IMMUNIZING AGAINST BAD SCIENCE: THE VACCINE COURT AND THE AUTISM TEST CASES

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I
INTRODUCTION

Despite assurances from healthcare providers, questions about vaccine safety remain in the media spotlight and public debate, particularly the concern that vaccines cause autism. Since 2002, the federal court that hears vaccine-injury disputes—commonly called the Vaccine Court—has been at the center of a debate about whether vaccines cause autism.[1] The year 2010 marked the conclusion of six cases selected to test the validity of theories about how vaccines cause autism.[2] In August 2010, a final decision was rendered in the last unresolved test case, *Cedillo v. Department of Health & Human Services*.[3] In *Cedillo*, the Federal Circuit affirmed the Vaccine Court's finding that the petitioner neither presented a viable theory about how vaccines cause autism, nor proved that the petitioner's vaccination caused her autism.

This decision affects approximately five thousand similar autism claims pending in the Vaccine Court.[4] Many families involved in these claims assert that the test cases satisfied the court's unique standard of proof, whereas the federal government argues that the cases failed to meet even a low standard.[5] In light of the complex, competing scientific claims considered by the court, the

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1. *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2002 WL 31696785, at *1 (Fed. Cl. July 3, 2002) [hereinafter July 2002 Autism Update].

2. *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder (Fed. Cl. filed Sept. 29, 2010) [hereinafter Sept. 2010 Autism Update], *available at* http://www.autism-watch.org/omnibus/update.shtml.

3. No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *reconsideration denied*, No. 98-916V, 2009 WL 996299 (Fed. Cl. Mar. 16, 2009), *and aff'd*, No. 98-916V, 2009 WL 2998429 (Fed. Cl. Aug. 6, 2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010).

4. Sept. 2010 Autism Update, *supra* note 2.

5. Wendy N. Davis, *The Immune Response: The Supreme Court May Tell Families with Autistic Children Whether They Can Sue Vaccine Makers*, 96 A.B.A. J. 48, 52 (2010).

autism test case decisions raise significant "science and law" issues.[6] Throughout the autism test cases, there has been an overarching concern that a decision to deny entitlement will result in a flood of autism claims in state courts. But considering current scientific and medical knowledge, the concern over autism cases moving into the civil sphere is likely overstated. Instead, attention should be paid to how these autism claims reflect a broader concern: a loss of public trust in vaccines.

The conclusion of the autism test cases is an opportunity to review the success of the vaccine-injury program and its relationship to U.S. vaccination practices. Part II of this note traces the history of vaccine-injury suits in the United States, the creation of the Vaccine Court, and how vaccine-injury claims are proven in the court. Part III introduces the vaccine–autism controversy and the Vaccine Court's decision to institute an omnibus proceeding to manage the autism claims. Part IV provides an overview of the omnibus autism proceedings, focusing on the *Cedillo* case. Part V sets forth an argument that the autism test cases demonstrate how the current standard of proof in vaccine cases trends too much toward awarding compensation and away from science. Vaccine Court decisions are unlikely to restore public trust in vaccines, but the decisions can contribute to public misperceptions. Compensating too many undeserving petitioners undermines the integrity of vaccine safety. Accordingly, this threatens to create a public health problem: If the standard of proof in the Vaccine Court is too low, the court implicitly validates public fears about vaccines and impacts public willingness to get vaccinated. To maintain public trust in vaccines, the standard of proof in the Vaccine Court must be clearer and more scientifically rigorous.

II
THE HISTORY OF VACCINE LITIGATION AND POLICY

A. Vaccine-Injury Lawsuits in the United States

Every state legally requires that children receive certain immunizations before attending school or daycare.[7] Many states provide medical, religious, and even philosophical exemptions to vaccination requirements.[8] Nevertheless, most children in the United States today receive routine immunizations against fourteen diseases.[9] In rare cases, vaccines cause serious and even fatal side-

6. 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, 1517–18 (2009).

7. Gordon Shemin, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 468 (2008) ("Today all fifty states as well as the District of Columbia mandate childhood immunizations.").

8. *See, e.g.*, *Toward a Twenty-First-Century*, 121 HARV. L. REV. 1820, 1825 (2008) (stating that most states allow religious exemptions and some provide philosophic exemptions to vaccination requirements).

9. *Frontline: The Vaccine Wars* (PBS television broadcast Apr. 27, 2010).

effects.[10] These side-effects can occur even if vaccines are produced and administered properly.[11]

In the mid- to late 1980s, there was a significant increase in the number of vaccine-injury suits against vaccine manufacturers,[12] possibly attributable to heightened media coverage at the time about the risks of vaccinations. Media coverage primarily focused on the diphtheria–tetanus–pertussis (DTP) vaccine.[13] Plaintiffs in these suits often sought millions in damages.[14] Manufacturers worried that juries would award substantial damages to sympathetic plaintiffs regardless of whether the manufacturers were at fault.[15] Experiencing difficulty obtaining liability insurance, some manufacturers withdrew from the market. Ultimately, only one commercial DTP manufacturer remained in the U.S. market.[16] In December 1984, the Centers for Disease Control and Prevention (CDC) predicted the United States would experience vaccine shortages as early as January 1985.[17]

B. The Vaccine Act

In 1986, Congress responded to the threat of a vaccine-supply crisis by passing the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act).[18] The Vaccine Act created a no-fault program for resolving vaccine-injury claims.[19] Key features of this program are its relaxed procedures and unique standard of proof.

1. The Vaccine Court

The Vaccine Act created a comprehensive vaccine policy for the United States. This policy included a National Vaccine Injury Compensation Program (NVICP or the Vaccine Program), designed to be more accessible and less

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10. *See, e.g.*, Okianer Christian Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 U. TOL. L. REV. 799, 800, 802 (1994) (stating that for some children, "the [DTP] vaccine is extremely dangerous" and that "even when manufactured and distributed properly, can cause serious injuries, including death," but noting that vaccine side-effects are rare).

11. *Id.* at 801 (discussing vaccine manufacturers' concerns that unavoidable vaccine side-effects would expose them to liability without wrongdoing).

12. *See, e.g.*, *id.* at 820, 831–32 (discussing the history of suits against vaccine manufacturers).

13. Alan R. Hinman, *DTP Vaccine Litigation*, 140 AM. J. DISEASES CHILD. 528, 529 (1986).

14. James O. Mason, *Vaccine Supply and Liability*, 101 PUB. HEALTH REP. 229, 229 (1986).

15. *See* James B. Currier, *Too Sick, Too Soon?: The Causation Burden Under the National Vaccine Injury Compensation Program Following* De Bazan v. Secretary of Health and Human Services, 19 FED. CIR. B.J. 229, 233 (2009) (noting that later studies confirmed most juries sympathized with vaccine-injury plaintiffs).

16. Mason, *supra* note 14, at 229.

17. Ctr. for Disease Control and Prevention, *Diphtheria-Tetanus-Pertussis Vaccine Shortage—United States*, 34 MORBIDITY MORTALITY WKLY. REP. WKLY. 695 (1984), http://www.cdc.gov/mmwr/preview/mmwrhtml/00000452.htm.

