expert witnesses were, it is noteworthy that none of the seventeen experts for the respondent had ever personally examined Michelle.¹⁸⁷ Also, on numerous occasions in his decision, Special Master Hastings alluded to the respondent’s expert witness’s credentials being “superior” to those of the Cedillo’s experts.¹⁸⁸ After nearly ten years had passed since Michelle had first filed for compensation, Special Master Hastings concluded that she had failed to establish a link between her

179. Reply Brief for Petitioners-Appellants, *supra* note 177, at 3-4.

180. *Cedillo v. Sec’y HHS*, No. 98-916V, 2009 WL 331968, at *15 (Fed. Cl. Feb. 12, 2009).

181. Reply Brief for Petitioners-Appellants, *supra* note 177, at 4.

182. See *Cedillo*, 2009 WL 331968, at *14 (describing the vast evidentiary record that Special Master Hastings considered before making his conclusions).

183. *Id.* at *10.

184. *Id.* at *14.

185. *Id.* at *1 (“The expert witnesses presented by the respondent were far better qualified, far more experienced, and far more persuasive than the petitioners’ experts, concerning most of the key points.”).

186. *Id.*

187. See Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of February 12, 2009, *supra* note 4, at 15-16 (noting that the respondent’s experts had based their conclusions on an examination of Michelle’s eleven year old medical records).

188. See *Cedillo*, 2009 WL 331968, at *1, *24, *58, *69, *81, *111.

autism and the MMR vaccine and dismissed the case.¹⁸⁹ *Cedillo* was appealed to the Court of Federal Claims¹⁹⁰ and to the Federal Circuit where Special Master Hastings's holding was affirmed in August 2010.¹⁹¹

III. RISK FACTORS AND COMPLICATIONS: AN UNRESOLVED TENSION MANIFESTS IN THE WAKE OF THE OMNIBUS AUTISM PROCEEDING

The Vaccine Act objective was essentially two-fold: (1) to protect vaccine manufacturers from civil litigation and (2) to provide vaccine-injured individuals with a simple and straightforward method to receive compensation.¹⁹² The Vaccine Program was advanced to alleviate the potential risks of “unavoidably unsafe,”¹⁹³ but unequivocally necessary vaccines by creating a system by which vaccine-injured individuals could receive compensation “quickly, easily, and with certainty and generosity.”¹⁹⁴ By insulating pharmaceutical companies from liability, the Program would allow manufactures to be better able to develop and distribute vaccines.¹⁹⁵ In fact, Congress specifically cited that the “relative certainty and generosity of the system’s awards” should divert a significant amount of civil lawsuits.¹⁹⁶ In addition, Congress recognized that vaccines were extremely advantageous to public health due to their cost-effectiveness and success at preventing catastrophic epidemics.¹⁹⁷ It was explicitly noted that due to their many successes, “the [f]ederal government has an interest in the development, distribution, and use of vaccines.”¹⁹⁸

A. *The Emergence of a Competing Policy Concern*

At a congressional hearing in 1999, Congressman Henry Waxman, a key sponsor of the Vaccine Act, suggested that many people today neglect to acknowledge the value of vaccines in favor of directing their

189. *Id.* at *135.

190. *Cedillo v. Sec’y of HHS*, 89 Fed. Cl. 158, 163 (2009).

191. *Cedillo v. Sec’y of HHS*, 617 F.3d 1328, 1334 (Fed. Cir. 2010).

192. See H.R. REP. NO. 99-908, at 3-4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.

193. See *id.* at 26, *reprinted in* 1986 U.S.C.C.A.N. at 6367 (explaining that the term “unavoidably unsafe” products, i.e. those products which in the present state of human skill and knowledge cannot be made safe appl[ies] to the vaccines covered in the bill and that such products not be the subject of liability in the tort system”).

194. *Id.* at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6344.

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

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

197. *Id.* at 4-5, *reprinted in* 1986 U.S.C.C.A.N. at 6345-46.

198. *Id.* at 5, *reprinted in* 1986 U.S.C.C.A.N. at 6346.

focus to the potential risks.¹⁹⁹ Congressman Waxman expressed his concern that “if children are frightened and parents discouraged about vaccines, we will quickly become vulnerable again to infectious diseases.”²⁰⁰ In 2008, Chief Special Master Gary Golkiewicz made an address to the Advisory Commission on Childhood Vaccines.²⁰¹ The address expounded upon the policy concerns that Congressman Waxman had articulated in his statement nearly ten years earlier.²⁰² Golkiewicz discussed a policy concern he called “protecting the vaccine’s integrity . . . that is that vaccine[s] do[] not cause every injury that follows immunization.”²⁰³ The Chief Special Master defended his views on the theory that generous remuneration to vaccine-injured petitioners may weaken public confidence in vaccines.²⁰⁴ Golkiewicz’s unease was also likely in response to survey results indicating the public felt an increasing body of concern as to the safety of vaccines.²⁰⁵ It is clear from this address that special masters feel the pressure between compensating vaccine-injured petitioners and sustaining public confidence in vaccines.²⁰⁶

Based on a reading of the legislative history, it seems Congress recognized that upholding the use of vaccines was a relevant policy concern.²⁰⁷ In fact, Congress specifically noted that the use of vaccines

199. See *Vaccines—Finding the Balance Between Public Safety and Personal Choice: Hearing Before the H. Comm. on Gov’t Reform*, 106th Cong. 14 (1999) (statement of Congressman Henry H. Waxman) (asserting that “today we are becoming complacent about our success against infectious diseases . . . [u]nlike our parents and grandparents, we aren’t terrorized every year by paralytic polio and whooping cough epidemics . . . [t]his makes it easier to forget the value of vaccines and focus on their potential risks”); see also Calandrillo, *supra* note 46, at 438-39 (“Today, one is more likely to hear about vaccine safety risks than she is about vaccine benefits . . . [t]he media and internet highly publicize stories regarding links between immunizations and autism, leading well-meaning parents to question whether the cure is worse than the disease.”).

