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Using and Misusing Legal Decisions: Why Anti-Vaccine Claims about NVICP Cases Are Wrong

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Abstract

The question of whether vaccines cause autism spectrum disorder (autism, or ASD) has been extensively studied. Studies from different countries around the world, looking at millions of children in total, examined it and found no link. Despite this powerful evidence, the actions of a small group who fervently believe that vaccines cause autism may lead people to question the data. One tactic used to argue that vaccines cause autism is the use of compensation decisions from the National Vaccine Injury Compensation Program to claim such a link. This article demonstrates that not only does the nature of proof in the program make its decisions ill-suited to challenging the science but also that the cases used do not, in their content, support that conclusion. Even the cases that most closely address the question of vaccines and autism do not show the link that opponents claim exists, and many of the cases used are misrepresented and misused.

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INTRODUCTION

This Article examines the use of certain decisions under the National Vaccine Injury Compensation Program (NVICP) by activists trying to assert that vaccines cause autism. It then explains how this effort collapses promptly when subjected to scrutiny.

In 2000, the Centers for Disease Control and Prevention (CDC) declared that measles had been eliminated in the United States.[1] This means that there were no more homegrown cases, although there inevitably continued to be a small number imported each year.[2] The very effective measles component of the vaccine against measles, mumps, and rubella[3] (MMR vaccine) was able to conquer a disease that once infected practically everyone. In the pre-vaccine era, measles led to 400–500 deaths and 48,000 hospitalizations each year in the United States alone,[4] and the World Health Organization estimates that it still caused the deaths of 145,700 people worldwide in 2013.[5] Measles has no treatment other than supportive care.[6] It can cause encephalitis, with deafness and intellectual disability

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1. Div. of Viral Diseases, Ctrs. for Disease Control & Prevention, Documentation and Verification of Measles, Rubella and Congenital Rubella Syndrome Elimination in the Region of the Americas 1 (2012), http://www.cdc.gov/measles/downloads/report-elimination-measles-rubella-crs.pdf [http://perma.cc/X8WK-M4K2].

2. *Id.* at 11.

3. *Id.* at 10.

4. Walter A. Orenstein et al., *Measles Elimination in the United States*, 189 J. INFECTIOUS DISEASES (SUPPL. 1) S1, S1 (2004)., http://dx.doi.org/10.1086/377693; *see also* S. W. Roush et al., *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 J. AM. MED. ASS'N 2155, 2156 tbl.1 (2007), http://dx.doi.org/10.1001/jama.298.18.2155.

5. *Global Progress Towards Regional Measles Elimination, Worldwide, 2000–2013*, 89 WKLY. EPIDEMIOLOGICAL REC. 509, 509, 511 tbl.1 (2014), available at http://www.who.int/wer/2014/wer8946.pdf [http://perma.cc/CQN8-V8YR].

6. Selina SP Chen, *Measles Management and Treatment*, MEDSCAPE, http://emedicine.medscape.com/article/966220-treatment (Last accessed August 29, 2017) ("Treatment of measles is essentially supportive care . . . ").

as possible results. It can also cause pneumonia,[7] and leads to hospitalization in a substantial percentage of cases.[8]

Measles is now seeing a resurgence, and in the majority of cases, the affected have not been vaccinated. In 2008, the United States saw 140 cases[9]; of the 131 cases reported through July, ninety-one percent of the victims were unvaccinated or had unknown vaccination status.[10] In 2011, there were 222 cases of measles, and eighty-six percent of those people were unvaccinated or had unknown status.[11] Between January 1 and August 24, 2013, 159 cases were recorded; eighty-two percent were in unvaccinated persons.[12] Finally, in 2014 the United States saw 667 cases of measles—again, the majority of these occurring among the unvaccinated.[13] A 2016 article found that between 2000 and 2015, the majority of cases in measles outbreaks were in the unvaccinated (most intentionally

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7. Ctrs. for Disease Control & Prevention, U.S. Dep't Health & Human Servs., Epidemiology and Prevention of Vaccine-Preventable Diseases ch. 13, 210–11 (William Atkinson et al., eds., 13th ed. 2015), http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf [http://perma.cc/WM9F-T5SN]. S*ee generally* Walter A. Orenstein et al., *The Clinical Significance of Measles: A Review*, 189 J. Infectious Diseases (Suppl. 1) S4 (2004), http://dx.doi.org/10.1086/377712 (providing an overview of complications).

8. *See e.g.*, *Measles—United States, January–May 20, 2011*, 60 MORBIDITY & MORTALITY WKLY. REP. 666, 666 (2011)., http://www.cdc.gov/mmwr/pdf/wk/mm6020.pdf ("[D]uring the first 19 weeks of 2011, 118 cases of measles were reported . . . Forty-seven (40%) patients were hospitalized and nine had pneumonia.").

9. *Measles—United States, January 1–August 24, 2013*, 62 MORBIDITY & MORTALITY WKLY. REP. 741, 741 (2013), http://www.cdc.gov/mmwr/pdf/wk/mm6236.pdf.

10. *Update: Measles—United States, January–July 2008*, 57 MORBIDITY & MORTALITY WKLY. REP. 893, 893 (2008), http://www.cdc.gov/mmwr/PDF/wk/mm5733.pdf.

11. *Measles—United States, 2011*, 61 MORBIDITY & MORTALITY WKLY. REP. 253, 253 (2012), http://www.cdc.gov/mmwr/PDF/wk/mm6115.pdf.

12. *Measles—United States, January 1–August 24, 2013*, *supra* note 9, at 741.

13. *Measles Cases and Outbreaks*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/measles/cases-outbreaks.html (last updated May 2, 2016. [https://perma.cc/E2TE-S8QR]. *See also* Paul A. Gastañaduy et al., *Measles—United States, January 1–May 23, 2014*, 63 MORBIDITY & MORTALITY WKLY. REP. 496, 496 (2014), http://www.cdc.gov/mmwr/pdf/wk/mm6322.pdf.

unvaccinated) in spite of the fact that a large majority of the population in the appropriate age brackets is vaccinated.[14]

Some people cannot be vaccinated for medical reasons, but other people make an active choice not to vaccinate themselves or, more often, their children. The full reasons are doubtlessly complex,[15] but there is evidence to suggest that this choice is influenced by antivaccine organizations that promote inaccurate—sometimes wild—claims about vaccine risks.[16] One of the most persistent (and least accurate) of these is that vaccines cause autism.[17]

The possibility of a link between vaccines and autism has been extensively studied for close to two decades. The conclusion from multiple large-scale, high-quality studies from around the globe is that there is no connection.[18] Aside from the evidence refuting the claim, there is no credible evidence that supports it.[19] While there still exist many questions about the etiology of

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14. Varun K. Phadke, et al., *Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United State: A Review of Measles and Pertussis*, 315 J.AM. MED. ASS'N 1149 (2016).

15. JENNIFER A. REICH, CALLING THE SHOTS: WHY SOME PARENTS REJECT VACCINES 67-75 (NYU University Press. 2016).

16. *See, e.g.*, E. David G. Macintosh et al., *Vaccine Hesitancy and Refusal*, 175 J. PEDIATRICS 248 (2016), http://dx.doi.org/10.1016/j.jpeds.2016.06.006 (focusing on the European Union). Examples of wild claims include references to the "Vaccine Holocaust," or claims that vaccines will cause permanent alterations of DNA.

17. PAUL A. OFFIT, AUTISM'S FALSE PROPHETS: BAD SCIENCE, RISKY MEDICINE, AND THE SEARCH FOR A CURE 176 (Columbia University Press 2010) [hereinafter OFFIT, FALSE PROPHETS].

18. Most recently, a large meta-review examining previous studies in over a million children reached the same conclusion. *See* Luke E. Taylor et al., *Vaccines Are Not Associated with Autism: An Evidence-Based Meta-Analysis of Case–Control and Cohort Studies*, 32 VACCINE 3623 (2014), http://dx.doi.org/10.1016/j.vaccine.2014.04.085. So did an Institute of Medicine Report about vaccines' adverse events. Margaret A. Maglione et al., *Safety of Vaccines Used for Routine Immunization of US Children: A Systematic Review*, 134 PEDIATRICS 325 (2014), http://dx.doi.org/10.1542/peds.2014-1079; *see also* Paul Offit & Frank DeStefano, *Vaccine Safety*, *in* VACCINES 1464, 1473–74 (Stanley A. Plotkin et al., eds., 6th ed. 2013), http://dx.doi.org/10.1016/B978-1-4557-0090-5.00076-8.

19. *See* Stanley Plotkin et al., *Vaccines and Autism: A Tale of Shifting Hypotheses*, 48 CLINICAL INFECTIOUS DISEASES 458 (2009), http://dx.doi.org/10.1086/596476. S*ee also* Joëlle Anne Moreno, *Toxic Torts, Autism, and Bad Science: Why the Courts May Be Our Best Defense Against Scientific Relativism*, 40 NEW ENG. L. REV. 409 (2006), http://www.nesl.edu/userfiles/file/lawreview/Vol40/2/Moreno.pdf [https://perma.cc/T85U-GZ5G]. To be clear, there are some studies that are

autism, the prevailing evidence points to a strong heritability, with an increasing number of identified genetic variations[20] and prenatal causes.[21]

One recent large-scale study found that the prevalence of autism, considered under today's diagnostic criteria, has been consistent over recent decades.[22] This study strongly suggests that the increase in autism is in fact due more to an increase in

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claimed to support such a connection; these, however, have proved either not actually to show such a link or to be fatally flawed in ways that make them unable to support the conclusion. See e.g. OFFIT, FALSE PROPHETS, *supra* note 17, at 42-45. One recent effort was retracted because the author both failed to disclose conflicts of interest and mishandled the analysis. *See* Brian S. Hooker, *Measles-Mumps-Rubella Vaccination Timing and Autism Among Young African American Boys: A Reanalysis of CDC Data*, 3:16 TRANSLATIONAL NEURODEGENERATION, Aug. 2014, http://dx.doi.org/10.1186/2047-9158-3-16. The retraction explains that "there were undeclared competing interests on the part of the author which compromised the peer review process. Furthermore, post-publication peer review raised concerns about the validity of the methods and statistical analysis, therefore the Editors no longer have confidence in the soundness of the findings." Retraction: Measles-Mumps-Rubella Vaccination Timing and Autism Among Young African American Boys: A Reanalysis of CDC Data, 3 TRANSLATIONAL NEURODEGENERATION, no. 22, Oct. 2014, http://dx.doi.org/10.1186/2047-9158-3-22.

20. Most recently, Mark N. Ziats & Owen M. Rennert, *The Evolving Diagnostics and Genetic Landscapes of Autism Spectrum Disorder*, 7 FRONTIERS IN GENETICS 65 (2016), https://www.ncbi.nlm.nih.gov/pubmed/27200076. *See also* T. Gaugler et al., *Most Genetic Risk for Autism Resides with Common Variation*, 46 NATURE GENETICS 881 (2014), http://dx.doi.org/10.1038/ng.3039 (the "narrow-sense heritability [of autism's genetic architecture] is ~52.4%, with most due to common variation"); G. Huguet, E. Ey, & Bourgeron T., *The Genetic Landscape of Autism Spectrum Disorders*, 14 ANNU REV GENOMICS HUM GENET. 191 (2013), https://www.ncbi.nlm.nih.gov/pubmed/23875794 ("For the majority of individuals with ASD, the causes of the disorder remain unknown; however, in up to [25%] of cases, a genetic cause can be identified.").

21. *See* Rich Stoner et al., *Patches of Disorganization in the Neocortex of Children with Autism*, 370 NEW ENG. J. MED. 1209 (2014), http://dx.doi.org/10.1056/NEJMoa1307491. Those who insist that vaccines cause autism have recently taken to claiming that if autism is indeed prenatal, the likely causes are the influenza vaccine and Tdap booster currently recommended for pregnant women. Aside from a lack of evidence, the timing simply does not work: routine vaccination of pregnant women only started in 2010, and rates of autism diagnosis (but not necessarily prevalence) were consistently rising long before that.

22. A.J. Baxter et al., *The Epidemiology and Global Burden of Autism Spectrum Disorders*, 45 PSYCHOL. MED. 601 (2014)., http://dx.doi.org/10.1017/S003329171400172X. For similar findings, see Stefan N. Hansen et al., *Explaining the Increase in the Prevalence of Autism Spectrum Disorders: The Proportion Attributable to Changes in Reporting Practices*, 169 J.AM. MED. ASS'N PEDIATRICS 56 (2015)., http://dx.doi.org/10.1001/jamapediatrics.2014.1893.

diagnoses than to an actual increase in incidence, with both the broadening of diagnostic criteria[23] and diagnostic substitution[24] playing substantial roles. Whatever increase exists that cannot be explained by diagnostic factors may well be due to extrinsic factors such as increased parental age.[25]

Despite this substantial body of research, a small but persistent group of activists continues to try to perpetuate and promote their firm belief that vaccines cause autism.[26] Some have children of their own with autism and, against all scientific evidence, refer to them as "vaccine injured."[27] With due consideration of the limits of operational definitions,[28] this group will herein be denoted the "Vaccines Cause Autism Community"

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23. Eric Fombonne, *Epidemiology of Autistic Disorder and Other Pervasive Developmental Disorders*, 66 J. CLINICAL PSYCHIATRY 3, 7 (2005), http://www.ncbi.nlm.nih.gov/pubmed/16401144 (follow "Full text links") ("Most of the upward trend in prevalence can be accounted for by methodological factors such as change in the diagnostic criteria.").

24. Paul T. Shattuck, *The Contribution of Diagnostic Substitution to the Growing Administrative Prevalence of Autism in US Special Education*, 117 PEDIATRICS 1028, 1028 (2006), http://dx.doi.org10.1542/peds.2005-1516 ("Higher autism prevalence was significantly associated with corresponding declines in the prevalence of mental retardation and learning disabilities."). *See also* Dorothy V.M. Bishop et al., *Autism and Diagnostic Substitution: Evidence from a Study of Adults with a History of Developmental Language Disorder*, 50 DEVELOPMENTAL MED. & CHILD NEUROLOGY 341 (2008), http://dx.doi.org/10.1111/j.1469-8749.2008.02057.x.

25. Marissa D. King et al., *Estimated Autism Risk and Older Reproductive Age*, 99 AM. J. PUB. HEALTH 1673 (2009), http://dx.doi.org/10.2105/AJPH.2008.149021.

26. For example, the blog Age of Autism summarizes its basic mission as:

> to give voice to those who believe autism is an environmentally induced illness, that it is treatable, and that children can recover. For the most part, the major media in the United States aren't interested in that point of view, they won't investigate the causes and possible biomedical treatments of autism independently, and they don't listen to the most important people—the parents, many of whom have witnessed autistic regression and medical illness after vaccinations. Dan Olmsted, *A Letter from the Editor*, AGE OF AUTISM, http://www.ageofautism.com/a-welcome-from-dan-olmste.html [http://perma.cc/EKX3-UCDA].

27. *See e.g.*, Cathy Jameson, *Things Said That Can Make the Parent of a Vaccine Injured Child Cringe*, AGE OF AUTISM (Sept. 20, 2015, 5:45 AM), http://www.ageofautism.com/2015/09/things-said-that-can-make-the-parent-of-a-vaccine-injured-child-cringe.html.

28. *See e.g.*, Jacobellis v. Ohio, 378 U.S. 184, 197 (1964) (Stewart, J., concurring) ("I shall not today attempt further to define the kinds of material I understand to be embraced within that shorthand description; and perhaps I could never succeed in intelligibly doing so. But I know it when I see it . . . ").

(VCAC).[29] Most, although not all, of its most vocal members participate in the activities of a small number of closely knit[30] organizations that support their cause, such as SafeMinds,[31] Age of Autism,[32] TACA,[33] Generation Rescue,[34] and the Canary Party.[35] To compensate for the large body of scientific evidence refuting the basic claim that vaccines cause autism, these groups employ various advocacy tactics, one of which is to insist that that successful claims under the NVICP represent concessions by the government that vaccines cause autism and thus prove the link.[36]

One possible response to this position is simply to observe that science is not decided by the courts[37] and that NVICP

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29. Or that the main cause of autism is vaccines; some admit the possibility of other contributing factors, such as wireless technology. *E.g.*, Ronald Kostoff, *Absence of Evidence is Not Evidence of Absence*, AGE OF AUTISM (Dec. 8, 2015), http://www.ageofautism.com/2015/12/absence-of-evidence-is-not-evidence-of-absence.html [http://perma.cc/6GA6-MB8F].

30. Matt Carey, *CNN: The Money Behind the Vaccine Skeptics*, LEFT BRAIN/RIGHT BRAIN (Feb. 6, 2015)., https://leftbrainrightbrain.co.uk/2015/02/06/cnn-the-money-behind-the-vaccine-skeptics [http://perma.cc/7V42-QHM4].

