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Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury

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ARTICLE

UNANSWERED QUESTIONS FROM THE VACCINE INJURY COMPENSATION PROGRAM: A Review of Compensated Cases of Vaccine-Induced Brain Injury

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INTRODUCTION

Is the Vaccine Injury Compensation Program ("VICP") of the U.S. Court of Federal Claims a fair forum? This is not a trivial question as it is the only forum in which parents may bring claims for vaccine injury to their children. Under the 1986 National Childhood Vaccine Injury Act ("1986 Law"), Congress created an administrative forum that it meant to ensure simple justice for children; it gave the VICP original jurisdiction for all vaccine injury claims.[1] Because almost all U.S. children must

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1. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-11(2)(A) (2006). "All individuals injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program." H.R. REP. NO. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344. After filing in the program, petitioners may reject program judgments or opt out of it to bring claims in state or federal court, but initial claims over $1,000 in damages must be made in the VICP. *Id.* at 12.

receive vaccinations to be able to attend daycare and school,[2] it is of utmost importance that this tribunal provides equitable treatment, transparency, and justice to those children who have the grave misfortune to be injured by the very vaccines intended to keep them healthy.

The VICP has had a mixed history in the eyes of the families of the vaccine-injured.[3] While some parents of vaccine-injured children supported the 1986 Law, over time many came to view it with "bitter disappointment."[4] Already by the mid-1990's, HHS had reduced the grounds for presumptive causation, and thus recovery, for vaccine injury in ways that many observers found troubling.[5] But the VICP's greatest challenge yet lay ahead.

That challenge began in 2002, when nearly five thousand families filed petitions with the VICP claiming that vaccines had caused their children's neurological disorder called "autism."[6] Starting in the late 1980's, the frequency of autism diagnoses

2. *See State Requirements*, NATIONAL NETWORK FOR IMMUNIZATION, http://www.immunizationinfo.org/vaccines/state-requirements (last visited Feb. 28, 2011) (providing a searchable list of vaccine requirements for children by state).

3. *See, e.g.,* Brief for the National Vaccine Information Center, et al. as Amici Curiae Supporting Petitioners, Bruesewitz v. Wyeth, 130 S.Ct. 1734 (2010) (No. 09-152), *available at* http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_09_10_09_152_PetitionerAmCuNVICand24Orgs.authcheckdam.pdf.

4. *Id.* at 13 (quoting the testimony of Barbara Loe Fisher before Congress in 1999: "There is bitter disappointment and pervasive unhappiness among parents . . . with the current structure and administration of the vaccine injury compensation program . . . .").

5. HHS removed the presumption of recovery from "residual seizure disorder" in March, 1995, forcing families, like the Bruesewitz family in *Bruesewitz v. Wyeth*, to prove causation. *See* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7680 (Feb. 8, 1995) (codified as amended at 42 C.F.R. pt. 100); *see also* Andreu *ex rel.* Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009).

6. *See* Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680, at *1 (Fed. Cl. Oct. 11, 2002), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Leroy%201.pdf.

began to skyrocket.[7] In an unprecedented proceeding, the VICP created and conducted the Omnibus Autism Proceeding, consolidated hearings meant to bring justice to these claims. The VICP dismissed all the "test case" claims of vaccine-induced autism, and the Court of Appeals for the Federal Circuit upheld all the decisions on review.[8]

Despite apparent judicial clarity and finality in these decisions, significant questions remain. Are the cases of "autism" that the VICP rejected in the Omnibus Autism Proceeding really different from the cases of "encephalopathy" and "residual seizure disorder" that the VICP has compensated before and since? Is it possible the VICP rejected cases of "autism" because of the hot-button label and not because of real differences in injuries or evidence?

This preliminary study suggests that the VICP has been compensating cases of vaccine-induced encephalopathy and residual seizure disorder associated with autism since the inception of the program. Through this preliminary study, the authors have found eighty-three cases of autism among those compensated for vaccine-induced brain damage.[9] This finding raises fundamental questions about the integrity, transparency, and fairness of this forum.

This assessment of compensated cases showing an association between vaccines and autism is not, and does not purport to be, science. In no way does it explain scientific causation or even necessarily undermine the reasoning of the decisions in the Omnibus Autism Proceeding based on the scientific theories and medical evidence before the VICP. Nor does this article have anything to say about state childhood immunization mandates in general.

What this article does point to are unanswered questions about vaccines and autism, a thorny issue that affects

7. Michael E. McDonald & John F. Paul, *Timing of Increased Autistic Disorder Cumulative Incidence*, 44 ENVTL. SCI. & TECH. 2112, 2112 (2010), *available at* http://www.all.org/pdf/McDonaldPaul2010.pdf.

8. *See infra* notes 127-135.

9. *See infra* Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms.

approximately one in one hundred and ten children.[10] On this point, this study strongly suggests the need for further Congressional and scientific investigation to explore the association between vaccine-induced brain injury and autism and the integrity of this federally-administered compensation program.[11]

In Part I, we review the 1986 Law that created the VICP and the Omnibus, background information on autism, the Department of Health and Human Services' ("HHS") concession in the *Poling* case, and attempts to get information about autism from compensated cases of vaccine injury. Part II details the published cases in the VICP that note autism or autism-like symptoms and information about settled cases manifesting autism that parental caregivers have confirmed. It discusses the cases and includes representative questionnaire responses from parents and caregivers. Part III highlights unanswered questions, makes recommendations, and draws conclusions. Appendices include diagnostic information, definitions, excerpts from a Freedom of Information Request, a list of previously published articles evaluating compensated cases from the VICP, and a copy of the parent structured interview form.

10. *See CDC Features, CDC Study: An Average of 1 in 110 Children Have an ASD,* CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/features/countingautism (last visited Jan. 18, 2010).

11. The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation. *See National Vaccine Injury Compensation Program, About VICP*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ (last visited Feb 28, 2011). HHS, DOJ, and the Court of Federal Claims jointly oversee the VICP. *Id.*

I. THE VACCINE INJURY COMPENSATION PROGRAM (VICP) AND THE OMNIBUS AUTISM PROCEEDING

1. The VICP and the 1986 National Childhood Vaccine Injury Act

Congress created the VICP as part of the 1986 National Childhood Vaccine Injury Act (1986 Law).[12] Congress passed this legislation to achieve several objectives: (1) to create the infrastructure for a national immunization program;[13] (2) to insulate industry and the medical profession from liability;[14] (3) to establish a program to compensate the injured;[15] and (4) to promote safer vaccines.[16]

The 1986 Law outlined an ambitious agenda for vaccine research, production, procurement, distribution, promotion, and purchase of vaccines.[17] It established the VICP to compensate "vaccine-related injury or death."[18] In its legislative history, Congress asserted that the purpose of the program was "to establish a federal no-fault program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity."[19] Congress enacted the statute to compensate children who had been injured while serving the public good.[20]

The program requires parents of vaccine-injured children to file first in the VICP before any other court.[21] The Court of Federal Claims in Washington, D.C. oversees the program.[22]

12. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to 34 (2006).
13. *Id.* § 300aa-2.
14. *Id.* § 300aa-11(a)(3).
15. *Id.* § 300aa-10(a).
16. *Id.* § 300aa-27(a).
17. *Id.* § 300aa-2.
18. 42 U.S.C. § 300aa-10(a).
19. H.R. REP. NO. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.
20. *Id.*
21. 42 U.S.C. § 300aa-11.
22. *Id.* § 300aa-12.

After filing in the VICP, however, petitioners retain the right to go to civil court after waiting a specified period of time or rejecting a VICP decision.[23] Congress intended to create a largely administrative program as an alternative to the civil tort law system.[24] The purpose of the VICP was to establish a federal "no-fault" compensation program. The Congressional Committee Report noted that the "system is intended to be expeditious and fair" and to compensate recognized vaccine injuries "without requiring the difficult individual determinations of causation of injury."[25] The purpose of the statute was to overcome the inadequacies of the existing tort system for vaccine-injured children. "[F]or the relatively few who are injured by vaccines – through no fault of their own – the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. . . .Yet futures have been destroyed and mounting expenses must be met."[26]

When Congress passed the 1986 Law, there were several recognized vaccine injuries, including anaphylaxis, encephalopathy, paralytic polio, chronic arthritis, residual seizure disorder, and death.[27] All the injuries on the Vaccine Injury Table were to have occurred within thirty days of vaccination.[28] Most injuries listed in the Table described events that must occur within hours or three days of a child receiving a vaccine.[29] If petitioners met the exact requirements of the specified injuries, then they would not be required to litigate and would receive compensation through an administrative "no-fault" process.[30]

23. *Id.* § 300aa-21.

24. H.R. REP. NO. 99-908, at 13 ("The Committee [on Energy and Commerce] anticipates that the speed of the compensation program, the low transactions 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.").

25. *Id.* at 12.

26. *Id.* at 6.

27. *See* P.L. 99-660, 100 Stat. 3743 (codified as amended at 42 U.S.C. § 300aa-14), *available at* http://www.hrsa.gov/vaccinecompensation/authorizinglegislation.pdf.

28. *Id.* Paralytic polio had a time period of 30 days; most injuries were to have occurred within 3 days. *Id.*

29. *Id.*

30. *Id.*

For injuries that were not listed on the Table, however, petitioners would have to prove these injuries based on a preponderance of the evidence, a "more likely than not" standard.[31]

The VICP insulates vaccine manufacturers from liability and requires that petitioners bring their petitions solely against HHS. They may not sue manufacturers or healthcare practitioners.[32] The rationale for this industry and professional protection was to ensure a stable childhood vaccine supply and to keep prices affordable.[33] The VICP awards compensation out of a Vaccine Injury Trust Fund collected from an excise tax of $0.75 imposed on the sale of every vaccine.[34]

Petitioners try their cases in the VICP before Special Masters of the Court of Federal Claims. Eight Special Masters act as the sole finders of fact and law.[35] The VICP is meant to be informal, without reliance on the federal rules of evidence and civil procedure.[36] Congress intended this informality to benefit the

31. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-13(a)(1) (2006).

32. *Id.* § 300aa-11(a); *see also* H.R. REP. NO. 99-908, at 12 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6353 ("[T]he bill requires that a person with an injury resulting from a vaccine that was administered after the enactment of this legislation file a compensation petition and go through the compensation program before proceeding with *any* litigation against a manufacturer." (emphasis added)).

33. *See, e.g.*, Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353, 408 (2004) ("Vaccine manufacturers quickly learned their lesson and threatened to halt production unless guaranteed indemnification by the federal government. As a result, vaccine shortages ensued, prices skyrocketed, and Congress was forced into action.").

34. *National Vaccine Injury Compensation Program, Vaccine Injury Compensation Trust Fund*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm (last visited Jan. 11, 2011) ("The Trust Fund is funded by a $0.75 excise tax on each dose of vaccine purchased (i.e., each disease prevented in a dose of vaccine)."). In other words, a consumer would pay $2.25 as an excise tax on the MMR vaccine, or $0.75 on each of the measles, mumps and rubella antigens.

35. 42 U.S.C. § 300aa-11.

36. U.S. CT. FED. CLAIMS VACCINE R. 8(b)(1) ("In 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.").

petitioners by making the forum simpler and less costly.[37] Decisions of the Special Masters do not serve as precedent in subsequent proceedings in state or federal court.[38]

Petitioners may receive $250,000 in the event of a vaccine-related death and a maximum amount of $250,000 for pain and suffering.[39] These caps have not changed since 1986.[40] The 1986 Law also provides for "reasonable attorney's fees and costs" for bringing a petition, so that petitioners do not have to pay lawyers out of pocket or out of the proceeds of a judgment (as they would have to do in civil court under a contingency fee arrangement).[41]

The 1986 Law requires that petitions be filed "[no more than] 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury [after the administration of the vaccine]."[42] This three-year statute of limitations is shorter than many state tort statutes and does not provide for tolling when plaintiffs did not, or could not, discover the injury within the three-year statute of limitations.[43]

In perhaps the most significant part of the statute, the 1986 Law restricts vaccine manufacturers' and vaccine administrators' liability in any court unless petitioners file first in the VICP.[44]

37. H.R. Rep. No. 99-908, at 3 (The purpose of the statute is "to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity.")

38. 42 U.S.C. § 300aa-12(4)(A), which provides that "information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information." In other words, all records are sealed and do not become part of the court record in subsequent civil lawsuits.