200. *Vaccines—Finding the Balance Between Public Safety and Personal Choice: Hearing Before the H. Comm. on Gov’t Reform*, *supra* note 199.

201. Golkiewicz, *supra* note 100.

202. *Id.*

203. *Id.*

204. See *id.*; see also Brief of Amici Curiae Elizabeth Birt Ctr. for Autism Law and Advocacy, et al. in Support of Appellants and in Favor of Reversal at 15, *Cedillo v. Sec’y of HHS*, 617 F.3d 1328 (Fed. Cir. 2010) (No. 98-916V), available at <http://www.rescuepost.com/files/filed-cedillo-amicus-brief-2.pdf> (explaining the “divided loyalties” of special masters in compensating vaccine-injured petitioners due to the competing policy concern of protecting vaccine integrity).

205. See Allen, *supra* note 39 (noting that a 2008 survey conducted by APCO Insight indicated that at least 18% of parents had changed their vaccine practices due to safety concerns). This was a 6% increase from 2006 when the same survey found that only 12% of parents had changed their vaccine practices as a result of safety concerns. *Id.*

206. Golkiewicz, *supra* note 100.

207. See H.R. REP. NO. 99-908, at 5 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6346 (noting five principal findings that formed the basis of the Vaccine Act).

It was determined that legislation was needed in the area of vaccines because: “(1) [t]he

was necessary to prevent diseases and that access to vaccines was a responsibility of the federal government.²⁰⁸ However, the *primary* concerns of Congress, as articulated in the House Report, were to stabilize the vaccine market and compensate those injured by vaccines.²⁰⁹ Nonetheless, Congress should have recognized the likelihood that a policy such as upholding the use of vaccines may clash with the Act's primary objectives and prepared a way to minimize or alleviate this inevitable tension.²¹⁰ Instead, the issue was left unresolved and has now trickled down to the special masters,²¹¹ whose role is limited to "apply[ing] the law."²¹² The fact that there are competing policies may be unavoidable, but special masters should not be left to strike a balance between them.²¹³

B. *The Fine Line Between the Policies*

The *Cedillo* case alone has experienced tremendous amounts of exposure²¹⁴ and much speculation that an award of compensation in that

availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities[;] (2) [t]he Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries[;] (3) [p]rivate or non-governmental activities have proven inadequate in achieving either of these goals [(1) and (2);] (4) [c]urrent economic conditions have resulted in an unstable and unpredictable childhood vaccine market, making the threat of vaccine shortages a real possibility[; and] (5) [b]ecause of their cost-effectiveness, the Federal government has an interest in the development, distribution, and use of vaccines, including those designed to prevent non-childhood diseases.

Id., reprinted in 1986 U.S.C.C.A.N. at 6346.

208. See *id.*, reprinted in 1986 U.S.C.C.A.N. at 6346.

209. See *id.* at 7, reprinted in 1986 U.S.C.C.A.N. at 6348.

210. See *infra* Part V.

211. See Golkiewicz, *supra* note 100 (articulating that "[t]here's a tension between these two objectives, a tension that affects dramatically the litigation of the cases, the parties' arguments and ultimately who wins").

212. See *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005) (explaining that "[t]he special master's role is to apply the law . . . [q]uestions of law regarding the interpretation or implementation of the Vaccine Act are matters for the courts").

213. See VACCINE RULES OF THE U.S. COURT OF FED. CLAIMS tit. II, r. 3(b) (2010) (listing the special master's duties as: "(1) conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded; and (2) endeavoring to make the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision").

214. *Cedillo* and the autism cases have received a significant amount of attention from several media outlets. For example, both Oprah Winfrey and Larry King have featured autism on their television programs, and several television shows have featured portrayals of autistic characters, including NBC's *Parenthood* and ABC's *Grey's Anatomy*. *Grey's Anatomy: All by Myself* (ABC television broadcast Dec. 4, 2008); *Larry King Live: Autism Breakthroughs* (CNN television

case would have a disastrous impact on the future of the VICP.²¹⁵ The publicity that has been afforded to the OAP and *Cedillo* has undoubtedly left the special masters well aware that a positive outcome for petitioners may result in the same fear of vaccines that drove down immunization rates in the 1980s.²¹⁶ On the other hand, the special masters also know that a definitive finding of no causal link between vaccines and autism in a highly publicized case like *Cedillo* would serve to bolster public confidence and provide reassurance²¹⁷ that vaccines are safe.²¹⁸

In addition to the fear of dwindling public confidence in vaccines, another overriding concern has been the very real likelihood that the autism cases, if compensated, would quickly bankrupt the Trust Fund.²¹⁹ However, if petitioners are unable to receive compensation via the Vaccine Court, there is a substantial possibility that civil lawsuits against vaccine manufacturers will be on the rise once again.²²⁰ Consequently,

broadcast Feb. 28, 2008); *Oprah Winfrey Show: Mothers Battle Autism* (ABC television broadcast Sept. 18, 2007); *Parenthood: Pilot* (NBC television broadcast Mar. 2, 2010).

215. See Regina Moreland, Comment, *National Vaccine Injury Compensation Program: The Potential Impact of Cedillo for Vaccine-Related Autism Cases*, 29 J. LEGAL MED. 363, 377-79 (2008) (explaining that if *Cedillo* were to establish a general causation link between vaccines and autism, the VICP would be detrimentally impacted because the Trust Fund is insufficient to compensate the autism cases and the Court of Federal Claims will be unable to handle the extreme influx of cases).

216. See Meredith Daniels, Note, *Special Masters in the National Vaccine Injury Compensation Program: Placing a Heightened Burden on Vaccine Program Petitioners by Straying from Precedent and Congressional Intent*, 6 J. HEALTH & BIOMED. L. 79, 105-06 (2010); see also Kevin Conway, *CODA: The Injustice Continues*, 33 THE AUTISM FILE 49, 50 (2009) ("Due to the extraordinary publicity this issue had received, officials feared parents would refuse to immunize their children, that immunization rates would fall, and that preventable diseases would return."); Gardiner Harris, *Measles Cases Grow in Number, and Officials Blame Parents' Fear of Autism*, N.Y. TIMES, Aug. 22, 2008, at A16 (discussing how the growing body of concern over the safety of vaccines has caused many parents to refuse to vaccinate their children).