31. SAFEMINDS, http://www.safeminds.org [http://perma.cc/5CYE-JYEM] ("Mission: To end the autism epidemic by promoting environmental research and effective treatments.").

32. AGE OF AUTISM, http://www.ageofautism.com (last visited Sept. 19, 2016).

33. TALK ABOUT CURING AUTISM, http://www.tacanow.org (last visited Sept. 19, 2016).

34. GENERATION RESCUE, http://www.generationrescue.org (last visited Sept. 19, 2016).

35. THE CANARY PARTY, http://www.canaryparty.org (last visited May 18, 2016). The Canary Party is also a registered Political Action Committee. *Political Committees and Political Funds Registration Information*, MINN. CAMPAIGN & FIN. PUB. DISCLOSURE BD., http://www.cfboard.state.mn.us/campfin/PCFDetail/PCF41056.html [http://perma.cc/G4PS-SQNP].

36. *Cf.* David Kirby, *Vaccine Court Awards Millions to Two Children with Autism*, HUFFINGTON POST: HUFFPOST HEALTHY LIVING (Jan. 14, 2013, 12:03 PM), http://www.huffingtonpost.com/david-kirby/post2468343_b_2468343.html [http://perma.cc/2DVM-9WM2] (hinting at the Department of Health and Human Services' (HHS) contradictory conduct by noting that despite its continued "underwriting [of] autism treatments" under its vaccination-injury program, HHS has never concluded that vaccination caused a case of autism)

37. *E.g.*, PAUL A. OFFIT, THE CUTTER INCIDENT 172–73 (2005) ("Judges, with little training in science or the scientific method, are often poor arbiters of . . . [the] truth[s]. . . . Jurors are also not usually well suited to decide complicated issues of medicine, science, and technology."); Emily Willingham, *Court Rulings Don't Confirm Autism–Vaccine Link*, FORBES: HEALTH & TECH. (Aug. 9, 2013, 5:20 PM), http://www.forbes.com/sites/emilywillingham/

claims—however they may turn—cannot overcome the abundant evidence refuting any such causal link.[38] Anna Kirkland, in her new book about Vaccine Court, makes a solid case that vaccine injuries are, in a real sense, political. But she makes that argument in the context of compensation, acknowledging that this is not a scientific answer.[39] As noted by others, there is a strong argument that courts of law are simply inappropriate forums for deciding scientific questions, because of the wholly different methods and modes of thinking that characterize the two realms.[40]

Another fundamental problem with this tactic, however, is the failure of the decisions being invoked to even support the claims being assigned to them. Several commentators have already made this case for specific decisions.[41] This Article pulls these claims together and adds new information, demonstrating that the decisions at issue do not support the claim that vaccines cause autism.

The assertions of vaccine opponents ultimately fall into just a few categories, none of which withstands scrutiny. One focuses on a small number of cases in which the word "autism" or "autism-like" was used by a special master but the claim was compensated for things that are not autism. Even worse, in some of these cases, claims of autism were made by the government as an argument for denying compensation and expressly rejected.

2013/08/09/court-rulings-dont-confirm-autism-vaccine-link.

38. David Gorski, *When You Can't Win on Science, Invoke the Law . . .* , SCI.-BASED MED. (May 11, 2011), https://www.sciencebasedmedicine.org/when-you-cant-win-on-science-invoke-the-law-2 [https://perma.cc/DBA5-DU9K].

39. Anna Kirkland, Vaccine Court: The Law and Politics of Injury (2016).

40. Joëlle Anne Moreno, *It's Just a Shot Away: MMR Vaccines and Autism and the End of the* Daubertista *Revolution*, 35 WM. MITCHELL L. REV. 1511, 1517 (2009). http://open.mitchellhamline.edu/cgi/viewcontent.cgi?article=1311&context=wmlr [https://perma.cc/X8JQ-R4XJ].

41. Matt Carey, *Sharyl Attkisson Blogs the Hannah Poling Settlement*, LEFT BRAIN/RIGHT BRAIN (Sept. 10, 2010), http://leftbrainrightbrain.co.uk/2010/09/10/sharyl-attkisson-blogs-the-hannah-poling-settlement [http://perma.cc/3KAY-QCF2]; David Gorski, *The Incredible Shrinking Vaccine–Autism Hypothesis Shrinks Some More*, SCI.-BASED MED. (Mar. 2, 2009), https://www.sciencebasedmedicine.org/the-incredible-shrinking-vaccine-autism-hypothesis-shrinks-even-more [http://perma.cc/D9AJ-PWN6]; Science Mom, *MMR–Encephalitis NVICP Decision*, JUST THE VAX (Jan. 14, 2013), http://justthevax.blogspot.com/2013/01/mmr-encephalitis-nvicp-decision.html [http://perma.cc/ZM93-F96J].

A separate group of assertions proceeds as follows: claims have been conceded or settled under the NVICP in which vaccines may have caused encephalopathy. Some such cases were compensated as "Table Injuries," i.e., those listed in the published Vaccine Injury Table,[42] for which causation is presumed.[43] Members of VCAC claim the symptoms of autism are similar to those of encephalopathy.[44] Therefore, the argument goes, cases have been settled or conceded under the NVICP because vaccines caused autism. This, too, fails to withstand straightforward examination.

Finally, the use of NVICP cases to claim that vaccines cause autism is especially problematic given that lengthy, detailed, well-supported decisions examining whether vaccines cause autism have been answered with a very clear negative—and the Court of Appeals for the Federal Circuit affirmed the two decisions brought before them (out of the six decided under the NVICP).[45] In the wake of those decisions, NVICP consistently rejected claims that vaccines cause ASD.[46]

The rest of this Article proceeds as follows: Part I discusses the NVICP and its special features and also makes some observations about legal analysis and the use of cases. Part II examines the use of concessions and settlements and shows that cases used do not support the claim that vaccines cause autism. Part III reviews decisions that were based on rulings on the facts by the Office of Special Masters within the Court of Federal Claims and explains why these likewise fail to support the claimed link between vaccines and autism. Part IV explains

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42. 42 C.F.R. § 100.3(a) (2015), http://www.ecfr.gov/cgi-bin/retrieveECFR?n=pt42.1.100#se42.1.100_13 [http://perma.cc/CU3C-PXYD].

43. Vaccine Injury Table § a, 42 U.S.C. § 300aa-14 (2015).

44. "In other words, lack of normal eye gazed, impaired social relations, and non-responsiveness to external stimuli are noted in both the DSM-VI and VICP encephalopathy classifications as diagnostic criteria." Holland et al, p 495.

45. *See* Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); Hazlehurst v. Sec'y of Dep't of Health & Human Servs., No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), *aff'd sub nom*. Hazlehurst *ex rel*. Hazlehurst v. Sec'y, Dep't of Health & Human Servs., 88 Fed. Cl. 473 (2009), *aff'd sub nom*. Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343 (Fed. Cir. 2010).

46. Hardy v. Sec'y of Health & Human Servs., Nov. 3, 2015 No. 08-108V, 2015 WL 7732603, *5 (Fed. Cl. 2015) ("In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.").

what the Omnibus Autism Proceeding did in fact do. A brief conclusion follows.

I. BACKGROUND

A. THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

A no-fault compensation program in the United States for vaccine injuries—as opposed to leaving potential plaintiffs at the mercy of the general court system—had been proposed as far back the 1970s.[47] Actual progress in this direction, however, was only spurred by a dramatic increase in lawsuits against manufacturers claiming damages due to vaccines in the 1980s and the announcement by two out of five producers of the diphtheria, tetanus, and pertussis vaccine (DTP vaccine) that they were leaving the market.[48] In 1986, Congress passed the National Childhood Vaccine Injury Act ("the Act").[49] A major component of the Act was the creation of the NVICP. The program has two main goals: to address the shortcomings of the tort system with a no-fault forum designed to resolve vaccine injury claims "quickly, easily, with certainty and generosity"[50] and to ensure the national vaccine supply and keep vaccine prices affordable by protecting manufacturers from unpredictable liability.[51]

A detailed discussion of the NVICP itself is beyond the scope of this paper.[52] For our analysis, the important point is that

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47. JAMES COLGROVE, STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY America 208–15 (2006).

48. *Id.* Note that the bases for some claims were problematic. *See*, *e.g.,* PAUL A. OFFIT, DEADLY CHOICES: HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL 98 (2010) [hereinafter OFFIT, DEADLY CHOICES] (arguing that recent NVICP decisions "weren't supported by science" but rather the testimony of questionable "experts").

49. Vaccine Injury Table § a, 42 U.S.C. §§ 300aa-1 to 34 (2015).

50. H.R. REP. NO. 99-908, pt. 1, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.

51. Geoffrey Evans et al., *Legal Issues*, *in* VACCINES 1481 (Stanley A. Plotkin et al. eds., 6th ed. 2013).

52. *See generally* ANNA KIRKLAND, VACCINE COURT, chapters 2, 5 and 6 (discussing the origins of the NCIVP as a solution to a perceived vaccine problem, the types of evidence submitted in NCVIP proceedings, and the NCVIP's Omnibus Autism Proceeding); *see also* Katherine M. Cook & Geoffrey Evans, *The National Vaccine Injury Compensation Program*, 127 PEDIATRICS S74 (2011), http://dx.doi.org/10.1542/peds.2010-1722K; Nora Freeman

those claiming vaccine injury are currently required to proceed through the NVICP before they are able to sue in state court. If the claim is one of design defect, there is no such recourse; the Supreme Court has ruled that design defect claims are federally preempted, and cannot be litigated in state court at all.[53] Suits predicated on manufacturing and warning defects, however, can be brought in state courts after proceeding through the program.[54] A claim would first be evaluated by the Department of Health and Human Services (the respondent), which may decide to award compensation in a concession—acknowledging that the case has, or may have, merit. Whether conceded or not, claims are heard before a special master appointed by the Court of Federal Claims. A petitioner unsatisfied with the results of the process can appeal, first to a judge of the Court of Federal Claims, then to the Federal Circuit Court of Appeals, and finally to the United States Supreme Court.[55]

Evidentiary and procedural rules are relaxed within the NVICP.[56] The special masters have substantial discretion to accept or reject evidence, and they have proved to be relatively generous in accepting evidence from petitioners.[57] For example, although they have the discretion to apply the *Daubert* test[58] to

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Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 U. PENN. L. REV. 1631 (2015), http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=9485&context=penn_law_review [http://perma.cc/9KAA-L373]; Anna Kirkland, *Credibility Battles in the Autism Litigation*, 42 SOC. STUD. SCI. 237 (2012), http://dx.doi.org/10.1177/0306312711435832.

53. Bruesewitz v. Wyeth, 562 U.S. 223, 232 (2011).

54. *Id*.

55. Internal Revenue Code, 26 U.S.C. § 9510 (2015).

56. Vaccine Injury Table, 42 U.S.C. § 300aa-12(d)(2)(B) (2015); *see also* Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

57. Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2015 WL 2507791 at *21 (Fed. Cl. June 15, 2010), ("In the Vaccine Program, then, exclusion from the record is an exceptional remedy, and should only be applied by the Court where the material sought to be excluded is so unreliable, it patently forfeits every trace of being helpful to the Court's consideration of the facts of the case.").

58. Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993). In *Daubert,* the Supreme Court made federal judges gatekeepers of scientific evidence, in charge of assessing its validity and reliability. The practical effect is to exclude claims and experts the court finds unreliable.

the opinions of the petitioners' experts,[59] they rarely do.[60] As pointed out recently, the program does away with most of the traditional requirements of a tort case—petitioners need only prove causation and the level of damages.[61]

The program offers two paths to proving causation: first, a petitioner may claim an injury included in the Vaccine Injury Table. If the alleged injury is found to have occurred within a prescribed period of time following the vaccination, there is a rebuttable presumption of causation.[62] If a petitioner either alleges an injury not listed on the Table ("off-Table" claims) or claims that a listed condition occurred outside the statutory time frame, it becomes necessary to prove causation.[63] In order to prove such a claim, a petitioner must

> show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a

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59. Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (1999); Cedillo, 89 Fed. Cl. 182 ("The Special Master had the discretion under *Terran* to apply *Daubert* when assessing the conclusions of the parties' expert witnesses . . . ."), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *see also* Moreno, *supra* note 40, at 1512 (2009).

60. This has led to the acceptance of experts who—deservedly—have received extensive criticism from special masters. For example,

> In other cases, special masters have gone so far as to conclude that Dr. Geier is not an honest, candid witness. In *Marascalco* . . . , Special Master Edwards described Dr. Geier's testimony as "intellectually dishonest" and "an egregious example of blatant, result-oriented testimony." In *Aldridge* . . . Special Master Abell stated that one aspect of Dr. Geier's testimony was "at best negligent if not a fraud on the court," and noted Dr. Geier's "lack of candor or preparation." In *Haim* . . . , Special Master Millman stated that "Dr. Geier's testimony is merely unsupported speculation," and that "Dr. Geier may be clever, but he is not credible." And I myself concluded that Dr. Geier was not offering an honest, candid opinion in *Platt* . . . .

King v. Sec'y of Health & Human Servs, No. 03-584V, 2011 WL 5926126 at *12 (Sept. 22, 2011).

61. Engstrom, *supra* note 52, at 1660 ("[T]he Vaccine Act winnows down a traditional tort action so that, instead of the many elements typically considered, only two must be addressed: (1) actual causation (did this vaccine cause this injury?) and (2) damages (how much compensation is due?).").

62. Vaccine Injury Table, 42 U.S.C. § 300aa-14 (2015).

63. Vaccine Injury Table, 42 U.S.C. § 300aa-13 (2015); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (2005).

> showing of a proximate temporal relationship between vaccination and injury.[64]

This, from the court in *Althen*, made clear that claimants were entitled to recover even if their theory linking a vaccine to an injury involved "a sequence hitherto unproven in medicine."[65] In other words, the *Althen* standard meant that mere medical opinion or circumstantial evidence could suffice for compensation under the Act.

This standard is less rigorous than that used for causation in regular tort cases, in which a plaintiff would also have to prove general causation, that is, to show scientifically that a particular vaccine can cause the type of injury claimed.[66] In other words, petitioners could win NVICP cases even without sound scientific evidence to support the proposition that the vaccine in question could cause the claimed harm in the first place.[67]

Later cases narrowed *Althen's* holding somewhat, often by drawing on *Daubert*[68] to do so. While *Althen* explicitly held that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Act,[69] later cases clarified the role such evidence, if present, can play. In *Andreu*, the Federal Circuit stated that

> where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. *Althen* makes clear that a claimant's theory of causation must be supported by a "reputable medical or scientific explanation."[70]

The Federal Circuit has also made it clear that expert opinions provided by petitioners in support of a claim must be

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

65. *Id.* at 1280.

66. *See, e.g.*, Globetti v. Sandoz Pharmaceuticals Corp., 111 F. Supp. 2d 1174 (N.D. Ala. 2000).

67. *See* Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) (explaining that petitioners cannot be required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.").

68. Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993).

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

70. Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009) (citation omitted).

"reliable," although there is more than one way to meet this requirement.[71]

The current standard preserves *Althen's* waiver of the requirement of general causation but allows a special master to consider scientific literature submitted by the parties to see whether it supports or detracts from the theory of causation advanced by a petitioner's expert.[72] It also reaffirms the special master's power to require some measure of reliability in support of an expert witness's assertions.[73] This is still a lower hurdle than the requirements of regular courts, but not every assertion by such expert witnesses will meet this standard. Today, these "off-Table" claims constitute the overwhelming majority of NVICP claims.[74] As in other civil forums,[75] most are settled.[76]

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71. *See* Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1325 (Fed. Cir. 2010) ("Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.). *See also* Caves v. Sec'y of Health & Human Servs., No. 07-443V, 2010 WL 5557542, at *11 (Fed. Cl. Nov. 29, 2010) (explaining how the Federal Circuit court approved of a special master using *Daubert's* four factors to weigh the reliability of an expert opinion).

72. *See* Flores v. Sec'y of Health & Human Servs., 115 Fed. Cl. 157, 164 (2014) (stating that a special master can consider medical literature in considering whether a proposed theory is "reputable" but that petitioner is not *required* to offer medical literature), *aff'd*, 586 F. App'x 588 (Fed. Cir. 2014).

73. *See id*. at 167 (citing Federal Circuit precedent that the special master may require "some indica of reliability") (citation omitted).

74. *See* U.S. Gov't Accountability Off., GAO-15-142, Vaccine Injury Compensation: Most Claims Took Multiple Years and Many Were Settled Through Negotiation 20 (2014) ("Overall, since 2009, more than 98 percent of the new claims filed alleged off-table injuries that required the petitioner to prove their injury was caused by the vaccine they received, according to the Office of Special Masters.") [hereinafter GAO].