39. *Id.* §§ 300aa-15(a)(2), (4).

40. *Id*. *Cf.* P.L. 99-660, 100 Stat. 3743 (codified as amended at 42 U.S.C. §§ 300aa-15(a)(2), (4)), *available at* http://www.hrsa.gov/vaccinecompensation/authorizinglegislation.pdf.

41. *See* 42 U.S.C. § 300aa-15(e)(1).

42. *Id.* § 300aa-16.

43. Cloer v. Sec'y of Health & Human Servs., 85 Fed. Cl. 141, 147 (Fed. Cl., 2008). A case on equitable tolling and discovery of injury in vaccine cases is currently before the Court of Appeals for the Federal Circuit for an *en banc* hearing to be heard in 2011. *See* Cloer v. Sec'y of Health & Human Servs., No. 2009-5052, 2010 WL 4269396 (Fed. Cir. Oct. 25, 2010).

44. *See* 42 U.S.C. § 300aa-22.

Starting in 1988, no vaccine manufacturer was liable for a vaccine-related injury or death from one of the recommended vaccines "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[45] This language stems from the Second Restatement of Torts.[46] The U.S. Supreme Court decided *Bruesewitz v. Wyeth*, which dealt specifically with this provision in February 2011.[47]

In addition to broad liability protection, the 1986 Law also provides another shield to manufacturers under federal law.[48] The 1986 Law permits them the right to not disclose known risks to parents or guardians of those being vaccinated. Resting on the "learned intermediary" doctrine, manufacturers bear no liability for giving, or failing to give, accurate or complete information to those vaccinated, and have only to provide relevant information to doctors, who must give patients CDC Vaccine Information Statements.[49]

The Court of Appeals for the Federal Circuit has established a petitioner's burden of proof in a series of cases.[50] It requires that a petitioner prove:

45. *Id.* § 300aa-22(b)(1).

46. Restatement (Second) of Torts § 402(A) cmt. k (1965).

47. In 2008, the Supreme Court of Georgia held that civil courts must decide on a case-by-case basis whether a vaccine-related injury is unavoidable for claims of vaccine design defect. Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236 (Ga. 2008). By contrast, in 2009, the Third Circuit Court of Appeals held that all vaccine injuries allegedly due to design defect are "unavoidable" under the 1986 Law because of federal preemption. Bruesewitz v. Wyeth, Inc., 561 F.3d 233, 242-46, 255-56 (3d Cir. 2009), *cert granted*, 130 S.Ct. 1734 (2010). On February 22, 2011, the Supreme Court affirmed the Third Circuit's ruling 6-2 that the 1986 Law preempts all civil vaccine design defect claims. Justice Scalia wrote the majority opinion; Justice Sotomayor wrote a dissent, strongly disagreeing with the majority's interpretation. Bruesewitz v. Wyeth, No. 09-152, 2011 WL 588789 (Feb. 22, 2011), *available* at http://www.supremecourt.gov/opinions/10pdf/09-152.pdf.

48. *See* 42 U.S.C. § 300aa-22(c).

49. *See id.*; CDC, *Vaccine Information Statements*, www.cdc.gov/vaccines/pub/vis/default.htm (last visited Mar. 21, 2011).

50. *See* Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also* Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); Andreu *ex rel.* Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374-75 (Fed. Cir. 2009).

(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.[51]

The Court articulated the reason for this lower burden than that necessary in civil court "to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."[52] Petitioners are not required to show the precise mechanism of injury[53] but are "merely required to show that the vaccine in question caused their injury. . .."[54] This burden of proof applied in the Omnibus, as it does in all VICP cases.

2. The Vaccine-Autism Controversy

Vaccines have been controversial since Edward Jenner initiated their widespread use in England in the 1700s.[55] Some argue that the contemporary U.S. movement for vaccine safety and choice began with Lea Thompson's television special *DPT Roulette* in 1982.[56] That film depicts many individuals who suffered from the kinds of injuries that the VICP later compensated. The individuals that the film depicted had devastating disabilities – seizures, mental retardation, autism, paralysis, blindness, and deafness, among others. That film led directly to the creation of Dissatisfied Parents Together, which later became the National Vaccine Information Center ("NVIC"),

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

52. *Id.* at 1280.

53. *See* Knudsen *ex rel* Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994).

54. Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 100 (Fed. Cl. 2005).

55. For history of controversy about vaccines, see Robert Johnston, *Contemporary Anti-Vaccination Movements in Historical Perspective*, *in* THE POLITICS OF HEALING: HISTORIES OF TWENTIETH-CENTURY NORTH AMERICAN ALTERNATIVE MEDICINE 259, 259-86 (Robert Johnston ed., 2004).

56. *See DPT: Vaccine Roulette* (NBC television broadcast Apr. 19, 1982); *see also* PAUL OFFIT, DEADLY CHOICES: HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL 2-7 (2010) [hereinafter DEADLY CHOICES].

the leading U.S. vaccine safety organization.[57] Throughout the late 1980's and early 1990's, NVIC publicly advocated for the right to informed consent for vaccination and highlighted the risks of vaccine injury. Harris Coulter and Barbara Loe Fisher's book, A SHOT IN THE DARK, about adverse reactions to the DPT vaccine, questioned the childhood immunization program's safety.[58]

The U.S. vaccine controversy grew in the late 1990's. In 1997, Congressman Frank Pallone of New Jersey attached an amendment to a Food and Drug Administration ("FDA") reauthorization bill, requiring the FDA to "compile a list of drugs and foods that contain intentionally introduced mercury compounds, and . . . provide a quantitative and qualitative analysis of the mercury compounds in the list."[59] The bill later evolved into the FDA Modernization Act of 1997 ("FDAMA") and was signed into law on November 21, 1997.[60]

In 1998 and 1999, U.S. vaccine manufacturers responded to FDA requests by providing detailed information about their mercury-containing vaccine preservative, thimerosal.[61] Thimerosal had been used as a preservative in vaccines since the 1930s because of its strong anti-bacterial properties.[62] The use of thimerosal allowed vaccine manufacturers to produce and distribute vaccines more cheaply by packaging and distributing them in multi-use vials.[63] Several of the vaccines on the routine

57. NAT'L VACCINE INFO. CTR., http://www.nvic.org/ (last visited Jan. 20, 2011).

58. *See generally* HARRIS LIVERMORE COULTER & BARBARA LOE FISHER, DPT: A SHOT IN THE DARK (1985).

59. Mercury Environmental Risk and Comprehensive Utilization Reduction Initiative, H.R. 2910, 105th Cong. § 9(a) (1997).

60. Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 301 (2006); *see also* AM. ACAD. OF PEDIATRICS, HEPATITIS CONTROL REPORT (1998), *available at* http://www.aapsonline.org/vaccines/hcr.pdf.

61. *Vaccines, Blood & Biologics, Thimerosal in Vaccines*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228.htm (last visited Feb 28, 2011).

62. *Id.*

63. *Id.*

childhood immunization schedule contained thimerosal, including the diphtheria-tetanus-pertussis combination vaccine.[64]

In 1999, the Public Health Service ("PHS") of HHS and the American Academy of Pediatrics ("AAP") issued a joint statement on thimerosal in vaccines. It stated:

> PHS and AAP continue to recommend that all children should be immunized against the diseases indicated in the recommended immunization schedule. Given that the risks of not vaccinating children far outweigh the unknown and much smaller risk, if any, of exposure to thimerosal-containing vaccines over the first 6 months of life, clinicians and parents are encouraged to immunize all infants even if the choice of individual vaccine products is limited for any reason.[65]

After the joint statement, parents of autistic children inferred the possibility that mercury-containing vaccines might have contributed to their children's developmental regression through a unique form of mercury poisoning. In 2001, several authors published an article in MEDICAL HYPOTHESES, entitled *Autism: a novel form of mercury poisoning*, postulating that autism might be the result of mercury in vaccines.[66] Parents of children with autism began to file lawsuits around the country for compensation from vaccine-induced injury.[67] Since the late 1990's, the vaccine-autism debate has continued, with new

64. In the 1990s, the DPT vaccines contained thimerosal. MMR notably does not contain thimerosal because it contains live viruses that the thimerosal might otherwise kill. For a list of childhood vaccines and their thimerosal content, see *id*. at Table 1.

65. Pub. Health Serv., U.S. Dep't. of Health & Human Servs., *Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*, 48 MORBIDITY & MORTALITY WKLY. REP. 563 (1999), *available at* http://www.cdc.gov/MMWR/PREVIEW/MMWRHTML/mm4826a3.htm.

66. *See generally* S. Bernard et al., *Autism: a Novel Form of Mercury Poisoning*, 56 MED. HYPOTHESES 462 (2001), *available at* http://www.nationalautismassociation.org/library/anovelform.pdf.

67. *See generally* 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 (2008).

developments in medicine and science,[68] and with authors taking positions both for and against a possible vaccine-autism link.[69]

3. What is Autism?

"What is autism?" This deceptively simple question is at the heart of this problem. Today, "autistic disorder" is considered a psychiatric diagnosis in the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-IV"), the standard reference for the classification.[70] The diagnostic criteria, included in Appendix I in full, include (1) impairments in social interaction, (2) impairments in verbal and non-verbal communication, and (3) stereotypical restricted or repetitive patterns of behavior and interests.[71] There are no universally accepted biomarkers such as physical characteristics or blood or urine tests. The three domains of diagnostic criteria for autistic disorder cover a wide spectrum, from individuals with no language, almost no social interaction and severe behavioral problems, to extremely high-functioning individuals with intense interests and quirky personalities. The range of autistic disorders in the DSM-IV formally includes autism, Rett's Disorder, Childhood Disintegrative Disorder, Asperger's Syndrome, and Pervasive Development Disorder Not Otherwise Specified ("PDD-NOS").[72]

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68. For a review of scientific studies supporting a possible link between vaccines and autism, *see* Carol Stott & Andrew Wakefield, *An Urgent Call for More Research*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN 49, 49 (Louise Kuo Habakus & Mary Holland eds., 2011). For scientific studies disconfirming a possible link between vaccines and autism, see *Vaccine Safety, Thimerosal*, CTRS. FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/vaccinesafety/Concerns/ thimerosal/index.html (last visited Jan. 18, 2011).

69. *See, e.g.*, SETH MNOOKIN, THE PANIC VIRUS: A TRUE STORY OF MEDICINE, SCIENCE, AND FEAR (2011); DEADLY CHOICES, *supra* note 56; PAUL A. OFFIT, AUTISM'S FALSE PROPHETS: BAD SCIENCE, RISKY MEDICINE, AND THE SEARCH FOR A CURE (2008); ARTHUR ALLEN, VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER (2007); DAVID KIRBY, EVIDENCE OF HARM: MERCURY IN VACCINES AND THE AUTISM EPIDEMIC: A MEDICAL CONTROVERSY (2005).

70. AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-IV-TR) § 299.00, 377-78 (4th ed. 2000).

71. *Id*. at 75.

72. *See id*. at 76-84.

Because autistic disorder is defined only by an aggregation of symptoms, there is no meaningful distinction between the terms "autism" and "autism-like symptoms." This article makes the distinction only to accurately reflect the terms that the Court of Federal Claims, caregivers, and others use. It is not a distinction to which the authors attach significance.

One of the most striking characteristics of autism is its dramatic rise since the early 1990's. For decades, the autism prevalence was approximately five cases per ten thousand children.[73] In December 2009, the Centers for Disease Control ("CDC") announced that the rate among eight-year olds was one case per one hundred and ten, or approximately 1% of all U.S. children.[74] Although for two decades, HHS and U.S. professional medical associations argued that rising rates of autism were attributable solely to better diagnoses, more inclusive categories, and diagnostic substitution, in 2009 the government acknowledged a real rise due at least in part to environmental factors. As Dr. Thomas Insel, Director of the National Institute of Mental Health and Chair of the Interagency Autism Coordinating Committee, said in light of the one in one hundred and ten numbers, "There is no question that there has got to be an environmental component here."[75] A recent study by scientists at the Environmental Protection Agency identified autism's "changepoint year" as 1988-89, pinpointing the start of a dramatic rise in prevalence.[76]

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73. Catherine Rice, *Prevalence of Autism Spectrum Disorders - Autism and Developmental Disabilities Monitoring Network, United States*, *2006*, 58 MORBIDITY & MORTALITY WKLY. REP. 1 (2009), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5810a1.htm ("Before the 1980s, the term 'autism' was used primarily to refer to autistic disorder and was thought to be rare, affecting approximately one in every 2,000 (0.5%) children," i.e. 5 per 10,000.).

