

Federal Court Reverses Denial of Vaccination Compensation Claim

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Last month, a United States Court of Appeals for the Federal Circuit held that a child given a diphtheria, whole-cell pertussis, and tetanus (DPT) vaccination at eight-weeks, which resulted in his seizure disorder and language and developmental delays, is entitled to compensation from the National Vaccine Injury Compensation Program, despite a ruling from the special “vaccine” court holding otherwise.¹ The appellate court’s decision comes less than six months after the vaccine court’s well-publicized rejection, in three cases, of a link between autism and thimerosal, a mercury preservative once used in many vaccines including the measles, mumps, rubella (MMR) vaccine.² Attorneys and legal commentators speculate that the ruling by the Court of Appeals may persuade the vaccine court to be more receptive to similar compensation claims in the future.³

Safety of Vaccines and Relationship to Autism

Pediatric and adolescent organizations such as the American Academy of Pediatrics (AAP) and a host of governmental agencies including the FDA, CDC, and the Department of Health and Human Services, tout vaccines as being safer now than at any other time in history.⁴ The AAP and other public health authorities assert that “the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against.”⁵ Most adverse reactions are not serious. However, many parents have had concerns for years that vaccines, specifically the MMR vaccine, contribute to a finding of autism in children.

¹ *Andreu v. Sec’y of Dep’t of Health and Human Servs.*, --- F.3d ---, 2009 WL 1688231 (Fed.Cir.2009); Sharyl Attkisson, *Growing Divide Among Courts On Vaccines*, CBS News.com, June 26, 2009, http://www.cbsnews.com/stories/2009/06/26/cbsnews_investigates/main5117439.shtml.

² Three families, the Cedillos, the Hazelhursts, and the Snyders, sought compensation from the Vaccine Injury Compensation Program alleging an MMR vaccine caused their child’s autism. To review the court’s decision in each of the cases, please visit <http://www.uscfc.uscourts.gov/node/5026> (last visited July 16, 2009). See, also, Donald G. McNeil, Jr., *Court Finds No Link of Vaccine and Autism*, N.Y. TIMES, Feb. 13, 2009 <http://query.nytimes.com/gst/fullpage.html?res=9805E2D6133CF930A25751C0A96F9C8B63>; CNN, *Vaccines Didn’t Cause Autism, Court Rules*, Feb. 12, 2009, <http://www.cnn.com/2009/HEALTH/02/12/autism.vaccines/index.html>; Dan Childs, *Ruling Won’t End Autism Debate, Groups Pledge*, ABC NEWS, Feb. 13, 2009, <http://abcnews.go.com/Health/AutismNews/Story?id=6866077&page=1>; Rex. W. Huppke, *Court Finds No Autism-Vaccine Link: Will It Matter?*, CHICAGO TRIB., Feb. 12, 2009, <http://archives.chicagotribune.com/2009/feb/12/health/chi-090212autism-analysis-story>.

³ See Attkisson, *supra* note 1; Sheri Qualters, *Federal Circuit Reverses Denial of Vaccine Injury Claim*, Law.com, June 26, 2009, <http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202431807196>.

⁴ See Am. Acad. of Pediatrics, *Facts for Parents About Vaccine Safety*, (June 2008), available at http://www.cisimmunize.org/fam/facts/VaccineSafety_English.doc (last visited May 18, 2009); U.S. Food & Drug Admin., *A Parent’s Guide to Kids’ Vaccines*, July 31, 2007, available at <http://www.fda.gov/consumer/updates/kidsvaccines073107.html>.

⁵ Immunization Action Coalition, *It’s Federal Law! You Must Give Your Patients Current Vaccine Information Statements*, (Dec. 2008), available at <http://www.immunize.org/catg.d/p2027.pdf> (last visited May 18, 2009).