75. *See e.g.*, Mathias Reimann*, Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard*?, 51 AM. J. COMP. L. 751, 806 n.286 (2003), http://www.jstor.org /stable/3649130 ("It is widely assumed that about 20% of all product liability cases filed are dropped and that 95% of the remaining ones end through settlement.").

76. *See* A. Melissa Houston, U.S. Health Res. & Servs. Admin., Advisory Comm'n on Childhood Vaccines, The National Vaccine Injury Compensation Program (VICP): Division of Vaccine Injury Compensation Update 5 (2014), http://www.hrsa.gov/advisorycommittees/childhoodvaccines/Meetings/20140605/vicpupdate.pdf. *See also* GAO, *supra* note 74, at 1 ("Since 2006, about 80 percent of compensated claims have been resolved through a negotiated settlement.").

B. CASES USED TO CLAIM THAT VACCINES CAUSE AUTISM

An oft-cited source relied upon to assert that the NVICP has compensated children for autism is a paper by a group of activists comprising Mary Holland, a research scholar and the director of the Graduate Legal Skills Program at the New York University School of Law, lawyers Robert Krakow and Lisa Colin, and "independent investigator" (and now fiction author in the anti-vaccine subgenre[77]) Louis Conte.[78] The authors ran searches for NVICP cases looking for both decisions and settlements that included both search terms "brain injury" and "autism" and then followed up by interviewing family members of those compensated.[79] On this basis, they claimed to have found eighty-three cases in which a child was compensated with autism as a vaccine injury.[80] As explained below, their article offers very poor support for the claim that vaccines cause autism.

In addition, VCAC members draw on a small number of NVICP cases that were not expressly mentioned by Holland et al. (usually because they were decided after the date that the article was published).[81] These include, for example, the cases of Emily Lowrie and Ryan Mojabi, who were described by writer David Kirby as having been compensated for autism.[82] Both children were compensated through settlement. The claims in these cases are discussed below, but the long and short of it is that neither child was compensated on the theory that a vaccine caused autism.

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77. Louis Conte, The Autism War: A Novel (Skyhorse Publishing 2014).

78. Mary Holland et al*., Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injur*y, 28 PACE ENVTL. L. REV. 480 (2011) (also providing the descriptions of the authors).

79. *Id.* at 503, 512.

80. *Id.* at 513 n.132.

81. *See e.g.*, Mojabi v. Sec'y of Health & Human Servs., No. 06-227V, 2012 WL 6869685 (Fed. Cl. Dec. 13, 2012). *Cf.* Tembenis v. Sec'y of Health & Human Servs., No. 03-2820V (Fed. Cl. Nov. 29, 2010); Lowrie v. Sec'y of Health & Human Servs., No. 03-1585V (Fed. Cl. Oct. 26, 2012), (sometimes, and generally in this article, identified as "Moller" because Emily's mother adopted a married name over the course of the proceedings).

82. David Kirby, *Vaccine Court Awards Millions to Two Children with Autism*, HUFFINGTON POST (Jan. 14, 2013). http://www.huffingtonpost.com/david-kirby/post2468343_b_2468343.html.

VCAC members also refer to two first-instance court cases from Italy.[83] Those decisions are somewhat beyond this the scope of this Article, since they were not NVICP decisions. Nonetheless, for completeness, they are briefly addressed here. One obvious point is that two decisions by low-level courts in another country offer very weak support for a scientific or legal causation claim in the United States. The need to emphasize those decisions highlights the weakness of the underlying argument, as do claims of a "media blackout"[84] in the United States, which ignores the fact that decisions by low-level foreign courts that do not include citizens of the country in which the media outlet operates are not usually considered to be newsworthy, regardless of country.

More importantly, the evidence of causation in both cases was extremely weak. In the first, a trial court's decision to compensate Valentino Bocca for his autism was overturned by an appeals court in a decision that included a (justifiably) scathing critique[85] of the lower court's reliance on the thoroughly discredited research of former British physician Andrew Wakefield.[86] The decision in Bocca's case was based on the

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83. *See e.g.*, Emily Willingham, C*ourt Rulings Don't Confirm Autism-Vaccine Link*, FORBES (Aug. 9, 2013) https://www.forbes.com/sites/emilywillingham/2013/08/09/court-rulings-dont-confirm-autism-vaccine-link/#76cddab82c88 (detailing how an anti-vaccination article highlighted a court case from Italy to claim that courts had recognized the autism-vaccine link).

84. Joseph Mercola, *Italian Court Reignites MMR Vaccine Debate After Award over Child with Autism*, MERCOLA.COM (June 12, 2012), http://articles.mercola.com/sites/articles/archive/2012/06/25/mmr-vaccine-caused-autism.aspx [https://perma.cc/6PQV-VVBB].

85. Dorit Rubinstein Reiss, *Italian MMR Autism Decision Overturned*, SKEPTICAL RAPTOR'S BLOG (Apr. 2, 2016), http://www.skepticalraptor.com/skepticalraptorblog.php/italian-mmr-autism-decision-overturned [http://perma.cc/E46S-VGFL].

86. Andrew Wakefield's now retracted paper reported on a small (purported) case series of 12 children, many of whom turned out to have been recruited from a litigation effort against vaccine manufacturers based on the theory that vaccines cause autism; this conflict of interest was not disclosed. *See* SETH MNOOKIN, THE PANIC VIRUS: THE TRUE STORY BEHIND THE VACCINE-AUTISM CONTROVERSY 116 (2012) (explaining the history of Wakefield's Lancet paper and the resulting fallout). *See generally* Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 609, 637 (1998), *retracted*. Wakefield was paid for participation in the litigation effort. OFFIT, FALSE PROPHETS, *supra* note 17, at 47 (explaining how the litigation team paid Wakefield $800,000 to support his research). He was later deemed to have committed serious ethical

opinion of a single expert, who relied to a large extent on just this work.[87] Wakefield's study has never been independently replicated and has been countered by numerous other studies in many countries, even before evidence of data manipulation surfaced.[88]

The second Italian decision relied on three causation arguments.[89] The first was a report by GlaxoSmithKline about the results of the clinical trial that mentioned autism in a section that included all reported adverse events that occurred while the trial was taking place, whether caused by vaccines or not (it included, e.g., bone fractures, and clearly vaccines do not break bones).[90] The expert appears to have led the court into error on this point.[91] The expert also claimed that some vaccine ingredients can cause autism—against the evidence.[92] Finally, the expert highlighted the temporal connection between getting the vaccine and the autism diagnosis, although one thing

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violations for, among other things, hiding this relationship. *Wakefield, Fitness to Practise Panel Hearing* (Gen. Med. Council Jan 28, 2010), http://briandeer.com/solved/gmc-charge-sheet.pdf [http://perma.cc/TY7K-Z5L2]; OFFIT, FALSE PROPHETS, *supra* note 17, at 52–53 (detailing the Wakefield hearings).

87. *See Autismo e vaccino trivalente. I pediatri: "Non esiste alcuna correlazione,"* LA STAMPA: SALUTE http://www.lastampa.it/2012/04/26/scienza/benessere/gravidanza-parto-pediatria/autismo-e-vaccino-trivalente-i-pediatri-non-esiste-alcuna-correlazione-vx7BxazujZdcla0ylpWuMI/pagina.html (explaining the Italian Society of Preventive and Social Pediatrics concern with the expert's reliance on Wakefield).

88. OFFIT, FALSE PROPHETS, *supra* note 17, 42–43.

89. *See* Dorit Rubinstein Reiss, *Italian Court Blames Autism on Vaccine—Relies on an Unreliable Expert*, SKEPTICAL RAPTOR'S BLOG (Feb. 3, 2015), http://www.skepticalraptor.com/skepticalraptorblog.php/italian-court-awards-compensation-autism-problem-unreliable-expert [http://perma.cc/2NX4-UC96] (explaining the three causation theories offered by the Italian decision).

90. Vanessa Coremans, GlaxoSmithKline, Combined Diphtheria, Tetanus and Acellular Pertussis, Hepatitis B Enhance Inactivated Poliomyelitis and *Haemophilus influenzae* Type B Vaccine: Infanfrix Hexa Summary Bridging Report 614 (Dec. 16, 2011), https://autismoevaccini.files.wordpress.com/2012/12/vaccin-dc3a9cc3a8s.pdf [http://perma.cc/EP79-2L54] (reporting a forearm and a skull fracture, as well as two joint dislocations).

91. *See* Reiss, *supra* note 89 ("By using the report in this way, the expert misled the court into a problematic decision.").

92. *Id.* (summarizing the expert's second claim that ingredients like thimerosal, aluminum, and polysorbate 80 can cause autism and refuting these claims with numerous other scientific studies).

happening after the other does not, in itself, show causation.[93] Unsurprisingly, the Italian scientific community criticized the decision, and it is under appeal.[94]

In July 2017 the Italian Cour de Cassation—the highest civil court—addressed the issue, ruling out a link between vaccines and autism.[95] Neither of these cases comes close to supporting the claim that vaccines cause autism and higher courts have since renounced the claim.[96]

We thus return to the NVICP cases that are characteristically relied upon by VCAC proponents.[97] As already alluded, they do not support the claim that vaccines cause autism any better than the Italian cases.

II. USING SETTLEMENT AND CONCESSION

Some of the cases used by members of VCAC to incorrectly argue that vaccines cause autism are either settlements—that is the case for the Mojabi and Moller decisions—or concessions based on Table Injuries, which create a presumption of causation.[98] Four of the decisions examined by Holland et al.[99]

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93. *Id.* ("As scientists point out again and again, a temporal connection alone is not evidence of causation.").

94. *See id.* (linking to translated summary of Italian scientific criticism to Judge's decision). *See also* Press Release, Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica et al., Autismo Causato Dai Vaccini? Dalla Comunità Scientifica Arriva un Secco No (Nov. 26, 2014), http://www.acp.it/wp-content/uploads/Quaderni-acp-2015_221_26.pdf [http://perma.cc/59GA-TK77].

95. *See e.g.* The Local, *Italy's Top Court Rules Out Autism Link In Vaccine Case,* THE LOCAL, (Jul. 25, 2017, 3:28 PM), https://www.thelocal.it/20170725/italys-top-court-rules-out-autism-link-in-vaccine-case ("The decision by the Court of Cassation upheld earlier verdicts from lower courts in the Campania city of Salerno, ruling out a link between the vaccine and autism.").

96. Michelle Bocci, *Autismo, Il Giudici Assolvono Il Vaccino,* La Repubblica (March 1, 2015) https://www.repubblica.it/salute/medicina/2015/03/01/news/autismo_i_giudici_assolvono_il_vaccino-108441541/

97. *See e.g.*, Willingham, *supra* note 83 (explaining how an anti-vaccination article relied on NVICP as evidence that Courts have "confirmed" the autism-vaccine link).

98. 42 U.S.C. 300aa-11(c)(1)(C)(i), setting that people with a table injury do not need to show causation, while people without – in subclause (ii) – do. Engstrom, *supra note* 52, at 1661.

99. Holland et al. *supra* note 78, at 511-512 (examining *Doe/77 v. Sec'y of Health & Human Servs.*, 2010 WL 3395654 at *1.) *See also* Underwood v. Sec'y of Dep't of Health & Human Servs., 90-719V, 1991 WL 156659 at *2, 4 (Cl. Ct. July 31, 1991*);* Koston v. Sec'y, Dep't of Health & Human Servs., 974 F.2d 157,

appear to be concessions, including the Hannah Poling case[100] and the Underwood case.[101] Many of the unpublished, unnamed decisions are also settlements.

Most cases that go through NVICP settle.[102] This is no different from other courts.[103] A smaller number of cases are decided by concession. Both settlements and concessions based on Table Injuries are problematic as evidence of causation. There are many possible reasons parties settle.[104] For example, parties may settle because trying the case would be too costly, because they are worried about reputation damage from a trial, even a winning trial, or other possible reasons—and parties tend not to tell us why they settled. In other words, a settlement is not good evidence that a plaintiff's claims had any merit.

In NVICP settlements, Respondent—the government—routinely adds a disclaimer denying causation. Typical language would be: "Respondent denies that the flu vaccine is the cause of petitioner's GBS or any other injury or his current condition."[105]

An information sheet from the Health and Human Resources Administration explains this:

> What reasons might a claim result in a negotiated settlement?
>
> - Prior to a decision by the U.S. Court of Federal Claims, both parties decide to minimize risk of loss through settlement
> - A desire to minimize the time and expense of litigating a case

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161 (Fed. Cir. 1992); Freeman v. Sec'y of Health & Human Servs, 2003 U.S. Claims LEXIS 285 at *7 (Fed. Cl. Sept. 25, 2003)).

100. 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." *Doe/77*, 2010 WL at *1 (Fed. Cl. July 21, 2010).

101. Underwood v. Sec'y of Dep't of Health & Human Servs., 90-719V, 1991 WL 156659 at *2, 4 (Cl. Ct. July 31, 1991) ("On January 7, 1991, respondent filed a report ("HHS Report") in this case conceding that petitioner had satisfied her burden of showing a presumptively vaccine-related residual seizure disorder. However, respondent did not concede that Travis suffered a vaccine-related encephalopathy.").

102. GAO, *supra* note 74, at 1 ("Since 2006, about 80% of compensated claims have been resolved through a negotiated settlement.").

103. *See e.g.*, Reimann, *supra* note 75 ("It is widely assumed that about 20 % of all product liability cases filed are dropped and that 95 % of the remaining ones end through settlement.").

104. *See* Health Resources and Services Administration, *Vaccine Injury Compensation Data,* 1 (Aug. 1, 2017), https://www.hrsa.gov/vaccinecompensation/data/ (listing potential reasons parties may settle).

105. Kelly v. Secretary of Health & Human Services, No. 15-167V, 2015 WL 9271599 (Fed. Cl. 2015).

- The need to resolve a case quickly [106]

In light of this, it is clear that using a settlement to show causation of any kind is simply incorrect.

Concessions are closer since they are an admission that the petitioner's claims do meet the statutory standard. It's important to remember, however, how low that standard is. For Table Injuries, all a concession means is that the government accepts that the petitioner showed that more likely than not a Table Injury happened within the relevant time period and it's not worth rebutting the presumption. This is especially problematic since some of the injuries on the Table are out of date: the evidence no longer supports a causal connection between the injury and the vaccines.[107] For a non-Table Injury, it means that the government concedes that the petitioner provided enough evidence to conclude that he or she can show that more likely than not there is a medical theory connecting vaccine and injury, a logical sequence between vaccine and injury, and a showing of a temporal relationship between the vaccine and the injury.[108]

For comparison, in a case addressing harm from a product in the civil court, the plaintiff would have to provide scientific evidence from which an inference can be drawn that the product could cause the health effects in question (general causation) and then that exposure to the product was the cause of this injury (specific causation).[109] The *Althen* standard applied to vaccine injuries in essence waives the requirement of general causation, instead just requiring a medical theory of causation, not even one that is strongly supported by science (and when you add to that the fact that the special masters are not required to apply *Daubert* standards, and usually do not, the requirement is even less exacting). In a concession, the evidence has not even been tested by a third party to see if it meets this lenient standard; the government is basically agreeing that the petitioner has a decent chance to meet it.

The settlements and concessions in question are especially problematic as evidence that vaccines caused a child's autism even beyond the fact that they are not good evidence of

106. Health Resources and Services Administration, *supra* note 104, at 1.

107. *See infra*, Part III, Subsection B further discussion.

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

109. Joseph Sanders, From Science to Evidence: The Testimony on Causation in the Bendectin Cases, 46 STAN. L. REV. 1, 14 (1993).

causation. First, we will address the settlement that has been used as evidence that vaccines cause autism by anti-vaccine websites: Ryan Mojabi's.

In Ryan Mojabi's case, his parents, the petitioners, claimed that as a result of "all the vaccinations administered to [Ryan] from March 25, 2003, through February 22, 2005, and more specifically, measles-mumps-rubella (MMR) vaccinations administered to him on December 19, 2003 and May 10, 2004," Ryan suffered "a severe and debilitating injury to his brain, described as Autism Spectrum Disorder ('ASD')."[110] Petitioners specifically asserted that Ryan "suffered a Vaccine Table Injury, namely, an encephalopathy."[111] In the alternative, petitioners asserted that "as a cumulative result of his receipt of each and every vaccination between March 25, 2003 and February 22, 2005, Ryan has suffered . . . neuroimmunologically mediated dysfunctions in the form of asthma and ASD."[112]

Petitioners are therefore claiming ASD, but not only ASD. And their ASD claim is not why the money was awarded. Compensation was awarded on the government's concession that: "it was respondent's view that Ryan suffered a Table Injury under the Vaccine Act—namely, an encephalitis within five to fifteen days following receipt of the December 19, 2003 MMR vaccine, see 42 C.F.R., § 100.3(a)(III)(B), and that this case is appropriate for compensation under the terms of the Vaccine Program."[113] In fact, in a later decision the court clarified which injury had been compensated:

> Petitioners have requested that three documents be removed from the USCFC website... Petitioners have made these requests because they have had the misfortune of being frequently contacted by members of the media who mistakenly believe they were compensated for their alternative autism allegation when Petitioners were actually compensated for a Table Injury encephalopathy.[114]

Not only was Ryan's compensation awarded for something other than autism, he did not exhibit ASD behaviors in CHAT

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110. Mojabi v. Sec'y of Health and Human Services, UNPUBLISHED No. 06-227V, 2012 WL 6869685 at *1 (Fed. Cl. 2012).