74. *See CDC Features, CDC Study: An Average of 1 in 110 Children Have an ASD,* CTRS. FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/features/countingautism (last visited Jan. 18, 2010).

75. David Kirby, *Rising Autism Numbers -- Leading Federal Official Says "No Question" That Environmental Exposures Are A Factor*, HUFFINGTON POST (Dec. 21, 2009), *available at* http://www.huffingtonpost.com/david-kirby/rising-autism-numbers_b_397978.html. (Article is accompanied by transcript).

76. Michael E. McDonald & John F. Paul, *Timing of Increased Autistic Disorder Cumulative Incidence*, 44 ENVTL. SCI. & TECH. 2112, 2112 (2010), *available at* http://www.all.org/pdf/McDonaldPaul2010.pdf; *see also* Irva Hertz-

Although there have been isolated historical accounts of individuals with autistic qualities, particularly with 'genius' or 'savant' qualities, the modern phenomenon was first described by child psychiatrist Leo Kanner in 1943.[77] Kanner first noted many of the characteristics that form the core of the syndrome: impaired language, social skills, and repetitive behaviors. But his careful case series analysis failed to ascribe significance to certain related symptoms, including unusual feeding patterns and gastrointestinal problems in the children, and he failed to look at possible environmental exposures that might have been causal.

In *The Age of Autism: Mercury, Medicine and a Manmade Epidemic*, a historical account of autism's rise, Dan Olmsted and Mark Blaxill traced the actual identities of most of the original children in Kanner's 1943 case series.[78] All of the identified children in the case series had experienced known or plausible exposures to ethyl mercury, a then newly-created synthetic chemical.[79] Ethyl mercury was used at that time in both vaccines and as an agricultural fungicide; the children in the case series had parents either in the medical profession working on vaccines or parents in agriculture using fungicides.[80] While the mercury connection to autism is not proven, there are many sources, including the Olmsted-Blaxill book,[81] that give the hypothesis plausibility.[82]

Picciotto & Lora Delwiche, *The Rise in Autism and the Role of Age at Diagnosis,* 20 EPIDEMIOLOGY 84 (2009).

77. *See* Leo Kanner, *Autistic Disturbances of Affective Contact*, 2 NERVOUS CHILD 217 (1943), *available at* http://affect.media.mit.edu/Rgrads/Articles/pdfs/Kanner-1943-OrigPaper.pdf.

78. *See* DAN OLMSTED & MARK BLAXILL, THE AGE OF AUTISM: MERCURY, MEDICINE, AND A MAN-MADE EPIDEMIC (2010).

79. *Id.* at 1-16, 347-64.

80. *See id.* at 163-365.

81. *See id.*

82. Other recent studies that note correlations between mercury, other environmental toxins and autism include Mary Catherine DeSoto & Robert T. Hitlan, *Sorting Out the Spinning of Autism: Heavy Metals and the Question of Incidence*, 70 ACTA NEUROBIOLOGIAE EXPERIMENTALIS 165 (2010); Mary Catherine DeSoto, *Ockham's Razor and Autism: The Case for Developmental Neurotoxins Contributing to a Disease of Neurodevelopment*, 30 NEUROTOXICOLOGY 331 (2009); Raymond F. Palmer et al., *Proximity to Point Sources of Environmental Mercury Release As a Predictor of Autism Prevalence*,

One must note that the DSM-IV definition of "autistic disorder" is similar on its face to the VICP's definitions of "encephalopathy, seizures and sequela."[83] The VICP's description of acute encephalopathy for children eighteen months of age and older, including "significant change in mental status" and "significantly decreased level of consciousness," is consistent with the DSM-IV's criteria for onset before age three of "autistic disorder." The dimensions of autistic disorder are consonant with the VICP's detailed description of "decreased level of consciousness":

> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
>
> (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
>
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).[84]

In other words, lack of normal eye gaze, impaired social relations, and non-responsiveness to external stimuli are noted in both the DSM-IV autism and VICP encephalopathy classifications as diagnostic criteria. To be sure, the DSM-IV classification differs from the VICP description, but DSM-IV "autistic disorder" does not contradict the VICP description of encephalopathy, seizures, and sequela. Indeed, scientific

15 HEALTH & PLACE 18 (2009). It is interesting that Kanner himself noted that a biological etiology of autism might have been overlooked. In the foreword to BERNARD RIMLAND, INFANTILE AUSTIM: SYNDROME AND ITS IMPLICATIONS FOR A NEURAL THEORY OF BEHAVIOR (1964), Kanner wrote:

The concept of 'early infantile autism' (I could not think of a better name) was diluted by some to deprive it of its specificity, so that the term was used as a pseudo-diagnostic wastebasket for a variety of unrelated conditions, and a nothing-but psychodynamic etiology was decreed by some as the only valid explanation, so that further curiosity was stifled or even scorned.

Id. at v.

83. *See infra* Appendices I and II.

84. *Compare infra* Appendix I *with infra* Appendix II.

literature acknowledges that the conditions often coexist.[85] These descriptions, when put side by side, show significant similarities.

4. The Omnibus Autism Proceeding

Families alleging vaccine-induced autism filed lawsuits against vaccine manufacturers in state and federal courts around the country starting in 1999. In 2002, the Court of Federal Claims *Leroy v. HHS* decision largely ended such litigation.[86] Finding that the mercury-containing preservative was "vaccine-related" under the 1986 Law, the Chief Special Master ruled that all thimerosal cases were required to be consolidated and filed first in the VICP, as all other vaccine-related injuries. Potential petitioners viewed thimerosal as a preservative, and not as truly vaccine-related. Furthermore, they wanted to litigate in regular civil courts, where they would enjoy rights to discovery, potentially high compensatory and punitive damages, and juries. None of those dimensions are available in the VICP.

Nonetheless, five thousand petitioners filed claims in the VICP of vaccine-induced autism on thimerosal and MMR causation theories. The VICP decided it would hold hearings on these two test theories with three "test cases" for each theory, to decide "general causation," that would apply to all cases with similar claims, and "specific causation," for the individual children's claims. Many thousands more cases were barred from filing because the strict three-year statute of limitations had expired. In addition, some petitioners filed in the VICP and then moved their cases to state and federal courts after the required waiting period to bring lawsuits against vaccine manufacturers on the theory of vaccine design defect.[87]

85. *See, e.g.*, S.E. Bryson et al., *Prevalence of Autism Among Adolescents with Intellectual Disabilities*, 53 CAN. J. PSYCHIATRY 449, 449 (2008); R. Tuchman & I. Rapin, *Epilepsy in Autism*, 1 LANCET NEUROLOGY 352, 353 (2002).

86. *See* Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680 (Fed. Cl. Oct. 11, 2002), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Leroy%201.pdf.

87. *See, e.g.,* Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236, 236-38 (Ga. 2008).

On February 12, 2009, Special Masters of the Federal Court of Claims released long-awaited decisions in the first Omnibus Autism Proceeding test cases. The Special Masters ruled that (1) there was no plausible link between the MMR vaccine and autism, and that (2) the three "test case" petitioners for this causation theory—Michelle Cedillo, Colten Snyder, and Yates Hazlehurst—deserved no compensation. The Special Masters did not simply conclude that the science disfavored petitioners. They issued scathing opinions that rejected and demeaned petitioners' scientific theories, expert witnesses and treating physicians.

Special Master Hastings proclaimed that the Cedillo case was "one-sided," that the doctors who advised Michelle Cedillo were "*very wrong*," (emphasis in original).[88] He wrote that the physicians who found a link between Michelle's severe maladies and her vaccines "misled" the Cedillos and "are guilty. . .of gross medical misjudgment."[89] Special Master Vowell, in the Snyder case, similarly characterized the petitioners as "victims of bad science," and suggested that "an objective observer would have to emulate Lewis Carroll's White Queen and be able to believe six impossible (or, at least, highly improbable) things before breakfast" to decide in petitioners' favor.[90] In short, the Special Masters decided that (1) there was no reliable science supporting an MMR-thimerosal-autism link, (2) the petitioners' physicians were "guilty of gross medical misjudgment," and (3) the parents who pursued unproven vaccine injury treatments were "misled by physicians."[91]

The next year, in 2010, the same Special Masters released their decisions in the William Mead, Jordan King, and Colin Dwyer test cases on the second theory of mercury-induced

88. Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968, at *134 (Fed. Cl. Feb. 12, 2009), *available at* http://www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Hastings-Cedillo.pdf.

89. *Id.* at *135.

90. Snyder v. Sec'y of Health & Human Servs., No. 01-162V, 2009 WL 332044, at *198 (Fed. Cl. Feb. 12, 2009), *available at* http://www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Vowell.Snyder.pdf.

91. *See Cedillo*, 2009 WL 331968, at *135.

autism, again finding no basis for compensation.[92] These three test case petitioners elected not to appeal their decisions. Among those arguing MMR-induced autism in the first set of test cases, both Cedillo and Hazlehurst lost on appeal[93] and Snyder did not appeal.[94]

The Court of Appeals for the Federal Circuit did not affirm automatically the *Cedillo* and *Hazlehurst* decisions. In the *Hazlehurst v. HHS* oral argument, the judges wanted to know what would happen if later science confirms the thimerosal-autism theory?[95] What will happen to the children's claims? The judge answered his own question, saying that Congress could add thimerosal-induced autism to the Table of Injuries and state that those who had previously been denied compensation would still be eligible.[96] The appellate court judges seemed not to find the vaccine-autism theory as implausible as had the Special Masters.

Similarly, the panel of appellate judges in *Cedillo v. HHS* asked the Department of Justice ("DOJ") tough questions.[97] Two of the three judges were clearly troubled that DOJ had introduced an expert report to rebut key petitioner biological evidence without introducing the underlying lab results or books, something that all parties agreed would have been impossible

92. *See* Mead v. Sec'y of Health & Human Servs., No. 03-215V, 2010 WL 3584449 (Fed. Cl. Aug. 20, 2010); King v. Sec'y of Health & Human Servs., No. 03-584V, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); Dwyer v. Sec'y of Health & Human Servs., No. 03-1202V, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010). All three cases are available online. *See Autism Decisions and Background Information,* U.S. FED. COURT OF CLAIMS, http://www.uscfc.uscourts.gov/node/5026 (last visited Mar. 1, 2011).

93. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1349-50 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/cedillo.fedcir.pdf; Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343, 1354 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/Hazlehurst_Affirmance.pdf.

94. *See Snyder*, 2009 WL 332044, at *198.

95. Transcript of Oral Argument, Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343 (Fed. Cir. 2010), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/2009-5128/all.

96. *Id.*

97. Transcript of Oral argument, Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/2010/all/cedillo.html.

under the Federal Rules of Civil Procedure.[98] They probed whether DOJ had asked for the lab books (they hadn't)[99] or how DOJ could be sure that the expert report was reliable when DOJ didn't have the underlying data (when the DOJ lawyer assured the judge that the data would have reinforced the expert's conclusions, the judge laughed, as did observers in the courtroom).[100] The judges were similarly troubled that DOJ failed to notify petitioners that they were seeking the expert report in the first place, as surely DOJ should have been well aware that surprise was an entirely inappropriate tactic in the VICP, which Congress meant to be petitioner-friendly and non-adversarial.[101] While the appellate judges in both *Hazlehurst* and *Cedillo* decided in favor of HHS and against petitioners, they did so after contentious oral argument, and the judges noted in *Cedillo v. HHS* that DOJ's conduct troubled them.[102]

After the final Omnibus appeals were decided in the summer of 2010, by all appearances, the vaccine-autism case in the VICP was closed. The Court of Federal Claims sent out letters to all petitioners telling them, in so many words, that unless they could allege different theories and provide compelling experts and evidence, their cases would be dismissed without hearing on the basis of the Omnibus general causation test cases.[103]

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1342 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/cedillo.fedcir.pdf; Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343, 1354 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/Hazlehurst_Affirmance.pdf ("We agree with petitioners that the government's failure to produce or even to request the documentation underlying Dr. Bustin's reports is troubling, but we think that in the circumstances of this case, that failure does not justify reversal.").

103. *See* Autism Update-September 29, 2010, *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2002 WL 31696785 (Fed. Cl. July 3, 2002), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/autism%20update%209%2029%2010.pdf; COURT OF FED. CLAIMS, GUIDANCE TO PETITIONERS ON HOW TO EXIT THE VACCINE PROGRAM 1 (2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/EXITING_GUIDANCE_TO_PRO_SES.pdf.

