

USING AND MISUSING LEGAL DECISIONS: WHY ANTIVACCINE CLAIMS ABOUT NVICP CASES ARE WRONG

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ABSTRACT

The question of whether vaccines cause autism has been extensively studied. Studies from different countries around the world, looking at millions of children in total, examined it and found no link. In spite of this powerful evidence, the actions of a small group of fervent believers 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 the cases used do not, in their content, support that conclusions. Even the cases that most closely address the question of vaccines and autism do not show the link 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 rubella³ was able to conquer a disease that once infected practically everyone. In the prevaccine 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

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)., <http://www.who.int/wer/2014/wer8946.pdf> [<http://perma.cc/CQN8-V8YR>].

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has no treatment other than supportive care.⁶ It can cause encephalitis, with deafness and intellectual disability as possible results, and pneumonia,⁷ as well as leading 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, 91% of the victims were unvaccinated or had unknown vaccination status.¹⁰ In 2011, there were 222 cases of measles, and 86% of those people were unvaccinated or had unknown status.¹¹ Between January 1 and August 24, 2013, 159 cases were recorded; 82% 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

⁶ Selina SP Chen, *Measles Management and Treatment*, Nov. 10, 2016 Medscape (“treatment of measles is essentially supportive care...”) <http://emedicine.medscape.com/article/966220-treatment> (Last accessed August 29, 2017).

⁷ Ctrs. for Disease Control & Prevention, U.S. Dep’t Health & Human Servs., *Epidemiology and Prevention of Vaccine-Preventable Diseases* ch. 13, at 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>]; see 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 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) (Last accessed August 29, 2017). [<https://perma.cc/E2TE-S8QR>]; see also Paul A. Gastañaduy et al., *Measles—*

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article found that between 2000-2015 the majority of cases in measles outbreaks were in the unvaccinated (most intentionally 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

United States, January 1–May 23, 2014, 63 MORBIDITY & MORTALITY WKLY. REP. 496, 496 (2014), <http://www.cdc.gov/mmwr/pdf/wk/mm6322.pdf>.

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 JAMA 1149 (2016).

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

¹⁶ 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).

Example of wild claims include references to the Vaccine Holocaust: Or claims that vaccines will cause permanent alterations of DNA: <http://www.ageofautism.com/2016/05/john-rappoport-new-vaccines-will-permanently-alter-human-dna.html>

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

¹⁸ Most recently, a large metareview examining previous studies in over a million children reached the same conclusion. 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*

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the claim, there is no credible evidence that supports it.¹⁹ While there still exist many questions about the etiology of autism, the prevailing evidence points to a strong heritability, with an increasing number of identified genetic variations²⁰ and prenatal causes.²¹

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 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>; see 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 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: Brian S. Hooker, *Measles-Mumps-Rubella Vaccination Timing and Autism Among Young African American Boys: A Reanalysis of CDC Data*, 3 *TRANSLATIONAL NEURODEGENERATION*, no. 16, 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, M. ZIATS AND O. RENNERT, *THE EVOLVING DIAGNOSTICS AND GENETIC LANDSCAPES OF AUTISM SPECTRUM DISORDER*, 7 *FRONT. GENE.* 65 (2016), <https://www.ncbi.nlm.nih.gov/pubmed/27200076>; 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”); see also G. Huguët, E. Ey, Bourgeron T., *The Genetic Landscape of Autism Spectrum Disorders*, 14 *Annu Rev Genomics Hum Genet.* 191 (2013), (“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 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

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One recent large-scale study has 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 diagnoses than to an actual increase in incidence, with both the broadening of diagnostic criteria²³ and diagnostic substitution²⁴ 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

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 JAMA PEDIATRICS 56 (2015), <http://dx.doi.org/10.1001/jamapediatrics.2014.1893>.

²³ Eric Fombonne, *Epidemiology of Autistic Disorder and Other Pervasive Developmental Disorders*, 66 J. CLINICAL PSYCHIATRY (SUPPL. 10) 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.org/10.1542/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

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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” (VCAC).²⁹ Most, although not all, of its most vocal members participate in the activities of a small number of closely knit³⁰ organizations that support their cause, such as SafeMinds,³¹ Age of Autism,³² TACA,³³ Generation Rescue,³⁴ and the Canary Party.³⁵ To

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>]. (Last accessed August 29, 2017).

²⁷ 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-criinge.html>.

²⁸ E.g., *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

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://www.safeminds.org) (“Mission: To end the autism epidemic by promoting environmental research and effective treatments.”) [<http://perma.cc/5CYE-JYEM>]. (Last accessed August 29, 2017).

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](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>].

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compensate for the large body of scientific evidence refuting the basic claim, various tactics have been deployed, one of which is to insist that that successful claims under the National Vaccine Injury Compensation Program (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 courts³⁷ and that NVICP 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

³⁶ E.g., 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>].

³⁷ E.g., PAUL A. OFFIT, *THE CUTTER INCIDENT* 172–74 (2005) (“Judges, with little training in science or the scientific method, are often poor arbiters of the truth. . . . 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/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>].

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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.

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

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-nvcp-decision.html> [<http://perma.cc/ZM93-F96J>].

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).

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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

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 *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328 (Fed. Cir. 2010); *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, p. 7: “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.”

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and autism. Part IV explains 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 (DTP) vaccine that they were leaving the market.⁴⁸ In 1986, Congress passed the National Childhood Vaccine Injury 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

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. PAUL A. OFFIT, *DEADLY CHOICES: HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL* 98 (2010) [hereinafter Offit, *Deadly Choices*].

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).

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A detailed discussion of the NVICP itself is beyond the scope of this paper.⁵² For our analysis, the important point is that those claiming vaccine injury are currently required to proceed through the NVICP before being 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

⁵² See generally Anna Kirkland, *Vaccine Court*, chapters 2, 5 and 6; 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 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*, 131 S. Ct. 1068, 1072 (2011).

⁵⁴ *Id.*

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

⁵⁶ Vaccine Injury Table § a, 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).

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be relatively generous in accepting evidence from petitioners.⁵⁷ For example, although they have the discretion to apply the *Daubert* test⁵⁸ to 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

⁵⁷ *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-0522V, slip op. at 25 (Fed. Cl. June 15, 2010), <http://www.uscfc.uscourts.gov/sites/default/files/opinions/ABELL.VERYZER061512.pdf> (“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.”) [<http://perma.cc/E7WQ-JV3G>].

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.

⁵⁹ *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (1999); *Cedillo v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 158, 182 (2009) (“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, slip op. at 15 (Sept. 22, 2011), <http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.KING092211.pdf> (citations omitted) [<http://perma.cc/QQM9-GK5B>].

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?).”).

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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”) 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 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

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

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

⁶⁴ *Althen*, 418 F.3d at 1278.

⁶⁵ *Id.* at 1280.

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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 Vaccine Act, 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.”⁶⁹

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

⁶⁷ *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (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 *Andreu v. Sec’y of Dep’t of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (citation omitted).

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The Federal Circuit has also made it clear that expert opinions provided by petitioners in support of a claim must be “reliable,” although there is more than one way to meet this requirement.⁷⁰

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.⁷¹ It also reaffirms the special master’s power to require some measure of reliability in support of an expert witness’s assertions.⁷² 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.⁷³ As in other civil forums,⁷⁴ most are settled.⁷⁵

⁷⁰ *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010). Including *Daubert (Caves v. Sec’y of Health & Human Servs.*, No. 07-443V, 2010 WL 5557542, at *10 (Fed. Cl. Nov. 29, 2010)).

⁷¹ *Flores v. Sec’y of Health & Human Servs.*, 115 Fed. Cl. 157, 164 (2014), *aff’d*, 586 F. App’x 588 (Fed. Cir. 2014).

⁷² *Flores*, 115 Fed. Cl. at 167.

⁷³ 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), <http://www.gao.gov/products/GAO-15-142> (“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.”). (Last accessed August 29, 2017).

⁷⁴ 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, 838 (2003), <http://www.jstor.org/stable/3649130>.

⁷⁵ 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/vicupdate.pdf>; U.S. Gov’t Accountability Off., *supra note 73*, at 1, 13.

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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 antivaccine subgenre⁷⁶) Louis Conte.⁷⁷ 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. On this basis, they claimed to have found 83 cases in which a child was compensated with autism as a vaccine injury. 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).⁷⁸ These include, for example, the cases of Emily Lowrie

⁷⁶ LOUIS CONTE, *THE AUTISM WAR: A NOVEL* (2014).

⁷⁷ Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480 (2011) (also providing the descriptions of the authors).

⁷⁸ *Mojabi v. Sec’y of Health & Human Servs.*, No. 06-227V (Fed. Cl. Dec. 13, 2012), <http://www.uscfc.uscourts.gov/sites/default/files/opinions/CAMPBELL-SMITH.MOJABI-PROFFER.12.13.2012.pdf>; *Tembenis v. Sec’y of Health & Human Servs.*, No. 03-2820V (Fed. Cl. Nov. 29, 2010), <http://www.uscfc.uscourts.gov/sites/default/files/opinions/LORD.TEMBENIS112910.pdf>; *Lowrie v. Sec’y of Health & Human Servs.*, No. 03-1585V (Fed. Cl. Oct. 26, 2012), <http://www.uscfc.uscourts.gov/sites/default/files/opinions/CAMPBELL-SMITH.LOWRIE%2010-26-2012.pdf> (sometimes identified as “*Moller*” because Emily’s mother adopted a married name over the course of the proceedings).

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and Ryan Mojabi, who were described by writer David Kirby as having been compensated for autism.⁷⁹ 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.

VCAC members also refer to two first-instance court cases from Italy. 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 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”⁸⁰ 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

⁷⁹ 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.html36.

⁸⁰ 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>].

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critique⁸¹ of the lower court's reliance on the thoroughly discredited research of former British physician Andrew Wakefield.⁸² The decision in Bocca's case was based on the opinion of a single expert, who relied to a large extent on just this work.⁸³ 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.⁸⁴

The second Italian decision relied on three causation arguments. 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).⁸⁵ The expert appears to have led the court into error on this

⁸¹ 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>].

⁸² 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. Wakefield was paid for participation in the litigation effort. He was later deemed to have committed serious ethical 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>]; See also SETH MNOOKIN, *THE PANIC VIRUS: THE TRUE STORY BEHIND THE VACCINE-AUTISM CONTROVERSY* (2012); OFFIT, *FALSE PROPHETS*, *supra* note 3717, at 45-56.

⁸³ 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-vx7BxazujZdcla0yIpWuMI/pagina.html> (Last accessed August 29, 2017) [<https://web.archive.org/web/20140503023456/http://www.lastampa.it/2012/04/26/scienza/benessere/gravidanza-parto-pediatria/autismo-e-vaccino-trivalente-i-pediatri-non-esiste-alcuna-correlazione-vx7BxazujZdcla0yIpWuMI/pagina.html>].

⁸⁴ OFFIT, *FALSE PROPHETS*, *supra* note 17.

⁸⁵ Vanessa Coremans, GlaxoSmithKline, Combined Diphtheria, Tetanus and Acellular Pertussis, Hepatitis B Enhance Inactivated Poliomyelitis and *Haemophilus influenzae* Type B Vaccine: Infanrix Hexa Summary Bridging Report 614 (Dec. 16, 2011),

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point.⁸⁶ The expert also claimed that some vaccine ingredients can cause autism—against the evidence.⁸⁷ Finally, the expert highlighted the temporal connection between getting the vaccine and the autism diagnosis—although one thing happening after the other does not, in itself, show causation.⁸⁸ Unsurprisingly, the Italian scientific community criticized the decision, and it is under appeal.⁸⁹

In July 2017 the Italian Cour de Cassation – the highest civil court – addressed the issue, ruling out a link between vaccines and autism.⁹⁰ Neither of these cases comes close to supporting the claim that vaccines cause autism, and higher courts have since renounced the claim.

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

<https://autismoevaccini.files.wordpress.com/2012/12/vaccin-dc3a9cc3a8s.pdf> (reporting a forearm and a skull fracture, as well as two joint dislocations) [<http://perma.cc/EP79-2L54>]. (Last accessed August 29, 2017)

⁸⁶ 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>].

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ 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>].

⁹⁰ 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>

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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. Four of the decisions examined by Holland et al⁹¹ appear to be concessions, including the Hannah Poling case⁹² and the *Underwood* case.⁹³ Many of the unpublished, unnamed decisions are also settlements.

Most cases that go through NVICP settle.⁹⁴ This is no different from other courts. 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. 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.

⁹¹*Doe/77 v. Sec’y of Health & Human Servs.*, 2010 WL 3395654 at *1, *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, 161 (Fed. Cir. 1992); and *Freeman v. Sec’y of HHS*, 2003 U.S. Claims LEXIS 285 at *FN 7 (Fed. Cl. Sept. 25, 2003).

⁹² Reference to page in Holland et al. . . . from the case: “Respondent has conceded that petitioners are entitled to compensation due to the significant aggravation of Child Doc/77’s pre-existing mitochondrial disorder based on an MMR vaccine Table presumptive injury of encephalopathy” *Doe/77 v. Sec’y of Health & Human Servs.*, 2010 WL 3395654 at *1 (Fed. Cl. July 21, 2010).

⁹³ “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. “*Underwood v. Sec’y of Dep’t of Health & Human Servs.*, 90-719V, 1991 WL 156659 at *2, 4 (Cl. Ct. July 31, 1991).