In 1988, Andrew Wakefield, M.D., of the Royal Free Hospital in London published a study suggesting that the MMR vaccine was linked to bowel disease and autism.⁶ Following publication of Wakefield's conclusions, vaccinations of British children against MMR dropped significantly and news of the study soon thereafter reached the United States.⁷ Since then, numerous scientific studies have been published regarding the relationship between autism and thimerosal, the mercury-based preservative. Those studies concluded there was no causal connection between the presence of thimerosal in vaccines and the incidence of autism in children.⁸ Amazingly enough, the London *Sunday Times* reported earlier this year that Wakefield "changed and misreported results in his research, creating the appearance of a possible link with autism."⁹

Thimerosal was removed from childhood vaccines in 2001, and the AAP states that autism rates have actually increased since, suggesting that the presence of thimerosal is not linked to autism.¹⁰ Additionally, a recent report from a CDC-funded study in Italy additionally concluded that thimerosal "once used in many vaccines doesn't hurt children, offering more reassurance to parents."¹¹ However, the scientific reassurance came too little, too late.

The Vaccine Trust Fund

Soon after Wakefield published his findings and other similar studies on vaccines concluded they posed various adverse health effects on children, most vaccine

⁶ Bruce Patsner, *Childhood Vaccines and Autism, Special Courts and Torts*, HEALTH L. PERSPECTIVES, Feb. 18, 2008, [https://www.law.uh.edu/healthlaw/perspectives/2008/\(BP\)%20autism.pdf](https://www.law.uh.edu/healthlaw/perspectives/2008/(BP)%20autism.pdf) (citing A.J. Wakefield, et al., *Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children*, 351 LANCET 637 (2004)).

⁷ *Id.*

⁸ See M.E. Pichichero, A. Gentile, N. Giglio, et al., *Mercury levels in newborns and infants after receipt of thimerosal-containing vaccines*, 121:2 PEDIATRICS e208-14 (2008) (finding relatively low blood mercury levels in all age groups); R. Schechter and J.K. Grether, *Continuing increases in autism reported to California's Developmental Services System: Mercury in retrograde*, 65:1 ARCH. GEN. PSYCH. 19-24 (2008) (data showed no decrease in rates of autism as exposure to thimerosal was reduced or eliminated); W.W. Thompson, C. Price, and B. Goodson, et al., *Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years*, 357:13 NEW ENG. J. MED. 1281-92 (2007) (data suggests no causal connection between increasing exposure to mercury in thimerosal early in life and subsequent neuropsychological issues at 7 to 10 years of age); S.K. Parker, B. Schwartz, J. Todd, and L.K. Pickering, *Thimerosal-Containing Vaccines and Autistic Spectrum Disorder: A Critical Review of Published Original Data*, 114 PEDIATRICS 793-804 (2004) (data demonstrated no association between thimerosal-containing vaccines and autism); J. Heron, J. Golding, et al., *Thimerosal Exposure in Infants and Developmental Disorders: A Prospective Cohort Study in the United Kingdom Does Not Support a Causal Association*, 114 PEDIATRICS 577-83 (2004) (study shows no evidence of any harmful effect of thimerosal-containing vaccines on neurologic or psychological outcomes); P. Stehr-Green, P. Tull, M. Stellfeld, et al., *Autism and thimerosal-containing vaccines: Lack of consistent evidence*, 25:2 AM. J. OF PREV. MED. 101-106 (2003) (study adds to evidence that thimerosal-containing vaccines do not cause autism or similar disorders).

⁹ Brian Deer, *MMR Doctor Andrew Wakefield Fixed Data on Autism*, THE SUNDAY TIMES, Feb. 8, 2009, http://www.timesonline.co.uk/tol/life_and_style/health/article5683671.ece.

¹⁰ Facts for Parents About Vaccine Safety, *supra* note 4.