5. The Poling Concession

During the preparation for the second set of test cases in the Omnibus that would consider whether thimerosal-containing vaccines cause autism, a major, unanticipated event occurred: HHS conceded one of the slated test cases. In a report required by Court Rule 4(c), leaked to the press, HHS conceded that vaccines, including the MMR, had triggered Hannah Poling's encephalopathy and subsequent developmental regression.[104] HHS's description of the child's condition implied a distinction between "autism-like symptoms" and "autism," although there was no ambiguity that Hannah Poling in fact had autism.[105] The concession document "concluded that the facts of this case meet the statutory criteria for demonstrating that the vaccinations CHILD received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder."[106] This concession led to some interest in the press on the vaccine-autism link and the role of mitochondrial conditions.[107] In 2010, the Poling financial compensation decision was published and showed that HHS paid over $1.5

104. *See* David Kirby, *The Vaccine-Autism Court Document Every American Should Read,* HUFFINGTON POST (Feb. 26, 2008), *available at* http://www.huffingtonpost.com/david-kirby/the-vaccineautism-court-d_b_88558.html; *see also* U.S. CT. FED. CLAIMS VACCINE R. 4(c), *available at* http://www.uscfc.uscourts.gov/sites/default/files/court_info/Vaccinerules_20100111_v4.pdf.

105. Jon S. Poling et al, *Developmental Regression and Mitochondrial Dysfunction in a Child With Autism*, 21 J. OF CHILD NEUROLOGY 170, 171 (2006).

106. *See* Kirby, *supra* note 104. A brief excerpt from this concession report is also available at Poling v. Sec'y of Health & Human Servs., No. 02-1466V, 2008 WL 1883059 (Fed. Cl. Apr. 10, 2008). It is notable that this initial concession report merely mentions the MMR vaccine as 3 of 9 antigens administered to Hannah Poling in one office visit, whereas the final compensation decision, noted below in the Published Case Chart as Case 21, specifies MMR as the principal cause of her injury.

107. *See* Ginger Taylor, *The Role of Government and Media*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN 150, 156-57 (Louise Kuo Habakus & Mary Holland eds., 2011).

million in damages.[108] The relevant VICP website notes carefully, however, that while one case received compensation from the Omnibus, "HHS has never concluded in any case that autism was caused by vaccination."[109]

The Poling concession left unclear just how Hannah Poling might differ from the other five thousand claims of vaccine-induced autism in the Omnibus. Indeed, what made the matter particularly acute was that HHS and DOJ relied on the very same medical expert, making the very same medical diagnosis, to both compensate the *Poling* case and to dismiss one of the test cases, without that expert ever being cross-examined or testifying in person in the Omnibus about this apparent contradiction.[110] In late 2010, *The Economist* noted that far from settling the matter of mitochondrial dysfunction and a possible vaccine-autism link, the HHS concession left the matter unresolved.[111] The *Poling* concession raised key questions about the VICP's transparency and equitable treatment of petitioners. Just how different was Hannah Poling's case?

6. Attempts to Gain Information About Autism in Compensated Cases

After the Poling concession, journalists began looking for possible evidence of other cases of autism among VICP-compensated cases. Robert F. Kennedy, Jr. and David Kirby reported on the case of Bailey Banks, a boy whom the VICP

108. Child Doe/77 v. Sec'y of Health & Human Servs., 2010 WL 3395654 at *4 (Fed. Cl. July 21, 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/CAMPBELLSMITH.%20DOE77082710.pdf.

109. *National Vaccine Injury Compensation Program, Statistics Report, February 8, 2011*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ statistics_report.htm (last visited Mar. 3, 2011). The compensation decision for the Poling case, included below at Case 21, is based on "an MMR vaccine Table presumptive injury of encephalopathy." *Child Doe/77*, 2010 WL 3395654, at *1.

110. *See* Mary Holland & Robert Krakow, *The Right to Legal Redress*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN 39, 42 (Louise Kuo Habakus & Mary Holland eds., 2011).

111. *Energy Drain: The Case of Autism May be Faulty Mitochondria,* ECONOMIST (Dec. 1, 2010), *available at* http://www.economist.com/node/17626677.

compensated for vaccine-induced acute demyelinating encephalomyelitis ("ADEM"), leading to Pervasive Development Disorder Not Otherwise Specified, an autistic disorder.[112] Kirby also published a response he received from HHS about autism as a feature of VICP-compensated cases. He entitled it "Communication from Human Resources and Services Administration of HHS that it Does not Track Autism." In it, HHS wrote:

> From: Bowman, David (HRSA) [mailto:DBowman@hrsa.gov]
> Sent: Friday, February 20, 2009 5:22 PM
> To: 'dkirby@nyc.rr.com'
> Subject: HRSA Statement
>
> David,
>
> In response to your most recent inquiry, HRSA has the following statement:
>
> The government has never compensated, nor has it ever been ordered to compensate, any case based on a determination that autism was actually caused by vaccines. We have compensated cases in which children exhibited an encephalopathy, or general brain disease. Encephalopathy may be accompanied by a medical progression of an array of symptoms including autistic behavior, autism, or seizures.
>
> *Some children who have been compensated for vaccine injuries may have shown signs of autism before the decision to compensate, or may ultimately end up with autism or autistic symptoms, but we do not track cases on this basis.*
>
> Regards,

112. *See generally* Robert F. Kennedy, Jr. & David Kirby, *Vaccine Court: Autism Debate Continues*, HUFFINGTON POST (Feb. 24, 2009), *available at* http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html; Banks v. Sec'y of Health & Human Servs., No. 02-0738V, 2007 U.S. Claims LEXIS 254 (Fed. Cl. July 29, 2007), *available at* http://www.uscfc.uscourts.gov/sites/default/files/ Abell.BANKS.02-0738V.pdf; *see also infra* Published Case Chart.

David Bowman
Office of Communications
Health Resources and Services Administration
301-443-3376[113]

The authors, perplexed by HHS's apparent disinterest in an association of vaccine injury with autism, decided to probe the issue further. Co-author Robert Krakow addressed a Freedom of Information Act ("FOIA") request to HHS asking whether it would be possible to obtain information[114] and documents regarding compensated vaccine injury claims. After receiving a response that such an undertaking would take four to five years and would cost approximately $750,000, the authors turned to Pace University School of Law to assist in their inquiry.

II. FURTHER INVESTIGATION

1. Compensated Cases of Vaccine Injury

The authors began a research project with Pace Law School students to locate and analyze VICP cases assessing whether the VICP had in fact compensated vaccine-induced brain damage, including autism, while perhaps not using that term specifically. Peer-reviewed medical and legal journals and prominent vaccine researchers have acknowledged the value of evaluating compensated claims in the past.[115] While recognizing that the legal standard of causation is not the same as scientific causation (also called "causality"), several authors have published articles on vaccine injury based on review of compensated claims for pertussis, polio, measles, rubella, and MMR vaccine injuries. The

113. *See* Ginger Taylor, *Vaccines Don't CAUSE Autism, They Just RESULT in Autism,* ADVENTURES IN AUTISM BLOG (Sept. 9, 2010, 4:13 PM), http://adventuresinautism.blogspot.com/2010/09/vaccines-dont-cause-autism-they-just.html (emphasis added). For an excerpt of the email, see also Kennedy & Kirby, *supra* note 112.

114. *See infra* Appendix III.

115. *See infra* Appendix IV, which highlights the governmental and scholarly use of the VICP-compensated cases as a source of valuable information on vaccine injury.

authors have included scientists at the CDC, the Institute of Medicine, and the VICP.

a. VICP Published Cases Compensating Encephalopathy and Residual Seizure Disorder, Noting or Suggesting Autism or Autism-like Symptoms

The authors, with the assistance of Pace Law students, created a database of VICP published decisions that used relevant terms related to autism. Through this search of final VICP decisions or case stipulations, we found twenty-one decisions that acknowledged autism or autism-like symptoms associated with vaccine-induced encephalopathy and seizure disorder. The following table summarizes the cases and stipulations with language that strongly suggests autistic features:

Published Case Chart

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
1	Alger v. Sec'y of Health & Human Servs.	1990 WL 293408, at *4 (Cl. Ct. July 13, 1990).	His mental development has been arrested. . . .He doesn't speak and will never communicate verbally. He doesn't respond to verbal communication. He is not toilet trained. . . .He is self-destructive and very difficult to manage. He needs constant one-on-one care to protect him from injuring himself and others."
2	Sorensen v. Sec'y of Health & Human Servs.	1990 WL 290491, at *1 (Cl. Ct. Dec. 6, 1990).	"Petitioners further maintain that the injuries resulted in permanent disabilities involving significant developmental delay, moderate autistic characteristics, and mental retardation."
3	Kleinert v. Sec'y of Health & Human Servs.	1991 WL 30664, at *2, *4 (Cl. Ct. Feb. 20, 1991).	"Today he has a seizure disorder which is under control and a condition known as over-focusing, similar in some respects to autism. . . . As a sequela to the encephalopathy, Wes Ian Kleinert suffered complications for more than six months after the administration of the DPT vaccine, and he continues to suffer from these complications, which have developed into a residual seizure disorder and autistic tendencies."
4	Connor v. Sec'y of Health & Human Servs.	1991 WL 133618, at *6 (Cl. Ct. July 3, 1991).	"[R]espondent's report. . .suggests vaguely. . .that Kenny's problems 'can be attributed in part to other causes such as a family history of epilepsy, autism and tonsillar hypotrophy. . .Dr. Spiro did not even purport to know what *did* cause Kenny's seizure disorder; his basic point was that in his view the DTP did *not* cause it."

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
5	Messner v. Sec'y of Health & Human Servs.	1991 WL 74145, at *4 (Cl. Ct. Apr. 22, 1991).	"Jennifer is a severely mentally retarded individual with hyperactive and destructive behaviors. . . .Her social functioning is extremely inappropriate: she is belligerent and sometimes aggressive; . . .she. . .practices self stimulating behavior; and she repeatedly bites her hand. . . .She presents a danger to herself and to family members."
6	Oxley v. Sec'y of Health & Human Servs.	1991 U.S. Cl. Ct. LEXIS 575, at *4.	"Richelle's disabilities include autistic-like behavior, hyperactivity, and partially controlled seizures. Richelle is totally dependent on others for her care and needs constant supervision and assistance. . . .She is non-verbal but signs several words."
7	Underwood v. Sec'y of Health & Human Servs.	1991 WL 156659, at *1 (Cl. Ct. July 31, 1991).	"In addition, respondent noted that Travis' medical records indicate that he suffered from mental retardation and autism. These conditions, according to respondent, are not related to the residual seizure disorder."
8	Sharpnack v. Sec'y of Health & Human Servs.	1992 WL 167255, at *8 (Cl. Ct. June 29, 1992).	"The evidence shows that Megan exhibits some very difficult behavioral problems that interfere with her education and social adjustment. Her behavior, which includes head banging, pulling her own hair, and scratching at things, must be constantly redirected. Her disruptive and noncompliant behavior has become a major barrier to progress in functioning."

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
9	Koston v. Sec'y of Health & Human Servs.	974 F.2d 157, 158-59 (Fed. Cir. 1992).	"[A]pproximately twelve hours after receiving her second DPT vaccination, Jenna experienced a seizure. . .Dr. Doris Trauner. . .concluded that Jenna suffers from a variant of Rett Syndrome. . . .[T]he Secretary wanted to assert that Jenna's seizures were caused by Rett Syndrome and not by the DPT vaccination."
10	Sanford v. Sec'y of Health & Human Servs.	1993 WL 177003, at *2 (Fed. Cl. May 10, 1993).	"Her condition is complicated by a behavior disorder. She is highly impulsive, has no concept of danger, cannot accept control, and has autistic tendencies."
11	Bastian v. Sec'y of Health & Human Servs.	1994 U.S. Claims LEXIS 196, at *16-17 (Fed. Cl. Sept. 22, 1994).	"Dr. Quinn opined that Kyle suffers from pervasive developmental disorder (PDD). . . .Dr. Quinn explained that PDD is caused by a brain insult. . . .Dr. Quinn indicated Kyle's post-vaccinal encephalopathy was the brain insult which in turn resulted in his PDD. Dr. Quinn opined, to a reasonable degree of medical certainty, that Kyle's condition is permanent."
12	Lassiter v. Sec'y of Health & Human Servs.	1996 U.S. Claims LEXIS 216, at *12 (Fed. Cl. Dec. 17, 1996).	"Respondent argues that Eric's current behavioral manifestations and retardation 'fit the pattern of autistic spectrum disorders with severe mental retardation.' Dr. Spiro summarizes: 'This child had a [DPT-related febrile] reaction following his DPT booster, but, it is clear that he currently fits into the autistic spectrum disorder with retardation. This group of disorders is totally unrelated to DPT, it usually constitutes a group of genetically determined or idiopathic disorders (without a clear known etiology.)'"