18. Pub. L. 99-660, title III, Sec. 311(a), Nov. 14, 1986, 100 Stat. 3758.

19. 42 U.S.C.A. § 300aa-1 (West 2011).

adversarial than the traditional tort system.[20] To adjudicate vaccine-injury claims, the NVICP created an Office of Special Masters (OSM) in the United States Court of Federal Claims (CFC),[21] unofficially dubbed the Vaccine Court.[22]

Petitioners must file vaccine-injury claims with the Vaccine Court before filing in state court.[23] Special masters, without a jury, issue decisions on entitlement.[24] The Secretary of Health and Human Services (HHS) serves as the respondent.[25] Petitioners are not required to obtain legal counsel, but may request reasonable attorneys' fees regardless of the outcomes of their claims.[26] Within thirty days after a petitioner files a claim with the Vaccine Court, the special master assigned to the case holds a status conference with the parties to assess the merits of the petitioner's claim and facilitate settlement.[27] If the case goes forward, the Vaccine Court has 240 days to issue a decision or the petitioner can exit the program and bring a claim in state court.[28] After the Vaccine Court issues a decision, a dissatisfied petitioner generally retains the right to reject the judgment and file in state court.[29] Additionally, either party may apply to the CFC for review of a special master's decision and appeal a CFC decision to the U.S. Court of Appeals for the Federal Circuit.[30]

2. Proving a Claim in the Vaccine Court

To receive compensation, petitioners must prove they suffered one of two kinds of injuries: "on-table" or "off-table." On-table injuries are those listed in the NVICP Vaccine Injury Table.[31] This table includes adverse events known by the medical community to occur after a vaccination.[32] Injuries not on the table or not occurring within the table's timeframe constitute off-table claims. If a petitioner proves, by a preponderance of the evidence, that he suffered an on-table injury following an immunization, the Vaccine Court presumes the

20. *Id.* § 300aa-10; *see also* Dark, *supra* note 10, at 803 (stating the Vaccine Act was intended to provide "an alternative to the tort law system").

21. *Vaccine Program Background*, U.S. CT. FED. CLAIMS OFF. SPECIAL MASTERS, http://www.uscfc.uscourts.gov/sites/default/files/vaccine.background.2010.pdf (last visited Jan. 3, 2010).

22. Mark Sherman, *Parents Lose Supreme Court Appeal in Vaccine Case*, U.S. NEWS & WORLD REP. (Feb. 22, 2011), *available at* http://www.usnews.com/news/articles/2011/02/22/parents-lose-high-court-appeal-in-vaccine-case.

23. 42 U.S.C.A. § 300aa-11(a)(2)(A).

24. *Id.* § 300aa-12(d).

25. *Id.* § 300aa-12(b)(1).

26. *See, e.g.*, Alexandra M. Stewart, *When Vaccine Injury Claims Go to Court*, 360 NEW ENG. J. MED. 2498, 2498 (2009) (describing the NVICP process).

27. VACCINE R. OF U.S. COURT OF FED. CLAIMS 5.

28. 42 U.S.C.A. § 300aa-21(b).

29. *Id.* Some claims, however, can only be brought in the Vaccine Court. *Id.* § 300aa-22.

30. *Id.* § 300aa-12(e), (f).

31. The original Vaccine Injury Table can be found at 42 U.S.C.A. §§ 300aa-14(a). The amended table can be found at 42 C.F.R § 100.3 (2011).

32. *E.g.*, Stewart, *supra* note 26, at 2498.

vaccine was the cause.[33] To succeed with an off-table injury, a petitioner must prove, by a preponderance of the evidence, that the vaccine was the cause-in-fact of the injury.[34] To prevent successful claims from effectively creating more on-table injuries, decisions by special masters or the CFC are not binding on special masters, except on remand in the same case.[35] Originally, Congress assumed that the majority of petitioners would file on-table claims. Recently, however, the number of off-table claims has increased.[36]

The Vaccine Act explicitly forbids the court from finding actual causation based solely on a petitioner's statements unsupported by medical records or expert medical opinion.[37] Although the Vaccine Act does not require expert testimony, experts have played an increasingly important role in successful off-table vaccine-injury claims (not unlike non-vaccine litigation).[38] This has spurred numerous Federal Circuit decisions addressing what evidence is necessary and sufficient to prove an off-table injury. These opinions have set a low evidentiary bar: For example, in *Knudsen v. Secretary of Department of Health & Human Services*, the Federal Circuit reversed and remanded a special master's decision to deny entitlement, stating that the petitioner's theory of causation needed only to be "'logical' and legally probable, not medically or scientifically certain."[39] The court explained, "to require [the] identification and proof of specific biological mechanisms would be inconsistent with the purpose and the nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation."[40] In a later case, the Federal Circuit supported this interpretation of the standard of proof, citing Congress's acknowledgement that the Vaccine Program would compensate some petitioners whose injuries were not actually vaccine-related.[41] In another case,

33. 42 U.S.C.A § 300aa-13(a)(1); *see also* Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005) ("The Act provides for the establishment of causation . . . through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ('Table Injury').").

34. 42 U.S.C.A §§ 300aa-11(c)(1)(C)(ii)–13(a)(1)(A).

35. *E.g.*, Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998) ("Special Masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except . . . on remand.").

36. This is partly because HHS modified the Vaccine Injury Table in the 1990s and removed some of the more common injuries. *See, e.g.*, Currier, *supra* note 15, at 247 ("HHS redefined the number of compensable injuries on the Injury Table. Although HHS added more vaccines to the Injury Table than it removed, the vaccines removed were involved in a large proportion of the claims before the vaccine courts."); Katherine E. Strong, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 443 (2007) (stating HHS modified the table based on reports from the Institute of Medicine about whether certain vaccines caused particular injuries).

37. 42 U.S.C.A. § 300aa-13(a)(1) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.").

38. *See, e.g.*, Currier, *supra* note 15, at 247 (stating that scholars have noted the increasing importance of expert testimony and medical studies in Vaccine Court cases).

39. 35 F.3d 543, 548–49 (Fed. Cir. 1994).

40. *Id.* at 549.

41. Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999) ("The

the Federal Circuit objected to the special master's requiring peer-reviewed literature linking a petitioner's vaccine and injury. The court stated that it saw "no 'objective confirmation' requirement in the Vaccine Act's preponderant evidence standard."[42]

In *Althen v. Secretary of Health & Human Services*, the Federal Circuit announced a new, three-prong standard of proof for off-table claims.[43] Under *Althen*, petitioners must present "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury."[44] If a petitioner satisfies all three prongs, the government must prove, by a preponderance of the evidence, an alternate cause for the petitioner's injury. The Federal Circuit stated that "close calls regarding causation are resolved in favor of injured claimants."[45] The CFC has characterized the petitioner's burden as needing only to "to 'tip the scale' by the slightest of evidentiary margins."[46]

Before *Althen*, the Federal Circuit stated that a petitioner's proof of causation must be supported by reliable scientific or medical explanations.[47] The Federal Circuit affirmed a special master's refusal to credit an expert opinion without support from medical literature or studies, remarking that "[a]n expert opinion is no better than the soundness of the reasons supporting it,"[48] and acknowledged that Congress intended special masters to have broad discretion to assess vaccine-injury evidence.[49] Even post-*Althen*, the Federal Circuit remarked that "[a]lthough a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of [an]

Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.") (quoting H.R. REP. NO. 99-908, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359).

42. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005).

43. *Id.* at 1278; *see also* Davis, *supra* note 5, at 52 ("[T]he Federal Circuit relaxed the causation standard in 2005 . . . . The special master denied Althen compensation because [the petitioner] hadn't proved that the vaccine caused her condition, but the appellate court reversed—and announced a new standard.").