¹¹ Carla K. Johnson, Assoc. Press, *Study Adds to Evidence of Vaccine Safety*, ABC NEWS, Jan. 26, 2009, <http://abcnews.go.com/Health/AutismNews/wireStory?id=6729335>.

manufacturers got out of the vaccine-producing market.¹² By 1986, Lederle Laboratories in New York was the sole manufacturer of the DPT vaccine in the United States.¹³ Faced with a looming public health crisis in which no company was actively willing to produce childhood vaccines, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act).¹⁴ The Vaccine Act created the National Vaccine Injury Compensation Program (VICP), a no-fault compensation system in the form of a Trust Fund designed to encourage manufacturers to produce childhood vaccines while providing a shield against potential liability in rare instances where an injury results from vaccination.¹⁵ Families who believe they have been injured by a covered vaccine¹⁶ file a claim against the federal government,¹⁷ not the vaccine's manufacturer, in the United States Court of Federal Claims seeking compensation from the program's Trust Fund.¹⁸

Since the program's inception in 1988, more than 1,500 people have been paid in excess of \$1.18 billion in compensation for injuries sustained.¹⁹ Not only have the monetary awards been a positive outcome under the program, but the creation of the Trust Fund has minimized litigation against drug manufacturers and healthcare professionals administering the vaccinations.

The Special Masters Decide Three Autism Cases

A Congressionally-created office within the U.S. Court of Federal Claims, the Office of the Special Masters, adjudicates claims brought under the Act in the often-termed "Vaccine Court."²⁰ There is one chief special master and five associate special masters appointed to four-year terms.²¹ As explained in a previous *Health Law Perspectives* article:

[t]here is no requirement that a special master has any formal medical training, and none of the current special masters have an extensive scientific background. The special masters have two primary functions: collection of relevant information in a timely manner, and rendering a final, enforceable decision.²²

¹² Patsner, *supra* note 6 at *2 (“[b]y 1985 many vaccine manufacturers had difficulty obtaining liability insurance”).

¹³ *Id.*

¹⁴ Pub. L. No. 99-660; 42 U.S.C. §§ 300aa-1 *et seq.* (West 2009).

¹⁵ *Id.*; Patsner, *supra* note 6 at *3; U.S. Dep’t of Justice, *About the National Vaccine Injury Compensation Program*, <http://www.usdoj.gov/civil/torts/const/vicp/about.htm> (last visited July 16, 2009).

¹⁶ Vaccines covered under the program include diphtheria, pertussis, tetanus (DPT); measles, mumps, rubella (MMR); polio; hepatitis B; varicella (chicken pox); Hemophilus influenzae type b; and rotavirus.

¹⁷ More specifically, because the Dep’t of Health and Human Services administers the vaccine program, claimants name the Secretary of the agency as a defendant.

¹⁸ See Patsner and U.S. Dep’t of Justice, *supra* note 6.

¹⁹ *Id.*

²⁰ *Id.* See also Qualters, *supra* note 3.

²¹ *Id.*

²² Patsner, *supra* note 6 at *3.

In February 2009, physicians, the American Medical Association, and vaccine supporters nationwide applauded the Vaccine Court's well-publicized decision that rejected the theory that the MMR vaccine directly attributed the disabling autism affecting three children.²³

In one case, a special master ruled that the Cedillo family had "failed to demonstrate that thimerosal-containing vaccines can contribute to causing immune dysfunction, or that the MMR vaccine can contribute to causing either autism or gastrointestinal dysfunction."²⁴ In the same case, another special master concluded that the government's expert witnesses were "far better qualified, far more experienced, and far more persuasive" than the family's experts.²⁵ In making their decisions, the special masters sifted through 5,000 pages of transcripts, nearly 1,000 medical articles, and heard extensive testimony from scientific and medical experts.²⁶

The decisions by the special masters may have temporarily deflated the hopes of other families seeking some sort of redress or answer to their child's unexplained occurrence of autism, but autism advocacy groups have declared that the decision will not deter them from their cause.²⁷ The advocacy groups gained a little bit of ammunition to fight back with a recent Federal Court of Appeals decision.

Andreu I: The Vaccine Court's Decision

In 1995, when Enrique Andreu was eight-weeks-old, he was inoculated with a diphtheria, whole-cell pertussis and tetanus (DPT) vaccine.²⁸ Prior to the vaccination, Enrique had undergone an uneventful birth and was developing normally; following the inoculation, Enrique cried consistently and began having "unusual arm movements," i.e., seizures.²⁹ After being instructed by the family's pediatrician to go to Miami Children's Hospital, several tests were performed and Enrique was admitted for evaluation.³⁰ An MRI taken produced normal results and Enrique was released from the hospital approximately four days later.³¹

By January 1998, Enrique's seizures had become "intractable and uncontrolled by medication."³² Later that year, a team of experts concluded that Enrique had an IQ of 63

²³ Susan J. Landers, American Med. Assoc., *Landmark Ruling Finds No Link Between Vaccine and Autism*, AM. MED. NEWS, Mar. 2, 2009, <http://www.ama-assn.org/amednews/2009/03/02/hll20302.htm>.

²⁴ See Donald G. McNeil, Jr., *Court Says Vaccine Not to Blame for Autism*, N.Y. TIMES, Feb. 13, 2009, <http://www.nytimes.com/2009/02/13/health/13vaccine.html?ref=health>.

²⁵ *Id.*

²⁶ Landers, *supra* note 23.

²⁷ See Dan Childs, *Ruling Won't End Autism Debate, Groups Pledge*, ABC News.com, Feb. 13, 2009, <http://abcnews.go.com/print?id=6866077>.

²⁸ *Andreu v. Sec'y of Dep't of Health & Human Servs.*, --- F.3d ---, 2009 WL 1688231 (Fed.Cir.) (a better discussion of the child's background and history is found in the Court of Appeals opinion).

²⁹ *Id.* at *1.

³⁰ *Id.*

³¹ *Id.*

³² *Id.* at *2.

and exhibited significant language and developmental delays.³³ In October 1998, the Andreus filed their claim with the Claims Court under the Vaccine Act seeking compensation and alleging that the DPT vaccine Enrique received caused his seizure disorder.³⁴

Nearly ten years later, in August 2007, a special master issued a decision denying Enrique compensation.³⁵ The Court of Federal Claims reviewed the special master's decision and reversed, holding that testimony from the Andreus' medical expert could meet the necessary requirements for compensation to be awarded; however, the court felt the evidence presented was too close to call and remanded the matter to the special master for a clearer determination from Enrique's treating physicians whether his seizure disorder was the direct result of the DPT vaccine he received.³⁶ On remand, testimony was heard from Enrique's treating physicians, both of whom explained that they believed his seizure disorder and developmental delays were the direct result of his receiving the DPT vaccination.³⁷ However, the special master disagreed and refused Enrique compensation concluding that the Andreus "failed to meet their burden to show a logical sequence of cause and effect" between the vaccine and Enrique's resulting seizure disorder.³⁸

On appeal, the Court of Federal Claims affirmed, concluding that the special master's decision to deny compensation was not arbitrary or capricious.³⁹ The court noted in summary that the evidence presented failed to sufficiently link Enrique's injury to the DPT vaccine he received.⁴⁰ The Andreus then appealed to the Federal Circuit Court of Appeals.

Andreu II: The Court of Appeals' Decision

After reviewing the procedural history of Enrique's case, the appeals court began its discussion by noting:

[c]hildhood vaccinations, though an important part of the public health program, are not without risk. Because vaccines often contain either killed bacteria or live but weakened viruses, they can cause serious adverse effects.⁴¹

³³ *Id.*

³⁴ *Andreu*, 2009 WL 1688231 at *2. Enrique's treating physician submitted a letter to the court stating, "[t]here has been no neurological cause found for his encephalopathy and no other explanation other than the DPT immunization given to him when he was an infant."

³⁵ *Id.* at *3.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* at *4.

³⁹ *Andreu v. Sec'y of Dep't of Health & Human Servs.*, 2008 WL 4725455 (Fed.Ct.Cl.).

⁴⁰ *Id.* at *3.

⁴¹ *Andreu*, 2009 WL 1688231 at *4 (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1306-07 (Fed.Cir.1999)).