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
13	Suel v. Sec'y of Health & Human Servs.	1997 WL 617034, at *1, *3 (Fed. Cl. Sept. 22, 1997).	"Petitioners alleged that David suffered significant aggravation of his pre-existing tuberous sclerosis (TS) in the form of an encephalopathy and a residual seizure disorder. . . .Having seizures early in life is likely to lead to mental underdevelopment or mental retardation. Autism is a frequent occurrence among TS patients. Dr. Gomez has never seen an autistic TS child who did not have seizures."
14	Reitz v. Sec'y of Health & Human Servs.	1998 WL 228421, at *1, *4, *5 (Fed. Cl. Apr. 21, 1998).	"He would bang his head approximately six times and then return to normal. These episodes. . .[occur] almost daily. . . .Derrick has the cognitive skills of a two or three year old, and improves slowly. Although he speaks, he cannot do so in complete sentences. He has behavioral problems due to frustration. He receives behavioral therapy, occupational therapy, physical therapy, and speech therapy. He was never the same baby after the third DPT vaccination. . . .He lost milestones and development."
15	Tebcherani v. Sec'y of Health & Human Servs.	55 Fed. Cl. 460, 468 (2003).	"Dr. MacDonald [respondent's expert] noted that Lena carries a diagnosis of pervasive developmental disorder, also known as autistic spectrum disorder. In Dr. MacDonald's opinion, Lena's autism is not related to the DaPT vaccination . . . ."
16	Freeman v. Sec'y of Health & Human Servs.	2003 U.S. Claims LEXIS 285, at *26, n. 7 (Fed. Cl. Sept. 25, 2003).	"It was noted at the hearing that Kienan's neurologic disorder has features that might cause it to be labeled as 'atypical autism,' a condition within the category of 'autistic spectrum disorder.' I note, however, that even assuming that Kienan's disorder is correctly classified within the 'atypical autism' category, that is essentially irrelevant to my ruling concerning the entitlement issue in this case. As Dr.

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
			Kinsbourne explained, Kienan's autistic-type features seem to be a result of the brain damage that caused his severe mental retardation. As Dr. Kinsbourne further explained, brain damage is one of the many possible causes of autism. Thus, I cannot see why the fact that Kienan's disorder may fall within the autism spectrum has any substantial relevance to the question of what caused Kienan's seizure disorder and mental retardation."
17	Gancz v. Sec'y of Health & Human Servs.	2003, No. 91-0178V, 1 (Stipulation).	"Petitioners allege that Sarah sustained the first symptom or manifestation of the onset of seizures within the period set forth in the Table. They further allege Sarah developed autism and behavioral problems as the sequelae of her Table injury."
18	Noel v. Sec'y of Health & Human Servs.	2004 WL 3049764, at *13 (Fed. Cl. Dec. 14, 2004).	"Dr. Shafrir testified that Rachel had a reaction to her acellular DPT, which consisted of lethargy, irritability, and a high-pitched cry. He stated that her seizure disorder was independent of her DPT reaction, and that the seizure disorder led to epilepsy, developmental delay, and autism. She died of sudden unexpected death in epilepsy."
19	Paulmino v. Sec'y of Health & Human Servs.	69 Fed.Cl. 1, 4 (2005).	"Erika was described as: A four-year old female with intractable epilepsy, PDD [pervasive developmental disorder] . . . .As of the filing of this action, Erika continues to suffer from a developmental and speech-and-language disorder and requires therapy."

	Published Case Name	**Case Citation**	**Language Suggesting Autism or Autism-like Symptoms**
20	Banks v. Sec'y of Health & Human Servs.	2007 U.S. Claims LEXIS 254, at *54 (Fed. Cl. July 20, 2007).	"Bailey's ADEM [acute disseminated encephalomyelitis] was severe enough to cause lasting, residual damage, and retarded his developmental progress, which fits under the generalized heading of Pervasive Developmental Delay, or PDD. Additionally, this chain of causation was not too remote, but was rather a proximate sequence of cause and effect leading inexorably from vaccination to Pervasive Developmental Delay."
21	Child Doe/77 v. Sec'y of Health & Human Servs.	2010 WL 3395654, at *1 (Fed.Cl. July 21, 2010).	"Respondent has conceded that petitioners are entitled to compensation due to the significant aggravation of Child Doe/77's pre-existing mitochondrial disorder based on an MMR vaccine Table presumptive injury of encephalopathy, which eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela."

Seventeen of the twenty-one cases noted above mention the word "autism," "autistic," or one of the autistic disorders, Rett's Disorder or Pervasive Developmental Disorder.[116] Four cases describe developmental regression and self-injurious behaviors highly consistent with descriptions of severe autism.[117] Some of the cases rule that a vaccine caused brain injury, including autism. For instance, in the *Banks v. HHS* case, the Special Master wrote that the brain damage led "inexorably from vaccination to Pervasive Developmental Delay."[118] *Child Doe/77 v. HHS* concedes that vaccines aggravated a pre-existing mitochondrial disorder "which eventually manifested as a chronic encephalopathy with features of autism spectrum disorder."[119]

Other cases deny that the autism in the child is in any way related to the vaccines or compensated brain injuries. For instance, in *Underwood v. HHS*, the government's position was that the child's mental retardation and autism "are not related to the residual seizure disorder."[120] Similarly, in *Koston v. HHS*, the government asserted that the "seizures were caused by Rett Syndrome and not by the DPT vaccination."[121] Whether or not vaccines "caused" or "resulted in" autism is not decided in all cases, although it is in some. What is clear, however, is that autism is sometimes associated with compensated vaccine-induced brain injury.

116. The four cases above not using a specific autism-related term are Case 1, Alger v. Sec'y of Health & Human Servs., No. 89-31V, 1990 WL 293407 (Cl. Ct. July 13, 1990); Case 5, Messner v. Sec'y of Health & Human Servs., No. 90-552V, 1991 WL 74145 (Cl. Ct. Apr. 22, 1991); Case 8, Sharpnack v. Sec'y of Health & Human Servs., No. 90-983V, 1992 WL 167255 (Cl. Ct. June 29, 1992); Case 14 Reitz v. Sec'y of Health & Human Servs., No. 90-1344V, 1998 WL 228421 (Fed. Cl. Apr. 21, 1998).

117. *See* Case 1, *Alger*, 1990 WL 293407, at *4; Case 5, *Messner*, 1991 WL 74145, at *4; and Case 8, *Sharpnack*, 1992 WL 167255 at *8; and, Case 14, *Reitz*, 1998 WL 228421, at *1, *4, *5.

118. Case 19, Banks v. Sec'y of Health & Human Servs., No. 02-0738V, 2007 U.S. Claims LEXIS 254, at *54 (Fed. Cl. July 29, 2007).

119. Case 20, Child Doe/77 v. Sec'y of Health & Human Servs., 2010 WL 3395654, at *1 (Fed. Cl. July 21, 2010).

120. Case 7, Underwood v. Sec'y of Health & Human Servs., No. 90-719V, 1991 WL 156659, at *1 (Cl. Ct. July 31, 1991).

121. Case 9, Koston v. Sec'y of Health & Human Servs., 974 F.2d 157, 159 (Fed. Cir. 1992).

b. Settled Cases Suggesting Autism

The authors then decided to explore settled cases, like the *Poling* concession, to see if there might be more compensation decisions of vaccine-induced brain injury that included autism. Using the Federal Public Access to Court Electronic Records ("PACER") database of federal court dockets, the authors examined docket reports filed with the VICP that HHS had compensated without hearing.[122] The authors identified compensated cases of brain injury that they believed might include autism diagnoses. Then they used telephone and internet databases to identify telephone numbers and addresses for the compensated families. Under the direction of co-author Louis Conte, trained volunteers contacted compensated families and conducted telephone interviews using the questionnaire in Appendix V about the injured child and the family's experience in the VICP. The volunteers received instruction on making calls and, in particular, were instructed never to lead parents in their answers. If a parent said that a child did not have autism or autism-like symptoms, the volunteer accepted that description with no further questions. Based on these telephone conversations, the volunteers reached over sixty families of individuals compensated for encephalopathy or residual seizure disorder, or both, who concomitantly have or had autism or autism-like symptoms.

While these families' names and docket numbers are in the public domain, and that is how the authors retrieved information about them, the authors seek not to subject these families to unnecessary invasion of their privacy. They have all suffered extreme hardship in coping with their children's injuries, or in some cases, deaths, and we seek to shield them from unwanted attention. The authors are confident that both HHS and DOJ can easily confirm the accuracy of these compensated families, amounts, and vaccine injury codes. The only information the government agencies may not be able to confirm are the parental

122. *Pacer,* PUB. ACCESS TO COURT ELEC. RECORDS, http://www.pacer.gov (last visited Mar. 3, 2011).

reports of autism, but they can easily do this through direct contact if they seek to verify this information.[123]

2. The Social Communication Questionnaire

Recognizing that some readers might be skeptical of parental reports of autism without further substantiation, the authors had twenty-two compensated families complete a written, well-recognized autism screening questionnaire. This questionnaire in no way "proves" that these individuals have an autism diagnosis. The completed questionnaires do, however, give further credibility to the parental reports of autism. Only complete medically supervised diagnoses could fully confirm autism diagnoses. Such diagnoses were beyond the scope of this study, but the authors hope that future inquiry will include full evaluation of compensated individuals and their medical complications.

The Social Communication Questionnaire ("SCQ") is a forty-item parental report screening measure that "taps the symptomology associated with the autism spectrum disorder."[124] The questionnaire, drafted by Drs. Rutter, Bailey, and Lord, contains forty yes/no questions selected to have "discriminative diagnostic validity."[125] This simple instrument is meant to correlate to the complete ninety three-item Autism Diagnostic Interview-Revised ("ADI-R"), also written by Rutter and Lord, who are internationally renowned autism experts.[126] (These scientists filed expert reports in the Omnibus on behalf of HHS, rejecting the theory of a vaccine-autism link.)[127] The SCQ

123. *See* Letter from Thomas Flavin, Freedom of Info. Officer, Dep't of Health & Human Servs., to Robert Krakow (July 9, 2009) (on file with authors); *see infra* Appendix III.

124. M. RUTTER ET AL., SCQ: THE SOCIAL COMMUNICATION QUESTIONNAIRE MANUAL 1 (2003).

125. *Id.*

126. *Id.*

127. *See* MICHAEL RUTTER, THIMEROSAL VACCINE LITIGATION (2008), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Expert%20Reports/King_03-584V/ExGG_Rutter_Report_03-584.pdf; *see also* CATHERINE LORD, THIMEROSAL VACCINE LITIGATION (2008), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Expert%20Reports/King_03-584V/Ex_W_Lord_Report_03-584.pdf.584.pdf.

focuses on behaviors that are "rare in nonaffected individuals."[128] The authors warn that while the screening questionnaire "is not suitable for individual diagnosis," the SCQ questions are based on the ADI-R, which is in turn used as the primary diagnostic instrument for the International Classification of Diseases-10 (World Health Organization, 1992) and the DSM-IV (American Psychiatric Association, 1994) diagnosis of autism. "These provide an operational diagnosis that is based on the behavioral item scores in three areas of functioning: Reciprocal Social Interaction; Communication; and Restricted, Repetitive, and Stereotyped Patterns of Behavior."[129]

The questionnaire recommends a cutoff score of fifteen or greater as an indication of a possible autism spectrum disorder. It notes that, "the mean score for children with autism was 24.2, which is well above the cutoff."[130] Rutter, Bailey, and Lord further clarify:

> [T]he agreement between the SCQ and the ADI-R at both the Total Score and domain score levels is high, with agreements being substantially unaffected by age, gender, language level, and performance IQ. The findings validate the SCQ as a screening questionnaire and show that it provides a reasonable index of symptom severity.[131]

Typically, caregivers received the SCQ questionnaires by email and returned the completed, scanned questionnaires by return email. While it was not possible to administer the SCQ to all the families, the volunteers did administer it to twenty-two parents or caregivers, representing 27% of the total number of cases.[132] All SCQ scores were at or above the cutoff point of fifteen, with most substantially above it.[133] The mean score of the twenty-two SCQ values is 24.4, or slightly higher than the

128. RUTTER ET AL., *supra* note 124, at 1.

129. *Id*. at 9.