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

45. *Id.* at 1280.

46. McClendon v. Sec'y of Dep't Health & Human Servs., 24 Cl. Ct. 329, 333 (1991).

47. *See, e.g.*, Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994) ("This 'logical sequence of cause and effect' must be supported by a sound and reliable medical or scientific explanation."); Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("A reputable medical or scientific explanation must support this logical sequence of cause and effect.").

48. Perreira v. Sec'y of Dep't of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)).

49. Whitecotten v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1999) ("Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned to [it].").

expert witness."[50] The Federal Circuit has confirmed recently that special masters may use *Daubert* factors to evaluate the reliability of scientific evidence presented in vaccine cases.[51] In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court announced the standard by which judges determine the admissibility of expert witness testimony in federal courts: the scientific validity of the underlying reasoning or methodology and its proper application to the facts of the case.[52] The Court specifically stated that judges may consider whether the theory can or has been tested, whether it has been published or peer-reviewed, and its reception in the scientific community.[53] Nevertheless, since *Althen*, the Federal Circuit has reversed and remanded a number of Vaccine Court decisions for impermissibly raising the standard of proof.[54] The autism cases demonstrate the possible practical consequences of the current low standard of proof on vaccination practices, underscoring the need for a more scientific standard.

III
THE VACCINE–AUTISM CONTROVERSY

A. Linking Vaccines to Autism

Since 1999, the Vaccine Court has received more than five thousand claims alleging that a vaccine caused or contributed to a petitioner's autism.[55] To understand the impact of these autism cases, it is important to know the history of the vaccine–autism controversy.

Autism spectrum disorders, which vary in degrees of severity, include complex conditions that affect individuals' abilities to interact socially and communicate. Symptoms typically emerge before age three.[56] There is no laboratory test for autism; diagnosis is based on certain behavioral criteria.[57] Since the 1980s, autism diagnoses have been on the rise in the United States, increasing public awareness about the disorder and fueling speculations about possible causes.[58]

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50. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010).

51. *See, e.g.*, Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010) ("We see no legal error in the standards applied by the Special Master either in judging causation or in utilizing *Daubert.*"); Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999).

52. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

53. *Id.* at 593–95.

54. *See, e.g.*, Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367 (Fed. Cir. 2009); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317 (Fed. Cir. 2006).

55. Regina Moreland, *National Vaccine Injury Compensation Program: The Potential Impact of* Cedillo *for Vaccine-Related Autism Cases*, 29 J. LEGAL MED. 363, 364 (2008).

56. Liza Gross, *A Broken Trust: Lessons from the Vaccine–Autism Wars*, 7 PLOS BIOLOGY, May 2009, at 1, 5 (2009).

57. Shemin, *supra* note 7, at 478 ("The etiology of autism remains a mystery and science has not yet been able to determine a cause.").

58. *See, e.g.*, Gross, *supra* note 56, at 4 (discussing the rise in autism diagnoses and public theories

The vaccine–autism theory is often attributed to British physician Andrew Wakefield. In 1998, Wakefield published an article in *The Lancet* linking the measles–mumps–rubella (MMR) vaccine to autism. *The Lancet* later retracted Wakefield's article, and in May 2010, Wakefield lost his medical license for reasons that included unethical conduct related to his autism research.[59]

In the United States, the vaccine–autism controversy has centered on thimerosal.[60] Thimerosal is an ethylmercury compound that has been used as a preservative in vaccines since the 1930s.[61] In the late 1990s, the FDA indicated that thimerosal-containing vaccines might expose children to mercury levels exceeding federal safe-intake guidelines.[62] Subsequently, the federal Public Health Service and American Academy of Pediatrics issued joint statements recommending thimerosal be removed from vaccines—both as a precautionary measure and as an effort to maintain public confidence in vaccine safety.[63]

Today, as many as one in four Americans believe that vaccines can cause autism.[64] The media has only inflamed the public's fears. News reports have cited studies linking thimerosal to autism and have featured scientists who supported the theory.[65] A number of high-profile politicians and celebrities have discussed the theory publically. In 2005, *Rolling Stone* magazine published an article by Robert Kennedy, Jr.—son of the late Senator Robert Kennedy—called "Deadly Immunity," in which Kennedy stated, "If, as the evidence suggests, our public-health authorities knowingly allowed the pharmaceutical industry to poison an entire generation of American children, their actions arguably constitute one of the biggest scandals in the annals of American medicine."[66] In 2008, celebrity Jenny McCarthy, whose son is autistic, appeared on Larry King's show on CNN and argued that vaccines can cause autism.[67] The vaccine–autism theory persists in public discourse at least in part because of media attention and affirmations from high-profile sources.

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about the causes).

59. Davis, *supra* note 5, at 53 ("Earlier this year, *The Lancet* retracted Wakefield's article, stating that 'several elements' of the paper were incorrect."); Gross, *supra* note 56, at 1 ("Wakefield faces charges of serious professional misconduct before the General Medical Council (GMC) for allegedly violating ethical research practices on several counts."); Davis, *supra* note 5, at 53 ("Wakefield was stripped of his medical license in May.").

60. Gross, *supra* note 56, at 1 (describing the history of the vaccine–autism controversy in the United Kingdom and United States).

61. Shemin, *supra* note 7, at 461 n.8.

62. Moreland, *supra* note 55, at 370.

63. *Id.* at 371.

64. Gross, *supra* note 56, at 2.

65. *See, e.g.*, *id.* at 6 (discussing published accounts of scientists who support the vaccine–autism theory).

66. Robert Kennedy Jr., *Deadly Immunity*, ROLLING STONE, June 20, 2005, *available at* http://www.rollingstone.com/plus/archive#/2/329/56/S.

67. *Larry King Live* (CNN television broadcast Feb. 28, 2008); s*ee also* Gross, *supra* note 56, at 5 (describing news and media coverage of the vaccine–autism controversy).

B. The Omnibus Autism Proceedings

"At its inception, it was unforeseen the [Vaccine] Program would receive over 5,000 cases in eight years arguing a link between a vaccine and autism."[68] A central question became how the Vaccine Program would manage the flood of cases. In 2002, the Vaccine Court created the Omnibus Autism Proceedings (OAP), which designated specific procedures for "aggressively, but fairly" resolving pending and anticipated autism claims.[69] Special Master George Hastings, Jr. was selected to preside over the OAP.[70] Shortly after he was chosen, Special Masters Denise Vowell and Patricia Campbell-Smith were also assigned to the OAP.[71]

Because autism is an off-table claim, petitioners must prove causation-in-fact.[72] The OAP employed a two-step process for resolving the autism claims. First, the special masters would conduct an inquiry into the issue of general causation: whether vaccines can cause autism. Second, the special masters would apply their evidentiary findings from the general-causation inquiry to the individual autism cases.[73] OSM selected attorneys representing petitioners in autism claims to constitute the Petitioner's Steering Committee (PSC).[74] PCS selected general-causation-theory test cases for the OAP. Petitioners with pending or potential autism claims could opt into the OAP. Special masters would defer proceedings for cases in the program until after deciding the test cases.[75]

Ultimately, PSC presented two general-causation theories, selecting three test cases for each theory. The first theory alleged that the MMR vaccine and thimerosal-containing vaccines together can cause autism. The second theory alleged that thimerosal-containing vaccines alone can cause autism.[76] PSC selected as the first theory test cases *Cedillo v. Secretary of Health & Human Services*,[77] *Hazlehurst v. Secretary of Department of Health & Human Services*,[78]

68. Moreland, *supra* note 55, at 364; *see also* July 2002 Autism Update, *supra* note 1, at *1 ("Processing such a large number of cases [would] stretch thinly the resources of both the court and the bar.").

69. *E.g.*, Shemin, *supra* note 7, at 461.

70. July 2002 Autism Update, *supra* note 1, at *3.

71. *The Autism Proceedings*, U.S. CT. FED. CLAIMS OFF. SPECIAL MASTERS, ftp://ftp.cafc.uscourts.gov/autism/vaccine/Background_on_the_autism_proceedings.pdf (last visited Jan. 3, 2010).

72. *E.g.*, Shemin, *supra* note 7, at 476 ("Because autism is not listed as an injury on the Vaccine Injury Table, claims alleging autism must proceed via the off-table theory.").

73. July 2002 Autism Update, *supra* note 1, at *2 (creating the OAP framework and Docket of the OAP, a public compilation of filings, court orders, decisions, and updates from the court).

74. *The Autism Proceedings*, *supra* note 71; Health Res. and Servs. Admin., *National Vaccine Injury Compensation Program: About the Omnibus Autism Proceedings*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hrsa.gov/vaccinecompensation/omnibusautism.html (last updated Aug. 19, 2010).

75. July 2002 Autism Update, *supra* note 1, at *6.

76. Sept. 2010 Autism Update, *supra* note 2.

77. No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

78. No. 03-654V, 2009 WL 332258 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

and *Snyder v. Secretary of Department of Health & Human Services*.[79] The second theory test cases were *Mead v. Secretary of Health & Human Services*,[80] *King v. Secretary of Health & Human Services*,[81] and *Dwyer v. Secretary of Department of Health & Human Services*.[82] The three special masters assigned to the OAP would hear the general-causation evidence jointly, but would separately decide each case assigned to them.[83] In 2007, the special masters conducted three weeks of evidentiary hearings on the first theory. Michelle Cedillo's case was the first to begin.[84]

IV
THE AUTISM TEST CASE DECISIONS

A. Michelle Cedillo's Case

For the first two years of Michelle Cedillo's life, she was apparently a healthy child.[85] In December 1995, Michelle received an MMR vaccine and one week later developed a high fever.[86] In January, she had a second fever, and Michelle's pediatrician diagnosed her with "sinusitis v. flu."[87] At her next doctor visit, Michelle's pediatrician noted that Michelle was "talking less" since the fever.[88] In 1997, a different pediatrician noted Michelle's development was delayed, suspecting the fevers had caused neurological damage but unable to determine if it was a "post-immunization phenomenon."[89] That same year, a developmental psychologist diagnosed Michelle with "severe Autism" and "profound Mental Retardation."[90]

The Cedillos filed a petition in the Vaccine Court, alleging that multiple thimerosal-containing vaccines had damaged Michelle's immune system.[91] They claimed this damage allowed the live measles virus in the MMR vaccine to replicate in Michelle's body and cause inflammation in her bowels and brain.[92] Michelle's case was grouped into the OAP. At the request of the PCS and the

79. No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

80. No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

81. No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

82. No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

83. Sept. 2010 Autism Update, *supra* note 2.

84. *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Order Concerning Case Processing (Fed. Cl. Spec. Mstr. June 5, 2007), http://www.uscfc.uscourts.gov/sites/default/files/autism/Untitled.pdf.

85. Before two years of age, Michelle reached her developmental milestones. Cedillo v. Sec'y of Health & Human Servs., No. 98–916V, 2009 WL 331968, at *4 (Fed. Cl. Feb. 12, 2009).

86. *Id.* at *4–5.

87. *Id.* at *5.

88. *Id.*

89. *Id.* (discussing the testimony of Dr. William Masland).

90. *Id.* (discussing the testimony of Dr. Karlsson Roth).

91. *Id.* at *13. The Cedillos first filed in 1998, and then filed an amended petition in 2002.

92. *Id.* at *15.

Cedillos' counsel, it became a test case for the first general-causation theory.[93]

B. A Theory Neither Recognized by the Medical Community nor Supported by Science

Special Master Hastings presided over Michelle's case.[94] He reviewed twenty-three medical expert reports and 658 medical journal articles and heard testimony from sixteen expert witnesses.[95] In February of 2009, he announced his decision to deny entitlement.

Special Master Hastings focused on the Cedillos' failure to produce reputable scientific evidence supporting either a general or a specific theory of causation. He found that many of the scientific studies cited "[came] down strongly against the petitioners' contentions" and that "[t]he expert witnesses presented by the respondent were far better qualified, far more experienced, and far more persuasive than the petitioners' experts."[96] He noted some of the Cedillos' evidence would not meet the *Daubert* standard.[97] For example, Special Master Hastings criticized a general-causation expert whose theory was neither recognized by the medical community nor supported by "sound scientific methods."[98] Special Master Hastings also found study results supporting the Cedillos' theory of specific causation unreliable.[99] He concluded that

> it is extremely unlikely that any of Michelle's disorders were in any way causally connected to her MMR vaccination, or any other vaccination. . . . After studying the extensive evidence in this case for many months, I am convinced that the reports and advice given to the Cedillos . . . advising the Cedillos that there is a causal connection between Michelle's MMR vaccination and her chronic conditions[] have been *very wrong.* Unfortunately, the Cedillos have been misled by physicians who are guilty, in my view, of gross medical misjudgment.[100]

The same day that *Cedillo* was announced, Special Masters Vowell and Campbell-Smith issued decisions in *Snyder* and *Hazlehurst*, respectively, also denying entitlement.[101] All three test case petitioners applied for review by the CFC. Although each of the test case decisions was made individually, they involved parallel reasoning.

In their appeal, the Cedillos alleged that Special Master Hastings had required too high a standard of proof,[102] citing several Federal Circuit decisions

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93. *Id.* at *9.

94. *Id.*

95. Moreno, *supra* note 6, at 1514–15.

96. *Cedillo*, 2009 WL 331968, at *1.

97. *Id.* at *3, *41, *91 (discussing *Daubert* and its use in the Vaccine Program, and applying *Daubert* factors to assess the reliability of petitioner's experts' unpublished work).

98. Janice G. Inman, *The Autism Cases, and What's Next: Part One of a Two-Part Article*, 26 No. 8 MED. MALPRACTICE L. & STRATEGY 1 (2009) (describing the *Cedillo* decisions).

99. *Id.*

100. *Cedillo*, 2009 WL 331968, at *134–35.

101. Sept. 2010 Autism Update, *supra* note 2.

102. Brief for Petitioners-Appellants at 15–16, Cedillo v. Sec'y of Health & Human Services, (Fed. Cir. 2010) (No. 2010-5004), 2010 WL 464240 (stating the special master "chose to impose upon Michelle

that reversed Vaccine Court decisions for applying a standard inconsistent with *Althen*.[103] Acknowledging that some of their evidence would not survive a *Daubert* motion, the Cedillos identified several vaccine-injury claims that were compensated on the basis of purportedly similar evidence.[104] According to the Cedillos, what distinguished Michelle's case from those compensated claims was that hers was an autism test case. The Cedillos claimed "the special master purposely turned a blind eye on [Michelle's] evidence . . . [and] inappropriately assumed the respondent's role as protector of the integrity of vaccines."[105]

C. Affirming Rational and Reasonable Decisions

In 2009, the CFC individually affirmed *Cedillo*, *Hazlehurst*, and *Snyder*.[106] Judge Wheeler issued the *Cedillo* opinion, agreeing that the Cedillos did not meet their prima facie causation burden.[107] Judge Wheeler stated that "[the] Court [of Federal Claims] will not second guess a Special Master's fact intensive conclusions, especially when medical evidence of causation is in dispute."[108] He noted that "[t]he evidentiary record in the [OAP test] cases easily is the largest of all cases presented to the Court in the history of the Vaccine Act."[109] He found that the special master had exercised valid discretion in choosing to discredit certain studies and experts. Judge Wheeler also held that Special Master Hastings did not improperly raise the *Althen* standard.[110] Regarding the Cedillos' allegation that a lower standard had been applied in other cases, Judge Wheeler noted that "[u]nlike medical issues raised in other Vaccine Act cases, autism is not an area 'bereft of complete proof.'"[111] He concluded that Special Master Hastings's decision was "rational and reasonable in all respects" and consistent with the law. [112]

Only *Cedillo* and *Hazlehurst* were appealed to the Federal Circuit. While the appeals were pending, the special masters issued decisions denying entitlement in the second theory test cases.[113] None of those petitioners

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an unattainable standard of proof").

103. *Id.* at 19; *see also* Janice G. Inman, *The Autism Cases: In Vaccination Case, Losing Side Casts Doubt on Special Master's Impartiality, Part Two of a Two-Part Article*, 26 No. 9 MED. MALPRACTICE L. & STRATEGY 1 (2009) (describing the *Cedillo* decisions).

104. Brief for Petitioners-Appellants, *supra* note 102, at 20–21. Further, the Cedillos asserted *Daubert* applied solely to judicial review of scientific methods, not to expert conclusions. *Id.* at 65.

105. Petitioner's Memo in Support of Motion for Review of Special Master's Decision of Feb. 12, 2009 at 4, Cedillo v. Sec'y of Dep't of Health & Human Servs., No.98-916V (Fed. Cl. Spec. Mstr. Mar. 16, 2009).

106. Sept. 2010 Autism Update, *supra* note 2.

107. Cedillo v. Sec'y of Health & Human Servs, 89 Fed. Cl. 158, 183 (2009).

108. *Id.* at 178 (citing Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir.1993); Moberly v. Sec'y Health & Human Servs., 85 Fed. Cl. 571, 597 (2009)).

109. *Id.* at 167.

110. *Id.* at 182–83.

111. *Id.* at 184.

112. *Id.*

113. Hearings for the second theory were held a year later, in 2008. Sept. 2010 Autism Update,

appealed; final judgments were entered in April of 2010.[114]

In their appeal to the Federal Circuit, the Cedillos described Michelle's experience in the Vaccine Program as "a disaster."[115] Their appeal concluded that

> it is essential that the Vaccine Program, rather than crippling civil litigation, resolve [Michelle's] case as well as those of all autistic children in OAP. Persons fairly compensated in the Vaccine Program will not sue manufacturers. How can these persons be kept in the Vaccine Program? The answer is simple. An evidentiary standard that promotes congressional intent must be employed.[116]

On May 13, 2010, the Federal Circuit affirmed the rulings below in *Hazlehurst.*[117] Then in August of 2010, the Federal Circuit held that it could find "no legal error in the standards applied by the special master" in *Cedillo*. Mirroring the *Hazlehurst* decision,[118] the Federal Circuit emphasized the importance of the *Althen* standard, but found the special master's use of the *Daubert* factors had not undermined *Althen.*[119] The Federal Circuit stated that weighing all of the evidence necessitated assessing its reliability[120] and cited cases that emphasized special masters' discretion to evaluate the reliability of evidence.[121] Michelle's mother commented publically on the decision: "We are obviously extremely disappointed. Michelle has a very strong case. The facts in her medical records speak for themselves. Our lawyers are currently reviewing the decision to see what legal options are available."[122]

Both the Cedillos and the petitioners in *Hazlehurst* notified the court that neither would seek certiorari from the Supreme Court. Subsequently, PSC notified the court that no further test cases are contemplated.[123]

V
LESSONS FROM THE AUTISM CASES

Despite fears to the contrary, given the current state of scientific and medical knowledge and standards of proof in the state courts, a flood of civil litigation is unlikely to result from the OAP decisions. Evidence that vaccines

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supra note 2.

114. *Id.*

115. Brief for Petitioners-Appellants, *supra* note 102, at 13.

116. *Id.* at 57–58.

117. Hazlehurst v. Sec'y of Health & Human Servs, 604 F.3d 1343 (Fed. Cir. 2010).

118. *See generally id.*

119. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1339 (Fed. Cir. 2010).

120. *Id.*

121. *Id.* at 1339 n.3 (citing Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1325 (Fed. Cir. 2010); Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999); Perreira v. Sec'y of Dep't of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994)). See *supra* Part II.B.2 for a discussion of the standard of proof in off-table claims.

122. Tony Mauro, *Federal Circuit Rules No Link Between Autism and Vaccine*, NAT'L L.J., Aug. 30, 2010.

123. Sept. 2010 Autism Update, *supra* note 2.

can cause autism simply is not available to meet the higher standards of proof in the civil sphere. There is, however, a more insidious danger underlying the autism cases: increasingly negative public opinion toward vaccines generally. The government and health professionals have looked to the Vaccine Court to emphasize vaccine safety. If the Vaccine Program focuses too much on compensation and not enough on science, decisions will implicitly validate public fears about vaccines.

A. The State Court Threat

Vaccines have been described as "the next big toxic-tort battleground."[124] A common refrain of critics is that, by denying entitlement, the Vaccine Court will drive autism cases into the civil sphere. At the CFC 2008 Judicial Conference, well-known plaintiff's lawyer Kevin Conway called preventing civil suits the Vaccine Act's "number one" purpose.[125] Mr. Conway also stated, "[M]y sense is that the [OAP] test cases will certainly result in probably a large majority of the cases in the vaccine program leaving . . . and going into the civil arena."[126] The Cedillos' last appeal to the Federal Circuit echoed Conway's remark.[127]

Nevertheless, it is unlikely that the conclusion of the OAP will result in a flood of vaccine–autism claims in the civil arena. First, the levels of review within the Vaccine Program will likely shield against many autism cases reaching state courts.[128] Second, evidence linking vaccines and autism is not currently available. As one scholar noted, "[b]ecause state courts must deliver judgments based on credible evidence that satisfies traditional legal standards, claims relying on evidence similar to that presented under the Omnibus Autism Proceeding will have difficulty surviving judicial scrutiny."[129] Although petitioners will have the benefit of full discovery, "it is highly unlikely that [autism] plaintiffs will succeed without additional scientific advancements to support their claims."[130] To date, there have been no successful vaccine–autism claims in state courts.

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124. Davis, *supra* note 5, at 49.

125. *Concurrent Vaccine Program/Vaccine Compensation Under the Act: A Mix of Science and Policy?*, at 16, lines 3–8 (Transcript of 2008 Judicial Conference of the U.S. Court of Fed. Claims) [hereinafter 2008 Transcript]. When enacting the Vaccine Act, Congress stated that the "relative certainty and generosity of the [Vaccine Program]'s awards [would] divert a significant number of potential plaintiffs from litigation." H.R. REP. No. 99-908, at 13 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6354.

126. Dep't of Health & Human Servs., Transcript of Advisory Comm'n on Childhood Vaccines Meeting 46 (June 10, 2010) [hereinafter Advisory Comm'n June Meeting] (statement of Kevin Conway, petitioner's attorney).

127. *See supra*, Part III.C (discussing the Cedillos' appeal to the Federal Circuit).

128. Stewart, *supra* note 26, at 2499–500.

129. *Id.* at 2500.

130. *Id.* Some plaintiffs' attorneys criticize the limited discovery in Vaccine Court cases as an impediment to their success.

B. The Resilience of the Autism Controversy in Public Discourse

The belief that vaccines cause autism raises important issues independent of the potential for increased civil litigation. Halfway through the *Cedillo* hearings, the government moved for summary judgment, but stated that it would go forward with the proceedings to answer petitioner's accusations for public policy reasons.[131] When the special masters released their decisions, HHS commented, "Hopefully, the determination by the Special Masters will help reassure parents that vaccines do not cause autism."[132]

In the OAP cases, the special masters reviewed a vast amount of scientific and medical evidence: twenty-eight medical expert testimonies, fifty expert reports, five thousand pages of proceedings, transcripts, and briefs, and nine hundred scientific articles.[133] The decisions contain careful, analytical assessments of the evidence and are readily accessible on the Internet through the Vaccine Court's website.[134] They are also complex, lengthy, and detailed. Most of the general public will not read the Vaccine Court's decisions. Accordingly, the public's understanding of the decisions will be informed largely by how the media and advocates (on both sides of the vaccine debate) portray the decisions. Vaccine-safety proponents are at a disadvantage. It is difficult for one hundred and seventy-four pages of scientific data and dry expert testimony to effectively counter an emotional story about a child who, shortly after being vaccinated, was diagnosed with a serious illness. The *Cedillo* decision thus acknowledges the persuasive power of a temporal narrative.[135] Further, the decisions can point only to a lack of evidence, not a definitive answer about vaccine safety.[136]

"[P]arents weigh choices about vaccination using conceptions of risk, benefit, and trust that are broader than anything that can be demonstrated through statistics or biology."[137] The OAP decisions can only affect public opinion about vaccines if they "encourage parents to base future healthcare

131. Moreland, *supra* note 55, at 373 (describing the *Cedillo* hearing).

132. Press Release, Statement from the Department of Health and Human Services Regarding the Decisions of the U.S. Court of Federal Claims in the Omnibus Autism Proceedings (Dep't of Health & Human Servs.) (Feb. 12, 2009), *available at* http://www.hhs.gov/news/press/2009pres/02/20090212a.html.

133. Ross D. Silverman, *Litigation, Regulation, and Education—Protecting the Public's HealthThrough Childhood Immunization*, 360 NEW ENG. J. MED 2500, 2500 (2009).

134. Moreno, *supra* note 6, at 1531 (describing the potential impact of the Vaccine Court decisions on public opinion because they contain "careful synthesis of available scientific evidence that is easily accessible to the public").

135. Cedillo v. Sec'y of Health & Human Servs., No. 98–916V, 2009 WL 331968, at *135 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) ("Nor do I doubt that Michelle's parents and relatives are sincere in their belief that the MMR vaccine played a role in causing Michelle's devastating disorders. Certainly, the mere fact that Michelle's autistic symptoms first became evident to her family during the months after her MMR vaccination might make them wonder about a possible causal connection.").

136. *E.g.*, Gross, *supra* note 56, at 6.

137. Silverman, *supra* note 133, at 2501 (describing the "extremely negative response to the decision by the governor of Texas to circumvent the legislature and issue an executive order mandating the vaccination of adolescent girls against the human papillomavirus").

decisions on the facts embodied in the growing body of scientific evidence and discourage . . . decisions based on fear and faith."[138] The lasting influence of the autism controversy has been attributed to a loss of public trust in science.[139] Medical anthropologist Sharon Kaufman, who has studied the vaccine–autism controversy, claims "many parents see even the most respected vaccine experts' perspective on the issue as just one more opinion."[140] The structure of the Vaccine Program compounds this lack of trust. Fear of government bias towards vaccine is a typical complaint of Vaccine Program critics; often containing somewhat sensational overtones of government–industry conspiracies. One scholar remarked that "NCVIA's effect on public confidence in vaccinations is . . . unclear . . . [but] the act's relatively broad immunity provisions and the barriers it creates for patients seeking jury trials have provided rich fodder for people who distrust vaccines."[141]

The autism controversy exemplifies how Vaccine Court decisions can be characterized as propaganda for the pharmaceutical industry. In a congressional hearing on the vaccine–autism controversy, Congressman Burton stated, "[T]he Justice Department filed a motion asking the Special Master to keep all information [in a case] secret . . . . That's very disconcerting to me."[142] He also said "The guy who headed that [Vaccine Program] advisory committee had a stock in a company that was making the Rotoshield virus vaccine. Shouldn't have done it. He had a tainted point of view."[143] Congressmen Weldon described the vaccine-injury problem as "trying to investigate a sacred cow. For a lot of people in the medical community, there's this tremendous fear. If you say anything negative about vaccines, then parents will stop vaccinating their kids and then you'll have all these outbreaks of these diseases."[144] Certainly many medical and public health professionals have expressed concerns about the autism controversy reducing vaccination rates.[145] Some critics have suggested that the tone of the OAP decisions was so "adamant that . . . the judges were aiming to broadcast a statement to the public that vaccines are safe."[146] Indeed, the Cedillos suggested that Michelle's case was treated differently because the court had an interest in protecting vaccines.

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138. Moreno, *supra* note 6, at 1517.

139. Gross, *supra* note 56, at 1.

140. *Id.* at 6.

141. Wendy E. Parmet, *Pandemic Vaccines—The Legal Landscape*, 362 NEW ENG. J. MED. 1949, 1950 (2010).

142. *Vaccines and the Autism Epidemic: Reviewing the Federal Government's Track Record and Charting a Course for the Future: Hearing Before the H. Comm. on Gov't Reform*, 107th Cong. 7 (2002) [hereinafter *Autism Hearings*] (statement of Rep. Dan Burton).

143. *Id.* at 27 (statement of Rep. Dan Burton, referring to Dr. Paul Offit).

144. *Id.* at 6 (statement of Rep. Dave Weldon).

145. *See* Thomas L. Hafemeister, *Other Developments*, 27 DEV. MENTAL HEALTH L. 73, 73 (2008) (stating that "many doctors and public health officials . . . are concerned that assertions of a vaccine–autism link may lead parents to forgo vaccinating their children").

146. Davis, *supra* note 5, at 53.

Critics also suggest that the Vaccine Court is motivated by a desire to protect the Vaccine Program itself.[147] These critics argue that there is simply not enough money in the Vaccine Trust fund to compensate all the autism claims pending before the Vaccine Court.[148] Following the OAP test case decisions, the Department of Justice (DOJ) noted a downward trend in autism cases.[149] Critics argue that if causation had been established, more claims would have been filed. The fact that the Vaccine Program cannot, in its present form, compensate the autism claimants is not itself evidence of prejudice. But concern over the financial viability of the Vaccine Program inevitably undermines the court's perceived objectivity and impedes its ability to influence public discourse in favor of vaccines. This is not to suggest that the Vaccine Court does not have the capacity to influence public opinion. The standard of proof in vaccine-injury cases makes a critical statement to the public about vaccine safety.