111. Id.

112. *Id.* at 1-2.

113. *Id.* at 2.

114. Mojabi v. Sec'y of Health & Human Servs., 06-227V, 2013 WL 6916777, at *5 (Fed. Cl. Nov. 27, 2013).

screenings.[115] Clearly, to cite this decision as evidence that vaccines cause autism is simply wrong.

Nor was Emily Moller, the second case mentioned in the article addressing Ryan Mojabi's case, compensated for autism. She, too, was compensated for encephalopathy.[116] This case also involved a Table Injury, where causation is presumed and does not have to be shown.

Holland et. al. state clearly that the settled cases they found were not compensated for autism. Under their section discussing settled cases they explain, "[t]he authors identified compensated cases of brain injuries that they believed might include autism diagnoses."[117] So not only were these cases settled, with no show of causation required—they were not about autism. Not only that, but looking at other settlements demonstrates that the government often denies causation in cases it has settled, which essentially nullifies a case's evidentiary value for this purpose.

The concessions mentioned by Holland et al. are also not of much help to the authors, as none supports a link between vaccines and autism. Four cases they list mention the word "conceded."[118] Three of those were related to seizures.[119] Two conceded a seizure disorder;[120] and one of those two stated explicitly that the secretary was not conceding an encephalopathy, or brain disorder.[121] A third case states, "[t]he

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115. Mojabi v. Sec'y of Health & Human Servs., 06-227V, 2009 WL 3288324, at *11 n.19 (Fed. Cl. Apr. 29, 2009). CHAT is the "Checklist for Autism in Toddlers," a psychological questionnaire designed to evaluate risk for ASD in young people. *See* LEARN ABOUT M-CHAT, https://m-chat.org/ (last visited Feb. 29, 2019).

116. Lowrie v. Sec'y of Health & Human Servs., 08-108V, 2012 WL 5853026, at *11 (Fed. Cl. Oct. 26, 2012). While the name of the parties in the case is Lowrie, the first name and fact description match the case described in a newspaper article as Emily Moller, and it's the only matching case found. *See* David Kirby, *Vaccine Court Awards Millions to Two Children with Autism*, HUFFINGTON POST (Jan. 14, 2013), http://www.huffingtonpost.com/david-kirby/post2468343_b_2468343.html.

117. Holland et al., *supra* note 78, at 512.

118. Holland et al., *supra* note 78, at 511.

119. The fourth, Hannah Poling's case, will be discussed separately in the next section.

120. Koston v. Sec'y, Dep't of Health & Human Servs., 974 F.2d 157, 161 (Fed. Cir. 1992); Underwood, 1991 WL 156659 at *1.

121. Underwood, 1991 WL 156659 at *1 (finding that "[o]n January 7, 1991, respondent filed a report ('HHS Report') in this case conceding that petitioner had satisfied her burden of showing a presumptively vaccine-related residual

Secretary conceded that the vaccination was the likely cause of the child's first seizure, but that such seizure had no lasting effect and the child's subsequent conditions were caused by a pre-existing brain abnormality."[122]

Seizure disorder, as will be discussed more in detail below,[123] is not autism, although the same child may have both. Since two of the cases concede only seizure disorder those concessions do not support a link to autism. Further, as will be discussed in the next sections, the authors' attempt to equate any encephalopathy with autism is incorrect. The third case concedes causation only for a single seizure, and ascribes another cause—a preexisting abnormality—for subsequent seizures.

Was autism also mentioned in these cases? In *Koston* the Secretary initially conceded a residual seizure disorder with no cause, and then apparently attempted to withdraw that concession and claim that the seizures were caused by Rett Syndrome (a genetic disorder that is included in the autism spectrum) and not the vaccine.[124] The child was in fact diagnosed with Rett Syndrome.[125] But the Special Master rejected the Secretary's claim that the seizures were caused by Rett Syndrome and compensated the child based on the initial concession that the seizures were caused by the DTP vaccine. In other words, the autism-related claim was brought to argue against compensation – and rejected. On appeal, the Federal Circuit Court of Appeals based compensation on different grounds: it found that Rett Syndrome is of "idiopathic origin," because a genetic cause was not known.[126] Under the act, an injury of idiopathic origin does not rebut the presumption of causation that a Table Injury creates.[127] In 1992, when *Koston* was decided, Rett syndrome could be seen as of idiopathic origin

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seizure disorder. However, respondent did not concede that Travis suffered a vaccine-related encephalopathy.").

122. Freeman, 2003 U.S. CLAIMS LEXIS 285 at *7.

123. *See infra* Part III.A.2.

124. *Koston,* 974 F.2d at 159.

125. *Id.* at 160.

126. Id.

127. Vaccine Injury Table, 42 U.S.C. 300aa-13(a)(2) (1944).

because the genetic basis for Rett Syndrome was discovered in 1999.[128]

Using *Koston* to claim that a child was compensated for ASD is simply incorrect. Holland et al. published their article in 2011, nineteen years after *Koston* was decided, and at a time when the genetic origins of the syndrome were well known. If the origin of the seizures was, in fact, Rett Syndrome, as the Federal Circuit Court of Appeals seemed to think, then the problem was genetic and not caused by the vaccine at all. But even if the seizures were not caused by Rett Syndrome, this case is still not about autism; the compensation was for a seizure disorder; not for ASD.[129]

In *Freeman*, a child was compensated for harm caused by seizure disorder. Both the petitioner's experts and the government's expert agreed that the child's initial prolonged febrile seizure was caused by the MMR vaccine.[130] There was, however, disagreement as to whether the child's seizure disorder or the child's brain damage, resulted from MMR—and there were competing experts on that question. The court highlighted that the question of causation was close in this case: "Although the question is a very close one, concerning which reasonable minds can differ, I find Dr. Kinsbourne's approach to be slightly more persuasive."[131]

What did the case say about autism? Footnote 7 states:

> 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." (Tr. 103-108.) 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. Kinsbourne explained, Kienan's autistic-type

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128. *The History of Rett Syndrome*, RETTSYNDROME.ORG, (Aug. 23, 2017, 5:41 PM), https://www.rettsyndrome.org/document.doc?id=159.

129. *See infra* Part III.A.2 for discussion of seizure disorders and the evidence on whether vaccines cause them.

130. Freeman, 2003 U.S. CLAIMS LEXIS, at *3. Research shows that febrile seizures, caused by fever, are in fact a potential side effect of MMR. *See, e.g.,* Nicola P. Klein et al., *Safety of Measles-Containing Vaccines in 1-Year-Old Children*, 135 PEDIATRICS 321, 327 (2015). Short febrile seizures, although frightening to parents, are usually harmless, but prolonged one can rarely be an issue. *See* FEBRILE SEIZURES FACT SHEET, NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, (2018), https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Febrile-Seizures-Fact-Sheet.

131. Freeman, 2003 U.S. CLAIMS LEXIS 285, at *2.

> features seem to be a result of the brain damage that caused his severe mental retardation. (Tr. 9, 21-22.) As Dr. Kinsbourne further explained, brain damage is one of the many possible causes of autism.[132]

That is the only mention of autism in the case, and it is there to highlight that the case was not being compensated for ASD. In other words, there is no official diagnosis of ASD in the case—and the Special Master highlighted that the basis of the compensation was Kienan's initial prolonged febrile seizure,[133] which may have led to the subsequent brain damage. Again, using this case as an example to suggest NVICP compensated children for autism is incorrect.

In *Underwood*, the concession was about seizure disorder and not encephalopathy. The court did find that the vaccine caused encephalopathy, but went on to say:

> According to Dr. Schultz, further support for his belief that Travis does not suffer from true autism is found in another article that respondent submitted to support its position. This article describes autistic-like behavior in people suffering from acquired epileptic aphasia. R.Ex. G at 204. Dr. Schultz believes that Travis' encephalopathy resulted in such acquired epileptic aphasia, signified by the spike discharges in the left temporal lobe of his brain evident on the 1980 EEG, which accounts for his resulting loss of speech. Moreover, the same article reports that encephalopathic illnesses can result in autistic-like syndromes.[134]

The child was not diagnosed with autism and, in fact, a full diagnosis of autism was rejected; instead, the child's encephalopathy was found to lead to having some autistic-like behaviors.[135]

A. THE HANNAH POLING CONCESSION

One of the cases most commonly brought up by members of the VCAC[136] is the Hannah Poling case,[137] on the (correct)

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132. *Id.* at *26 n.7.

133. *Id.* at *22-23.

134. Underwood, 1991WL 156659, at *3.

135. *See infra* Table 1 for a discussion of the distinction between autistic-like features and autism.

136. Dan Olmsted, *Age of Autism: Weekly Rap,* AGE OF AUTISM, (Aug. 23, 2017, 5:45 PM), http://www.ageofautism.com/2015/02/age-of-autism-weekly-wrap-beginning-to-see-the-light.html; Sharyl Attkisson, *CDC: "Possibility" That Vaccines Rarely Trigger Autism,* SHARYL LATTKISSON, (Aug. 23, 2017, 5:48 PM), http://sharylattkisson.com/cdc-possibility-that-vaccines-rarely-trigger-autism/. (both last accessed August 29, 2017).

137. Doe/77, 2010 WL 3395654 at *1.

assumption that this case comes closest to what VCAC is looking for and is the case most easily presented as the compensation of a child for autism caused by vaccines. In addition to its constant use in other contexts, Holland et. al devote a separate section to the Poling case.[138] Using the Poling concession as evidence that vaccines cause autism, however, is extremely problematic—even putting aside the fact that the concession stands alone, with no similar cases: it's very much *sui generis*.

What happened in that case? As an infant, Hannah Poling was apparently healthy, active and developing well in her infancy, except for recurring ear infections:

> At seven months of age, CHILD was diagnosed with bilateral otitis media. Pet. Ex. 31 at 20. In the subsequent months between July 1999 and January 2000, she had frequent bouts of otitis media, which doctors treated with multiple antibiotics. Pet. Ex. 2 at 4. On December 3, 1999, CHILD was seen by Karl Diehn, M.D., at Ear, Nose, and Throat Associates of the Greater Baltimore Medical Center ("ENT Associates"). Pet. Ex. 31 at 44. Dr. Diehn recommend [sic] that CHILD receive PE tubes for her "recurrent otitis media and serious otitis." Id. CHILD received PE tubes in January 2000. Pet. Ex. 24 at 7. Due to CHILD's otitis media, her mother did not allow CHILD to receive the standard 12 and 15-month childhood immunizations. Pet. Ex. 2 at 4.[139]

At nineteen months, Hannah came in for a well-baby check, was found healthy and active, and was given five vaccines: "diphtheria–tetanus–acellular pertussis, Haemophilus influenzae type b (Hib), MMR, varicella, and inactivated polio."[140] Dr. Offit describes what happened next:

> At the time, Hannah was interactive, playful, and communicative. Two days later, she was lethargic, irritable, and febrile. Ten days after vaccination, she developed a rash consistent with vaccine-induced varicella.
>
> Months later, with delays in neurologic and psychological development, Hannah was diagnosed with encephalopathy caused by a mitochondrial enzyme deficit. Hannah's signs included problems with language, communication, and behavior — all features of autism spectrum disorder.[141]

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138. Holland et al., *supra* note 78, at 500-503.

139. *See* Daivd Gorski, *The Hannah Poling Case: Autism Rebranded Again*, SCIENCE BLOGS, http://scienceblogs.com/insolence/2008/03/10/the-hannah-poling-case-and-the-rebrandin/ (Last accessed on August 29, 2017).

140. Paul A. Offit, *Vaccines and Autism Revisited—The Hannah Poling Case*, 358 NEW ENG. J. MED. 2089 (2008).

141. *Id.*

Unsurprisingly, Hannah's parents blamed the vaccines she received and filed a claim with NVICP.[142] At the time, Hannah's case was included in the Autism Omnibus Proceeding;[143] later, for unknown reasons, it was pulled out and the government conceded it separately. The decision explains that:

> 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.[144]

The concession document leaked and cited in articles used by members of the VCAC said:

> In sum, DVIC has 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.[145]

Members of VCAC believe this concession is an admission by the government that vaccines cause autism.[146] Is it?

B. POLING DOES NOT SHOW VACCINES CAUSE AUTISM FROM A SCIENTIFIC PERSPECTIVE

> As highlighted by several scientists, the Hannah Poling case does not show that vaccines cause autism generally.[147] The evidence pointed to a preexisting mitochondrial disorder caused by a mutation in a specific gene.[148] Mutations in this specific gene "are very rare . . . [t]he gene plays a pivotal role in protein production, so any mutation that damages this function could have a huge impact on

142. Id.

143. *See infra* Part IV.

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

145. David Gorski, *The Hannah Poling Case: Autism Rebranded Again,* SCIENCEBLOGS (Mar. 10, 2008), http://scienceblogs.com/insolence/2008/03/10/the-hannah-poling-case-and-the-rebrandin/ (quoting the government's concession document).

146. *See, e.g.*, David Kirby, *David Kirby: Hannah Poling Really Did Change Everything,* AGE OF AUTISM, (June 18, 2008, 4:27 PM), https://www.ageofautism.com/2008/06/hannah-poling-r.html (referring to government's claim that Hannah Poling did not have autism: "[W]e were falsely told: She just had "autism like features."); *see also* Kim Stagliano, *Age of Autism Awards 2008 Child of the Year: Hannah Poling,* AGE OF AUTISM (Dec. 27, 2008, 5:45 AM), http://www.ageofautism.com/2008/12/age-of-autism-aware-2008-child-of-the-year-hannah-poling.html.

147. *See, e.g.*, Gorski, *supra* note 146.

148. *Id.*

> other mitochondrial genes and energy production by cells."[149] Mitochondrial disorders generally are rare (while higher among children with autism, the rate is still very low),[150] and the subset that is linked to "autism-like symptoms is even more rare."[151]

Children with this problem can regress between their first and second year,[152] and any stress—a disease, a vaccine, or something else—can cause such regression.[153] In Hannah's case, Dr. Offit points out,

> [A]lthough experts testifying on behalf of the Polings could reasonably argue that development of fever and a varicella-vaccine rash after the administration of nine vaccines was enough to stress a child with mitochondrial enzyme deficiency, Hannah had other immunologic challenges that were not related to vaccines. She had frequent episodes of fever and otitis media, eventually necessitating placement of bilateral polyethylene tubes.[154]

In other words, it could have been the vaccines that caused the regression—or it could *not* have been. It is not even clear that vaccines can cause such regression.[155] The United Mitochondrial Disease Foundation said, in a statement:

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149. Andy Coghlin, *Can Autism Be a Mitochondrial Disease?*, Sidebar to Jim Giles, *Autism Payout Reignites Vaccine Controversy*, NEW SCIENTIST (Mar. 5, 2008), http://www.newscientist.com/article/mg19726464.100-autism-payout-reignites-vaccine-controversy.html [http://perma.cc/FW8T-78VE] (paraphrasing Columbia University neurology professor Salvatore DiMauro).

150. *See* Gorski, *supra* note 146("[I]t has indeed been noted that mitochondrial diseases may be more prevalent in children with autism or ASDs. . .").

151. Id.

152. See Kim. M. Cecil et. al., Mitochondrial Encephalopathies: Potential Relationships to Autism?, NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE (June 29, 2008), (citing Joseph L. Edmonds et al., The Otolaryngological Manifestations of Mitochondrial Disease and the Risk of Neurodegeneration with Infection, 128 ARCHIVES OF OTOLARYNGOLOGY—HEAD & NECK SURGERY, 355–62 (2002), http://wayback.archive-it.org/1170/20161005013715/https://www.ninds.nih.gov/news_and_events/proceedings/20090629_mitochondrial.htm [https://perma.cc/T3NQ-T5US] ("One study in young children definitively diagnosed with mitochondrial disease found that 60% showed an episodic disease course. In 72% of those cases, deterioration was associated with a naturally acquired infection.").

153. *See* Jim Giles, *Autism Payout Reignites Vaccine Controversy*, NEW SCIENTIST (Mar. 5, 2008), http://www.newscientist.com/article/mg19726464.100-autism-payout-reignites-vaccine-controversy.html?page=2#.VF1YvkthlpE.

154. Offit, *supra* note 140, at 2090.

155. *See id. See also* Cecil et al., *supra* note 153 ("To reduce the risk presented by acquired infections, the workshop panelists strongly encourage vaccinations in the hundreds of children they treat for mitochondrial disease.

> There are no scientific studies documenting that childhood vaccinations cause mitochondrial diseases or worsen mitochondrial disease symptoms. In the absence of scientific evidence, the UMDF cannot confirm any association between mitochondrial diseases and vaccines.[156]

Because a fever, or similar stress, can trigger a regression, the CDC emphasizes the importance of protecting children with mitochondrial problems against the preventable diseases that are such a high risk for them:

> At present, we do not know definitively if vaccines can trigger neurological or developmental declines among children with mitochondrial disorders. We do know, however, that infections can cause neurological and developmental declines among these children—and we also know that childhood vaccinations protect children against some of the same infections known to cause developmental decline among children with mitochondrial disorders. These include vaccine-preventable diseases like measles, chickenpox, and influenza.[157]

In a real sense, declining vaccination rates, the result of unfounded fears about vaccines, put these children more at risk than others.[158] The last thing they need is for preventable diseases to reemerge.

Since the Hannah Poling case, it has become fashionable among the VCAC to claim that a child's autism was due to a preexisting mitochondrial defect triggered or aggravated by

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Among thousands of patients they had collectively seen, very few had deteriorated following vaccination, and in those few cases, it is difficult to determine that other stressors besides the vaccine did not play a role in the neurologic deterioration. In addition to febrile illnesses, other potential precipitating factors noted by the panelists included dehydration, reduced caloric intake, and in some cases, exercise. The exact mechanisms that lead to deterioration after these triggers are not well understood, nor is it known why some individuals recover function after deterioration while others are irreversibly impaired.").

156. *Facts for Parents About Autism and Vaccine Safety,* AM. ACAD. PEDIATRICS, (Mar. 2008), https://www.childhealthspecialists.com/images/docs/autismfactsforparents.pdf (citing *The UMDF Scientific and Medical Advisory Board Statement on the Connection Between Mitochondrial Disease and Autism,* UNITED MITOCHONDRIAL DISEASE FOUND., (Apr. 29, 2008)).

157. *CDC Responds to Questions About Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Mar. 28, 2008), https://web.archive.org/web/20150906034734/http://www.cdc.gov/news/2008/03/VaccineQuestions.html.

158. *See, e.g.*, S.L., *This Whole Mito Thing (My Final Vent , , . Hopefully!)*, LEFT BRAIN/RIGHT BRAIN (Feb. 29, 2008), http://leftbrainrightbrain.co.uk/2008/02/29/this-whole-mito-thing-my-final-venthopefully/ [http://perma.cc/452X-FC9F].

vaccines.[159] But that, too, is problematic. As mentioned, there is some evidence that mitochondrial disorders are more common among children with ASD than among the general population.[160] A few things are important to note, however. This is still a small minority of children with ASD. And as noted above, the type of mitochondrial problem Hannah Poling had is rarer still, in fact, extraordinarily rare, very severe, and genetic: not all mitochondrial disorders are the same.[161] Further, as neurologist Steven Novella pointed out, it is not at all clear whether there is a causal connection between mitochondrial disorders and ASD or if similar initial problems cause both.[162] And further, it is unclear whether vaccines actually cause regression in children with mitochondrial problems, and it is very clear that the diseases we vaccinate against are very dangerous to those children—which is a good reason to vaccinate them.[163] If those children are not vaccinated, they more than anyone else need the protection of herd immunity, because of the harm vaccine preventable disease can cause them; those promoting inaccurate, misleading claims that lead to fewer children being vaccinated and to a reduction of herd immunity are directly putting those children at risk.

From the other direction, not all ASD cases are cases of regression. A relatively small subset are,[164] and as pointed by Michael Fitzpatrick, in many of those cases it is possible in

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159. *See, e.g.*, Megan Brooks, *Molecular Psychiatry Medscape: Mitochondrial Dysfunction Linked to Autism,* AGE OF AUTISM, (Jan. 31, 2011), http://www.ageofautism.com/2011/02/molecular-psychiatry-medscape-mitochondrial-dysfunction-linked-to-autism.html; *see also* David Gorski, *The New Strategy of the Antivaccination Movement: Autism is a "Misdiagnosis" for Mitochondrial Disease*, SCIENCEBLOGS, (Mar. 6, 2008), http://scienceblogs.com/insolence/2008/03/06/the-new-strategy-of-the-antivaccination/.

160. *See* G. Oliveira et al., *Mitochondrial Dysfunction in Autism Spectrum Disorders: A Population-Based Study*, 47 DEVELOPMENTAL MED. & CHILD NEUROLOGY 185 (2005), http://dx.doi.org/10.1017/S0012162205000332 (stating that "[f]ive of 11 patients studied were classified with definite mitochondrial respiratory chain disorder, suggesting that this might be one of the most common disorders associated with autism (5 of 69; 7.2%) and warranting further investigation.").

161. *See* Gorski, *supra* note 146.

162. *Id.*

163. *See* S.L., *supra* note 159.

164. *See* MICHAEL FITZPATRICK, MMR AND AUTISM: WHAT PARENTS NEED TO KNOW 61 (2004).

retrospect to recognize problems that were not identified by parents or professionals.[165]

C. POLING DOES NOT SHOW THAT VACCINES CAUSE AUTISM FROM A LEGAL PERSPECTIVE

The Government decided to concede that there was enough evidence that the vaccines aggravated an encephalopathy, a Table Injury, in the time required.[166] To reiterate, the problem was already there, and the child was predisposed to regress, but because it was a Table Injury and it was possible that it was the vaccines that caused the aggravation, the presumption of causation came into play.[167] The government was not willing to try to prove it was not the vaccines because the legal standard for compensation was met. [168] This was an appropriate case to compensate a vaccine injury, but not strong proof of causation.[169]

Furthermore, later cases do not support the use members of VCAC make of the Poling concession. The more recent Holt case, examining the scientific literature, concluded that the literature did not support a connection between vaccination and mitochondrial disease—even when the vaccine led to a fever.[170] Even under the more lax *Althen* standard, the court found the claim of a connection between vaccines and developmental

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165. Id.

166. *See* Gorski, *supra* note 146 (citation omitted) ("VCIP . . . was created in response to fears that vaccine manufacturers would abandon the vaccine business due to liability concerns (a legitimate fear) and . . . designed to compensate *any* injury that could be attributed to vaccines, with a standard of evidence that is a *legal*, not a scientific standard that's been likened to '50% and a feather.'").

167. See id.

168. *See id.* ("[T]he government decided that the temporal course of vaccination and regression was close enough that under the law 'compensation is justified.'").

169. *See id.* (stating that the government's concession in the Poling case "*doesn't* mean, contrary to all the P.R . . . . that the government has conceded that vaccines cause autism.").

170. *See* Holt, 2015 WL 4381588 at *30 (Fed. Cl. June 24, 2015) ("Even the support for vaccination accompanied by a fever as an aggravating event was scant.").

delays due to mitochondrial disease unsupported.[171] And with no fever, the Special Master expressly rejected such a connection.[172]

In *Paluck v. Secretary of Health and Human Services*, the Federal Circuit Court of Appeals examined another case including a mitochondrial disorder and affirmed that the petitioner had met his burden to show a causation theory and that the Special Master had been wrong to reject the case.[173] But there are several important differences between that case and Holt. First, in *Paluck* the government conceded that the treating doctor had a plausible causation theory; this was accepted by the Court of Appeals.[174] What was contested was the application of the doctor's theory to the case itself,[175] the main question being whether, in order to be applicable, the theory required that the problems appear within a specific time period; the court decided that it did not.[176] There was, therefore, no judicial finding that mitochondrial disorders contribute to vulnerability to vaccine injury—it was accepted as given on the strength of the parties' agreement.[177] Furthermore, the problem in that case was not autism; the child in question had gross motor delays before the vaccines and ended up essentially paralyzed.[178] These were not

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171. *See id.* at 80 ("Unfortunately, this case does not present the "close call" in which the balance of the evidence might be tipped toward petitioner.")

172. *See id.* at 79. The Special Master also rejected many of the parents' factual claims in that case, but that is beyond the scope of this paper.

173. *See* Paluck v. Sec'y of Health & Human Servs., 786 F.3d 1373, 1386 (Fed. Cir. May 20, 2015) ("The Palucks' burden was to show, by a preponderance of the evidence, that K.P.'s mitochondrial disorder was significantly aggravated by the vaccines he received, not to rule out every other potential cause of his injury.").

174. *See id.* at 1380 ("[B]efore the special master the government conceded that vaccination could have, in theory, exacerbated K.P.'s underlying mitochondrial disorder.").

175. *See id.* ("The government contends, however, that the Court of Federal Claims erred in setting aside the special master's finding that K.P.'s health did not deteriorate as quickly or as consistently as anticipated by Frye's medical theory.").

176. *See Id.* at 1384 ("The Shoffner article, the Edmonds article, and the Poling case study—which collectively discuss only a very small number of patients—do not purport to establish any definitive timeframe for the onset of clinical symptoms of neurological regression in individuals afflicted with mitochondrial disorders.").

177. *See id.* at 1385 ("Thus, the Palucks were entitled to rely on the statements from K.P.'s physicians that his condition could be due to a 'toxic . . . event' as evidence supporting a causal nexus between K.P.'s vaccinations and his subsequent neurological regression.").

178. *See id.* at 1375.

the only problems, but this is a case that is tragic, terrible—and not autism or autism related.[179] It was also clear that the problems predated the vaccination, though on the strength of the government concession the court found that the case met the standard for compensation for aggravating the problems.[180]

In the later Hardy decision, the Special Master explained:

> In all those cases, there also has been a lack of persuasive evidence that even genuine mitochondrial disorders are of any relevance—i.e., as in this case, a lack of any persuasive evidence that the existence of a true mitochondrial disorder can make a child more susceptible to the causation or aggravation of an ASD by vaccination.
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> . . . [I]n no case presented to me, nor in any of the cases cited above, has there been presented any persuasive evidence that even in a child with an actual mitochondrial disorder, vaccines can cause or aggravate that child's ASD.[181]

In other words, the most recent word from NVICP is that the evidence does not support a causal connection between mitochondrial disease and vaccine injuries, and more particularly, does not support the claim that mitochondrial disorders make it more likely that vaccines will cause ASD in a child. The role of the presumption of causation was also pointed out in *Holt*.[182]

The Poling case is the closest to compensation for autism available to the members of the VCAC, and it is not quite there. It is also unique: there has only been one case like it. As support for the vaccines-cause-autism link, even ignoring the abundant science going the other way, Hannah Poling's case is insufficient.

III. USING CASES AGAINST THEIR FACTS

Rulings by the Special Masters are not quite court decisions, and they are not treated as such by the higher courts, which apply different standards of assessment to the Special Master's decisions.[183] Discretionary decisions are evaluated using the

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179. *See id*.

180. *See id*. at 1377-80.

181. Hardy, 2015 WL 7732603 at *35.

182. *See* Holt, 2015 WL 4381588 at *27 ("Even though the Poling claim was compensated, a published decision in the case indicates that compensation was based on the presence of a Table injury, in which entitlement to compensation is legally presumed.") (citation omitted).

183. *See* Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992) ("Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the

same standard for abuse of discretion that is used by appellate courts to assess the decisions of trial courts,[184] but factual determinations are held to the "arbitrary and capricious" standard usually used to evaluate agency decisions.[185] Nonetheless, they are fact-based decisions, and as such, cannot be used against their facts.

It is, in fact, probably unethical for a lawyer to use a case against its facts, at least not without alerting the court clearly to the discrepancy between what is said and what is in the case. One source states that a member of the bar: "Shall not intentionally misquote to a tribunal the language of a book, statute, or decision . . . ."[186]

This provision does not, of course, address authors of an article and certainly not lay commentators in other forums, but it highlights that using a case against its facts, without clearly stating that this is being done and explaining the choice, is problematic.

The facts as found in the case determine the boundaries of what the case means. While there is room to maneuver here—you can present the facts more or less broadly—you cannot completely ignore the finding of facts by a judge and still use the case to support a factual claim, and you certainly cannot misrepresent them. If you do either, you will be called out. Those calling you out will be in the right.

Using cases against their facts is exactly what the Holland et al. article does.[187] The cases it points to as suggesting that NVICP has been compensating autism cases under another name are not that at all; they are cases where compensation was for something other than autism. In some cases, an autism claim was expressly rejected.

Further, the question they raised as unanswered—whether autism is just another name for encephalopathy or seizure

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abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.").

184. *See, e.g.*, Milmark Servs. v. U.S., 731 F.2d 855, 860 (Fed. Cir. 1984) ("Since the admissibility of expert testimony is within the discretion of the trial judge, this action is to be sustained unless manifestly erroneous.").

185. Munn, 970 F.2d at 870 n.10.

186. MODEL RULES OF PROF'L CONDUCT r. 3.1 (AM. BAR ASS'N 2013); CAL. RULES OF PROF'L CONDUCT 5-200: Trial Conduct (C).

187. Holland et. al, *supra* note 78, at 511.

disorder[188]—is not an open question for doctors. As explained below, there is an answer, and the answer is a clear no. This too highlights the fact that cases compensated for encephalopathy or encephalitis or seizure disorder, especially the latter, are quite distinct from cases actually compensated for autism. I've already addressed some of these cases in the section that examines concessions. This section will focus on the others.

Appendix A presents the cases discussed in Holland et al. in detail, adding the cases of Ryan Mojabi and Elias Tembenis. None of these cases compensated a child for autism, nor do they, in actuality, call into question the scientific consensus that vaccines do not cause ASD.

The vast majority of decided cases provided by Holland et al. were compensated for under either encephalopathy or seizure disorder distinctions. There are two parts to the problem with use of encephalopathy and seizure disorder in the article. First, encephalopathy isn't autism, though a single child might have both. The Table Injury of encephalopathy is not an indication that the government acknowledges that vaccines can cause autism. Second, the evidence doesn't support a causal connection between vaccines and seizure disorder or encephalopathy or encephalitis. The Table of Injuries has already been changed to remove seizure disorder and should be changed to remove the presumption of causation for encephalopathy or encephalitis too.

A. ENCEPHALOPATHY AND SEIZURE DISORDER ARE NOT AUTISM

1. Encephalopathy

Holland et al. suggest that there is no difference between acute encephalopathy as described in the Table of injuries and autism as defined in the DSM-IV.[189] This is problematic.

The Table of Injuries includes encephalopathy or encephalitis within 72 hours of pertussis-containing vaccines and within 5-15 days of measles-containing vaccines.[190] To qualify, for the purpose of the Table of Injuries the petitioner has

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188. *Id.* at 528.

189. Holland et al., *supra* note 78, at 495.

190. Hardy, 2015 WL 7732603 at *24–25. The Table has since been changed, but the definition discussed here is the one that applied to the cases in question. The new definition includes limits on what can be an encephalopathy. Under the new definition, at least some of the cases and settlements may have ended differently.

to meet a narrow definition of acute encephalopathy, outlined below, and also have chronic encephalopathy for more than six months.[191]

The definition of acute encephalopathy for the purpose of the Table of Injuries is age dependent. In a child under eighteen months, there must be "a significantly decreased level of consciousness lasting for at least 24 hours."[192] Children who also had a seizure have to meet additional criteria.[193] An older child or adult needs to have two out of three 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.[194]

In addition, the acute encephalopathy must be "sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)."[195]

The authors seize onto the idea of "a significantly decreased level of consciousness."

> 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:
>
> (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).[196]

They suggest this is similar to autism. Specifically, they suggest that what they see as regressive autism is the same as these symptoms. There are a number of problems with that claim.

An altered state of consciousness is merely a symptom that is common to many different disease processes, including encephalopathy. Although there may be some overlap in features of certain conditions, to distinguish between different

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191. *Id.* at 25.
192. *Id.*
193. *Id.*
194. Holland et al., *supra* note 78, at 534.
195. *Id.*
196. *Id.* at 535 (citation omitted).

diseases, one must explore many other features beyond a few select symptoms. For a doctor, just as it is easy to distinguish a clubfoot from a broken ankle, it is easy to distinguish autism from encephalopathy.

First, even within the altered conscious state, it is possible to distinguish between autism and encephalopathy. Note that in a child over eighteen months, altered consciousness alone does not meet the diagnostic criteria for encephalopathy without the additional features identified above.[197] However, even in the child under eighteen months, the decrease in level of consciousness is quite different between autism and encephalopathy. Acute encephalopathy is a medical emergency, and the change in a level of consciousness is usually dramatic, immediate, global change, in which a child may be drowsy or irritable, and has lost alertness, responsiveness, and the ability to function and interact.[198] Even when it is claimed that a child regressed immediately after vaccination, the medical descriptions are different and easy to distinguish to the trained eye.[199]

Second, encephalopathy affects more than just the conscious state and ability to interact with the outside world. People with encephalopathy often have signs of systemic disease such as fever, neck pain and stiffness, headache, nausea, and vomiting. Altered level of consciousness is merely one aspect of the disease,

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197. That is, disease severe enough to warrant hospitalization, and one out of either seizures or a significant change in mental status.

198. *See* Karen A. Horridge, *Assessment and Investigation of the Child with Disordered Development*, 96 ARCH. DIS. CHILD EDUC. PRACT. ED. 9 (2010). *See also* Hardy 2015 WL 7732603 at *26 (Describing an acute encephalopathy as an event "that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred) . . . The clinical signs and symptoms of an acute encephalopathy were incorporated into the QAI to 'clearly distinguish infants and children with brain dysfunction from those with transient lethargy.'") (citations omitted).

199. *See* Claudia A. Chiriboga, *Acute Toxic-Metabolic Encephalopathy in Children*, UPTODATE (Jul. 2017), http://www.uptodate.com/contents/acute-toxic-metabolic-encephalopathy-in-children (describing encephalopathy diagnosis); *see also* Masashi Mizuguchi et al., *Acute Encephalopathy Associated with Influenza and Other Viral Infections*, 115 ACTA NEUROL. SCAND. 45, 45 (2007). *See* Chris P. Johnson & Scott M. Myers, *Identification and Evaluation of Children with Autism Spectrum Disorders,* 120 PEDIATRICS 1183, 1185 (2007) for diagnosing autism, and how it's different.

which can be immediately life threatening.[200] A child with autism, however, lacks the same symptoms, though she may have other health problems and her ability to interact with her external environment is altered. Note that autism is not protection against having encephalopathy. A child with autism may also have encephalopathy and exhibit the symptoms of it. In this situation, the child would have two distinct conditions, not two of the same conditions.

Furthermore, in several cases where parents claimed changes occurred immediately after vaccination, videos of the child at a younger age show symptoms of autism that had not been recognized as such by the parents.[201] In other words, parental testimony that a child was developing normally and suddenly regressed following vaccines, however sincere, may not reflect the reality. Parents, however devoted, are not necessarily experts at identifying developmental problems.

Third, when discussing encephalitis, which is what many parents claim their children experienced, there are other differences. Encephalitis, or brain inflammation, is common in many or most encephalopathies.[202] The results of numerous investigations display marked differences between encephalitis and autism, reflecting the different etiological processes and pathology involved. Blood tests, cerebrospinal fluid examination, EEG, and MRI findings may be different between the two pathologies, even if the result of a clinical examination is doubtful.

These points are summarized in Figures 1 and 2.

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200. *See* Chiriboga, *supra* note 200 (reporting "interruption of neuronal activity in the developing brain can have a long-lasting effect [and] prompt recognition and treatment are important").

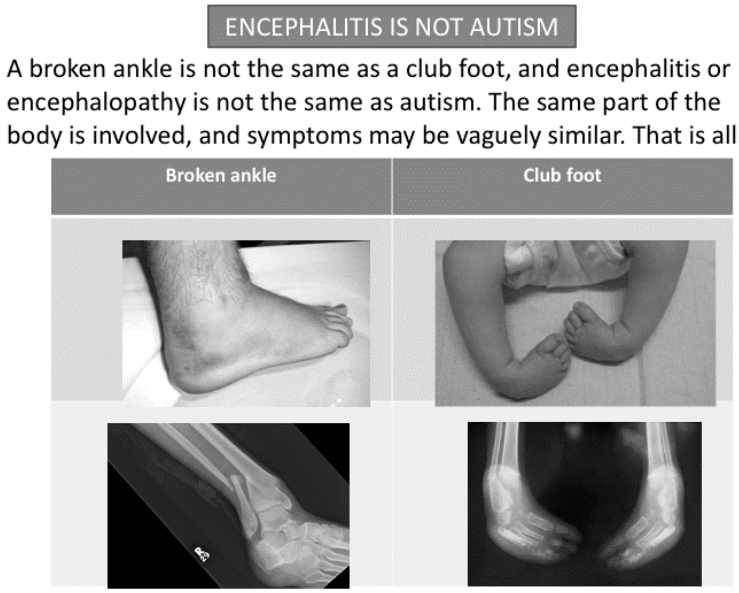
201. Cedillo, 617 F.3d at 215.

202. Mizuguchi et al., *supra* note 200, at 45.

Figure 1. Encephalitis and Autism, Point by Point Comparison[203]

	ENCEPHALITIS	AUTISM
Definition	Inflammation of the brain, with an adaptive (specific) immune response.	A complex disorder of brain development characterized by difficulties in social interaction, verbal and nonverbal communication and repetitive behaviors.
Signs/symptoms	Fever. Neck pain and stiffness. Photophobia. Confusion. Lethargy. Headache. Nausea and vomiting. Coma. Death.	Developmental regression. Atypical reactions to environmental stimuli. Atypical social interactions. Absence of typical responses to pain and physical injury. Language delays and deviations. Absence of symbolic play. Repetitive and stereotyped behaviour.
Causes	Infective – viral, bacterial, fungal, protozoal. Inflammatory –demyelination, vasculitis, auto-immune disease. Other – including idiopathic, metabolic eg liver or mitochondrial disease, chronic progressive trauma, hypoxia or tumours.	Not fully understood. Probable factors include genetic susceptibility and maternal fever during pregnancy. If there is an inflammatory component, changes are as a result of changes in the innate immune system.
MRI appearance	Characteristic signal intensity changes can be focal or diffuse.	Essentially normal, may have larger brain size (especially white matter) with decreased corpus callosum volume.
EEG	Generalized slowing. Periodic patterns (such as burst-suppression). Background suppression, and electrocerebral inactivity (ECI). Alpha coma, beta coma, spindle coma, and triphasic waves.	Essentially normal, except in cases of concurrent epilepsy. May have increased spectral coherence.
Spinal fluid	Pressure – increased White cell count – increased Microscopy and culture/PCR – may be positive Glucose – decreased Protein - increased	Normal.

Figure 2. Wrong Comparison: Club Foot and Broken Ankle



2. Seizure disorder

Seizure disorder is not autism. They have different definitions and characteristics, although the same child may have both. Seizure disorders are more common among children with autism than in the general population,[204] but that does not

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203. *See* John E. Greenlee, *Encephalitis*, MERCK MANUAL (Jan. 2019), http://www.merckmanuals.com/professional/neurologic-disorders/brain-infections/encephalitis (outlining key characteristics of encephalitis); ROBERT M. KLIEGMAN ET AL., NELSON TEXTBOOK OF PEDIATRICS 2061 (19th ed.) (2011); GIUSEPPE RAVIOLA ET AL., *Autistic Disorder*, NELSON TEXTBOOK ON PEDIATRICS, 100 (19th ed.) (2011).

204. See Eric Rubenstein et al., A Review of the Differences in Developmental, Psychiatric, and Medical Endophenotypes Between Males and Females with Autism Spectrum Disorder, J. DEVELOPMENTAL & PHYSICAL DISABILITIES 119, 130 (2015) ("Epilepsy and other seizure disorders co-occur in 5 % to 40 % of children with ASD and there is differential prevalence based on ID"); see also Patricia O. Shafer, Epilepsy Statistics, EPILEPSY (Oct. 2010), https://www.epilepsy.com/learn/about-epilepsy-basics/epilepsy-statistics

mean the autism is caused by the seizures, and this is still a minority of children with autism. Many seizure disorders are genetic in origin.[205] As highlighted elsewhere, there is a powerful argument that the same prenatal influences that lead to autism may also lead to a seizure disorder, but both are the end result of a common trigger rather than one being caused by the other.[206]

Encephalopathy and seizure disorder are entities in their own right. Both are distinguishable from ASD through clinical history, examination, and the results of investigations such as EEG, MRI, blood tests and cerebrospinal fluid examination.

Both encephalopathy and seizures are capable of causing symptoms and signs that are similar to those of autism, and either or both may occur in individuals with autism. However, medical evidence is able to distinguish clearly between the two disorders, and evidence shows that they neither cause autism, nor are they caused by autism.

B. DO VACCINES CAUSE ENCEPHALOPATHY AND SEIZURE DISORDER?

When the Table of Injuries was written, it was believed that the DTP vaccine caused encephalopathy, MMR caused encephalopathy and encephalitis, and DTP caused seizure disorder. Recent evidence supports none of these claims.

In large part, NVICP was created because of claims that DTP caused brain damage in children, instigating a subsequent flood of litigation.[207] Encephalopathy from DTP was included in the Table of Injuries because, at the time, scientists also believed the vaccine caused encephalopathy, based, to a large extent, on a large-scale British study conducted by Miller et al.[208] However, subsequent large-scale epidemiological studies did not support

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(reporting epilepsy prevalence as 5 to 8.4 for every 1,000 people in the general US population).

205. *See* Nienke E. Verbeek et al., *Etiologies for Seizures Around the Time of Vaccination*, 134 PEDIATRICS 658, 658 (2014); *see also* Steven C. Schachter et al., *Is Epilepsy Inherited?* EPILEPSY FOUNDATION (2013), http://www.epilepsy.com/learn/epilepsy-101/epilepsy-inherited.

206. *See* Canitano Roberto, *Epilepsy in Autism Spectrum Disorders,* 16 EUROPEAN CHILD AND ADOLESCENT PSYCHIATRY 61, 62 (2007) (reporting a possible "common genetic basis" between autism and epilepsy).

207. *See* Offit, supra note 141 at 2089–90.

208. David Miller et al., *Pertussis Immunisation and Serious Acute Neurological Illness in Children*, 307 BRITISH MED. ASS'N J. 1171 (1993).

that study's conclusion.[209] As part of a court case where an English plaintiff claimed to be brain damaged by DTP, it was discovered that the Miller et al. study was biased in a way that skewed the evidence to make it look like DTP caused brain damage meanwhile reexamination did not support it.[210]

In short, the evidence does not support a claim that DTP causes encephalopathy. The political decision not to remove encephalopathy from the Table of injuries does not substitute for science showing a link between the vaccine and the harm.

What about MMR? That's a somewhat different situation. There are apparently two reasons MMR was assumed to cause encephalitis or encephalopathy. First, the measles virus does clearly cause encephalitis.[211] There was a biological basis to think the attenuated form in the vaccine might also, if less often. Second, there was a study suggesting such a link that has not been discredited the way the Miller et al. study was.[212]

A closer look at that study, however, combined with more recent work, suggests otherwise. This was a small-scale study based on reported cases—not an epidemiological study—that looked at the population with no comparison between those that got MMR and those that did not. The study was based mostly on clustering of reporting of encephalitis after the vaccine, using a passive reporting system.[213] While suggestive of a link, this study is not strong evidence of one.

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209. See Samuel Bedson et al., Vaccination Against Whooping Cough: Relation Between Protection in Children and Results of Laboratory Tests, 2 BMJ 454, 454 (1956); T.M. Pollack & Jean Morris, A 7-Year Survey of Disorders Attributed to Vaccination in North West Thames Region, 1 THE LANCET 753 (1983); William D. Shields et al., Relationship of Pertussis Immunization to the Onset of Neurologic Disorders: A Retrospective Epidemiologic Study, 113 J. PEDIATRICS, 801 (1988); Alexander M. Walker et al., Neurologic Events Following Diphtheria-Tetanus-Pertussis Immunization, 81 PEDIATRICS 345 (1988); M.R. Griffin et al., Risk of Seizures and Encephalopathy after Immunization with the Diphtheria-Tetanus-Pertussis Vaccine, 263 J.AM. MED. ASS'N 1641 (1990). See generally OFFIT, DEADLY CHOICES, supra note 48, at 29–31.

210. *See* OFFIT, DEADLY CHOICES, *supra* note 48, at 38–39.

211. *See* Andrew Kroger, *Measles,* 13 CDC: EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 209 (2015).

212. *See* 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).

213. *VAERS Data*, VACCINE ADVERSE EVENT REPORTING, https://vaers.hhs.gov/data/index (last visited Feb. 4, 2019).

The question of whether there is a link between MMR and encephalitis was further examined in a 2012 Institute of Medicine (IOM) report.[214] The IOM report examined epidemiological studies and concluded that two of the relevant three found no causal connection, and the third suffered from methodological problems that prevented relying on it.[215] It also addressed eighteen case reports of encephalitis after MMR—14 of which had no evidence that the vaccine caused the harm besides a temporal connection (i.e. the encephalitis happened after the vaccine), and others that had specific problems.

In short, taken all in all, the evidence in the IOM report did not support a connection between MMR and encephalitis. The IOM concluded that they cannot accept or reject causality; but for an outside observer, there really isn't good evidence supporting a causal connection. Recent studies have not found a link between MMR and encephalitis either.[216]

In a telephone discussion with Dr. Offit, he pointed out that we do not have the same biological basis to assume MMR causes encephalitis as we do for the wild measles virus.[217] The wild measles virus, he explained, replicates in the body many thousands of times.[218] The vaccine measles virus, in contrast, replicates only several tens of times.[219] And while the wild measles virus has been found in the central nervous system, the vaccine virus has not, meaning that the deduction that the vaccine virus can cause encephalitis because the wild measles virus sometimes does stands on shaky ground at best.[220]

It is clear, on the other hand, that diseases vaccines prevent can cause both encephalopathy and encephalitis, for example, influenza, measles, chickenpox, and rotavirus can, and probably pertussis as well.[221] This point is also relevant because if the

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214. *See* Kathleen Stratton et al., *Adverse Effects of Vaccines: Evidence and Causality*, NAT'L ACADEMIES PRESS at 101–111 (2012).

215. *Id.* at 118.

216. Ali Rowhani-Rahbar et al., Lack of Association Between Childhood Immunizations and Encephalitis in California 1998-2008, 30 VACCINE 247 (2012); Nicola P. Klein et al., Safety of Measles-Containing Vaccines in 1-Year-Old Children, 135 PEDIATRICS e321 (2015).

217. Telephone Interview with Dr. Paul Offit, Director of the Vaccine Education Center, Children's Hospital of Philadelphia (Sept. 5, 2014).

218. *Id.*

219. *Id.*

220. *Id.*

221. Mizuguchi et al., *supra note* 200, at 45-46.

claim that encephalopathy or encephalitis are in fact autism were true, with the decrease in diseases that are the more common cause of those conditions (and the diseases in question dropped after vaccines),[222] you would see a decrease in autism. But autism rates have not decreased.

Nor is there good evidence that vaccines cause recurring seizures. Although febrile seizures can be caused by fever, and fever can be caused by both vaccines and the diseases we vaccinate against, vaccines do not cause a long term seizure disorder.[223] Most childhood seizure disorders have genetic origins.[224] The Secretary of Health took action to remove residual seizure disorder from the schedule as the evidence accumulated, but did not remove either encephalitis or encephalopathy.[225] Given the lack of evidence, it is probably time now for the Secretary to likewise remove encephalopathy and encephalitis.

IV. THE OMNIBUS AUTISM PROCEEDING

Not only did NVICP not find that a vaccine caused a child's autism in any of those cases,[226] but NVICP directly confronted

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222. Sandra W. Roush et al., Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States, 298 J.AM. MED. ASS'N 2155, tables 1 and 2 (2007).

223. Anne M. McIntosh et al., *Effects of Vaccination On Onset and Outcome of Dravet Syndrome: A Retrospective Study*, 9 THE LANCET No. 6 592, 596 (June 2010), http://www.thelancet.com/journals/laneur/article/PIIS1474-4422(10)70107-1/abstract; Anne T. Berg, *Seizure Risk With Vaccination,* AMERICAN EPILEPSY SOCIETY (Jan. 2002), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC320893/; Vincent Iannelli, *Best Books on Vaccines and Vaccination,* VERYWELL (Aug. 08, 2017), http://pediatrics.about.com/b/2011/08/15/dravet-syndrome-an-alternative-explanation-for-vaccine-encephalopathy.htm; Nienke E. Verbeek et al., *Etiologies for Seizures Around the Time of Vaccination,* AAP NEWS & JOURNALS (Sept. 2014), http://pediatrics.aappublications.org/content/early/2014/09/09/peds.2014-0690.abstract.

224. R. Nabbout & O. Dulac, *Epileptic Syndromes in Infancy and Childhood,* 21 CURRENT OPINION IN NEUROLOGY, 161 (2008). See also OFFIT, DEADLY CHOICES, *supra* note 48, 227.

225. Geoffery Evans M.D., *Update on the National Vaccine Injury Compensation Program (VICP),* NATIONAL VACCINE ADVISORY COMMITTEE (June 6, 2012), https://www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2012/evans_062512.pdf.

226. KIRKLAND, *supra* note 52, at 252.

the question of whether vaccines can cause autism—and rejected the claim.[227] In 2002,

> Chief Special Master Golkiewicz issued Autism General Order #1 ["Autism Gen. Order # 1"] to address issues arising from the unprecedented filing of more than 300 petitions for compensation in a six-month period, all alleging that vaccines caused a neurodevelopmental disorder known as autism or an ASD. Autism Gen. Order # 1 established the OAP to process efficiently and expeditiously the current ASD petitions as well as the large number of anticipated petitions presenting the same claims.[228]

This was the result of discussions with lawyers for the increasingly growing number of petitions in which petitioners claimed vaccines caused their child's autism. At the end, over 5,000 such petitions were filed with NVICP.[229]

The court, in consultation with a Petitioners Steering Committee whose members were chosen by petitioners, set up a proceeding to aggregate these cases and try the general causation claims together.[230] The proceeding involved limited discovery (unusual for NVICP) and was accompanied by repeated delay, mostly aimed at allowing petitioners ample time to gather evidence and find experts.[231] After several years, in February 2009, NVICP handed down its first three decisions, examining the question whether thimerosal in vaccines, combined with the MMR vaccine, caused autism.[232] All three special masters decided the cases handed down clear, detailed, thorough and comprehensive decisions concluding that no, there is no link between vaccines and autism.[233] Two of the decisions were challenged, first before the United States Court of Federal Claims and then in the Federal Circuit, and the challenges failed.[234] In other words, in thoroughly reviewed decisions

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227. *Id.*

228. *Snyder v. Sec'y of Health and Human Servs.*, No. 01–162V, 2009 WL 332044, at *4 (2009).

229. Holland et al., *supra* note 77, at *481.

230. KIRKLAND, *supra* note 52, at 238.

231. *Id.* at 239, 247.

232. *Id.* at 252.

233. *Id.*

234. *See* Hazlehurst v. Sec'y of Dep't of Health & Human Servs., No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), *aff'd sub nom*. Hazlehurst ex rel. Hazlehurst v. Sec'y, Dep't of Health & Human Servs., 88 Fed. Cl. 473 (2009), *aff'd sub nom*. Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343 (Fed. Cir. 2010); Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010)

NVICP concluded, after examination of the evidence, that vaccines do not cause autism.

In *Cedillo*, the Court of Appeals for the Federal Circuit said:

> [W]e have carefully reviewed the decision of the Special Master and we find that it is rationally supported by the evidence, well-articulated, and reason- able. We therefore affirm the denial of the Cedillos' petition for compensation.[235]

This is not a lukewarm or hesitant endorsement. The court is making it very clear that the Special Master's decision deserves to be upheld. While the *Hazlehurst* court did not conclude with such an affirmative statement, it went through the Special Master's decisions on the issues appealed and clearly endorsed the Special Master's decision on each.[236]

In their article, Holland et al. attempt to cast doubt on the decisions in these cases. They do so by emphasizing questions asked by the judges during oral argument. In *Hazlehurst* they emphasize a question from one judge asking what would happen if later science found a link between thimerosal containing vaccines and autism, the answer being that the law could change.[237]

The contents of oral argument do not, of course, overturn a decision. But, in this case, there is a further problem with the way that Holland et al. make use of this argument. In the decision, the Federal Circuit explained that the Hazlehurst family was not claiming that thimerosal caused their son's autism, but that the MMR vaccine alone did.[238] Beside the fact that the words spoken in oral argument carry no legal weight and do not negate the strongly affirming decision. They are not, as quoted, relevant to the case at hand.

In relation to *Cedillo*, Holland et al. claim that the judges asked hard questions about allowing the testimony of Dr. Bustin, without providing access to the raw data on which that testimony relied.[239]

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235. Cedillo, 617 F.3d at 1350.

236. *See generally* Hazlehurst, 604 F.3d 1343.

237. Holland et al., *supra* note 77, at 498.

238. Hazlehurst, 604 F.3d at 1345 ("The Hazlehursts initially presented that theory of causation, but in post-hearing briefing they relied on the theory that Yates's autism was caused by the MMR vaccine alone.")

239. Holland et al., *supra* note 77, at 498-99.

In the decision, the court directly addressed this. The *Cedillo* court said:

> 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. In our recent decision in Hazlehurst, we specifically addressed this question and held that the failure to exclude the testimony and reports of Dr. Bustin did not constitute reversible error. See Hazlehurst, 604 F.3d at 1348-52. In particular, we concluded that the Special Master's decision to admit and consider Dr. Bustin's testimony was "in full accord with the principle of fundamental fairness" under Vaccine Rule 8(b)(1) and did not "contravene[] the purpose[] of the Vaccine Act" to avoid proceedings resembling tort litigation. Id. at 1351. We also concluded that even if the admission of the Bustin evidence was improper, the Special Master would have reached the same conclusions regarding the unreliability of the Unigenetics testing in the absence of the Bustin evidence. Id. Curiously, neither the government nor petitioners in this case ever mentioned the Hazlehurst decision. And while Hazlehurst did not consider the bearing of Rule 26 on this case, we think that the decision in Hazlehurst was correct and that it governs here.[240]

The court went further into why allowing the Bustin testimony does not negate the decision, but this language clarifies the general points. While not as affirming as Hazlehurst on this,[241] the court made it clear this does not negate or undermine the finding that thimerosal containing vaccines and MMR do not cause autism.[242]

In short, the claim of whether vaccines cause autism was placed directly before NVICP and examined in detail. The claim was rejected, and that rejection strongly upheld on appeal.

In recent years, additional attempts were made to convince NVICP to compensate children for vaccines-related autism, and were consistently rejected.[243] On August 31, 2017, in a decision

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240. Cedillo, 617 F.3d at 1342.

241. Hazlehurst, 604 F.3d at at 1349. ("The special master's decision to admit and consider Dr. Bustin's testimony and reports was in full accord with the principle of fundamental fairness.").

242. Cedillo, 617 F.3d at 1338.

243. *See, e.g.* R.K. v. Sec'y of Dep't of Health & Human Servs., 03-632V (Fed. Cl. Sept. 28, 2015) available at: https://lbrbblog.files.wordpress.com/2016/06/krakow-decision.pdf; Brian Hooker v. Sec'y of Dep't of Health & Human Servs., 02-472V (Fed. Cl. May 19, 2016), available at: https://www.skepticalraptor.com/blog/wp-content/uploads/2016/06/Hooker-NVICP-decision.pdf.

filed in what was termed a mini-omnibus proceeding, a special master addressed the court's autism jurisprudence, saying:[244]

> All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit unanimously rejected the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism . . . .
>
> In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can cause autism.[245]

In these circumstances, using off-topic NVICP cases to claim vaccines cause autism is simply without basis.

CONCLUSION

The question whether vaccines cause autism is first and foremost a scientific one. The scientific consensus on this question, backed by abundant data—dozens of large-scale studies from all around the world—is clear: vaccines do not cause autism. There is no real scientific support to the opposing view.

Despite this, a dedicated minority—parents, alternative practitioners, doctors rejecting the evidence and others—clings to a belief that vaccines cause autism. Unable to support it using traditional scientific tools, they seek alternatives.

NVICP cases are one tempting alternative. But it is a broken reed. It is almost inevitable that some children compensated by NVICP would also have autism. Rates of autism in the population are high. Autism is not a barrier against a vaccine injury. And parents of children with autism who believe vaccines cause autism—a claim prevalent in the popular press for several years, and still heard in the public sphere and social media—may be more likely to sue (and if they join the VCAC, they will likely be directed to do so). But in its years of existence, NVICP has never compensated a child on the theory that vaccines caused that child's autism. It rejected such claims in

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244. J.M. v. Sec'y of Dep't of Health & Human Servs., 02-10V (available at: https://www.skepticalraptor.com/blog/wp-content/uploads/2018/03/JM-Mini-OMnibus-NVICP.pdf)

245. *Id*. p. 7-9. For a detailed analysis of the mini-omnibus proceeding, see: Dorit Rubinstein Reiss, *Italian NVICP Mini-Omnibus Autism Decision – Vaccines Still do not Cause Autism*, SKEPTICAL RAPTOR'S BLOG (March 6, 2018) https://www.skepticalraptor.com/skepticalraptorblog.php/nvicp-mini-omnibus-autism-decision-vaccines/.

detailed, well-reasoned decisions in the Omnibus Autism Proceeding. The only way to use NVICP cases to support the claim that vaccines cause autism is to take them out of context, ignore their actual content, and occasionally directly misrepresent them—in other words, to misuse them.

When your best evidence for a claim is misusing cases by an adjudicative forum that, when addressing your claim, ruled against you, it is time to reconsider. Vaccines do not cause autism, say both science and law.

APPENDIX: REVIEW OF CASES DETAILED IN HOLLAND ET AL.

The vast majority of the cases summarized in Table 1 were brought subsequent to an alleged seizure disorder, and most were linked to the DTP vaccine. The next largest category was compensated for the table injury of encephalopathy following DTP. See the body text for a discussion of these claims and their meaning. In addition, the court in Bastian v. Secretary of the Department of Health & Human Services noted that the NVCIA's definition of encephalopathy is significantly less stringent than the medical definition:

> The Act defines an encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." A seizure is a manifestation or symptom of abnormal brain function, and thus indicative of an encephalopathy as contemplated by the Act. Even a single seizure has been found to be indicative of a Table encephalopathy.[246]

246. Bastian v. Sec'y of Dep't of Health & Human Servs., No. 90-1161V, 1994 U.S. Claims LEXIS 196, at *6 (Fed. Cl. Sept. 22, 1994).

Table 1:[247] Appraisal of Selected Cases Employed by Holland et al.[248]

Case	Relevant Language	Analysis in Context
Alger v. Sec'y of Dep't of Health & Human Servs., No. 89-31V, 1990 WL 293408, at *4 (Cl. Ct. Mar. 14, 1990)	"Daniel has a persistent refractory seizure disorder and suffers from severe and profound mental and physical retardation. His I.Q. does not exceed 30." Compensation for residual seizure disorder.	There is no mention of autism to be found in the entire case. The focus is on seizure disorder, which allegedly led to developmental delays, and encephalopathy.
Sorensen v. Sec'y of Dep't of Health & Human Servs., No. 89-124V, 1990 WL 290491, at *3 (Cl. Ct. Dec. 6, 1990)	"Jonathan is a severely retarded[249] twelve-year-old with cognitive, physical, and social developmental delay. Jonathan has an intellectual age of 4–5 and has many autistic features." Compensation for residual seizure disorder.	The focus is on the child's severe intellectual disability. During discussion of the actual compensation, several conditions, such as eye problems, were discussed and not compensated because the condition could not be established as being related to the vaccine. Within the discussion of the various conditions and compensation, autism and autistic features are never discussed. Thus, although the court acknowledged

247. Page citations in the first column correspond respectively to individual quotes in the second. Short forms in the analysis column refer to the row's case. Internal footnotes and citations have been omitted.

248. Mary Holland et al., *supra* note 78.

249. The term "retarded" was used instead of "intellectual disability" when the court described the child. Our intent is to correctly quote the language used at the time.

		that the injured child has autistic symptoms, it did not compensate for them, and the case, therefore, provides no support for Holland et al.
Kleinert v. Sec'y of Dep't of Health & Human Servs., No. 90-211V, 1991 WL 30664, at *1 (Cl. Ct. Feb. 20, 1991)	"The Petitioner claims that Wes Ian Kleinert suffered an encephalopathy as defined by the Table within three days of the receipt of the DPT vaccine on February 24, 1981. The Petitioner goes on to maintain that Wes suffers from a residual seizure disorder as a sequela to the encephalopathy with cognitive and developmental delays." Compensation for encephalopathy.	For purposes of compensation, the petitioner did not claim that their injured child had autism, only that he suffered from encephalopathy. The court noted that "[t]oday he has a seizure disorder which is under control and a condition known as overfocussing, similar in some respects to autism." Kleinert at 2. However, the court never explicitly stated that Wes has autism but, rather, noted that he has a disorder that overlaps with some symptoms of autism.
Connor v. Sec'y of Dep't of Health & Human Servs., 90-388V, 1991 WL 133618, at *6 (Cl. Ct. July 3, 1991)	The claim was for harm from a seizure disorder allegedly caused by DTP. "In this regard, respondent's report (filed September 7, 1990) 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.' But in the attached expert report, upon which respondent based	Here the petitioner never sought compensation for autism. Instead, the Secretary, attempting to avoid payment by attributing the petitioner's condition to something presumptively unrelated to vaccines, attributed the condition to autism. Even this attenuated claim was rejected by the court as pure speculation.

	that assertion, Dr. Spiro candidly admitted that he can only 'speculate' as to such possibilities. And certainly at the hearing, 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." Compensation for seizure disorder.	
Messner v. Sec'y of Dep't of Health & Human Servs., No. 90-552V, 1991 WL 74145, at *4 (Cl. Ct. Apr. 22, 1991)	"Jennifer is a severely mentally retarded individual with hyperactive and destructive behaviors. Her cognitive functioning is in the one to two-year-old range." Petitioners' claim was for residual seizure disorder from DTP, encephalopathy, "mental retardation" and developmental delays. Compensation for residual seizure disorder.	No mention of autism or autistic behavior.
Oxley v. Sec'y of Dep't of Health & Human Servs., 1991 U.S. Cl. Ct. LEXIS 575, at *2 (Cl. Ct. Nov. 27, 1991)	"The second petition (No. 90-566V) alleges that Richelle suffered a grand mal seizure and cardio-respiratory arrest within 12 hours of the administration of the vaccine and that these symptoms were the first manifestations of a vaccine-related residual	The discussion in the article also encompasses the contents of Oxley v. Sec'y of Dep't of Health & Human Servs., 1991 U.S. Cl. Ct. LEXIS 381 (Cl. Ct. Nov. 27, 1991). Second, compensation is based upon the claims of the petitioner, which here are for encephalopathy and a residual seizure

	seizure disorder and encephalopathy." Compensation for residual seizure disorder.	disorder. They are not compensating for autism. Although the court mentions "autistic-like behavior" in the opening part of the decision, this is never attributed to vaccines.
Underwood v. Sec'y of Dep't of Health & Human Servs., No. 90-719V, 1991 WL 156659, at *2, *4 (Cl. Ct. July 31, 1991)	The claim was for encephalopathy and residual seizure disorder after DTP. "[R]espondent contends that Travis suffers from autism, which has produced his severe mental retardation and developmental delay. Consequently, respondent urges that compensation, in this case, be limited to those expenses that reasonably might be incurred for Travis' residual seizure disorder, not for expenses he might accrue because of his mental retardation, developmental delay and autistic behaviors." "While Dr. Schultz believes that Travis suffers from some autistic-like features, he does not now nor has he ever believed that Travis suffers from true autism. Conceding that some autistic children suffer from seizures, Dr. Schultz maintains that	The injured child was found to have developed an encephalopathy after receiving a vaccine. The reference to autism is the Secretary's attempt to claim that some of the boy's problems— "mental retardation and autism," in the words of the case— were not due to the vaccine and that he should not be compensated for them. In other words, autism was brought up to deny compensation. The court accepted the position of the petitioners' expert that the child did not have autism.

	the seizures are generally easily controlled and are not the hallmark of their disease. Furthermore, autistic children would present with bilateral or diffuse spike discharges on EEG rather than the unilateral focal discharges of the left temporal lobe as seen in Travis. This is important, according to Dr. Schultz, because Travis' 1980 EEG abnormalities show brain damage that would account for his loss of language skills. Moreover, Dr. Schultz testified that Travis is distinguishable from children with true autism because he (1) seeks affection; (2) makes eye contact; (3) doesn't require sameness in routine as usually found with autistic children; and (4) doesn't engage in twirling, flinging and other self-stimulatory behaviors to the same degree as autistic children. "According to Dr. Schultz, further support for his belief that Travis does not suffer from true autism is found in another article that respondent submitted to

	support its position. This article describes autistic-like behavior in people suffering from acquired epileptic aphasia. Dr. Schultz believes that Travis' encephalopathy resulted in such acquired epileptic aphasia, signified by the spike discharges in the left temporal lobe of his brain evident on the 1980 EEG, which accounts for his resulting loss of speech. Moreover, the same article reports that encephalopathic illnesses can result in autistic-like syndromes." Compensation for encephalopathy.	
Sharpnack v. Sec'y of Dep't of Health & Human Servs., No. 90-983V, 1992 WL 167255, at *7 (Cl. Ct. June 29, 1992), aff'd, 27 Fed. Cl. 457 (1993), aff'd, 17 F.3d 1442 (Fed. Cir. 1994)	Claim: residual seizure disorder caused physical disabilities and diminished mental capacity. "If not arrested promptly, [Megan's] seizures progress to grand mal status epilepticus . . . These occurrences are potentially life-threatening. . . According to petitioners' rehabilitation consultant, following these severe seizures, Megan typically loses any developmental progress she has made."	No mention of autism or autistic-like symptoms. With this case, Holland et al. are grasping at scattered language, such as "[h]er behavior, which includes head banging, pulling her own hair, and scratching at things, must be constantly redirected" as evidence of autism, despite there being no mention of it in the actual case.

	Compensation for residual seizure disorder.	
Koston v. Sec'y of Dep't of Health & Human Servs., 974 F.2d 157 (Fed. Cir. 1992)	No relevant language. No mention of autism or autistic-like symptoms. Compensation for seizure disorder.	Here Holland et al. attempt to use a diagnosis of Rett syndrome, which can cause autistic-like symptoms in its early stages, as evidence that the NVICP compensates for autism. At the relevant time, the genetic basis of Rett syndrome was not known; now it is.
Sanford v. Sec'y of Dep't of Health & Human Servs., No. 90-2760V, 1993 WL 177003, at *2 (Fed. Cl. May 10, 1993)	Claim: residual seizure disorder and encephalopathy from DTP. "Rebecca will be 14 years old at her next birthday. She has been assessed as being in the moderate to severe range of mental retardation. Her overall IQ is 32, but some areas range higher (5 years) and some lower (2½ years). She can learn but at a slow rate described as 'baby steps.' She suffers severe language impairment and communication disorder, both receptive and expressive, with auditory processing problems. She has severe attention deficit disorder, described by her teacher as 'the worst attention deficit situation' she has known. She also has severe motor problems	As demonstrated by this quote, the disorder being compensated is retardation, not autism. The autistic tendencies mentioned were never complained of or argued to be caused by the retardation, which was the basis for compensation.

	with gait, balance, and gross and fine motor skills. Her condition is complicated by a behavior disorder. She is highly impulsive, has no concept of danger, cannot accept control, and has autistic tendencies." Compensation for encephalopathy and residual seizure disorder.	
Bastian v. Sec'y of Dep't of Health & Human Servs., No. 90-1161V, 1994 U.S. Claims LEXIS 196, at *16–18 (Fed. Cl. Sept. 22, 1994)	"Dr. Quinn opined that Kyle suffers from pervasive developmental disorder (PDD). Dr. Spiro, however, opined that Kyle is autistic. "Dr. Quinn explicated on the differences between autism and PDD. Dr. Quinn pointed out that PDD and autism are sometimes incorrectly used interchangeably. She stated that autism may be one of a spectrum of disorders under PDD but that it is a separate classifiable disorder. She concluded that Kyle does not have autism, but has 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	Holland et al. omit the intervening text stating both that there was no autism and that PDD and autism are different disorders. Autism is listed under PDD but Kyle was not found to have autism, and this case draws a clear distinction between the two. This all comes from the testimony of the physician favored by the court: "Dr. Quinn's explanations again are the most persuasive. For the reasons stated supra, her testimony is given greater weight than that of respondent's expert." Bastian at *33.

	opined, to a reasonable degree of medical certainty, that Kyle's condition is permanent. "Dr. Ira Lourie, treating child psychiatrist, also testified for petitioner. Kyle was first referred to Dr. Lourie's practice in 1990. Dr. Lourie indicated that Kyle is not autistic, and, in fact, he is not certain that he even has PDD—although he has characteristics of PDD. Kyle has never actually been diagnosed with autism according to Dr. Lourie's analysis of the medical records. Nor is he mentally retarded." Compensation for encephalopathy.	
Lassiter v. Sec'y of Dep't of Health & Human Servs., No. 90-2036V, 1996 U.S. Claims LEXIS 216, at *11, *18–19 (Fed. Cl. Dec. 17, 1996)	"In this case, respondent claims that Eric is autistic and that autism is not caused by DPT." "A careful interpretation of the literature indicates that autism can be mirrored by a condition that includes 'autistic-like' signs or symptoms. Eric's condition has never been diagnosed conclusively as autism according to the medical records. The predominating diagnosis refers instead to 'static encephalopathy' with autistic tendencies in	Parents claimed encephalopathy. Respondent tried to use a claim of autism to deny compensation, and the court rejected the claim. Here we have the same physician representing respondent as in Bastian, Dr. Alfred Spiro, a physician who is often contracted by HHS to argue that the petitioner's injured child does not have encephalopathy but rather autism. Dr. Spiro never has appeared as the claimant's primary physician and

	addition to 'delayed development.' The diagnosis of autism proposed by Dr. Spiro is explained only briefly and is without adequate foundation. Based on a review of the medical literature, it appears that some term other than autism is probably more accurate. Petitioner quotes, for example, the following from Merritt's Textbook of Neurology, 9th ed., 1995: '"The term "pervasive developmental disorder (PDD) is preferred to "autism" because it stresses variability in symptoms and severity and denies that autism is a disease with a single cause.' PDD is used in the Revised Diagnostic and Statistical Manual of the American Psychiatric Association as an umbrella term for frankly autistic children and for other children with similar but fewer, less severe symptoms. "Dr. Spiro has not explained clearly why he believes, first, that Eric meets the criteria for autism." Compensation for encephalopathy.	appeared to have had limited f over medical records. Id. at *2q4–25 ("Dr. Quinn's explications more believable than the expositions of Dr. Spiro. Dr. Quinn has been a treating physician to Kyle for years; Dr. Spiro has never seen Kyle. Dr. Quinn's opinions evolved over the years; Dr. Spiro ascertained his opinions by a review of the records over an abbreviated time span.").

Suel v. Sec'y of Dep't of Health & Human Servs., No. 90-935V, 1997 WL 617034, at *10.	"The court holds that David be compensated fully for the damages he has suffered as a consequence of the significant aggravation of his TS. These sequelae include his seizure disorder, autism, and mental retardation."	Here, vaccinee David had an underlying medical condition known as tuberous sclerosis (TS), which is a common cause of autism and seizures. The court seems to hold that because David had never had a seizure prior to his DTP vaccine, even though his chance of seizure due to TS was very high, the fact that he had a seizure shortly after his vaccination meant that the vaccination caused his seizures and resulting problems. The core reason for the adjudged injury, however, was the TS, not the vaccine. Since TS is a common cause of seizures and autism regardless of vaccines, this does not support Holland et al.'s claim that this case shows that vaccines cause autism.
Reitz v. Sec'y of Dep't of Health & Human Servs., No. 90-1344V, 1998 WL 228421, at *4 (Fed. Cl. Apr. 21, 1998)	"Derrick currently has good and bad days. The week prior to trial, he had twenty-five seizures in an hour consisting of head drops. . . . 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."	The court notes that Derrick had possible seizures and had behavioral problems, including head banging. Holland et al. file this as "autism" despite no such showing in the record.

	There is no mention of autism in the opinion. Compensation for encephalopathy.	
Tebcherani v. Sec'y of Dep't of Health & Human Servs., 55 Fed. Cl. 460, 468, 470–71, 475, 477, 479 (Fed. Cl. 2003)	Petitioners brought a claim that Lena had suffered an encephalopathy. "Dr. MacDonald 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." "The Special Master concluded that the government had provided, through expert testimony, sufficient evidence to prove, by a preponderance of the evidence, that there was another cause for Lena's injuries, specifically an autistic condition, which was unrelated to the vaccine . . . respondent asserts that the Special Master based his opinion upon reliable evidence that prior to the immunization, Lena exhibited symptoms specifically related to autism, including poor eye contact and difficulty interacting with outsiders."	There are two problems with the first quote (Tebcherani at 468), which was selected by Holland et al. to support their contention.[b] The first is the statement that PDD is the same thing as autism, which is factually incorrect. The second is that the quoted expert plainly opined that Lena's autism was not related to the vaccination. The decision notes that "there is ongoing research to determine whether there exists evidence of medical and legal causation" [of vaccines causing or aggravating autistic conditions in some recipients] in response to "concern in recent years that certain childhood vaccinations might be causing or contributing to an apparent increase in the diagnosis of a type of serious neurodevelopmental disorder known as 'autism spectrum disorder' or 'autism.'" The research itself is mentioned, but not any results, and no evidence is presented that actually identifies

	"The Special Master's suggestion that Lena exhibited developmental delays prior to the administration of the vaccine, is not reversible error."	vaccines as a cause or aggravating factor of autism.
	"Dr. MacDonald's conclusions were not driven by the Special Master's inferences regarding the alleged viral illness, but rather that Lena's autism was caused by incidents suffered at birth which, he concluded, led to a lifetime of developmental delay."	
	"On remand, the Special Master must address the questions of whether evidence of autism, in combination with evidence of the onset of symptoms, is sufficient to demonstrate significant aggravation of the autistic condition and whether Lena's case may be appropriate for consideration pursuant to the procedures set forth pursuant to the Vaccine Program."	
	Here the court is giving the Special Master instructions to investigate a potential link on remand but is not claiming that a connection between	

	vaccines and autism is factually present.	
Freeman v. Sec'y of Dep't of Health & Human Servs., No. 01-390V, 2003 U.S. Claims LEXIS 285, at *FN 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. 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." Compensation for seizure disorder and retardation.	This statement appears in a footnote to the opinion, because autism was never alleged or established as an injury resulting from the MMR vaccine by petitioners. This footnote is a cautionary warning by the Special Master that the fact that their child may also exhibit behavior that falls within the autism spectrum does not mean he is compensating for vaccine-caused-autism: the compensation is for other alleged harms.
Gancz v. Sec'y of Health & Human Servs., No. 91-0178V, 2000 WL 246236 (Fed.	Compensation for seizure disorder allegedly caused by DTP.	The decision mentions that the petitioners claim injury to their daughter based on the theory that DTP caused her to have a seizure. There is no

Cl. Feb. 15, 2000)		mention in the case of autism.
Noel v. Sec'y of Dep't of Health & Human Servs., No. 99-538V, 2004 WL 3049764, at *13, *17 (Fed. Cl. Dec. 14, 2004)	"Dr. Shafrir [respondent's expert] 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." "The undersigned [Special Master] holds that acellular DPT caused a fever in Rachel, which prompted a seizure (with symptoms of staring, grinding, lethargy) and transient acute encephalopathy (with symptoms of moaning, high-pitched and eerie crying, and unresponsiveness), leading to a seizure disorder manifested by seizures of every variation interspersed with periods of normalcy until developmental	To reiterate the first quote, "her seizure disorder was independent of her DPT reaction." Since the time of this decision, studies have shown that DTP very likely does not cause seizures.[250]

250. *See, e.g.,* Anne P. McIntosh, et al. *Effects of Vaccination on Onset and Outcome of Dravet Syndrome: A Retrospective Study*, 9 LANCET NEUROLOGY 592 (MAY 5, 2010).

	delay was noticed months later, culminating in Rachel's death due to her seizure disorder (epilepsy)." Note that the Special Master is not compensating Rachel's estate for autism.	
Paulmino v. Sec'y of Health & Human Servs., 69 Fed. Cl. 1, 4 (Fed. Cl. 2005)	"On May 18, 2004, Erika was described as: 'A four-year old female with intractable epilepsy, PDD [persuasive developmental delay] . . . .' As of the filing of this action, Erika continues to suffer from a developmental and speech-and-language disorder and requires therapy." Compensation for seizure. The Special Master rejected the claim that the seizure caused seizure disorder and developmental delays as contrary to the medical literature. However, the Court of Federal Claims reversed, highlighting that the petitioners did not have to show support from the literature under *Althen*. To remind readers, a plausible theory is enough under *Althen*.[251]	Holland et al. here again seize upon a mention of PDD to denote autism. There is no actual mention of autism in the case, and a diagnosis of PDD does not mean autism.

251. *See* discussion beginning *supra* note 56.

Banks v. Sec'y of Dep't of Health & Human Servs., No. 02-0738V, 2007 U.S. Claims LEXIS 254, at *13, *19 (Fed. Cl. July 20, 2007)	"Dr. Lopez's diagnosis appears to conflict with the diagnosis given by Bailey's pediatrician on 20 May 2004, who saddled Bailey's condition with the generalized term 'autism'; [footnote omitted] however, that pediatrician later acknowledged that use of the term autism was used merely as a simplification for non-medical school personnel, and that pervasive developmental delay 'is the correct [i.e. technical] diagnosis.' Another pediatrician's diagnosis noted that Bailey's condition 'seems to be a global developmental delay with autistic features as opposed to an actual autistic spectrum disorder.'" "On Redirect Examination, Dr. Lopez agreed that, despite several neurological examinations, no one heretofore has made a definitive diagnosis of Bailey's condition other than PDD."	The quote given by Holland et al. for this case attempts to equate PDD with autism. However, the quotes selected here speak for themselves. PDD was the only condition actually medically diagnosed for the petitioner, and the autism label was a misnomer.
Doe/77 v. Sec'y of	"Respondent has conceded that petitioners	See discussion in the text.[253] Petitioner is

253. *See* discussion beginning *supra* note 136.

Health & Human Servs., 2010 WL 3395654, at *1 (Fed. Cl. July 21, 2010)[252]	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."	compensated for the table injury of encephalopathy, where causation is presumed. Petitioner had an extremely rare underlying mitochondrial disorder that predisposed her to regress as a result of stressors, including fever. Responded conceded that vaccines may have aggravated this preexisting condition, and there's enough evidence to meet the legal standard in Althen in this case. Note that, as discussed in the text, the court has since rejected attempts to claim compensation based on mitochondrial disorders.
Tembenis v. Sec'y of Health & Human Servs., No. 03-2820V, 2010 WL 5164324, at *1, *6 (Fed. Cl. Nov. 29, 2010)	"Petitioner filed a 'Short-Form Autism Petition for Vaccine Compensation,' and joined the Omnibus Autism Proceeding . . . . On August 27, 2008, Petitioner filed a notice to proceed separately from the OAP, and he also filed an amended petition that alleged that a Diphtheria-Tetanus-	Nowhere in the opinion did the court find that a vaccine caused the autism that Tembenis may have had. In fact, the family decided to leave the OAP proceeding, in essence not requesting compensation for autism. Instead, they were requesting compensation for an epilepsy disorder.

252. This is the Hannah Poling case, leaked by David Kirby. *See* David Gorski, *The Hannah Poling Case and the Rebranding of Autism by Antivaccinationists as a Mitochondrial Disorder*, SCI.-BASED MED. (Mar. 10, 2008), https://www.sciencebasedmedicine.org/on-the-rebranding-of-autism-as-a-mitochondrial-disorder-by-antivaccinationists [http://perma.cc/3J7X-4V62]; Paul A. Offitt, *Vaccines and Autism Revisited—The Hannah Poling Case*, 358 NEW ENG. J. MED. 2089 (2008), http://www.nejm.org/doi/pdf/10.1056/NEJMp0802904.

	acellular-Pertussis . . . vaccination administered on December 26, 2000, caused Elias to develop a seizure disorder that eventually led to his death." "In 2002, doctors observed that Elias displayed signs of other disorders. On January 31, 2002, Dr. Anselm noted that Elias had features of Pervasive Developmental Disorder . . . , which is an autism spectrum disorder. On March 13, 2002, it first was noted that Elias's condition was consistent with Sotos syndrome." Compensation for seizure disorder.	Furthermore, PDD is again conflated with autism in the second quote.
Mojabi v. Sec'y of Health & Human Servs., No. 06-227V, 2013 WL 6916777, at *5 (Fed. Cl. Nov. 27, 2013)	"Petitioners have requested that three documents be removed from the USCFC website: (1) the May 29, 2009, Revised Ruling Regarding Factual Findings, (2) the September 3, 2009, Order Regarding Affidavits, and (3) the December 13, 2012, Decision Awarding damages. In addition, Petitioners' request that the undersigned refrain from posting the motion under consideration, and	In this case, petitioners originally alleged ASD; they later introduced new evidence to advance a Table claim of encephalopathy. They were compensated for that injury, under the presumption of causation in the act. In this ruling, the matter before the court was that petitioners were seeking to have the public records of their case removed because they were being "frequently contacted by members of the media

	any order ruling on the motion under consideration. Petitioners have made these requests because they have had the misfortune of being frequently contacted by members of the media who mistakenly believe they were compensated for their alternative autism allegation when Petitioners were actually compensated for a Table injury encephalopathy."	who mistakenly believe they were compensated for their alternative autism allegation when Petitioners were actually compensated for a Table Injury encephalopathy." Petitioners were tired of this mistaken attention.