130. *Id.* at 3.

131. *Id*. at 22.

132. *See infra* Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms, including 22 SCQ scores, representing 27% of the total of 83 cases reported.

133. *Id.*

mean score of 24.2 that Rutter, Bailey, and Lord describe.[134] When caregivers reported that children were relatively high functioning, their children's scores were in fact closer to the cutoff point, suggesting the accurate nature of the screening device and of parental reports.[135] All SCQ scores on the table below fell between fifteen and thirty three, with both ends of this spectrum in the "autistic disorder" range.[136]

3. Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms

134. M. RUTTER ET AL., *supra* note 124, at 3.

135. Inference based on case histories on file with authors and validated by Rutter et al.'s findings that the SCQ "provides a reasonable index of symptom severity." *Id.* at 22.

136. *See infra* Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms (for SCQ scores).

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
1	1989-1	DPT	UNAV	EN & RSD	B, D, F	25	$2,300,000	
2	1989-2	DPT	UNAV	EN & RSD	A		$1,400,000	
3	1990-1	DPT	UNAV	EN & RSD	A		Unknown	
4	1990-2	DPT	UNAV	EN & RSD	A		$1,700,000	
5	1990-3	DPT	UNAV	EN & RSD	A		$1,700,000	deceased, 25
6	1990-4	DPT	UNAV	RSD	D,F	30	$1,000,000	
7	1990-5	DPT	UNAV	EN & RSD	B, D, F	24	Unknown	
8	1990-6	DPT	UNAV	EN & RSD	B, F		$500,000	
9	1990-7	DPT	UNAV	EN & RSD	A		$2,000,000	
10	1990-8	DPT	UNAV	EN & RSD	A		$1,900,000	
11	1990-9	DPT	404	EN & RSD	F		$700,000	
12	1990-10	DPT	404	EN & RSD	D, F	25	$470,000	
13	1990-11	DPT	UNAV	EN & RSD	C, E, F		$2,100,000	
14	1990-12	DPT	404	RSD	E, F		$360,000	deceased, 23
15	1990-13	DPT	404	RSD	D, E	26	$917,000	
16	1990-14	DPT	400	RSD	B, F		$2,000,000	
17	1990-15	MMR	460	RSD	F		$465,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
18	1990-16	DPT	404	EN & RSD	A		$ 1,400,000	
19	1990-17	MMR	408	EN & RSD	B, E, F		$500,000	
20	1990-18	DPT	404	EN & RSD	D, F	18	$1,700,000	
21	1990-19	DPT	404	RSD	F		$1,000,000	
22	1990-20	DPT	406	RSD	F		$80,000	
23	1990-21	DPT	400	RSD	F		$778,000	
24	1990-22	DPT	404	EN & RSD	B,D,F	33	$1,900,000	
25	1990-23	DPT	404	RSD	F		$1,300,000	
26	1990-24	DPT	404	EN & RSD	D,F	24	$990,000	
27	1990-25	DPT	400	RSD	F		$2,600,000	
28	1990-26	DPT	404	EN & RSD	D, E, F	18	$1,200,000	
29	1990-27	DPT	404	EN&RSD	F		$919,000	
30	1990-28	DPT	404	RSD	F		$920,000	
31	1990-29	DPT	404	RSD	F		$1,200,000	
32	1990-30	DPT	404	RSD	C, D, F	22	$3,300,000	
33	1990-31	DPT	404	RSD	F		$630,000	
34	1990-32	DPT	404	EN & RSD	A		$2,400,000	
35	1990-33	MMR	408	RSD	F		$956,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
36	1990-34	MMR	408	RSD	F		$375,000	
37	1990-35	DPT	406	RSD	F		$519,000	deceased, 31
38	1990-36	DPT	404	RSD	D, F	23	$2,300,000	deceased, 15
39	1990-37	DPT	404	EN & RSD	D, F	21	$2,300,000	
40	1990-38	DPT	404	EN & RSD	A		$1,300,000	
41	1990-39	DPT	404	RSD	F		$747,000	
42	1900-40	DPT	404	EN & RSD	F		$1,700,000	
43	1990-41	DPT	404	EN & RSD	F		$2,500,000	
44	1990-42	DPT	404	RSD	F		$2,500,000	
45	1991-1	DPT	404	EN & RSD	D, F	27	$1,600,000	
46	1991-2	DPT	404	EN& RSD	F		$1,300,000	
47	1991-3	DPT	404	RSD	F, S		$4,400,000	
48	1992-1	DPT	458	EN & RSD	F		$820,000	deceased, 12
49	1992-2	DPT	404	RSD	F		$1,400,000	
50	1992-3	DPT	404	RSD	F		$1,300,000	
51	1992-4	DPT	458	RSD	F		$1,800,000	
52	1992-5	DPT	458	RSD	F		$535,000	
53	1993-1	DPT	458	RSD	C,D, F	15	$590,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
54	1993-2	DPT	400	RSD	F		$2,200,000	
55	1993-3	DPT	456	EN & RSD	F		$980,000	deceased, 21 (lightning)
56	1994-1	DPT	458	RSD	F		$1,700,000	
57	1995-1	DPT	404	RSD	D, F	23	$500,000	
58	1995-2	DPT	458	RSD	C, D, E, F	33	$2,000,000	
59	1995-3	DPT	458	RSD	D, F	20	$1,100,000	
60	1995-4	DPT	458	RSD	F		$1,100,000	
61	1995-5	DPT	456	RSD	F		$2,300,000	
62	1996-1	MMR	460	RSD	F		$3,100,000	
63	1997-1	DPT	458	RSD	D, F	21	$4,000,000	
64	1997-2	MMR	460	RSD	C, D, F	26	Unknown	
65	1997-3	DPT	456	RSD	E, F		$3,900,000	
66	1997-4	DPT	458	RSD	D, F	28	$985,000	
67	1998-1	DPT	458	EN & RSD	A, F		$600,000	
68	1998-2	DPT	458	EN & RSD	B, E, F		$1,100,000	
69	1998-3	DPT	458	EN & RSD	A		Pending	
70	1998-4	DPT	400	EN & RSD	A		$2,100,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
71	1999-1	DpaT & HiB	472	EN & RSD	A		$250,000	deceased, 5
72	1999-2	MMR	460	RSD	C, F		$335,000	
73	2000-1	MMR	460	RSD	E, F		$602,000	
74	2001-1	MMR	460	EN & RSD	A		$5,900,000	
75	2002-1	MMR	460	EN & RSD	E, F		$4,000,000	
76	2002-2	MMR	460	EN & RSD	A		$800,000	
77	2002-3	MMR	460	EN & RSD	A, D, E, F	31	$2,500,000	
78	2003-1	Thim.	492	EN	B, C		Pending	
79	2003-2	DpaT	458	EN & RSD	A, F		$1,600,000	
80	2003-3	DpaT	458	EN & RSD	A, E, F		Pending	deceased, 4
81	2006-1	MMR	460	EN & RSD	B, F		Pending	
82	2009-1	MMR	460	EN	E, F		Pending	
83	2010-1	DpaT	458	EN	D, F	23	$1,300,000	

Key to Chart:
UNAV – unavailable

Vaccines
DPT – diphtheria-pertussis-tetanus
DpaT – diphtheria – acellular pertussis - tetanus
MMR – measles-mumps-rubella
Thim. – thimerosal, an ethyl mercury containing preservative used in vaccines

Vaccine Injury Codes – from Court of Federal Claims "Nature-of-Suit Codes for Vaccine Cases"
400 – no longer on chart
404 – no longer on chart
406 – no longer on chart
408 – no longer on chart
456 – injury – DPT & polio
458 – injury – DTP/DPT
460 – injury – M/M/R
469 - other
472 – death – DTP/DPT

Injury Compensated and Symptoms Described
EN – Encephalopathy
RSD – Residual Seizure Disorder

Documentation Codes
A - Decision of Court of Federal Claims stating petitioner has autism or autism-like symptoms
B – Decision of Court of Federal Claims detailing symptoms and behavior consistent with autism
C – Third party medical, educational, or court records confirming autistic disorder on file with authors
D – Completed Social Communication Questionnaire by caregiver on file with authors (SCQ)

E – Previous public documentation by parents or caregivers in written, electronic or film media stating that the subject has autism or autism-like symptoms
F – Telephone interview with parent or caregiver in which the interviewee states that the subject has autism or autism-like symptoms
S – Stipulation in docket using term "autism" or "autism-like symptoms"

4. Interpretation

This discussion must start with the caveat that we are able only to interpret the subgroup of eighty-three compensated cases that we have located. Out of a total number of approximately two thousand five hundred compensated vaccine injury claims,[137] we recognize that this is a small subset.[138] It is our hope that this preliminary study will lead to more complete study of all cases of compensated vaccine injury. Such a study might provide a far more comprehensive understanding of vaccine injury.

Despite its limitations, this study suggests that compensated cases of vaccine-induced encephalopathy associated with autism started from the inception of the VICP in 1989 and have continued at least through 2010. Of these eighty-three compensated cases including autism, seventeen note an autistic disorder in a published decision of the Court of Federal Claims and twenty-two have SCQ questionnaires confirming caregiver reports of autism. In other words, thirty-nine of the eighty-three cases, or 47% of this sample, have confirmation of autism beyond parental report alone. The evidence of an association in these

137. *National Vaccine Injury Compensation Program, Claims Filed and Compensated or Dismissed by Vaccine, October 12, 2010,* U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited Mar. 3, 2011).

138. While beyond the scope of this preliminary study, it is worth noting that in addition to these claims for compensation from vaccine injury, many parents and doctors have filed reports of autism as a vaccine injury in the federally-funded Vaccine Adverse Event Reporting System (VAERS). These reports of autism as an adverse vaccine event can be retrieved at www.medalerts.org by inputting "autism" as a symptom. There are 83 reports of autism as an adverse event that were filed between July 1, 1990 and June 30, 1999.

cases between recognized vaccine injuries (encephalopathy and residual seizure disorder) and autism exists.

It is notable that over a twenty-year period the VICP did not publicly acknowledge an apparent vaccine-encephalopathy-autism link. While in the early years of the program there might have been no particular attention to this association, certainly by the late 1990's, the question of vaccine injury and autism was one of general public interest. The finding of so many cases of autism among compensated cases calls into question HHS's assertions on the topic.

Several of the damage awards that HHS compensated included expenses uniquely related to autism. For example, such expenses included Applied Behavior Analysis ("ABA"), a form of educational intervention created and used for individuals on the autism spectrum.[139] In other cases, VICP-appointed life planners recommended that families install a fence as the child would be likely to wander later in life. Wandering is a well-recognized characteristic and danger for children with autism.[140]

In addition to the corroboration from the SCQs, the authors have newspaper, magazine, and blog articles on file, discussing the children's autistic symptoms and challenges. The authors also received medical and educational records confirming the children's autism diagnoses for some of the compensated individuals.

All of the cases of vaccine-induced encephalopathy associated with autism noted in the Table of VICP-Compensated Claims above were the result of combination vaccines – MMR, DTP or DTaP. The 1998 Weibel, et al. study of VICP-compensated cases of acute encephalopathy associated with the measles vaccine, alone or in combination, identified no cases of encephalopathy after administration of monovalent mumps and rubella vaccines

139. *Mental Health, A Report of the Surgeon General*, *Other Mental Disorders in Children and Adolescents, Autism*, SURGEON GEN., http://www.surgeongeneral.gov/library/mentalhealth/chapter3/sec6.html#autism (last visited Mar. 3, 2011) ("Thirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior.").