⁹⁴ U.S. GOV’T ACCOUNTABILITY OFF., GAO-15-142, VACCINE INJURY COMPENSATION: MOST CLAIMS TOOK MULTIPLE YEARS AND MANY WERE SETTLED THROUGH NEGOTIATION 15 (2014), <http://www.gao.gov/products/GAO-15-142>.

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In other words, a settlement is not good evidence that the plaintiff's claims—petitioner's, in this case—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.”⁹⁵

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
- The need to resolve a case quickly⁹⁶

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

⁹⁵Kelly v. Secretary of Health & Human Services, No. 15-167V, (2015).
<http://www.leagle.com/decision/In%20FDCO%2020151221919/KELLY%20v.%20SECRETARY%20OF%20HEALTH%20AND%20HUMAN%20SERVICES> (Last accessed August 29, 2017)

⁹⁶ Health Resources and Services Administration, *Vaccine Injury Compensation Data*, (Aug. 1, 2017)., <https://www.hrsa.gov/vaccinecompensation/data/>

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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.⁹⁷ 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.⁹⁸

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).⁹⁹ 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.

⁹⁷ see below, part ##### for further discussion.

⁹⁸ *Althen*, 418 F.3d at 1278.

⁹⁹ Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 14 (1993-1994).

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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 causation. Let's start with the settlement that has been used as evidence that vaccines cause autism by antivaccine 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')." ¹⁰⁰ Petitioners specifically asserted that Ryan "suffered a Vaccine Table Injury, namely, an encephalopathy." ¹⁰¹ 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." ¹⁰²

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

¹⁰⁰ *Mojabi v. Sec'y of Health and Human Services*, UNPUBLISHED No. 06-227V, 2 (2012). <http://www.usfc.uscourts.gov/sites/default/files/opinions/CAMPBELL-SMITH.MOJABI-PROFFER.12.13.2012.pdf>

¹⁰¹ *Id.*

¹⁰² *Id.* at 1-2.

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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.”¹⁰³

In fact, in a later decision the court clarified which injury had been compensated.¹⁰⁴

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.

Not only was Ryan’s compensation awarded for something other than autism, he did not exhibit ASD behaviors in CHAT screenings.¹⁰⁵ Clearly, to cite this decision as evidence that vaccines cause autism is simply wrong.

Nor was Emily Lowrie (Moller?), the second case mentioned in the article addressing Ryan Mojabi’s case, compensated for autism. She, too, was compensated for encephalopathy.¹⁰⁶ This case too involved a Table Injury, where causation is presumed and does not have to be shown.

¹⁰³ *Id.* at 2.

¹⁰⁴ *Mojabi v. Sec’y of Health & Human Servs.*, 06-227V, 2013 WL 6916777 at *5 (Fed. Cl. Nov. 27, 2013). <http://www.uscfc.uscourts.gov/sites/default/files/opinions/CAMPBELL-SMITH.MOJABI-PROFFER.12.13.2012.pdf>

¹⁰⁵ *Mojabi v. Sec’y of Health & Human Servs.*, 06-227V, 2009 WL 3288324, at footnote 19 (Fed. Cl. Apr. 29, 2009). <http://www.uscfc.uscourts.gov/sites/default/files/opinions/CAMPBELL-SMITH.MOJABI-PROFFER.12.13.2012.pdf>

¹⁰⁶ *Lowrie v. Sec’y of Health and Human Servs.*, 08-108V, *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

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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.”¹⁰⁷ 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.”¹⁰⁸ Three of those¹⁰⁹ were related to seizures. Two conceded a seizure disorder;¹¹⁰ and one of those two stated explicitly that the secretary was not conceding an encephalopathy, or brain disorder.¹¹¹ A third case states, “[t]he Secretary conceded that the vaccination was the likely cause of the child's first seizure,

¹⁰⁷ Holland et al., *supra* 77, at 512.

¹⁰⁸ *Doe/77, supra* 91.

¹⁰⁹ The fourth, Hannah Poling’s case, will be discussed separately in the next section.

¹¹⁰ *Koston v. Sec’y, Dep’t of Health & Human Servs.*, 974 F.2d 157, 161 (Fed. Cir. 1992); *Underwood v. Sec’y of Dep’t of Health & Human Servs.*, 90-719V, 1991 WL 156659 at *2, 4 (Cl. Ct. July 31, 1991).

¹¹¹ “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.”; *Underwood v. Sec’y of Dep’t of Health & Human Servs.*, 90-719V, 1991 WL 156659 at *2, 4 (Cl. Ct. July 31, 1991).

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but that such seizure had no lasting effect and the child's subsequent conditions were caused by a pre-existing brain abnormality."¹¹²

Seizure disorder, as will be discussed more in detail below,¹¹³ 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.¹¹⁴ The child was in fact diagnosed with Rett Syndrome. 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

¹¹² *Freeman v. Sec'y of Health and Human Services*, 2003 U.S. Claims LEXIS 285 at *FN 7 (Fed. Cl. Sept. 25, 2003).

¹¹³ Text near footnotes ##-##.

¹¹⁴ *Koston*, 974 F.2d at 159.

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known.¹¹⁵ Under the act, an injury of idiopathic origin does not rebut the presumption of causation that a Table Injury creates.¹¹⁶ In 1992, when *Koston* was decided, Rett syndrome could be seen as of idiopathic origin because the genetic basis for Rett Syndrome was discovered in 1999.¹¹⁷

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.¹¹⁸

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.¹¹⁹ There was, however, disagreement as to whether the child's seizure disorder or the child's brain damage, resulted from

¹¹⁵ *Id.* at 160.

¹¹⁶ Vaccine Injury Table § a, 42 U.S.C. 300aa-13(a)(2).

¹¹⁷ Rettsyndrome.org, *The History of Rett Syndrome*, RETT SYNDROME (Aug. 23, 2017, 5:41 PM). <https://www.rettsyndrome.org/document.doc?id=159>

¹¹⁸ Seizure disorders, and the evidence on whether vaccines cause them, are addressed in part III (A)(2).

¹¹⁹ *Freeman*, LEXIS 285, at *3. Research shows that febrile seizures, caused by fever, are in fact a potential side effect of MMR; Nicola P. Klein et al., *Safety of Measles-Containing Vaccines in 1-Year-Old Children*, 135 PEDIATRICS no. 2, (2015). Short febrile seizures, although frightening to parents, are usually harmless, but prolonged one can rarely be an issue: http://www.ninds.nih.gov/disorders/febrile_seizures/detail_febrile_seizures.htm.

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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.”¹²⁰

What did the case say about autism? Well, 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 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.

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, 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.

¹²⁰ *Freeman*, LEXIS 285, at *2.

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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.

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.¹²¹

The Hannah Poling Concession

One of the cases most commonly brought up by members of the VCAC¹²² is the Hannah Poling case,¹²³ on the (correct) 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

¹²¹ And see text near footnotes ### below for a discussion of the distinction between autistic-like features and autism.

¹²² 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 ATTKISSON, (Aug. 23, 2017, 5:48 PM). <http://sharylattkisson.com/cdc-possibility-that-vaccines-rarely-trigger-autism/>. (both last accessed August 29, 2017)

¹²³ *Doe/77 v. Sec'y of Health & Human Servs.*, 2010 WL 3395654 at *1 (Fed. Cl. July 21, 2010).

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for autism caused by vaccines. In addition to its constant use in other contexts, Holland et. al devote a separate section¹²⁴ to the Poling case. 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 4.¹²⁵

At 19 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*

¹²⁴ Holland et al., *supra* note 77, at pp. 500-503.

¹²⁵ Concession documented cited at: <http://scienceblogs.com/insolence/2008/03/10/the-hannah-poling-case-and-the-rebrandin/>. (Last accessed on August 29, 2017)

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type b (Hib), measles–mumps–rubella (MMR), varicella, and inactivated polio.”¹²⁶ 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.¹²⁷

Unsurprisingly, Hannah’s parents blamed the vaccines she received and filed a claim with NVICP. At the time, Hannah’s case was included in the Autism Omnibus Proceeding;¹²⁸ 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 Doc/77’s pre-existing mitochondrial disorder based on an MMR vaccine Table presumptive injury of encephalopathy.¹²⁹

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

¹²⁶ Paul A. Offit, *Vaccines and Autism Revisited—The Hannah Poling Case*, 358 NEW ENG. J. MED. 2089, 2089 (2008).

¹²⁷ *Id.*

¹²⁸ See Part IV.

¹²⁹ *Doe/77 v. Sec’y of Health & Human Servs.*, 2010 WL 3395654 at *1 (Fed. Cl. July 21, 2010).

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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.¹³⁰

Members of VCAC believe this concession is an admission by the government that vaccines cause autism.¹³¹ Is it?

A. 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. The evidence pointed to a preexisting mitochondrial disorder caused by a mutation in a specific gene.¹³² Mutations in this specific gene are very rare, and “[t]he gene plays a pivotal role in protein production, so any mutation that damages this function could have a huge impact on other mitochondrial genes and energy production by cells.”¹³³ Mitochondrial disorders generally are rare (while higher among

¹³⁰ Orac, *The Hannah Poling Case: Autism Rebranded Again*, SCIENCEBLOGS, (Aug. 23, 2017, 5:51 PM). <http://scienceblogs.com/insolence/2008/03/10/the-hannah-poling-case-and-the-rebrandin/>

¹³¹ E.g., David Kirby, *David Kirby: Hannah Poling Really Did Change Everything*, AGE OF AUTISM, (Aug. 23, 2017, 5:52 PM).; <http://www.ageofautism.com/2008/12/age-of-autism-aware-2008-child-of-the-year-hannah-poling.html>

¹³² Orac, *supra* note 130.

¹³³ 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> (paraphrasing Columbia University neurology professor Salvatore DiMauro) [<http://perma.cc/FW8T-78VE>].

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children with autism, the rate is still very low),¹³⁴ and the subset that is linked to autism-like symptoms is even more rare.¹³⁵

Children with this problem can regress between their first and second year,¹³⁶ and any stress—a disease, a vaccine, or something else—can cause such regression.¹³⁷ In Hannah’s case, Dr. Paul Offit points out,

although 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.¹³⁸

¹³⁴ 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>].

¹³⁵ Orac, *supra* note 130.

¹³⁶ Kim. M. Cecil et. al., *Mitochondrial Encephalopathies: Potential Relationships to Autism?*, NAT’L INST. OF NEUROLOGICAL DISORDERS & STROKE (June 29, 2008), http://wayback.archive-it.org/1170/20161005013715/https://www.ninds.nih.gov/news_and_events/proceedings/20090629_mitochondrial.htm (“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.”) (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 (2002), <http://dx.doi.org/10.1001/archotol.128.4.355>) [<https://perma.cc/T3NQ-T5US>]. (last accessed August 26, 2017)

¹³⁷ Jim Giles, *Autism Payout Reignites Vaccine Controversy*, NEW SCIENTIST, (Aug. 23, 2017, 5:58 PM). <http://www.newscientist.com/article/mg19726464.100-autism-payout-reignites-vaccine-controversy.html?page=2#.VF1YvkthlpE>

¹³⁸ Offit, *supra* note 125, at 2090.

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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.¹³⁹ The United Mitochondrial Disease Foundation said, in a statement:

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.¹⁴⁰

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

¹³⁹ *Id.* The National Institute of Neurological Disorders and Stroke also recounted the following:

To reduce the risk presented by acquired infections, the workshop panelists strongly encourage vaccinations in the hundreds of children they treat for mitochondrial disease. 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.

Mitochondrial Encephalopathies: Potential Relationships to Autism?, *supra* note 136.

¹⁴⁰ *The UMDF Scientific and Medical Advisory Board Statement on the Connection Between Mitochondrial Disease and Autism*, UNITED MITOCHONDRIAL DISEASE FOUND. (Apr. 29, 2008), <https://secure.umdf.org/site/apps/nlnet/content2.aspx?c=jtJWJaMMIsE&b=4090185&ct=5315363¬oc=1> ; <http://www2.aap.org/advocacy/releases/autismparentfacts.htm>

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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.¹⁴¹

In a real sense, declining vaccination rates, the result of unfounded fears about vaccines, put these children more at risk than others. 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 vaccines.¹⁴² 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.¹⁴³ 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

¹⁴¹ *CDC Responds to Questions About Vaccines*, CTNS. FOR DISEASE CONTROL & PREVENTION (Mar. 28, 2008) [<https://web.archive.org/web/20150906034734/http://www.cdc.gov/news/2008/03/VaccineQuestions.html>].

¹⁴² Megan Brooks, *Molecular Psychiatry Medscape: Mitochondrial Dysfunction Linked to Autism*, AGE OF AUTISM, (Aug. 23, 2017, 6:02 PM). <http://www.ageofautism.com/2017/02/molecular-psychiatry-medscape-mitochondrial-dysfunction-linked-to-autism.html>; and see: Orac, *The New Strategy of the Antivaccination Movement: Autism is a “Misdiagnosis” for Mitochondrial Disease*, SCIENCEBLOGS, (Aug. 23, 2017, 6:04 PM). <http://scienceblogs.com/insolence/2008/03/06/the-new-strategy-of-the-antivaccination/>

¹⁴³ 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>.

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mitochondrial problem Hannah Poling had is rarer still, in fact, extraordinarily rare, very severe, and genetic: not all mitochondrial disorders are the same. 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.¹⁴⁴ And as mentioned, 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.¹⁴⁵ 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 is,¹⁴⁶ and as pointed by Michael Fitzpatrick, in many of those cases it is possible in retrospect to recognize problems that were not identified by parents or professionals.¹⁴⁷

B. Poling Does Not Show That Vaccines Cause Autism from a Legal Perspective

¹⁴⁴ Gorski, *supra* note 134.

¹⁴⁵ For a passionate appeal on this from a mother to a child with a mitochondrial problem, see 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>].

¹⁴⁶ MICHAEL FITZPATRICK, MMR AND AUTISM: WHAT PARENTS NEED TO KNOW 61 (2004).

¹⁴⁷ *Id.*

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The government decided to concede that there was enough evidence that the vaccines aggravated an encephalopathy, a Table Injury, in the time required. 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. The government was not willing to try to prove it was not the vaccines. The legal standard for compensation was met. This was an appropriate case to compensate a vaccine injury, but not strong proof of causation.

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.¹⁴⁸ Even under the more lax *Althen* standard, the court found the claim of a connection between vaccines and developmental delays due to mitochondrial disease unsupported. And with no fever, the Special Master expressly rejected such a connection.¹⁴⁹

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

¹⁴⁸ *Holt v. Sec’y of Health & Human Servs.*, No. 05-0136V, slip op. at 34–43 (Fed. Cl. June 24, 2015), http://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2005vv0136-97-0.

¹⁴⁹ *Id.* at 38–39. The Special Master also rejected many of the parents’ factual claims in that case, but that is beyond the scope of this paper.

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been wrong to reject the case.¹⁵⁰ 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.¹⁵¹ What was contested was the application of the doctor’s theory to the case itself,¹⁵² the main question being whether, in order to be applicable, the theory required that the problems appear within a specific time frame. The court decided that it did not.¹⁵³ 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. 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.¹⁵⁴ These were not the only problems, but this is a case that is tragic, terrible—and not autism or autism related. It was also very 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 compensating for aggravating the problems.¹⁵⁵

In the later *Hardy* decision, the Special Master explained:

¹⁵⁰ *Paluck v. Sec’y of Health & Human Servs.*, No. 14-580 (Fed. Ct. May 20, 2015) [<https://archive.org/download/gov.uscourts.cafc.14-5080/gov.uscourts.cafc.14-5080.56.0.pdf>].

¹⁵¹ *Id.*, slip op. at 11 (“[B]efore the special master the government conceded that vaccination could have, in theory, exacerbated K.P.’s underlying mitochondrial disorder.”).

¹⁵² *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.”)

¹⁵³ *Id.*, slip op. at 17–18.

¹⁵⁴ *Id.*, slip op. at 4, 15–16.

¹⁵⁵ *Id.*, slip op. at 22–23.

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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*.

. . . [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*.¹⁵⁶

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*.¹⁵⁷

The Poling case is the closest to compensation for autism available to the members of the VCAC—and it's not quite there. And it's 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.

¹⁵⁶ *Hardy v. Sec'y of Health & Human Servs.*, No. 08-108V, slip op. at 43 (Fed. Cl. Nov. 3, 2015), https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2008vv0108-77-0.

¹⁵⁷ *Holt*, *supra* note 148, slip op. at 36 (“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.”).

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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.¹⁵⁸ Discretionary decisions are evaluated using the same standard for abuse of discretion that is used by appellate courts to assess the decisions of trial courts,¹⁵⁹ but factual determinations are held to the “arbitrary and capricious” standard usually used to evaluate agency decisions.¹⁶⁰ 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: “(C) Shall not intentionally misquote to a tribunal the language of a book, statute, or decision;”¹⁶¹

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

¹⁵⁸ *Munn v. Sec’y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

¹⁵⁹ *Milmark Servs. v. U.S.*, 731 F.2d 855, 860 (Fed. Cir. 1984).

¹⁶⁰ *Munn*, 970 F.2d at 870 n.10.

¹⁶¹ MODEL RULES OF PROF’L CONDUCT 3.1 (AM. BAR ASS’N 2013); California Rules of Professional Conduct 5-200: Trial Conduct.

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support a factual claim, and you can certainly not misrepresent them. If you do either, you will be called out—and those calling you out will be in the right.

Using cases against their facts is exactly what the Holland et al. article does.¹⁶² 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 the compensation was for something other than autism. In some of them, an autism claim was expressly rejected.

Further, the question they raised as unanswered—whether autism is just another name for encephalopathy or seizure disorder¹⁶³—is not an open question for doctors: as explained below, there is an answer to it, and the answer is a clear no. This, too, highlights the fact that cases compensated for encephalopathy or encephalitis or seizure disorder—especially the last—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 goes over the cases discussed in Holland et al. one by one in detail, adding to them 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 either encephalopathy or seizure disorder. There are two parts to the problem with the use

¹⁶² Holland et. al, *supra* note 77, at 511

¹⁶³ *Id.*, at 528

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of encephalopathy and seizure disorder in the article. First, encephalopathy isn't autism (though a single child might have both), and 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.¹⁶⁴ 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.¹⁶⁵ To qualify, for the purpose of the Table of Injuries the petitioner has to meet a narrow definition of acute encephalopathy, outlined below, and also have chronic encephalopathy for more than six months.¹⁶⁶

¹⁶⁴ Holland et al., *supra* note 77, at 495.

¹⁶⁵ *Hardy, supra* note 156 at 24-25. The Table has since been changed (hence the reference to the case, rather than table), 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, and under this definition, at least some of the cases and settlements may have ended differently.

¹⁶⁶ *Id.*

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The definition of acute encephalopathy for the purpose of the Table of Injuries is age dependent. In a child under 18 months, there must be “a significantly decreased level of consciousness lasting for at least 24 hours”¹⁶⁷ (children who also had a seizure have to meet additional criteria). 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.¹⁶⁸

In addition, the acute encephalopathy must be sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).¹⁶⁹

The authors seize onto the idea of “a significantly decreased level of consciousness,” defined as “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

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

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(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).¹⁷⁰

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 some features of certain conditions, to distinguish between different diseases, one must explore more many other features other than just 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 between autism and encephalopathy.

First, even within the altered conscious state, it is possible to distinguish the two conditions. Note that in a child over 18 months, altered consciousness alone does not meet the diagnostic criteria for encephalopathy without the additional features identified above (that is, disease severe enough to warrant hospitalization, and one out of either seizures or a significant change in mental status). But even in the child under 18 months, the decrease in the 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

¹⁷⁰ *Id.*

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interact.¹⁷¹ Even when it is claimed that a child regressed immediately after vaccines, the medical descriptions are different and easy to distinguish to the trained eye.¹⁷²

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. Their altered level of consciousness is merely one aspect of their disease, and encephalopathy can be immediately life threatening.¹⁷³ A child with autism, however, lacks the same symptoms, though she may have other health problems and her ability to interact with her

¹⁷¹ Karen A. Horridge, *Assessment and Investigation of the Child With Disordered Development*, 96 *Arch Dis Child Educ Pract Ed.* 9 (2009); See also Hardy at 27: “An acute encephalopathy is an event “that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).” § 100.3(b)(2)(i).

...

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.’” Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7687. As noted in Waddell, by then-Chief Special Master Campbell-Smith,²⁵ the QAI definition of “significantly decreased level of consciousness” implies “a state of diminished alertness that is much more than mere sleepiness or inattentiveness [It] requires markedly impaired--or strikingly absent--responsiveness to environmental or external stimuli, for a sustained period of at least twenty-four hours.” Waddell v. HHS, No. 10-316V, 2012 WL 4829291, at *7 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). Special Master Campbell-Smith added that the symptoms of a “Table Injury encephalopathy” are not “subtle.” Id. at 6.”

¹⁷² On diagnosing encephalopathy: Claudia A. Chiriboga, *Acute Toxic-Metabolic Encephalopathy in Children*, UPTODATE (Jul. 2017). <http://www.uptodate.com/contents/acute-toxic-metabolic-encephalopathy-in-children>; See also: M. Mizuguchi et al, *Acute Encephalopathy Associated with Influenza and Other Viral Infections*, 115 *Acta Neurol. Scand.* 45, 45 (2007); For diagnosing autism, and how it’s different: Chris Plauché Johnson, Scott M. Myers, *Identification and Evaluation of Children with Autism Spectrum Disorders*, 120 *PEDIATRICS* 1183 (2007).

¹⁷³ *Id.*

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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. But it would be a situation of one child having two conditions, not the two conditions being the same.

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 just not been recognized as such by the parents.¹⁷⁴ 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 of the parents claim their children experienced – there are other differences. Encephalitis, brain inflammation, is common in many or most encephalopathies.¹⁷⁵ The results of numerous investigations display marked differences between encephalitis and autism, reflecting the different aetiological 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 through 3.

¹⁷⁴ *Cedillo, supra* note 45, at 215.

¹⁷⁵ M. Mizuguchi et al., *supra* note 173, at 45.

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Figure 1: Encephalitis and Autism, Point by Point Comparison¹⁷⁶

¹⁷⁶ On Encephalitis, John E. Greenlee, *Encephalitis*, MERCK MANUAL, (Jan. 2017). <http://www.merckmanuals.com/professional/neurologic-disorders/brain-infections/encephalitis> and ROBERT M. KLIEGMAN et al., NELSON TEXTBOOK OF PEDIATRICS (19th edition) 2061 (2011). On autism, Giuseppe Raviola et al., *Autistic Disorder*, in NELSON TEXTBOOK ON PEDIATRICS, CH. 28.1 (19th edition). [Giuseppe Raviola et al., *Autistic Disorder*, NELSON TEXTBOOK OF PEDIATRICS (19th edition) 100 (2011).]

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	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.

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Figure 2: Wrong Comparison: Club Foot and Broken Ankle**ENCEPHALITIS IS NOT AUTISM**

A broken ankle is not the same as a club foot, and encephalitis or encephalopathy is not the same as autism. The same part of the body is involved, and symptoms may be vaguely similar. That is all.



2. Seizure disorder

Seizure disorder is not autism. They have different definitions and characteristics, although the same child may have both—but may not. Seizure disorders are more common among children with autism than in the general population,¹⁷⁷ but that does not

¹⁷⁷ Eric Rubenstein et al., *A Review of the Differences in Developmental, Psychiatric, and Medical Endophenotypes Between Males and Females with Autism Spectrum Disorder*, J.

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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.¹⁷⁸ 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.¹⁷⁹

Encephalopathy and seizure disorder are entities in their own right, and 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, but the medical evidence is able to distinguish clearly between them, and the evidence also shows clearly 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 and MMR caused encephalopathy and encephalitis and that DTP caused seizure disorder. Recent evidence supports none of these claims.

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”). The rate in the general population is 0.5-0.8%. <http://www.epilepsy.com/learn/epilepsy-statistics>

¹⁷⁸ Nienke E. Verbeek et al., *Etiologies for Seizures Around the Time of Vaccination*, 134 PEDIATRICS 658 (2014); *see also* Steven C. Schachter et al., *Is Epilepsy Inherited?*, EPILEPSY FOUNDATION, (Jul. 2013). <http://www.epilepsy.com/learn/epilepsy-101/epilepsy-inherited>

¹⁷⁹ Canitano Roberto, *Epilepsy in Autism Spectrum Disorders*, 16 EUROPEAN CHILD AND ADOLESCENT PSYCHIATRY 61-66, p. 62 (2007).

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In large part, NVICP was created because of claims that DTP caused brain damage in children and a subsequent flood of litigation.¹⁸⁰ Encephalopathy from DTP was included in the Table of Injuries because at the time scientists, too, believed the vaccine caused encephalopathy, based, to a large extent, on a large-scale British study.¹⁸¹ However, as summarized by Dr. Paul Offit in the book *Deadly Choices*,¹⁸² subsequent large-scale epidemiological studies did not support that study's conclusion.¹⁸³ And as part of a court case where an English plaintiff claimed to be brain damaged by DTP, it was discovered that David Miller's study was biased in a way that skewed the evidence to make it look like DTP caused brain damage - when reexamination did not support it.¹⁸⁴

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

¹⁸⁰ OFFIT, *supra* note 48, at 17–22.

¹⁸¹ David Miller et al., *Pertussis Immunisation and Serious Acute Neurological Illness in Children*, 307 *BMJ* 1171 (1993).

¹⁸² OFFIT, *DEADLY CHOICES*, *supra* note 48, at 29–31.

¹⁸³ S. Bedson et al., *Vaccination Against Whooping Cough: Report to the Medical Research Council*, 2 *BMJ* 454, 454-462 (1956); T.M. Pollack and J. Morris, *A 7-Year Survey of Disorders Attributed to Vaccination in North West Thames Region*, 1 *THE LANCET* 753, 753-757 (1983); W. D. Shields et al, *Relationship of Pertussis Immunization to the Onset of Neurologic Disorders: A Retrospective Epidemiologic Study*, 113 *Journal of Pediatrics*, 801, 801-805 (1988); A. M. Walker et al, *Neurologic Events Following Diphtheria-Tetanus-Pertussis Immunization*, 81 *Pediatrics* 345, 345-349 (1988); M.R. Griffin et al, *Risk of Seizures and Encephalopathy after Immunization with the Diphtheria-Tetanus-Pertussis Vaccine*, 263 *JAMA* 1641, 1641-1645 (1990). Quoted by Offit, *id.*, at 223.

¹⁸⁴ OFFIT, *DEADLY CHOICES*, *supra* note 48, at 38–39.

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virus does clearly cause encephalitis.¹⁸⁵ So 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 Miller's was.¹⁸⁶

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. It was based mostly on clustering of reporting of encephalitis after the vaccine—using a passive reporting system.¹⁸⁷ While suggestive of a link, this is not strong evidence of one.

The question of whether there is a link between MMR and encephalitis was further examined in a 2011 Institute of Medicine (IOM) report.¹⁸⁸ 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.¹⁸⁹ It also addressed 18 case reports of encephalitis after MMR—14 of which had no

¹⁸⁵ Andrew Kroger, *Measles*, CENTER FOR DISEASE CONTROL, (2015).
<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf> (Last accessed August 29, 2015).

¹⁸⁶ Benor DE 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*, NCBI, (Mar. 1998).
<http://www.ncbi.nlm.nih.gov/pubmed/9481001>

¹⁸⁷ <https://vaers.hhs.gov/data/index>.

¹⁸⁸ 2011 report, “Adverse Effects of Vaccines: Evidence and Causality” 111-118
<http://iom.nationalacademies.org/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx> [ANDREW FORD ET AL., ADVERSE EFFECTS OF VACCINES 108 (2011)]

¹⁸⁹ *Id.*

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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. 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. And recent studies have not found a link between MMR and encephalitis.¹⁹⁰

In a telephone discussion with Dr. Paul 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.¹⁹¹ The wild measles virus, he explained, replicates in the body many thousands of times. The vaccine measles virus, in contrast, replicates only several tens of times. And while the wild measles virus had 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.

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.¹⁹² This point is also relevant because if the claim that encephalopathy or encephalitis are in fact autism was true, with the decrease in

¹⁹⁰ Rowhani-Rahbar A et al., *Lack of Association Between Childhood Immunizations and Encephalitis in California 1998-2008*, NCBI (Nov. 2012), <http://www.ncbi.nlm.nih.gov/pubmed/22080172>; Nicola P. Klein et al., *Safety of Measles-Containing Vaccines in 1-Year-Old Children*, AAP NEWS & JOURNALS (Jan. 2015), <http://pediatrics.aappublications.org/content/early/2015/01/01/peds.2014-1822.abstract>

¹⁹¹ Telephone Interview with Dr. Paul Offit, Director of the Vaccine Education Center at the Children's Hospital of Philadelphia, (September 5, 2014).

¹⁹² Mizuguchi et al., *supra note* 173, at 45-46.

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diseases that are the more common cause of those conditions (and the diseases in question dropped after vaccines),¹⁹³ 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.¹⁹⁴ Most childhood seizure disorders have genetic origins.¹⁹⁵ 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.¹⁹⁶ Given the lack of evidence, it is probably time now for the Secretary to likewise remove encephalopathy and encephalitis.

¹⁹³ Sandra W. Roush et al., *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 JAMA 2155, tables 1 and 2 (2007).

¹⁹⁴ Anne M. McIntosh et al., *Effects of Vaccination On Onset and Outcome of Dravet Syndrome: A Retrospective Study*, 9 THE LANCET No. 6 592, 598 (Jun. 2010).

[http://www.thelancet.com/journals/laneur/article/PIIS1474-4422\(10\)70107-1/abstract](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 (Sep. 2014),

<http://pediatrics.aappublications.org/content/early/2014/09/09/peds.2014-0690.abstract>

¹⁹⁵ R. Nabbout & O. Dulac, *Epileptic Syndromes in Infancy and Childhood*, 21 Current Opinion in Neurology, 161 (2008). quoted in Offit, *Deadly Choices*, 40, 227.

¹⁹⁶ Geoffery Evans M.D., *Update on the National Vaccine Injury Compensation Program (VICP)*, NATIONAL VACCINE ADVISORY COMMITTEE (Jun. 6, 2012).

https://www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2012/evans_062512.pdf

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IV. THE OMNIBUS AUTISM PROCEEDING

Not only did NVICP not find a vaccine caused a child's autism in any of those cases, but NVICP directly confronted the question of whether vaccines can cause autism—and rejected the claim. 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.¹⁰ 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.¹⁹⁷

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.

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. 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. After several years, in February 2009 NVICP handed down its first three decisions, examining the question

¹⁹⁷ Snyder v. Sec'y of Health and Human Services, No. 01-162V, at 6 (2009), http://www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Vowell.Snyder.pdf

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whether thimerosal in vaccines, combined with the measles, mumps and rubella vaccine (MMR), caused autism. 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.¹⁹⁸ 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.¹⁹⁹ In other words, in thoroughly reviewed decisions NVICP concluded, after examination of the evidence, that vaccines do not cause autism.

In *Cedillo*,²⁰⁰ the Court of Appeals for the Federal Circuit said:

we 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.²⁰¹

This is not a lukewarm or hesitant endorsement. The court is making is very clear that the Special Master's decision deserves to be upheld. While the Hazelhurst 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.

¹⁹⁸ reference to *Snyder*, *Hazelhurst*, and *Cedillo*; See also Holland et al., *supra* note 77, at pp. 497-498. **Kirkland**.

¹⁹⁹ *Hazelhurst v. Sec'y of the HHS*, No. 03-654V, (Fed. Cl. Feb. 12, 2009), LEXIS 183 (2009), http://www.uscfc.uscourts.gov/sites/default/files/Hazlehurst_Affirmance.pdf ; *Cedillo v. Sec'y of HHS*, No. 98-916V, (Fed.Cl. Feb. 12, 2009) LEXIS 146 (2009) <http://www.uscfc.uscourts.gov/sites/default/files/cedillo.fedcir.pdf>

²⁰⁰ *Cedillo*, No. 98-916V, at 34.

²⁰¹ *Id.*, at 35

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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 *Hazelhurst* 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.²⁰²

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 *Hazelhurst* family was not claiming that thimerosal caused their son's autism, but that the MMR vaccine alone did.²⁰³ So we see that 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.²⁰⁴

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

²⁰² *Hazelhurst*, No. 03-654V, at 498. The article spoke of "judges" but then mentioned that one judge "answered his own question." Since the link to the voice recording in the article no longer works, and the recording is not found, we cannot check which it is.

²⁰³ *Id.*, pp. 2-3.

²⁰⁴ Holland et al., *supra* note 77, at pp. 498-499.

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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.²⁰⁵

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,²⁰⁶ the court made it clear this does not negate or undermine the finding that thimerosal containing vaccines and MMR do not cause autism.

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

²⁰⁵ *Cedillo*, No. 98-916V, at p. 20.

²⁰⁶ *Hazlehurst*, No. 03-654V,, at 11. “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.”

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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 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

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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's time to reconsider. Vaccines do not cause autism, say both science and law.

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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.²⁰⁷

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Table 1
Appraisal of Selected Cases Employed by Holland et al.

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)	<p>“Daniel has a persistent refractory seizure disorder and suffers from severe and profound mental and physical retardation. His I.Q. does not exceed 30.”</p> <p>Compensation for residual seizure disorder.</p>	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)	<p>“Jonathan is a severely retarded twelve-year-old with cognitive, physical, and social developmental delay. Jonathan has an intellectual age of 4–5 and has many autistic features.”</p> <p>Compensation for residual seizure disorder.</p>	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 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)	<p>“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.”</p> <p>Compensation for encephalopathy.</p>	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.” <i>Kleinert</i> 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)	<p>The claim was for harm from a seizure disorder allegedly caused by DTP.</p> <p>“In this regard, respondent’s report (filed September 7, 1990) suggests vaguely that Kenny’s problems ‘can be attributed in part to other causes</p>	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.

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	such as a family history of epilepsy, autism and tonsillar hypotrophy.’ But in the attached expert report, upon which respondent based 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.	Even this attenuated claim was rejected by the court as pure speculation.
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 seizure disorder and encephalopathy.” Compensation for residual seizure disorder.	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 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	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

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	<p>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."</p> <p>"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 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.</p> <p>"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</p>	<p>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.</p>

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	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), <i>aff'd</i> , 27 Fed. Cl. 457 (1993), <i>aff'd</i> , 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." Compensation for residual seizure disorder.	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.
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	As demonstrated by this quote, the disorder being compensated is retardation, not autism. The autistic <i>tendencies</i> mentioned were never complained of or argued to be caused by the retardation, which was the basis for compensation.

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<p>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)</p>	<p>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 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.”</p> <p>Compensation for encephalopathy and residual seizure disorder.</p> <p>“Dr. Quinn opined that Kyle suffers from pervasive developmental disorder (PDD). Dr. Spiro, however, opined that Kyle is autistic.</p> <p>“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 opined, to a reasonable degree of medical certainty, that Kyle’s condition is permanent.</p> <p>“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</p>	<p>Holland et al. omit the intervening text stating both that there was no autism and that PDD and autism are different disorders.</p> <p>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 <i>supra</i>, her testimony is given greater weight than that of respondent’s expert.” <i>Bastian</i> at *33.</p>

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	<p>diagnosed with autism according to Dr. Lourie’s analysis of the medical records. Nor is he mentally retarded.”</p> <p>Compensation for encephalopathy.</p>	
<p>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)</p>	<p>“In this case, respondent claims that Eric is autistic and that autism is not caused by DPT.”</p> <p>“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 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 <i>Merritt’s Textbook of Neurology</i>, 9th ed., 1995:</p> <p>“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.</p> <p>“Dr. Spiro has not explained clearly why he believes, first, that Eric meets the criteria for autism.”</p>	<p>Parents claimed encephalopathy. Respondent tried to use a claim of autism to deny compensation, and the court rejected the claim.</p> <p>Here we have the same physician representing respondent as in <i>Bastian</i>, 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.</p> <p>Dr. Spiro never has appeared as the claimant’s primary physician and appeared to have had limited f over medical records. <i>Id.</i> 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.”).</p>

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	Compensation for encephalopathy.	
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.” There is no mention of autism in the opinion.	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.
	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 are two problems with the first quote (<i>Tebcherani</i> 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 <i>not</i> related to the vaccination. The decision notes that “there is ongoing research to determine whether there exists evidence of medical and legal causation” [of

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	<p>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.”</p> <p>“The Special Master’s suggestion that Lena exhibited developmental delays prior to the administration of the vaccine, is not reversible error.”</p> <p>“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.”</p> <p>“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.”</p> <p>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.</p>	<p>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 vaccines as a cause or aggravating factor of autism.</p>
<p>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)</p>	<p>“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</p>	<p>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</p>

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	<p>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.”</p> <p>Compensation for seizure disorder and retardation.</p>	<p>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.</p>
Gancz v. Sec’y of Health & Human Servs., No. 91-0178V, 2000 WL 246236 (Fed. Cl. Feb. 15, 2000)	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 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)	<p>“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.”</p> <p>“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</p>	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. ²⁰⁸

²⁰⁸ [http://www.thelancet.com/journals/lanour/article/PIIS1474-4422\(10\)70107-1/abstract](http://www.thelancet.com/journals/lanour/article/PIIS1474-4422(10)70107-1/abstract).
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC320893/>
<http://pediatrics.about.com/b/2011/08/15/dravet-syndrome-an-alternative-explanation-for-vaccine-encephalopathy.htm>

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Paulmino v. Sec’y of Health & Human Servs., 69 Fed. Cl. 1, 4 (Fed. Cl. 2005)	<p>seizures of every variation interspersed with periods of normalcy until developmental delay was noticed months later, culminating in Rachel’s death due to her seizure disorder (epilepsy).”</p> <p>Note that the Special Master is not compensating Rachel’s estate for autism.</p>	<p>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.</p>
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)	<p>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 <i>Althen</i>. To remind readers, a plausible theory is enough under <i>Althen</i>.²⁰⁹</p> <p>“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</p>	<p>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.</p>

²⁰⁹ Refer to relevant pages in the body of the article.

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	<p>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.’”</p> <p>“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.”</p>	
Doe/77 v. Sec’y of Health & Human Servs., 2010 WL 3395654, at *1 (Fed. Cl. July 21, 2010) ^c	<p>“Respondent has conceded that petitioners are entitled to compensation due to the significant aggravation of Child Doe/77’s pre-existing mitochondrial disorder based on an MMR vaccine Table presumptive injury of encephalopathy, which eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela.”</p>	<p>See discussion in the text.²¹⁰ Petitioner is 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.</p> <p>Note that, as discussed in the text, the court has since rejected attempts to claim compensation based on mitochondrial disorders.</p>
Tembenis v. Sec’y of Health & Human Servs., No. 03-2820V, 2010 WL 5164324, at *1, *6 (Fed. Cl. Nov. 29, 2010)	<p>“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-acellular-Pertussis . . . vaccination administered on December 26, 2000, caused Elias to develop a seizure disorder that eventually led to his death.”</p> <p>“In 2002, doctors observed that Elias displayed signs of other disorders.</p>	<p>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.</p> <p>Furthermore, PDD is again conflated with autism in the second quote.</p>

²¹⁰ Add reference to actual paper.

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	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.	
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 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.”	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 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.

NOTE. —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.

^a The term “retarded” is used instead of “intellectual disability” when the court so described the child. The intent is not to offend, but simply to correctly quote the language used at the time.

1. ^b Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480, 508 (2011) (table entry 15).

^c This is the Hannah Poling case, leaked by David Kirby. 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*

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<i>Revisited—The Hannah Poling Case</i> , 358 NEW ENG. J. MED. 2089 (2008), http://www.nejm.org/doi/pdf/10.1056/NEJMp0802904 .		