217. See *Statement from the Department of Health and Human Services Regarding the Decisions of the U.S. Court of Federal Claims in the Omnibus Autism Proceeding*, U.S. DEP'T OF HEALTH & HUMAN SERVS., (Feb. 12, 2009), <http://www.hhs.gov/news/press/2009pres/02/20090212a.html> ("Hopefully, the determination by the Special Masters will help reassure parents that vaccines do not cause autism.").

218. Compare Allen, *supra* note 39 (explaining the hope that the ruling against *Cedillo* will reverse the trend of parents refusing to vaccinate their children), with Brief of Amici Curiae Elizabeth Birt Ctr. for Autism Law and Advocacy, et al. in Support of Appellants and in Favor of Reversal, *supra* note 204, at 4, 16 (asserting that "Michelle's case exemplifies the conflict of interest in the Program between compensating victims and protecting the vaccine program. . . . [t]o rule in Michelle's favor is to reaffirm that vaccines are not harmless, and that they do sometimes cause adverse reactions").

219. Moreland, *supra* note 215, at 378-79 (noting that there are approximately 560,000 people with autism in the United States). Moreover, if each of these people were to file for compensation under the OAP and receive the average amount of compensation that has been awarded to other petitioners in the VICP, the Trust Fund (which is currently valued at approximately \$3.3 billion) would have to pay out \$4,328,800,000,000,000. *Id.*

220. See Daniels, *supra* note 216, at 105-06; see also Shemin, *supra* note 124, at 464 (noting

the ability of vaccine manufacturers to produce adequate supplies of vaccines and continue vaccine research may again be hindered, placing the vaccine supply and public health in jeopardy yet again.²²¹

IV. SIDE EFFECTS: *CEDILLO* ILLUSTRATES THE TENSION

Cedillo provides an excellent demonstration of the tension that has been left unresolved.²²² Instead of striking a balance between the competing policies, Congress has thrust them upon the special masters, without any guidance, to be resolved under the guise of fact-finding.²²³ Due to the lack of guidance, a special master presiding over a case may be swayed towards making a finding based on whichever policy concern he chooses to emphasize. *Althen* sought to limit this issue by reasoning that “close calls regarding causation are resolved in favor of injured claimants.”²²⁴ *Althen*’s direction regarding “close calls” was based on the understanding that the system created by Congress was one in which circumstantial evidence was adequate to meet the petitioner’s burden.²²⁵

Special Master Hastings undeniably considered a great deal of hard evidence²²⁶ and ultimately opined that *Cedillo* was “*not a close case*.”²²⁷ However, reasonable minds could differ on this issue, as an examination of the record reveals that *Cedillo* is replete with instances of what might be “close calls” under *Althen*.²²⁸ Michelle Cedillo concedes there is currently no direct evidence to substantiate the claim that vaccines can cause autism.²²⁹ However, *Althen* and its progeny²³⁰ instruct that a

that if the Cedillos are not awarded compensation, it is likely that many petitioners will opt out of the Vaccine Court and bring their claim in civil court . . . [i]n civil court, petitioners may be able to obtain necessary discovery documents that would probably have been denied in vaccine court, have their trial decided by a jury, and be entitled to greater damage awards); Reply Brief for Petitioners-Appellants, *supra* note 177, at 3.

221. Daniels, *supra* note 216, at 106.

222. See Brief of Amici Curiae Elizabeth Birt Ctr. for Autism Law and Advocacy, et al. in Support of Appellants and in Favor of Reversal, *supra* note 204, at 4.

223. See VACCINE RULES OF THE U.S. COURT OF FED. CLAIMS tit. II, r. 3(b)–(d) (2010) (listing the duties of the special master in Vaccine Court cases, none of which include making policy determinations).

224. *Id.* at 1280.

225. See *id.*

226. See discussion *supra* Part II.E.4.

227. *Cedillo v. Sec’y of HHS*, No. 98-916V, 2009 WL 331968, at *134 (Fed. Cl. Feb. 12, 2009) (noting that “this is a case in which the evidence is so one-sided that any nuances in the interpretation of the causation case law would make no difference to the outcome of the case”).

228. See discussion *infra* Part IV.A–D.

229. Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of February 12, 2009, *supra* note 4, at 32-33.

230. See *Andreu ex rel. Andreu v. Sec’y of HHS*, 569 F.3d 1367, 1370 (Fed. Cir. 2009); *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1319 (Fed. Cir. 2006).

petitioner need not offer direct evidence.²³¹ Instead, a petitioner need only offer proof of causation by a preponderance of circumstantial evidence.²³² The fact that the autism cases are characterized by so many gaps in evidence²³³ means that there are many various “close calls” that could sway the special master in either direction. The purpose of this Note is not to second-guess Special Master Hastings’s conclusions of fact, but rather to illustrate examples of “close calls” within *Cedillo* where fundamental policy clashes could have influenced the findings.

A. *Unigenetics and the Uhlmann Article*

Many of the respondent’s experts’ opinions and Special Master Hastings’s conclusions were based on the alleged unreliability of the data from the Unigenetics Ltd.²³⁴ laboratory (“Unigenetics”) in Ireland.²³⁵ However, much of Michelle’s case was dependent upon the reliability of a test conducted at the Unigenetics lab.²³⁶ Unigenetics’s credibility has been questioned due to the controversial article authored by V. Uhlmann and his colleagues in 2002 (“Uhlmann Article”)²³⁷ providing support for the proposition that the MMR vaccine causes autism.²³⁸ The Unigenetics test of Michelle’s intestinal tissue indicated a continuing presence of measles virus RNA in Michelle’s gut.²³⁹ The presence of measles virus RNA in Michelle’s tissue is essential to the

231. See *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005).

232. Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of Feb. 12, 2009, *supra* note 4, at 33.

233. See generally Bartholomew C. Wacek, Comment, *Taking Sides in the Vaccine/Autism Legal Battle*, 8 DEPAUL J. HEALTH CARE L. 305 (2004) (summarizing the theories and scientific studies for and against a causal relationship between vaccines and autism). Evidence is further confused by the recent government’s concession that the MMR vaccine aggravated an existing condition in a young girl and resulted in autism. See Donovan, *supra* note 30, at 248-49.

234. See *Cedillo v. Sec’y of HHS*, No. 98-916V, 2009 WL 331968, at *26 (Fed. Cl. Feb. 12, 2009) (explaining that Unigenetics is a laboratory run by Dr. John O’Leary and his colleagues) In 2002, Unigenetics tested a sample of Michelle Cedillo’s gut tissue for the detection of measles virus. The results of the test indicated that measles virus RNA had been detected in Michelle’s intestinal tissue. *Cedillo*, 2009 WL 331968, at *26.

235. *Id.*

236. See Brief of Amici Curiae Elizabeth Birt Ctr. for Autism Law and Advocacy, et al. in Support of Appellants and in Favor of Reversal, *supra* note 204, at 17-22.

237. See V. Uhlmann et al., *Potential Viral Pathogenic Mechanism for New Variant Inflammatory Bowel Diseases*, 55 J. CLINICAL PATHOLOGY 84, 87-88 (2002). The Uhlmann Article was co-authored by eleven people, including Andrew Wakefield. The Uhlmann Article published the findings of the O’Leary laboratory tests indicating a presence of measles virus RNA in the gut tissue of most of the developmentally disabled children who were tested. *Cedillo*, 2009 WL 331968, at *31 (noting that the same type of testing, called polymerase chain reaction was conducted on Michelle Cedillo’s gut tissue).

238. See *Cedillo*, 2009 WL 331968, at *32; see also Wakefield, *supra* note 25, at 637.

239. *Cedillo*, 2009 WL 331968, at *30.

Cedillo's medical theory that intestinal inflammation played an etiological role in the development of her autism.²⁴⁰

In response to the Uhlmann Article, the respondent provided testimony from Dr. Stephen Bustin, a Ph.D. molecular biologist, who personally studied the Unigenetics lab, the lab's equipment, and all of the data compiled by the Uhlmann researchers.²⁴¹ Dr. Bustin testified that there were serious defects with regard to Unigenetics's measles virus detection and that the data was not reliable.²⁴² Dr. Bustin also alleged that contamination was "rampant" in the Unigenetics lab.²⁴³ However, Dr. Bustin could only identify one episode of contamination in the Unigenetics laboratory notebooks.²⁴⁴

No other evidence has been submitted to support Dr. Bustin's conclusion that Unigenetics has contamination issues.²⁴⁵ In fact, multiple experts acknowledged that some contamination occurs in every lab, and every lab has set protocol to eliminate contamination.²⁴⁶ In addition, Dr. Bustin's testimony was refuted by that of Dr. Ronald Kennedy, a Ph.D. in microbiology, who testified that Unigenetics lab had taken appropriate measures to minimize contamination.²⁴⁷ It is clear that the petitioner and respondent presented conflicting reports concerning the reliability of the Unigenetics data.²⁴⁸ Ultimately, each of the arguments contained enough evidence that the issue of Unigenetics's reliability could qualify as a "close call" under *Althen*.²⁴⁹

B. Was Unigenetics's Test Unable to be Replicated?

In addition to Dr. Bustin's testimony, the respondent provided other experts to discount the Unigenetics lab and offered evidence that other laboratories were unable to replicate the results of Unigenetics findings with respect to measles virus RNA detection.²⁵⁰ The respondent's

240. Petitioners' Memorandum in Support of Motion for Review of the Special Master's Decision of February 12, 2009, *supra* note 4, at 32, 34-35.

241. *Cedillo*, 2009 WL 331968, at *35.

242. *Id.* at *36.

243. *Id.*

244. Petitioners' Memorandum in Support of Motion for Review of the Special Master's Decision of February 12, 2009, *supra* note 4, at 46; *see also Cedillo*, 2009 WL 331968, at *36 (noting Dr. Bustin's theory that the laboratory notebooks had been altered to potentially conceal instances of contamination).

245. Petitioners' Memorandum in Support of Motion for Review of the Special Master's Decision of February 12, 2009, *supra* note 4, at 46 n.62 and accompanying text.

246. *Id.* at 46.

247. *Cedillo*, 2009 WL 331968, at *34.

248. *See supra* Part IV.A.

249. *See Althen v. Sec'y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

250. *Cedillo*, 2009 WL 331968, at *40.

experts asserted that two independent research teams, as well the Cotter laboratory and the Oldstone laboratory, had attempted to replicate Unigenetics's findings to no avail.²⁵¹ The Cedillos disputed this information based on the fact that both the Cotter and Oldstone laboratories *were* able to replicate the test results with respect to high copy numbers.²⁵² Copy number variation is determined by conducting a polymerase chain reaction ("PCR")²⁵³ test on a sample of biologic tissue.²⁵⁴ The copy number is "derived from a *ratio* between the number of actual copies found of the target, such as the F-gene of the measles virus, and the number of copies found of a 'housekeeping gene' (which is found in all cells of the body)."²⁵⁵ The Cedillos assert that the high copy number of measles virus on her sample tissue is evidence that the virus remains active in her body.²⁵⁶

In his testimony, Dr. Bustin reported that he only questioned Unigenetics with respect to low copy numbers, and admitted that Michelle had high copy numbers.²⁵⁷ Dr. Bustin also acknowledged that "[h]igh copy numbers are considered accurate because the detection of RNA occurs at a lower cycle number . . . earlier in the experiment, and makes them inherently reliable."²⁵⁸ Nevertheless, Special Master Hastings did not find the high copy number argument to be persuasive.²⁵⁹ Special Master Hastings agreed with testimony from Drs. Brian Ward and Bertus Rima, both of whom were experts for the respondent, suggesting that evidence of a high copy number does not necessarily confirm that a test is reliable.²⁶⁰ In addition, Special Master Hastings gave no credit to the Cotter and Oldstone laboratory replications because the findings were never published.²⁶¹ In sum, Special Master Hastings was offered inconsistent accounts regarding the

251. *See id.* at *40-41.

252. Petitioners' Memorandum in Support of Motion for Review of the Special Master's Decision of February 12, 2009, *supra* note 4, at 46.

253. *See* Gerald Schochetman, Chin-Yih Ou & Wanda K. Jones, *Polymerase Chain Reaction*, 158 J. INFECTIOUS DISEASES, 1154, 1154 (1988) (explaining that the PCR was developed in the 1980s for "in vitro amplification of the DNA or RNA of an organism or gene defect . . . [t]he PCR takes advantage of an enzyme that uses a defined segment in a strand of DNA as a template for assembling a complementary strand").

254. *Cedillo*, 2009 WL 331968, at *50.

255. *Id.*

256. Petitioners' Memorandum in Support of Motion for Review of the Special Master's Decision of February 12, 2009, *supra* note 4, at 48.

257. *See id.* at 43.

258. *Id.*

259. *Cedillo*, 2009 WL 331968, at *51.

260. *Id.* at *50-51.

261. *Id.* at *41.

reliability of high copy numbers.²⁶² The evidence to support both arguments was such that it gave rise to a “close call” in which Special Master Hastings could have tipped the scale in either direction.²⁶³

C. Presence of Measles Virus RNA and the Possibility of Virus Replication

Michelle’s expert, pediatric neurologist Dr. Marcel Kinsbourne, testified that the persisting measles virus in Michelle’s body eventually entered her brain.²⁶⁴ Dr. Kinsbourne testified that in response to the persisting measles virus, Michelle’s immune system produced inflammation, which “disorganized certain critical circuits in her brain” and resulted in autism.²⁶⁵ Special Master Hastings was unconvinced by Dr. Kinsbourne’s theory, and instead afforded great deference to the respondent’s expert Dr. Diane Griffin, a medical doctor who specializes in biology, immunology, and virology.²⁶⁶ Dr. Griffin testified that the presence of measles virus RNA in Michelle’s intestinal tissue alone is not indicative of disease.²⁶⁷ Instead, Dr. Griffin stated that the presence of protein is also necessary in order for the virus to persist and replicate.²⁶⁸ However, Dr. Griffin’s statement was contradictory to an article she co-authored, stating in part “the presence of measles virus RNA represents continued measles virus replication.”²⁶⁹ In addition, Dr. Griffin admitted that she had not reviewed the Uhlmann Article, and was therefore oblivious to the fact that the Unigenetics lab had in fact found protein in Michelle’s intestinal tissue.²⁷⁰ In this case, the “close call” was precisely whether Special Master Hastings should have afforded more weight to Dr. Kinsbourne’s theory or to Dr. Griffin’s testimony.²⁷¹

D. Does Michelle Have Inflammatory Bowel Disease?

The Cedillos also presented evidence that the persisting measles virus from her MMR vaccine caused Michelle to suffer from

262. See *supra* Part IV.B.

263. See discussion *supra* Part IV.

264. *Cedillo*, 2009 WL 331968, at *65 (explaining that Dr. Kinsbourne’s theory relied heavily on the Unigenetics lab results indicating a persisting presence of measles virus RNA in Michelle’s body).

265. *Id.*

266. See *id.* at *68, *83.

267. Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of February 12, 2009, *supra* note 4, at 39.

268. *Id.*

269. *Id.*

270. *Id.* at 50.

271. See *supra* Part IV.C.

inflammatory bowel disease (“IBD”).²⁷² The Cedillos have asserted that the fever Michelle experienced after receiving the MMR vaccine could have damaged her immune system, thus impeding her body’s ability to clear the measles virus and allowing it to persist and replicate.²⁷³ Michelle’s argument was dependent on the theory that “[t]here is a strong relationship between the immune system, gastrointestinal disorders, and autism.”²⁷⁴ Dr. Byers, an expert witness for the Cedillos, expressed the view that IBD may be evidence of an abnormal immune system.²⁷⁵ Thus, proof that Michelle suffers from IBD would bolster her claim that her chronic inflammatory conditions were evidence of her body’s inability to clear the MMR vaccine.²⁷⁶

The respondent’s expert Dr. Hanauer, an adult gastroenterologist, denied that viruses might cause IBD.²⁷⁷ This statement directly contradicted a 2006 article authored by Dr. Hanauer in which he expressed the view that IBD can be triggered by “a chronic inflammatory response precipitated by [an] infection with a particular pathogen or virus.”²⁷⁸ Dr. Hanauer denied that Michelle has IBD at all based on the lack of inflammation on Michelle’s pathology slides.²⁷⁹ However, he did admit that Michelle suffers from other conditions, including arthritis and eye disorders, which are commonly associated with IBD.²⁸⁰ In addition, both Dr. Hanauer and Special Master Hastings neglected to recognize that Michelle has been prescribed a drug treatment called Remicade to treat her IBD.²⁸¹ Remicade is likely responsible for the lack of inflammation on her pathology report.²⁸² Thus, Special Master Hastings was presented with evidence amounting to a “close call” as to whether a virus may trigger IBD and whether Michelle has IBD at all.²⁸³

272. See Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of February 12, 2009, *supra* note 4, at 34, 53 (asserting that Michelle’s current treating gastroenterologist Dr. Ziring has no doubt that Michelle has IBD).

273. See *Cedillo v. Sec’y of HHS*, No. 98-916V, 2009 WL 331968, at *16 (Fed. Cl. Feb. 12, 2009).

274. Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of February 12, 2009, *supra* note 4, at 64.

275. See *Cedillo*, 2009 WL 331968, at *26.

276. *Id.*

277. Petitioners’ Memorandum in Support of Motion for Review of the Special Master’s Decision of February 12, 2009, *supra* note 4, at 35.

278. See *id.* at 35.

279. *Id.* at 54.

280. *Id.* at 36.

281. *Id.* at 53, 55.

282. *Id.* at 55.

283. See discussion *supra* Part IV.D.

V. TREATMENT OPTIONS FOR ALLEVIATING THE SPECIAL MASTERS' TENSION

It is undeniable that the future of the OAP means a great deal to a countless number of people whose lives have been affected by autism. The remaining five thousand petitioners in the OAP still await their day in court with a glimmer of hope that they will receive compensation to help alleviate the many financial burdens of the disorder.²⁸⁴ As a test case, it was determined that *Cedillo* failed to establish the causal relationship between vaccines and autism upon which so many other claims in the OAP are dependent.²⁸⁵ Nevertheless, *Cedillo* is significant for revealing that the inadequately resolved tension between incompatible policies has fallen unreasonably on the shoulders of the special masters presiding over the OAP.²⁸⁶

The tensions between the two policies are difficult to reconcile, as they are inherently at odds with one another. At surface level, the driving principle behind the Vaccine Act was to ensure continued production and supply of vaccines and simultaneously provide compensation for individuals who have been injured by a vaccine.²⁸⁷ Going deeper, the legislative history of the Act acknowledges that there is an interest in promoting the use of vaccines to prevent childhood diseases.²⁸⁸ However, the *use* of vaccines is necessarily dependent upon the public's recognition that the benefits of vaccines outweigh the risks. Thus, it is not difficult to sense the special masters' dilemma—even a slight concession that suggests a causal relationship between vaccines and autism may emasculate the public's confidence in the safety vaccines.

284. See Bortfeld, *supra* note 15 (noting that the lifetime cost of treatment for autism ranges from three to seven million dollars); see also Catherine Lord & Somer L. Bishop, *Autism Spectrum Disorders: Diagnosis, Prevalence, and Services for Children and Families*, 24 SOC. POL'Y REP. No. 2, 2010 at 1, 11 (explaining that most insurance packages provide little or no coverage for autism related expenses and in fact, employers are permitted to set up “autism riders” when negotiating employee health insurance plans); *Insurance Coverage for Autism*, NAT'L CONF. OF STATE LEGISLATURES (Nov. 2010), <http://www.ncsl.org/?tabid=18246> (describing that legislation has been enacted in several states since 2007 mandating insurance companies to provide some coverage for autism, but, the coverage provided is still insufficient to cover the majority of autism related expenses); *Economics of Autism*, THE SMART FOUNDATION, <http://www.thesmartfoundation.org/Challenges/Economics.htm> (last visited July 4, 2011) (estimating that 87% of families with autism subsist at poverty level).

285. See *supra* Part II.E.2, II.E.4.

286. See *supra* Part IV.

287. See H.R. REP. NO. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348.

288. *Id.* at 5, *reprinted in* 1986 U.S.C.C.A.N. at 6346 (noting that legislation was needed in the area of vaccines because “[t]he availability and use of vaccines to prevent childhood diseases is among the Nation’s top public health priorities . . . [b]ecause of their cost-effectiveness, the Federal government has an interest in the . . . use of vaccines”) (emphasis added).

A. A Workable Solution

Going forward, it is evident that special masters need more guidance from some authority as to how to strike the balance between the two policies in causation-in-fact cases. Precedent has clearly established that the task of creating more rules is a responsibility for the Federal Circuit, not the special masters.²⁸⁹ Striking the balance between the policies is not an issue that requires new legislation or a revision of the Vaccine Act. The clearest answer to the situation at hand is a process solution in which the Federal Circuit steps in to provide more rules for the special masters to apply when making their findings of fact.

1. What is a “Close Call,” Anyway?

Causation-in-fact claims have represented an undoubtedly murky territory in the history of Vaccine Court.²⁹⁰ As noted previously, the Federal Circuit has made several attempts to carve out rules to interpret the statutory language provided in the Vaccine Act.²⁹¹ For example, in *Althen*, the Federal Circuit altered the legal landscape by providing special masters with useful guidance on fact-finding by setting forth the three-prong test for a showing of causation-in-fact.²⁹² In the same vein, the Federal Circuit attempted to provide more guidance by determining that “the system created by Congress, [is one] in which close calls regarding causation are resolved in favor of injured claimants.”²⁹³ Interestingly, a careful review of *Althen* suggests that the Federal Circuit *has* in fact made some attempt to strike a balance between the competing policies. If “close calls” are to be weighed in favor of the petitioner, it seems that the Federal Circuit has determined that compensation of the injury is more important than protecting the integrity of vaccines.²⁹⁴

289. *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1281 (Fed. Cir. 2005) (“The special master’s role is to assist the courts by judging the merits of individual claims on a case-by-case basis, not to craft a new legal standard to be used in causation-in-fact cases.”); *see also* Golkiewicz, *supra* note 100 (remarking that “the Federal Circuit sets the law that’s binding on the special masters and the parties”).

290. *See* Currier, *supra* note 130, at 237-40 (summarizing a brief history of case law regarding causation-in-fact claims).

291. *See* discussion *supra* Part II.D.1.

292. *See* discussion *supra* Part II.D.2.

293. *Althen*, 418 F.3d at 1280. This statement was based on *Althen*’s understanding of the early Vaccine Court case *Knudsen ex rel. Knudsen v. Secretary of Health and Human Services* which held that “to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” *Knudsen ex rel. Knudsen v. Sec’y of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994).

294. Currier, *supra* note 130, at 240 (discussing how compensation is tipped in favor of claimants such that “scholars have noted that there has been an increasing trend in vaccine courts in favor of granting compensation . . . [t]his trend is an unavoidable and laudable result of the history

The “close call” recommendation has become something of a catchphrase as several recent cases have cited to it.²⁹⁵ However, analysis of *Cedillo* demonstrates that the common idiom “close call” is actually quite subjective and leaves too much room for interpretation.²⁹⁶ Ultimately, the phrase loses most of its utility in the sense that there have been no real attempts to clarify it. Instead of expounding upon its meaning or creating a working definition of it, the Federal Circuit cases that have cited *Althen* regarding “close calls” have simply quoted the original text.²⁹⁷ Without clarification of what actually constitutes a “close call,” special masters have no way of consistently applying it to their conclusions in causation-in-fact cases.²⁹⁸

This paradox played out in *Cedillo*, a case that arguably contained several “close calls.”²⁹⁹ If “close calls” were truly to weigh in favor of the petitioner, Michelle Cedillo might have won her case. However, Special Master Hastings was of the opinion that there were no real “close calls.”³⁰⁰ The idea of a “close call” is so ambiguous that some special masters may feel that they can either ignore it or assign it very little weight when making their conclusions.³⁰¹ In his 2008 address, Chief Special Master Golkiewicz remarked, “there’s clearly plenty of interpretative room left in the Federal Circuit’s opinions. And that means parties looking at the same evidence are reaching different conclusions.”³⁰² Thus, the Federal Circuit must be prompted to establish a definition or test to clearly delineate what constitutes a “close call” and how a special master might recognize one. In addition, the clarification

and text of the Vaccine Act . . . Congress’s response to the vaccine ‘crisis’ of the 1980s demonstrates that the federal government would rather pay uncertain claims than revert back to a tort system that simultaneously burdens vaccine manufactures, civil courts, and the general public”). In fact, Chief Special Master Golkiewicz alluded to this when he stated, “I think it’s fair to say that the recent Fed Circuit opinions lean more heavily towards promoting of vaccine[s] by setting a standard whereby more cases are compensated. Thus, the pool of potential cases for seeking redress against the manufacturer or administrator is reduced.” Golkiewicz, *supra* note 100.

295. See *Andreu ex rel. Andreu v. Sec’y of HHS*, 569 F.3d 1367, 1378 (Fed. Cir. 2009); *Walther v. Sec’y of HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007); *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1324 (Fed. Cir. 2006).

296. See *supra* Part IV.A-D.

297. See *Andreu*, 569 F.3d. at 1378; *Walther*, 485 F.3d at 1150; see also *Capizzano*, 440 F.3d at 1324.

298. See Golkiewicz, *supra* note 100 (noting that following the *Althen* decision, there still remains a great deal of uncertainty as to how much proof is necessary to establish causation).

299. See discussion *supra* Part IV.A-D.

300. See *Cedillo v. Sec’y of HHS*, No. 98-916V, 2009 WL 331968, at *134 (Fed. Cl. Feb. 12, 2009).

301. See e.g., *Moberly ex rel. Moberly v. Sec’y of HHS*, 592 F.3d 1315, 1321-23 (Fed. Cir. 2010). *Moberly* is a 2010 case that provided a generous discussion of *Althen*, but no reference to *Althen*’s “close call” direction. *Id.*

302. Golkiewicz, *supra* note 100.

of “close calls” may be further supported by the creation of more rules concerning the sufficiency of evidence.

2. “Close Calls” Versus the Preponderance Standard

In addition to defining a “close call,” the Federal Circuit must clarify how the term is to be reconciled with the preponderance standard.³⁰³ This is because the dichotomy between the two standards presents a further conflict for special masters. The special masters are simultaneously directed by statute to weigh the evidence by the preponderance standard, while the Federal Circuit dictated that “close calls” are to be resolved in favor of the petitioner.³⁰⁴ *Althen* determined that the preponderance standard referred to by the Act was one of “simple preponderance, of ‘more probable than not’ causation.”³⁰⁵ However, other precedent interpreting the preponderance standard has determined that the petitioner’s burden is met when his evidence demonstrates by “fifty percent and a feather” that the vaccine caused his injury.³⁰⁶ Thus the preponderance standard, by its very nature, would seem to supersede any “close calls.”

Interestingly, *Pafford v. Secretary of Health and Human Services*³⁰⁷ noted “[t]he Court has painstakingly looked for the feather in Petitioner’s argument that would tip the scales past the fifty percent threshold.”³⁰⁸ The *Pafford* decision was decided one year prior to *Althen*, meaning the “close call” principle had yet to be articulated.³⁰⁹ Nonetheless, *Pafford* is important because it implies that there might be a relatively straightforward way to square “close calls” and the preponderance standard.³¹⁰ It appears feasible that the Federal Circuit could establish a rule whereby once a special master identifies a “close call,” he is to

303. The statutory language of the Vaccine Act and Federal Circuit precedent confirm that the traditional tort preponderance of the evidence standard is to be applied in vaccine cases. 42 U.S.C. § 300aa-13(a)(1) (2006) (specifying that compensation shall be awarded to petitioners who demonstrate by a preponderance of the evidence that the vaccine caused their injury and that there is not a preponderance of the evidence that the injury is due to factors unrelated to the vaccine); see also *De Bazan v. Sec’y of HHS*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *Pafford v. Sec’y of HHS*, 451 F.3d 1352, 1365 (Fed. Cir. 2006); *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1279 (Fed. Cir. 2005).

304. *Althen*, 418 F.3d at 1280.

305. *Id.* at 1279.

306. See *Pafford v. Sec’y of HHS*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. July 16, 2004) (indicating that the preponderance test is one in which the petitioner must show by “at least fifty percent and a feather” that the vaccine caused his injuries).

307. 2004 WL 1717359 (Fed. Cl. July 16, 2004).

308. *Id.* at *9.

309. *Althen*, decided in 2005, was the first Federal Circuit decision to specifically use the “close call” language. *Althen*, 418 F.3d at 1280.

310. *Pafford*, 2004 WL 1717359, at *9.

carefully consider all evidence that might facilitate a finding in favor of the petitioner. In this regard, both the “close call” directive and the preponderance standard are satisfied.

B. Prognosis: Efficiency and Ease

Althen’s line regarding “close calls” could actually prove to be quite instrumental in the attempt to strike a balance between the competing policies that burden special masters. However, a better understanding of “close calls” will require some effort by the Federal Circuit to clarify the concept. The Federal Circuit must revisit the Vaccine Act and carefully consider the fundamental values underlying its inception. It is evident from the legislative history that while Congress had an interest in promoting the use of vaccines,³¹¹ a primary objective of the Act was to compensate those who had been injured by vaccines.³¹² As discussed earlier in this Note, the decisions of special masters are afforded great deference by reviewing courts.³¹³ Thus, the Federal Circuit must structure more rules that will give guidance to special masters as to how to correctly reach their findings of fact and conclusions of law.

There is a possibility that a clarification of “close calls” will not provide enough guidance to the special masters to strike any meaningful balance. However, this option is still the best starting point because it is considerably quicker and easier than amending the Vaccine Act. Time is certainly of the essence to the five thousand petitioners in the OAP whose claims await judgment.³¹⁴ An effort to reform the Vaccine Act could tack on months or years before these cases are decided. Finally, revision of the Vaccine Act is simply not necessary. Congress structured the Act and then deferred to the Federal Circuit to interpret the legislative intent and implement it in the form of revised rules.³¹⁵ Thus, all that is necessary for the future is additional interpretation and more concrete rules from the Federal Circuit to remedy the deficiency in guidance that currently encumbers special masters.

311. See H.R. REP. NO. 99-908, at 5 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6346 (“[T]he Federal government has an interest in the development, distribution, and use of vaccines, including those designed to prevent non-childhood diseases.”).

312. See discussion *supra* Part III.

313. See discussion *supra* Part II.C.3.

314. Medical and non-medical costs for a person with extreme autism can accumulate up to \$72,000 a year, and treatment for people with mild to moderate autism can cost upwards of \$67,000 per year. Walecia Konrad, *Dealing with the Financial Burden of Autism*, N.Y. TIMES, Jan. 23, 2010, at B6.

315. See *supra* Part II.C.1, 3.

VI. CONCLUSION

The use of vaccines has protected millions of people from life-threatening diseases and is undoubtedly one of the most significant public health achievements in history. However, vaccines carry certain unavoidable risks, and it is inevitable that some individuals will suffer a serious injury as the result of a vaccination. In recognizing both the risks and benefits of vaccines, Congress envisioned a system that would simultaneously ensure the continued supply of vaccines and compensate those who had been injured. Congress also recognized an interest in upholding the use of vaccines and mandated vaccination schedules for all children wishing to enroll in schools and daycare centers. As a result, the public health in general has dramatically increased and several once-deadly diseases have been eradicated or are on a significant decline.

The fact that the vaccine supply has remained stable and that several people have been compensated for injuries is a testament to the many successes of the Vaccine Injury Compensation Program. However, the system has been frustrated in recent years by the overwhelming increase in petitions asserting a link between vaccines and ASD. The vaccine-ASD controversy became so powerful that it eventually influenced the creation of the OAP, a unique procedure to assist the Vaccine Court in handling the large volume of these claims.

Cedillo, a test case in the OAP, failed to establish the necessary link between vaccines and autism.³¹⁶ However, *Cedillo* is important for other reasons because it highlights the existence of incompatible policy concerns that may influence the outcome of many of the OAP cases.³¹⁷ The policy tensions that surround the VICP have remained unresolved and now beleaguer the special masters during the process of fact-finding.

The *Cedillo* decision was undeniably a tremendous disappointment for the approximately five thousand petitioners remaining in the OAP.³¹⁸

316. See *supra* Part II.E.2, 4.

317. See *supra* Part IV.

318. *Cedillo v. Secretary of Health and Human Services Highlights Failure of the Vaccine Injury Compensation Program*, ELIZABETH BIRT CTR FOR AUTISM L. & ADVOCACY (Aug. 30, 2010, 16:12 PM), <http://www.ebcala.org/areas-of-law/vaccine-law/cedillo-vs-secretary-of-health-and-human-services-highlights-failure-of-the-vaccine-injury-compensation-program> (quoting the mother of an OAP petitioner, “[t]hese are government lawyers, representing a government agency, presenting government-funded science to government judges, with no jury and no normal rules of evidence . . . [w]here’s the justice in that?”). The Birt Center asserts that the Court failed to do justice to Michelle Cedillo and the other OAP petitioners and that the case emphasized the overall failure of the VICP. *Id.* Mary Holland, Executive Director of the Birt Center, stated that “[i]mpartiality is the bedrock of any judicial system, and the VICP failed to exhibit it in the Omnibus Autism Proceeding.” *Id.*; see also Avery Johnson, *U.S. Court Rejects Vaccine Connection to Autism: Rulings Deny Notion That Mercury Preservative Interacts With Other Childhood Inoculations to Cause the Disorder*, WALL ST. J., Feb. 13, 2009, at A3 (quoting the mother of

Nevertheless, *Cedillo* does not end the vaccine-autism controversy, and it will not deter the pending petitioners or new petitioners who believe in a causal link from attempting to receive compensation.³¹⁹ Regardless of the Court's denial of a link between vaccines and ASD, the policy tensions that have fallen to the special masters must be acknowledged and resolved to ensure that future OAP claims are decided correctly and that the intent of the Vaccine Act is upheld.

Laura A. Binski*

another VICP petitioner, “‘I listened to the test case and I honestly felt it was a strong case . . . [i]t puts us at an enormous disadvantage when the first three test cases are found for the Department of Health and Human Services . . . [w]hen does anecdotal evidence become enough?’”).

319. See Gardiner Harris, *Opening Statements in Case on Autism and Vaccinations*, N.Y. TIMES, June 12, 2007, at A21. (“Many parents who claim that vaccines gave their children autism are deeply suspicious of what they see as the government’s role in their children’s illness. Most have dismissed the many government-sponsored studies and panels that found no link between vaccination and autism.”).

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