140. *See e.g.*, AUTISM & WANDERING, NAT'L AUTISM ASS'N (2010), *available at* http://www.nationalautismassociation.org/pdf/autism_wandering_FULL%20SHEET%20BROCHURE.pdf.

and fewer cases of encephalopathy after administration of monovalent measles vaccines than of combination vaccines.[141] Geoffrey Evans, M.D., Director of the Division of Vaccine Injury Compensation of Health Resources and Services Administration ("HRSA"), was a co-author of the study.[142]

About half of the eighty-three reviewed cases have encephalopathy, residual seizure disorder, and autism. The other half of the reviewed cases have residual seizure disorder and autism. There is no obvious distinction in symptoms or gravity of injury among these cases. In addition, eight of the compensated children, or 10% of the group we identified, died before age thirty one. Seven of the eight died from seizures; one died from lightning. A shorter lifespan is associated with seizure disorder.[143]

5. Caregiver Responses

We include a few representative responses from families about their children and experiences in the VICP that families provided in telephone interviews. It bears remembering that these are the families who "won" in the VICP. On balance, it is logical to imagine that the "winning" families' views are at least

141. Robert E. Weibel et al., *Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated with Further Attenuated Measles Vaccines: A Review of Claims Submitted to the National Vaccine Injury Compensation Program*, 101 PEDIATRICS 383, 383 (1998) ("No cases were identified after the administration of monovalent mumps or rubella vaccine.") In 48 cases of acute encephalopathy after measles vaccine, alone or in combination, 8 children received monovalent measles vaccines; 40 received multiple vaccines, including rubella, mumps, diphtheria, tetanus, pertussis, oral polio, and *Haemophilus influenza* Type B, together with measles vaccine. *Id.* at 384 -85.

142. Dr. Evan's position is noted at *National Vaccine Injury Compensation Program, Advisory Commission on Childhood Vaccines (ACCV) Roster,* U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/roster.htm (last visited Jan. 19, 2011).

143. *Seizures and Epilepsy: Hope Through Research*, NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, NAT'L INSTS. OF HEALTH, http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm (last visited Mar. 3, 2011) ("People with severe seizures that resist treatment have, on average, a shorter life expectancy and an increased risk of cognitive impairment, particularly if the seizures developed in early childhood.").

somewhat more favorable than the views of families who received no financial compensation.

Here are a few representative answers from families who participated in telephone interviews:

Question: How is your child's life today?

(A) A. is profoundly autistic. She is non-verbal, has major behavioral issues, is self-injurious. . .classic and very severe autism. . ..She cannot be left alone ever. . ..A. was a beautiful baby, who was developing normally, but who had obvious reactions to her first two DPT vaccines. One left her leg swollen and red, and she developed a high fever and screamed after the other. But the doctors did not hesitate to give A. her third DPT shot when she was 5 months old, and she went over the edge. She had the shot at 4:00 p.m., and by 6:00 p.m. she had a fever of 105 to 106 degrees. . ..After that day, she was gone. Over the years, we have lost many friends and are distant from many family members because A. is so hard to love and be around. It is very heartbreaking to see people reject her, and to have them suggest that we should have institutionalized her.[144]

(B) B. (aged 44) has no speech, no functional use of his hands, and will no longer stand. . ..He has a couple of seizures every day. . ..B.'s teeth had to be pulled because he would not allow anyone near his mouth to brush them. He is not potty trained. He is very sensory defensive, flaps his hands, and makes moaning noises.[145]

(C) C. is a "giant baby" because although she is an overweight 18-year-old, she functions at the level of a 2-year old. She has no life really, compared to her peers. She has very little functional communication, and can only say a few words, like "eat" or short phrases that she repeats incessantly. . ..She is still in diapers, with no probability that she will ever be potty trained. . ..C. now

144. Telephone Interview with M.M. and C.M., Parents of Vaccine Claimant (Sept. 30, 2010) (on file with authors as Case 13).

145. Telephone Interview with E.L. and L.L., Parents of Vaccine Claimant (July 22, 2010) (on file with authors as Case 30).

has frequent periods (every 4 to 6 months) of frustration, extreme rage, and self-injurious behavior.[146]

Question: What was the impact of the vaccine injury on your family?

Devastating.[147]

Question: Was your child's claim resolved fairly?

(A) No, it was a war.[148]

(B) DOJ attorneys were disrespectful and combative. . ..The Compensation Program should be about compensation and not about defense of the vaccine program.[149]

(C) The attorney for the government was absolutely horrible. She was cold, insulting, and did whatever she could to keep us from being compensated. She pushed for C. to be put in a group home because it would be cheaper than allowing her to live with her family, and she argued against very basic home safety devices, like latches on cupboards, a fence for the yard, and a special swing where C. would not fall out when a seizure hit.[150]

Question: What would you recommend in terms of changes for the VICP?

(A) The court spends far too much time looking for ways NOT to compensate families.[151]

(B) It should be overhauled.[152]

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146. Telephone Interview with K.N. and S.N., Parents of Vaccine Claimant (Aug. 18, 2010) (on file with authors as Case 59).

147. Telephone Interview with J.A. and E.A., Parents of Vaccine Claimant (Apr. 11, 2010) (on file with authors as Case 1); Telephone Interview with S.G., Parent of Vaccine Claimant (July 15, 2010) (on file with authors as Case 54); Interview with E.Z. and B.Z., Parents of Vaccine Claimant (2010) (on file with authors as Case 81).

148. Telephone Interview with E.Z. and B.Z., *supra* note 147.

149. Telephone Interview with J.A., Parent of Vaccine Claimant (Mar 13, 2010) (on file with authors as Case 27).

150. Telephone Interview with K.N. and S.N., *supra* note 146.

151. Telephone Interview with S.G., *supra* note 146.

> (C) There should be a program in place that would allow the court to reassess the children later in life to see if their needs have changed. This would make the life care planning less contentious and would allow for changes in laws, insurance coverage, and mostly the child's level of functioning. It is ridiculous to assume that you can adequately plan when a child is very young for every possible consequence of the vaccine damage throughout the child's life.[153]

The overwhelming majority of petitioners in the VICP have not received compensation. Of the 13,755 claims filed in the VICP to date, 2,621 awards have been paid, or less than 1 in 5 of the total number of claims filed. So far, 5,277 claims have been dismissed and 5,857 claims are pending. As most of the pending claims are in the Omnibus, they are likely to be dismissed.[154] The March 3, 2011 HHS Statistics Report notes that "HHS has never concluded in any case that autism was caused by vaccination."[155]

III. UNANSWERED QUESTIONS

In light of the strongly worded decisions in the Omnibus and the HHS Statistical Report noting that no case of vaccine-induced autism has ever been compensated, it is extremely puzzling to find so many cases of autism among VICP-compensated cases. While it is understandable that petitioners in these cases set out to prove encephalopathy and residual seizure disorder, and not autism, it also seems hard to understand that the Special Masters, experts, treating physicians, lawyers, and judges would all have been unaware of the presence of autistic symptoms in so many cases. To find eighty-three cases of confirmed autism among cases of confirmed vaccine-induced brain injury, with the

152. Telephone Interview with E.Z. and B.Z., *supra* note 147.

153. Telephone Interview with K.N. and S.N., *supra* note 146.

154. *National Vaccine Injury Compensation Program, Statistics Report, March 3, 2011*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ statistics_report.htm (last visited Mar. 10, 2011).

155. *Id.*

likelihood that there may be many more among those compensated for vaccine injury, raises several questions:

(1) Were HHS and DOJ aware of the prevalence of autism diagnoses among those who have been compensated for encephalopathy and residual seizure disorder?

(2) What percentage of the remaining VICP-compensated cases of vaccine-induced injuries manifest autism?

(3) Is "autism" perhaps a different term for slightly less severe encephalopathy and residual seizure disorder? Is it possible that "autism" is a form of brain damage similar to acute encephalopathy and residual seizure disorder, but vaccine-induced brain damage all the same? This argument has been made for over two decades; unfortunately, the hypothesis has been inadequately studied.[156]

1. Likely Criticism

We anticipate lively critique of this preliminary assessment. Here are several of the most likely counterarguments:

(1) "Secondary autism" exists, but vaccines only "resulted in" autism and did not "cause" it.

Some may argue that vaccines indirectly caused autism as a result of other vaccine-induced brain damage. Whether autism is considered a secondary injury to encephalopathy and residual seizure disorder or a primary injury appears to be a semantic point having little legal significance. Under either theory, vaccines led to brain injury, and the VICP has compensated that vaccine-induced brain injury, including autism. In other words, HHS has been compensating certain expenses of vaccine-induced autism for more than twenty years, when labeled as "encephalopathy" and "residual seizure disorder," but not compensating it when labeled "autism" without cogent explanation.

156. *See generally* HARRIS L. COULTER, VACCINATION, SOCIAL VIOLENCE AND CRIMINALITY: THE MEDICAL ASSAULT ON THE AMERICAN BRAIN (1990); *see also* BARBARA LOE FISHER, VACCINES, AUTISM & CHRONIC INFLAMMATION: THE NEW EPIDEMIC (2008).

(2) These individuals suffered from Dravet's Syndrome, a genetic disorder; they would have had the same outcomes without vaccination.

Vocal proponents of the U.S. vaccine program are likely to argue that many of these cases were wrongly compensated in the first place. They will argue that these brain damaged individuals suffered from a rare genetic condition called Dravet's Syndrome, and thus their seizures and encephalopathy shortly after vaccination were coincidental. For example, Dr. Paul Offit, prominent spokesperson for the U.S. vaccine industry, points to a single study by Dr. Samuel Berkovic of fourteen patients in Australia, funded by Bionomics "a productive drug discovery and development engine room focused on new treatments for cancer and serious disorders of the central nervous system."[157] Dr. Offit concludes, apparently on the basis of this one case series, that individuals who developed seizures within seventy two hours of vaccination would have developed their severe seizure disorders in any event because of their genetic mutations in the SCN1A gene.[158] Dr. Offit states:

> [A]fter Berkovic's paper, it was clear that all the time spent by parents to get health officials to admit that pertussis vaccine had permanently harmed children, all the money spent by pharmaceutical companies to compensate alleged victims, all the work of lawmakers to create a system to deflect lawsuits away from these companies, and all the ink devoted by the media to support these children and their parents had been an enormous diversion from the real cause of the problem.[159]

He concludes that parents were wrong to believe that vaccines were the cause of their children's epilepsy and mental retardation.[160]

157. *About Bionomics,* BIONOMICS, http://www.bionomics.com.au/page.php?section=42 (last visited Jan. 19, 2011); *see also* A.M. McIntosh et al., *Effects of Vaccination on Onset and Outcome of Dravet Syndrome: A Retrospective Study*, 9 LANCET NEUROLOGY 592 (2010).

158. S. F. Berkovic et al., *De-novo Mutations of the Sodium Channel Gene SCN1A in Alleged Vaccine Encephalopathy: A Retrospective Study*, 5 LANCET NEUROLOGY 465, 465 (2006).

159. DEADLY CHOICES, *supra* note 56, at 42-43.

160. *Id*. at 43.

While Dravet's Syndrome surely merits further study, to posit that a single drug company-sponsored study proves that all individuals who develop mental retardation or epilepsy (or encephalopathy and residual seizure disorder) in the immediate aftermath of vaccination would have developed it under any other circumstances strains credulity. Far more research would be needed, including large, population-based epidemiological studies, to conclude that vaccines played no role or even no aggravating role in the onset of such catastrophic symptoms.[161]

(3) Parents are poor reporters of their children's condition.

Critics will assert that parental caregivers are poor reporters of their children's conditions, subject to "confirmation bias." As a result, they will argue that these findings are not credible. Because of these concerns, we administered the SCQ to 27% of the total number of compensated families (and 35% of the cases having no published decisions) and found a high correlation between parental reports and scores for autism using this recognized screening tool. The accuracy of the autism assessment in the cases for which we have such corroboration suggests the likely accuracy of the parental reports for which we lack such corroboration. The authors would be delighted to have this study replicated with a more rigorous analysis of these and other compensated families, including full ADI-R diagnoses.

2. Recommendation: Congressional Inquiry

Autism is the most prevalent developmental disorder in the United States, conservatively affecting about one in one hundred and ten children.[162] This preliminary evaluation suggests that vaccine-induced encephalopathy and seizure disorder may be associated with autism. We recommend that Congress open an investigation of all compensated cases of vaccine-induced injury

161. *See* Yuval Shafrir, *Vaccination and Dravet Syndrome*, 9 LANCET NEUROLOGY 1147, 1147-48 (2010), *available at* http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2802%2900160-6/abstract; Anne McIntosh et al., *Vaccination and Dravet Syndrome- Author's reply*, *Lancet Neurol.* 9 LANCET NEUROLOGY 1148, 1148-49 (2010), *available at* http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2810%2970289-1/fulltext.