C. Clarifying *Althen*: The Need for a More Scientific Standard of Proof

Vaccine–autism claimants and supporters have alleged that they face a higher burden of proof than other vaccine-injury claims, frustrating congressional intent.[150] Throughout *Cedillo*, the petitioner questioned the standard of proof applied in the case. Complaints about the standard of proof are not unique to autism claims. The Vaccine Program has long been criticized as being as adversarial as the tort system, and the DOJ has been criticized for being overzealous in its defensive role.[151] In off-table claims in particular, critics argue that the petitioner does the "heavy lifting" and that the government tends to assume "a more adversarial position."[152] This criticism is not entirely unfounded. In a 2001 congressional hearing, the director of the NVICP stated, "The program significantly reduces, but cannot eliminate, the tension and

147. *Id.* at 51 ("Parents and their lawyers . . . [have] been vocal critics of the vaccine court, arguing that the judges decided to 'protect' the vaccine program by reassuring parents that vaccinations are safe, rather than fulfilling their responsibility to help injured children.").

148. *See* Shemin, *supra* note 7, at 493 n.185 ("Simple calculation demonstrates that there is currently not enough money in the Vaccine Trust Fund to compensate the approximately 4900 claims should the special masters find in their favor."); Moreland, *supra* note 55, at 369 (stating that the NVICP "could be bankrupt if petitioners in autism cases are given compensation through the Program").

149. Advisory Comm'n June Meeting, *supra* note 126, at 10 (statement of Geoffrey Evens, Dir., Div. of Vaccine Injury Comp. Program).

150. Davis, *supra* note 5, at 51. Alexandra Dunn, Assistant Dean of Environmental Law Programs at Pace Law School, commented, "The disappointing factor here is that a court that was created to be the best venue for these injuries is not fulfilling its purpose . . . . Over time, when it comes to [autism claims], the court seems to be raising the bar for causation." *Id.*

151. *The National Vaccine Injury Program: Is It Working As Congress Intended?: Hearing Before the H. Comm. on Gov't Reform*, 107th Cong. 3 (2001) [hereinafter *NVIP Hearing*] (statement of Rep. Dan Burton) ("The Government hires teams of medical witnesses to try to disprove families' cases. . . . We're supposed to be helping these people. But if you talk to some of these families, they feel like they've been put through the wringer by their own Government.").

152. Shemin, *supra* note 7, at 476.

adversity inherent with any litigation process for resolving claims."[153] Paul Harris, representing the DOJ, attributed petitioners' complaints not to adversity within the system, but to "denial of scientifically unsupported petitions."[154]

In 2010, the DOJ reported a forty percent compensation rate for vaccine-injury claims including the autism cases, but a sixty-six percent compensation rate for injury claims excluding autism cases.[155] DOJ Deputy Director Mark Rogers stated, "We've been tracking the autism cases separately because we think they mask the background performance of the program."[156] This statement implicitly suggests that the rate of compensation measures the success of the Vaccine Program and demonstrates a fundamental flaw in how people think about the system. As the Director of the NVICP remarked in 2001, "the program was never intended to serve as a compensation source for wide range of naturally occurring illnesses and conditions, which unfortunately affect many of our children."[157] Instead, the program was intended to compensate for vaccine-related injuries. Its success, therefore, should not be defined by its rate of compensation independent of whether the claims merit compensation. Admittedly, vaccine injuries are difficult to prove. In creating the Vaccine Act, Congress stated, "The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related."[158] Recognizing that some undeserving claims will be compensated is not an endorsement of compensating frivolous claims.

Compensating for vaccine injuries is only one of the Vaccine Program's multiple goals. The Vaccine Program is also intended to promote vaccine production and protect immunization programs and practices. These goals, although not fundamentally inconsistent, are best served by different standards of proof. A lower standard that liberally compensates petitioners may satisfy them and divert them from state courts. But it also may decrease public confidence in the safety of vaccines that actually cause injury to only a very small number of persons.

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153. *NVIP Hearing*, *supra* note 151, at 59 (statement of Thomas E. Balbier, Jr., Dir., Nat'l Vaccine Injury Comp. Program).

154. *Id.* at 85 (written statement of Paul C. Harris, Sr., Deputy Assistant Att'y Gen., Civil Div., U.S. Dep't of Justice).

155. Advisory Comm'n June Meeting, *supra* note 126, at 24–25 (statement of Mark Rogers, Deputy Dir., U.S. Dep't of Justice).

156. *Id.* at 24.

157. *NVIP Hearing*, *supra* note 151, at 60 (statement of Thomas E. Balbier, Jr., Dir., Nat'l Vaccine Injury Comp. Program).

158. H.R. REP. No. 99-908, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. The Cedillos quoted this passage in their appeal to the Federal Circuit.

With *Althen* and *Andreu*, the Federal Circuit expressly rejected a heavily scientific standard.[159] After *Althen*, special masters cannot require medical literature to support a claim or the identification of a specific biologic mechanism.[160] But *Althen* did not dismiss the need for theories of causation to be supported by "reputable medical or scientific explanation[s],"[161] leaving the standard of proof unclear. Both Special Master Hastings' and Judge Wheeler's remarks in their respective *Cedillo* decisions indicate that the Cedillos lacked credible evidence to satisfy any standard of causation. Nevertheless, both judges suggested that there may be different, result-changing standards of causation for off-table claims. During the 2008 Judicial Conference, vaccine expert Dr. Paul Offit argued it would be possible to prove that peanut butter sandwiches cause cancer under the *Althen* standard.[162] Because the majority of claims are now off-table and one of the goals of the Vaccine Court is the consistent and streamlined adjudication of cases, a well-defined standard of proof is critical to the functionality of the program.[163]

The standard of proof is not merely a legal issue. The autism cases also exemplify how the standard of proof may impact public health. Dr. Offit warned that the Vaccine Court "has a tremendous responsibility and needs to realize that [it does] send a message with certain decisions [it] make[s]."[164] He stated that moving away from a scientific standard "in the name of policy . . . run[s] the risk of sending the message . . . that vaccines are causing harms that they don't."[165] Outbreaks of vaccine-preventable disease often start with persons who refuse vaccination; children exempted from immunization requirements are more likely to contract or transmit vaccine-preventable diseases.[166] An

159. *Althen* rejected a prior case requiring proof of confirmation of medical plausibility from the medical community and literature because such a standard would prevent "the use of circumstantial evidence . . . and negate[] the system created by Congress" with the Vaccine Act. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005). Subsequently, in *Andreu*, the Federal Circuit noted, "a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recover." Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009).

160. Minutes of Advisory Commission on Childhood Vaccines Meeting, Agenda Item: Omnibus Autism Proceedings Update and Implications of Causation Standard in the Program—Chief Special Master Gary Golkewicz, at 8 (Mar. 6, 2008) [hereinafter Advisory Comm'n OAP Update].

161. 418 F.3d at 1278.

162. 2008 Transcript, *supra* note 125, at 26, lines 5–10, 16–18.

163. *See* H.R. REP. No. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344 (describing the aims of the program as adjudicating claims "quickly, easily and with certainty and generosity"); *see also* Davis, *supra* note 56, at 43 (citing one lawyer's description of the court as "streamlined and intended to provide consistency"); Currier, *supra* note 15, at 240 ("In light of the objectives of the Vaccine Act, the proper allocation of the burden of proving causation is essential to ensure that the Compensation Program remains an accessible forum for recovery.").

164. 2008 Transcript, *supra* note 125, at 25, lines 19–25.

165. *Id.* at 24, lines 1–22.

166. Saad B. Omer et al., *Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases*, 360 New Eng. J. Med 1981, 1982–84 (2009) (describing study results finding children who were exempted from required vaccines were thirty-five times as likely to contract measles as non-exempted children and stating that a 2008 measles outbreak originated in individuals who

unscientific standard of proof may not only allow compensation of claims in which vaccines did not cause injuries, but may also affect public perceptions about vaccine safety. The worst case scenario is not, as petitioner's attorney Kevin Conway suggested, merely compensating an ineligible claim.[167] "[A] court ruling linking autism to vaccines could spur parents to eschew immunizations, sparking a potentially deadly epidemic . . . [and] a resurgence of potentially fatal diseases."[168]

The serious consequences of low public confidence in vaccine safety are not purely speculative. The vaccine–autism controversy has led some parents to delay or refuse to vaccinate their children. Recently, the number of nonmedical exemptions sought from immunization requirements has risen.[169] In 2008, the largest outbreak of measles in the United States since 2000 was reported. This outbreak was tied to exemptions from routine immunizations.[170]

Further, a scientific standard is not inconsistent with congressional intent. At the Vaccine Program's conception, Congress stated, "No-fault vaccine compensation proceedings raise fewer legal issues than issues of medicine."[171] In the interest of compensating generously, the Vaccine Court should be flexible and open to new science. Liberality is built into the structure of the Vaccine Program. Because the Vaccine Court is not governed by federal evidentiary rules, "petitioners may introduce a broader array of documentation . . . including expert medical opinion, circumstantial evidence, and widely accepted, albeit unproven, scientific theories."[172] The legislative history of the Vaccine Act does not indicate Congress approved of an even lower standard. Indeed, Congress rejected legislation in 2001 to lower the standard of proof[173] after public health officials expressed concerns that moving away from "a scientific evaluation of the connection between the injury and the vaccine" might open up compensation too broadly.[174]

Current direction from the Federal Circuit, however, may be inconsistent

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refused immunization).

167. 2008 Transcript, *supra* note 125, at 17, lines 23–25 ("The worst thing that could happen is somebody gets compensated who wasn't injured by a vaccine, and as a matter of policy, that's acceptable to us.").

168. Davis, *supra* note 5, at 51.

169. Omer et al., *supra* note 166, at 1982 (stating that "[b]etween 1991 and 2004, the mean state-level rate of nonmedical exemptions increased from 0.98 to 1.48%," but noting exemption rates are not uniform across states).

170. Gross, *supra* note 56, at 2.

171. H.R. REP. NO. 101-386, at 515 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3118 (also stating that the special masters need not be lawyers but should "be well-advised on matters of health, medicine, and public health"). Historically, all of the special masters have been lawyers. MOLLY T. JOHNSON, CAROL E. DREW & DEAN P. MILETICH, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 14–15 (1999).

172. Stewart, *supra* note 26, at 2498.

173. H.R. 1287, 107th Cong. (1st Sess. 2001).

174. *NVIP Hearing*, *supra* note 151, at 16–17 (statement of Rep. Henry Waxman).

with congressional intent. Concluding his decision to deny entitlement, Special Master Hastings asserted: "I have not required a level of proof greater than 'more probable than not.' . . . [T]his 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."[175]

Special Master Hastings was referring to *Althen*, which instructed special masters to resolve "close calls regarding causation . . . in favor of injured claimants."[176] If by "close call" the Federal Circuit meant that cases in which the petitioner's favorable evidence is only slightly greater than that of respondent's, the instruction seems unnecessary. In such cases, the petitioner has met his burden. But if the Federal Circuit meant cases in which the evidence is in equipoise should be resolved in favor of the petitioner, this direction seems inconsistent with the text of the Vaccine Act.[177] In *Cedillo*, Special Master Hastings notes, "Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of causation-in-fact evidence, to a listed vaccination."[178] The Vaccine Act explicitly requires proving causation-in-fact in off-table claims by a preponderance of the evidence.[179]

Finally, an explicitly non-scientific standard of proof makes adjudication of vaccine-injury cases all the more challenging for the court and the parties.[180] The autism cases are an extreme example of how vaccine claims are increasingly a battle of experts. Although the *Cedillo* decisions held that the evidence supporting a link between vaccines and autism was not compelling, proponents of the vaccine–autism theory adamantly disagree. In their appeal to the Federal Circuit, the Cedillos characterized the respondent's experts as "honest scientists who strongly disagree with the conclusions of the petitioners' experts."[181] The Vaccine Court must have appropriate metrics for assessing experts' claims. Uncertainty does not obviate the need for the scientific method, it demonstrates it. Science should be determined through the scientific method, not through the courts.[182] As Judge Wheeler stated, "[t]he issue before [the] Court is not to

175. Cedillo v. Sec'y of Health & Human Servs., No. 98–916V, 2009 WL 331968, at *134 (Fed. Cl. Feb. 12, 2009).

176. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

177. Advisory Comm'n OAP Update, *supra* note 160 (Chief Special Master Gary Golkewicz stating, "I'm one of those that does not understand how you have close calls go to one side or the other because the standard of proof in the statute is preponderance of evidence which by definition is 50.1 percent.").

178. *Cedillo*, 2009 WL 331968, at *135.

179. 42 U.S.C.A. § 300aa-13 (requiring a preponderance of the evidence).

180. Advisory Comm'n OAP Update, *supra* note 160 (stating that uncertainty regarding what proof is required "means the parties looking at the same evidence are reaching different conclusions").

181. Brief for Petitioners-Appellants, *supra* note 102, at 35.

182. *E.g.*, Autism Hearings, *supra* note 142, at 5 (statement of Rep. Henry Waxman) ("But I think still these issues of science ought to be decided by the scientific method."); 2008 Transcript, *supra* note 125, at 9, lines 8–11 (Dr. Paul Offit stating, "I think that scientific questions are answered in scientific

determine the causes of autism. The Court can only hope that medical professionals succeed in identifying the causes and developing a cure for this tragic disease."[183]

VI
CONCLUSION

The Vaccine Court sits at the intersection of law and public health. Although many have expressed concerns that the decision to deny entitlement in the autism cases will result in a flood of civil litigation, this is unlikely given the evidence available. Although the Vaccine Program may stave off state court suits, public health officials cannot rely on Vaccine Court decisions to restore lost trust in science and resolve the vaccine–autism controversy. The current standard of proof in the Vaccine Program threatens to undermine public confidence in the safety of vaccines. To protect the integrity of U.S. vaccination policy, the Federal Circuit should announce a clearer, more rigorously scientific standard of proof for causation in off-table vaccine-injury claims.

venues. The Court seems to me a place where one settles disputes only.").

183. Cedillo v. Sec'y of Health & Human Servs., 89 Fed. Cl. 158, 184 (2009).