Writing for the court, Circuit Judge Haldane Robert Mayer articulated the rationale behind the enactment of the Vaccine Act and establishment of the Trust Fund:

...[t]he tort system had proven ineffective in providing redress for vaccine-injured individuals “because it resulted in lengthy delays, high transaction costs, and sometimes no recovery.”⁴² On the other hand, the persistent threat of tort claims caused pharmaceutical companies to consider abandoning this field of therapy to the detriment of all concerned. Accordingly, Congress created a federal no-fault compensation scheme under which awards were to be “made to vaccine-injured persons quickly, easily, and with certainty and generosity.”⁴³

Due to the type of injury Enrique suffered, he was required to show that his seizure disorder was “caused in fact” by the DPT vaccine he received.⁴⁴ In evaluating whether the Andreus established the required causation, the court relied on a hallmark case used widely by the claims court and federal courts in determining compensation claims, *Althen v. Secretary of Health & Human Services*.⁴⁵ In *Althen*, a three-prong test was set forth to determine whether an injury was caused “in fact” by a particular vaccine; a claimant must show by a preponderance of the evidence that:

[t]he vaccination brought about [the] 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. If [a claimant] satisfies this burden, she is entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.⁴⁶

The Andreus argued that they satisfied all of the *Althen* prongs. The Court agreed. Judge Mayer chastised the special master’s decision by noting three fundamental errors.

Judge Mayer wrote that there was “no dispute” that the Andreus met the first and third prongs of the test. The first prong was satisfied through expert witness testimony who presented a “biologically plausible” theory connecting the DPT vaccination to Enrique’s seizure disorder.⁴⁷ The third prong was satisfied by the giving of the vaccine to Enrique and his experiencing a seizure the following day.⁴⁸ Thus, a temporal and proximate relationship had been established.

⁴² *Id.* (citing *Lowry v. Sec’y of Health & Human Servs.*, 189 F.3d 1378, 1381 (Fed.Cir.1999)).

⁴³ *Id.* (citing H.R. Rep. No. 99-908 at 3 (1986)).

⁴⁴ *Id.* at *5.

⁴⁵ 418 F.3d 1274 (Fed.Cir.2005).

⁴⁶ *Andreus*, 2009 WL 1688231 at *5 (citing *Althen*, 418 F.3d at 1278).

⁴⁷ *Id.* at *6.

⁴⁸ *Id.*

According to Judge Mayer, the special master (1) incorrectly concluded that testimony by Enrique's treating physicians was insufficient to establish a "logical sequence of cause and effect" between the DPT vaccine and his resulting seizure disorder; (2) placed an impermissible burden of proof on the Andreus that "hinders the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants";⁴⁹ and (3) erroneously determined that Enrique's "clinical picture" precluded a finding that his seizure disorder was caused by an injury to the brain from the DPT inoculation.⁵⁰

Judge Mayer wrote, "[n]either the special master nor the Court of Federal Claims 'is to be seen as a vehicle for ascertaining precisely how and why [the DPT vaccine] sometimes destroy[s] the health and lives of certain children while safely immunizing most others.'"⁵¹ By the same token, "neither tribunal is to be seen as a vehicle for ascertaining why the DPT vaccine might immediately cause a devastating brain injury in one child and a more modest initial injury in another."⁵² The pivotal issue, wrote Judge Mayer, was whether the DPT vaccine triggered Enrique's seizure disorder.⁵³ He concluded that it did, based upon an evaluation of the evidence.

Conclusion

It is important to note that the term "autism" was not mentioned or referenced in Enrique's case. Regardless, some commentators believe the Appeals Court "sent a message" to the vaccine court that it was judging these types of cases too harshly.⁵⁴ With the three rejected autism cases currently on appeal, it is decidedly unclear what affect, if any, the ruling from the Appeals Court in the *Andreu* case will have on those, and the remaining 5,000, suits.

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⁴⁹ *Id.*; see also *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed.Cir.2006).

⁵⁰ *Id.*

⁵¹ *Id.* at *11 (citing *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed.Cir.1994)).

⁵² *Id.*

⁵³ *Id.*

⁵⁴ Sharyl Attkisson, *Growing Divide Among Courts On Vaccines*, CBS NEWS.COM, June 26, 2009, http://www.cbsnews.com/stories/2009/06/26/cbsnews_investigates/main5117439.shtml.