162. Rice, *supra* note 73.

to find out how frequently this association occurs. Congress should find out what HHS, DOJ, and the VICP knew about the existence of autism as a characteristic of those compensated for encephalopathy and residual seizure disorder.

CONCLUSION

While there are likely many routes to "autism," including prenatal neurological insults and toxic post-natal exposures,[163] this preliminary analysis of VICP-compensated cases suggests that autism is often associated with vaccine-induced brain damage. It raises the question if the VICP's decisions have been fair to reject all claims of vaccine injury that use the term "autism." This preliminary assessment also suggests the possibility that other contemporary childhood neurological disorders, including attention deficit disorder and learning disabilities, might be less severe after-effects, on the same spectrum of vaccine-induced brain injury.

Based on this preliminary assessment, there may be no meaningful distinction between the cases of encephalopathy and residual seizure disorder that the VICP compensated over the last twenty years and the cases of "autism" that the VICP has denied. If true, this would be a profound injustice to those denied recovery and to all who have invested trust in this system that Congress created. This preliminary study calls for Congress to investigate the VICP and for scientists to investigate all compensated cases of vaccine injury to gain a fuller understanding of the totality of consequences of vaccine injury.

163. *See* Marcel Kinsbourne & Frank Wood, *Disorders of Mental Development in* JOHN H. MENKES ET AL., CHILD NEUROLOGY 1097, 1112-21 (7th ed., 2006).

APPENDIX I

Diagnostic Criteria for 299.00 Autistic Disorder[164]

The following is from *Diagnostic and Statistical Manual of Mental Disorders: DSM IV*

(A) A total of six (or more) items from (1), (2), and (3), with at least two from (1), and one each from (2) and (3)

(1) qualitative impairment in social interaction, as manifested by at least two of the following:

a. marked impairments in the use of multiple nonverbal behaviors such as eye-to-eye gaze, facial expression, body posture, and gestures to regulate social interaction

b. failure to develop peer relationships appropriate to developmental level

c. a lack of spontaneous seeking to share enjoyment, interests, or achievements with other people, (e.g., by a lack of showing, bringing, or pointing out objects of interest)

d. lack of social or emotional reciprocity

(2) qualitative impairments in communication as manifested by at least one of the following:

a. delay in, or total lack of, the development of spoken language (not accompanied by an attempt to compensate through alternative modes of communication such as gesture or mime)

b. in individuals with adequate speech, marked impairment in the ability to initiate or sustain a conversation with others

c. stereotyped and repetitive use of language or idiosyncratic language

d. lack of varied, spontaneous make-believe play or social imitative play appropriate to developmental level

(3) restricted repetitive and stereotyped patterns of behavior, interests, and activities, as manifested by at least one of the following:

164. AM. PSYCHIATRIC ASS'N, *supra* note 70, at 75.

a. encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus
b. apparently inflexible adherence to specific, nonfunctional routines or rituals
c. stereotyped and repetitive motor mannerisms (e.g. hand or finger flapping or twisting, or complex whole-body movements)
d. persistent preoccupation with parts of objects

(B) Delays or abnormal functioning in at least one of the following areas, with onset prior to age 3 years:

(1) social interaction
(2) language as used in social communication,
(3) symbolic or imaginative play.

(C) The disturbance is not better accounted for by Rett's Disorder or Childhood Disintegrative Disorder.

APPENDIX II

VICP's Definitions of Encephalopathy, Seizure and Sequela[165]

Qualifications and Aids to Interpretation

(2) **Encephalopathy.** For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An **acute encephalopathy** is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) **For children less than 18 months of age** who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) **For adults and children 18 months of age or older**, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

165. *National Vaccine Injury Compensation Program, Vaccine Injury Table*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/table.htm (last visited Jan. 20, 2010).

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things). [ed. emphasis added]

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) **Chronic encephalopathy** occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the

encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) **Seizure and convulsion.** For purposes of paragraphs (b)(2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(4) **Sequela.** The term "sequela" means a condition or event which was actually caused by a condition [*ed., i.e. a vaccine*] listed in the Vaccine Injury Table.

APPENDIX III

Excerpt of HHS Response to FOIA Request[166]

Health Resources and Services
Administration
Rockville, MD 20857

July 9, 2009
Freedom of Information Act (FOIA) Case No. HRSA 09-176

Dr. Mr. Krakow:

I am responding to your FOIA request for records regarding the Vaccine Injury Compensation Program (VICP). You requested the following items:

1. Records containing all decisions, including Special Masters written decisions and orders or other explanatory material, granting entitlement to compensation under the [VICP].
2. Duplicate of point 1.
3. All memoranda or other material evidencing the outcome of petitions filed with the [VICP].
4. All records containing statistics or other analysis of decisions granting or denying entitlement to compensation of petitions filed with the [VICP].
5. All records indicating criteria used by HRSA or related agencies to determine whether a vaccine injury claim should or should not be compensated.

Needless to say, this is an exceptionally large and complicated request that will be both costly and take a minimum of four to five years to complete. . . .

166. *See* Letter from Thomas Flavin, Freedom of Info. Officer, Dep't of Health & Human Servs., to Robert Krakow (July 9, 2009) (on file with authors).

The costs are detailed in the attached receipt and total $754,625. If you will send us a deposit for half of the estimated costs – $377,312.50 – we will proceed with assembling and reviewing these records**. I must caution you that it will require at least 4 to 5 years to complete your request. . . .** [*emphasis added*]

The Department of Health and Human Services' policy calls for the fullest responsible disclosure consistent with the requirements of administrative necessity and confidentiality which are recognized by the FOIA, 5 U.S.C. § 552, and the Department's implementing Public Information Regulations, 45 CFR Part 5.

If you require any further assistance, please call this office at (301) 443-28655.(*sic*)

Sincerely,
/s/
Thomas Flavin
Freedom of Information Officer

APPENDIX IV

Previous Studies using VICP Compensated Cases as Data

Year	Authors	Institutional Affiliation	Article Title and Journal of Publication
1993	Cowan et al.	IOM	"Acute encephalopathy and chronic neurological damage after pertussis vaccine," *Vaccine* 1993, 11(14): 1371-9[167]
1994	Prevots et al.	CDC	"Completeness of reporting for paralytic poliomyelitis, United States, 1980-1991. Implications of estimating the risk of vaccine-associated disease," *Arch. Pediatr. Adolesc. Med.*, 1994 148(5): 479-85.[168]
1996	Weibel & Benor	NVICP/USPHS	"Chronic arthropathy and musculoskeletal symptoms associated with rubella vaccines. A review of 124 claims submitted to the National Vaccine Injury Compensation Program," *Arthritis Rheum.*, 1996, 39(9): 1529-34.[169]
1996	Weibel & Benor	NVICP	"Reporting Vaccine-Associated Paralytic Poliomyelitis: Concordance between the CDC

167. Linda D. Cowan et al., *Acute Encephalopathy and Chronic Neurological Damage after Pertussis Vaccine*, 11 VACCINE 1371 (1993).

168. D. Rebecca Prevots et al., *Completeness of Reporting for Paralytic Poliomyelitis, United States, 1980-1991: Implications of Estimating the Risk of Vaccine-associated Disease*, 148 ARCHIVES OF PEDIATRICS & ADOLESCENT MED. 479 (1994).

169. Robert E. Weibel & David E. Benor, *Chronic Arthropathy and Musculoskeletal Symptoms Associated with Rubella Vaccines. A Review of 124 Claims Submitted to the National Vaccine Injury Compensation Program*, 39 ARTHRITIS & RHEUMATISM 1529 (1996).

Year	Authors	Institutional Affiliation	Article Title and Journal of Publication
			and the National Vaccine Injury Compensation Program," *Am. J. of Public Health*, 1996, 86(5): 734-73.[170]
1998	Ridgway	Univ. of Calif., Berkeley	"Disputed claims for pertussis vaccine injuries under the National Vaccine Injury Compensation Program," *J. Investig. Med.*, 1998, 46(4): 168-74.[171]
1998	Weibel	NVICP	"Acute encephalopathy followed by permanent brain injury or death associated with further attenuated measles vaccines: a review of claims submitted to the National Vaccine Injury Compensation Program," *Pediatrics*, 1998, 101(3 Pt1): 383-7.[172]
1999	Ridgway	Lineberry Research Assoc.	"No fault vaccine insurance: Lessons from the National Vaccine Injury Compensation Program," *J. of Health Politics, Policy & Law*, 1999, 24(1):59-90.[173]

170. Robert E. Weibel & David E. Benor, *Reporting Vaccine-Associated Paralytic Poliomyelitis: Concordance Between the CDC and the National Vaccine Injury Compensation Program*, 86 AM. J. OF PUB. HEALTH 734 (1996).

171. Derry Ridgway, *Disputed Claims for Pertussis Vaccine Injuries Under the National Vaccine Injury Compensation Program*, 46 J. OF INVESTIGATIVE MED. 168 (1998).

172. Robert E. Weibel et al., *Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated with Further Attenuated Measles Vaccines: A Review of Claims Submitted to the National Vaccine Injury Compensation Program*, 101 PEDIATRICS 383 (1998).

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

Year	Authors	Institutional Affiliation	Article Title and Journal of Publication
2010	Atanasoff	U.S. HHS, HRSA, NVICP	"Shoulder Injury Related to Vaccine Administration (SIRVA)," Powerpoint presentation given to the Advisory Commission on Childhood Vaccines, Sept. 3, 2010.[174]

174. Sarah Atanasoff, Med. Officer, Health Res. & Servs. Admin., Div. of Vaccine Injury Comp.& Rosemary Johann-Liang, Chief Med. Officer, Health Res. & Servs. Admin., Div. of Vaccine Injury Comp., Presentation to the Advisory Commission on Childhood Vaccines (Sept. 2-3, 2010). For minutes of this meeting, go to http://www.hrsa.gov/vaccinecompensation/ ACCVMinutes-September2010.pdf.

APPENDIX V

Parent Structured Interview Form

National Vaccine Compensation Justice Project
Petitioner Parent Structured Interview Form

Case #: CD Child's Name: DOB:
Dkt.#: Special Master/Judge:
Mother's name: Father's name: Attorney name:
Guardian:
Address:

Telephone:
E-mail:
Mother's DOB: Father's DOB:
Siblings (gender and ages):

Mother's occupation at the time of filing:
Father's occupation at the time of filing:
Mother's occupation now:
Father's occupation now:

Status of Child
Subject child's present age:
Living situation: (With family, group home, etc.)
How is your child's life today?
What was the impact of the vaccine injury on your family?

Perceptions of Program Justice
In your opinion. . .
Was your child's claim resolved quickly?
Was your child's claim resolved with compassion?
Was your child's claim resolved fairly?
Has the Program met the needs of your child?

What were the positive aspects of the program?
What were the negative aspects of the program?
What would you recommend in terms of changes for the NVICP?
Would you be willing to write a letter describing your perceptions of the NVICP?
Would you be willing to speak publicly if given the opportunity?

Vaccine Injury - Encephalopathy
Does your child's vaccine injury induced encephalopathy include seizures?
Does your child's vaccine injury induced encephalopathy include an autism diagnosis, autistic features or autistic-like behaviors (which one)?
Does your child's vaccine injury induced encephalopathy include a diagnosis of Attention Deficit Disorder?
Does your child's vaccine injury induced encephalopathy include a diagnosis of Developmental Delay?

Vaccine Injury – Seizure Disorder
Does your child's vaccine injury induced seizure disorder include a diagnosis of Attention Deficit Disorder?
Does your child's vaccine injury induced seizure disorder include an autism diagnosis, autistic features or autistic-like behaviors (which one)?
When your child is not suffering from seizures, does the child exhibit autism-like behaviors?
Does your child's vaccine injury induced seizure disorder include a diagnosis of Developmental Delay?

Vaccine Injury Generally
Does your child's vaccine injury include myelin disorders?
Does your child also suffer from asthma, now or in the past?
Does your child have language difficulties?
Does your child have a diagnosis of CP?
Would you be willing to provide written material that verifies your child's diagnosis?
Would you be willing to release copies of your child's reports from medical experts (used only for verification purposes)?

Would you be willing to write a letter describing your child's medical condition?

Initial date of interview: Time:

Interviewer:
Follow up date:
Additional notes:

Follow up date:
Additional notes: