

Childhood Vaccines and Autism, Special Courts and Torts

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Introduction

The plaintiffs' bar, large pharmaceutical companies, the medical profession, the United States government, and thousands of parents of autistic children are now clashing in a little-known branch of the U.S. Court of Federal Claims in Washington, D.C. sometimes called the "vaccine court."¹ At issue is whether autism is caused by childhood vaccines. On June 11, 2007, lawyers for the parents of 4,900 autistic children began arguments in an unprecedented class action suit first filed in the vaccine court July 3, 2002.² The original claim by the parents was that MMR (measles-mumps-rubella) vaccines and thimerosal-containing vaccines could combine to cause autism.³ Recently, the Petitioners' Steering Committee representing the parents also proposed two new claims: (1) that MMR vaccine alone can cause autism; and (2) that the mercury-based preservative thimerosal alone, routinely used from the 1930's until 2001 to prevent bacterial contamination of multi-dose vials of non-MMR vaccines, can cause autism.⁴ The plaintiffs' demand is for monetary compensation from the United States government. No decision has yet been reached by the court, nor is one on the horizon.⁵

The issue of whether childhood vaccination causes autism or related syndromes and is somehow responsible for the alleged autism "epidemic" in the United States is highly controversial, high-profile, and has received extensive media coverage for years.⁶ Popular magazines such as Rolling Stone⁷ have recently published on the controversy, and just this month the pilot episode of the newest law drama series on television specifically focused on the topic of autism caused by childhood vaccines.⁸ The public health stakes for the vaccine court's decision are enormous and will dramatically affect whether drug manufacturers will continue to market childhood vaccines in the United States.

¹ UNITED STATES COURT OF FEDERAL CLAIMS, OFFICE OF SPECIAL MASTERS, *available at* <http://www.uscfc.uscourts.gov/OSMPage.htm> (last accessed January 21, 2006).

² *In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder*, Various Petitioners v. Secretary of Health and Human Services, Office of Special Masters, United States Court of Federal Claims, Filed July 3, 2002.

³ *Id.*

⁴ *In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder*, Amendment to Master File, January 17, 2008.

⁵ *Id.* "evidentiary hearing in three test cases in *each* of these additional two theories are to be completed by September 30, 2008."

⁶ MMR vaccine [transcript]. "60 Minutes", CBS Television, November 12, 2000.

⁷ Robert F. Kennedy, Jr., *Deadly Immunity*, ROLLING STONE, June 30, 2005.

⁸ About.com Autism Blog, *New TV Drama Will Explore Autism, Vaccines, and the Law*, *available at* <http://www.autism.about.com/b/2008/01/023/new-tv-drama-will-explore-autism-vaccines-and-the-law>, (last accessed February 5, 2008). "The title character of 'Eli Stone,' adopting the message of his visions to fight for the little guy, takes his first case: suing his former client on behalf of the mother of an autistic child who believes a mercury-based preservative in a vaccine caused her son's autism."

Statutory Protection for Vaccine Manufacturers in the United States

The issue of whether childhood vaccines cause neurological injury is not a new one. In 1998 Dr. Andrew Wakefield of the Royal Free Hospital in London suggested that the MMR vaccine caused bowel disease and autism.⁹ Following this often-criticized and recently discredited study,¹⁰ the percentage of British children vaccinated against measles dropped from over 90% to approximately 80%, and several outbreaks of the disease followed.

Wakefield's study came on the heels of 1970's British medical data¹¹ which suggested that whooping cough (pertussis) vaccine caused permanent brain damage in children. Fears of the pertussis component of the DPT or Diphtheria-Pertussis-Tetanus combination vaccine soon spread to the United States and ultimately resulted in verdicts against manufacturers of pertussis vaccine for causing SIDS (Sudden Infant Death Syndrome, later found to be caused by sleeping position), Reye's Syndrome (subsequently found to be the result of analgesic exposure), coma, and mental retardation. The validity of some of the science in these lawsuits may have been marginal and most was later discredited,¹² but the effect of the litigation on vaccine manufacturers' liability exposure was devastating. By 1985 many vaccine manufacturers had difficulty obtaining liability insurance. Within a year Lederle Laboratories in New York was the sole manufacturer of DPT vaccine in the United States and was threatening to cease production.

Faced with a potential public health disaster of national proportions and the prospect that the United States was about to become the only Western nation with no pharmaceutical company willing to manufacture vaccines for prevention of devastating childhood infections, Congress passed the National Childhood Vaccine Injury Act of 1986.¹³ From a public health point of view the penultimate rationale for this legislation was the recognition that compensating families for infrequent but inevitable adverse events in their children would be the necessary price to pay for "laws to mandate vaccines for diseases that are highly contagious, cause significant morbidity and mortality, and can be prevented with currently available vaccines."¹⁴ Shielding vaccine manufacturers from tort liability so they would stay in the vaccine manufacturing business, even if the business were not particularly profitable, was the other main rationale for the law.

⁹ AJ Wakefield, SH Murch, A Anthony, et al, *Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children*, 351 LANCET 637 (2004).

¹⁰ SH Murch, A Anthony, DH Casson, et al, *Retraction of an Interpretation*, 363 LANCET 750 (2004).

¹¹ GT Stewart, *Vaccination against whooping-cough: efficacy versus risks*, 1 LANCET 234 (1977).

¹² G Evans, *Update on vaccine liability in the United States: presentation at the National Vaccine Program Office Workshop on strengthening the supply of routinely recommended vaccines in the United States*, 12 February 2002, 42 CLIN. INFECT. DIS. S130 (2006).

¹³ NATIONAL CHILDHOOD VACCINE INJURY ACT (NCVIA) OF 1986, 42 U.S.C. §§ 300aa-1 to 300aa-34.

¹⁴ Kathryn M. Edwards, *State Mandates and Childhood Immunization*, 284 JAMA 3171 (2000).

Part 2 of the Act created the National Vaccine Injury Compensation Program (“Vaccine Program”),¹⁵ a no-fault compensation scheme funded in part by sales of the vaccines themselves. Because this is a federal “trust fund” for compensating victims of alleged vaccine-related injuries, any dispute over whether families will receive compensation requires that the United States government, not the pharmaceutical manufacturer, be named as the defendant. The Vaccine Program contains a list of specific injuries¹⁶ for which families may be compensated provided they and their physicians navigate a relatively straightforward set of medical and regulatory documents describing the type and circumstances of the injury. The injuries and awards vary from vaccine to vaccine, as do the administrative hurdles (e.g. deadlines for seeking redress). The Vaccine Program became effective in 1988 and immediately provided a generous, fair, and rapid mechanism for compensating hundreds of families whose children were damaged by childhood vaccinations. The Program was also successful in its two other goals of lessening frivolous litigation and preserving domestic childhood vaccine production. At the present time four pharmaceutical companies continue to market childhood vaccines in the United States.¹⁷

How the Vaccine Court Decides: The Special Masters

Damage claims under the Vaccine Program are managed and adjudicated by the Office of Special Masters, a Congressionally-created office within the U.S. Court of Federal Claims which has one chief special master and five associate special masters who are appointed to four year terms.¹⁸ The special masters comprise the subsection of the court which specifically handles vaccine injury claims arising under the 1986 Act. There is no requirement that a special master have any formal medical training, and none of the current special masters have an extensive scientific background.¹⁹ The special masters have two primary functions: collection of relevant information in a timely manner, and rendering a final, enforceable decision.²⁰ The special masters’ rules and orders are easily accessible through the Office of Special Masters website.²¹ Both published and unpublished decisions may be accessed, and the website is available to the public. It is comprehensive, easy to navigate, and provides a transparent roadmap to the entire procedural history and evidentiary basis provided to the court for the ongoing vaccine-autism litigation.

When a dispute involving a new injury or claim which does not fall under the administrative guidelines for compensation is brought, the special masters gather and evaluate the evidence, meet with both sides, allow testimony, and issue a ruling.²² In

¹⁵ NATIONAL VACCINE INJURY COMPENSATION PROGRAM (NVICP), NATIONAL CHILDHOOD VACCINE INJURY ACT (NCVIA) OF 1986, 42 U.S.C. §§ 300aa-1 to 300aa-34, *available at* www.uscfc.uscourts.gov (last accessed February 7, 2008).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ NATIONAL CHILDHOOD VACCINE INJURY ACT (NCVIA) OF 1986, *supra* note 15.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

these disputes over compensation for alleged injuries the entire process is designed to give parties on all sides of dispute access to the decision-making process. Typically this includes counsel representing the petitioner (usually the parents) and a Department of Justice attorney representing the Secretary of Health and Human Services.²³ Plaintiffs must only prove that it is more likely than not that the alleged injury was caused by the vaccine in question. Decisions may be appealed to the Court of Appeals for the Federal Circuit, a panel of three judges housed in the same building as the vaccine court.²⁴

The Problem and the Data the Vaccine Court is Facing

According to the World Health Organization autism is a “type of pervasive developmental disorder that is defined by: (a) the presence of abnormal or impaired development that is manifest before the age of three years, and (b) the characteristic type of abnormal functioning in all three areas of psychopathology: reciprocal social interaction, communication, and restricted, stereotyped, repetitive behavior.”²⁵ Along with these specific diagnostic features, autistic children commonly exhibit sleeping and eating disturbances, phobias, temper tantrums, and self-directed aggression.²⁶ Autism is one of the five pervasive childhood developmental disorders and is not rare; the incidence in the United States is approximately one in 600 births and seems to be increasing.²⁷ Whether this increase is simply due to more expansive definitions of what constitutes autism or is a true increase is not clear.²⁸

No one disputes the fact that autism is usually a devastating event for families, and not surprisingly the parents of autistic children have been looking for the cause of autism for decades. That there is some inherited, genetic basis for the disease is not disputed,²⁹ but the precise etiology of autism is not known.³⁰ The scientific evidence linking childhood vaccines, with or without the preservative thimerosal, to autism is sparse. Widely publicized cases involving methylmercury exposure demonstrated that mercury causes seizures, deafness and mental retardation but not autism.³¹

The consensus of the academic medical community,³² an expansive Institute of Medicine Report,³³ a comprehensive U.S. Food and Drug Administration analysis done by the

²³ *Id.*

²⁴ *Id.* THE COURT OF APPEALS FOR THE FEDERAL CIRCUIT, *available at* www.cafc.uscourts.gov (last accessed February 7, 2008).

²⁵ WORLD HEALTH ORGANIZATION, ICD VERSION 2007, F84.0 CHILDHOOD AUTISM, *available at* <http://who.int/classifications/apps/icd/icd10online/gf80.htm> (last accessed February 5, 2008).

²⁶ *Id.*

²⁷ CJ Newschaffer, LA Croen, J Daniels, et al, *The epidemiology of autism spectrum disorders*, 28 ANN. REV. PUBLIC HEALTH 235 (2007).

²⁸ M Rutter, *Incidence of autism spectrum disorders: changes over time and their meaning*, 94 ACTA PAEDIATRICA 2 (2005).

²⁹ Christine M Freitag, *The genetics of autistic disorders and its clinical relevance: a review of the literature*, 12 MOL. PSYCHIATRY 2 (2006).

³⁰ *Id.*

³¹ Editorial, *Methylmercury Exposure and Neurotoxicity*, 280 JAMA 737 (1998) (evaluating mercury exposure from eating fish).

³² Paul A. Offit, *Thimerosal and Vaccines – A Cautionary Tale*, 357 N. ENGL. J. MED. 1278 (2007).

Center for Biologics Evaluation and Research,³⁴ and well-designed, large epidemiological studies³⁵ have all failed to establish a link between childhood vaccines, with or without thimerosal,³⁶ and autism. Studies published since 2007 looking at either MMR vaccine alone or thimerosal exposure alone have only continued to reinforce this position.³⁷ Notably, the incidence of autism in the United States and Europe has seemingly continued to rise every year despite the fact that vaccines have not been formulated with thimerosal for years.³⁸

Implications of the Upcoming Decision

Although the special masters have an advantage over state civil courts in their extensive experience with vaccine-related disputes, and there is no danger of a jury being swayed by “junk science,” no vaccine case in recent memory has been so high-profile. There is always the risk that non-scientifically trained judiciary may make a poor decision despite overwhelming scientific evidence because of the dramatic nature of the alleged injuries and media attention. This has happened in high profile cases before,³⁹ and valuable medications with negligible proven morbidity were withdrawn from the market.

A vaccine court decision against the vaccine manufacturers awarding compensation to the plaintiffs will quickly wipe out the trust fund which pays for established childhood vaccine-related injuries, and will guarantee that personal injury attorneys will file product liability suits against the vaccine manufacturers in state civil courts. However, the question of whether the plaintiffs will be able to prevail in any state court action even if the vaccine court rules in their favor is far from decided. Congress clearly intended that the Vaccine Injury Act would “preempt” the entire playing field for alleged vaccine-related injuries,⁴⁰ and efforts to try these cases in state court have been unsuccessful.⁴¹

³³ IMMUNIZATION SAFETY COMMITTEE, INSTITUTE OF MEDICINE, *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders*, National Academy Press (2001).

³⁴ UNITED STATES FOOD AND DRUG ADMINISTRATION, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, *Thimerosal in Vaccines*, available at <http://www.fda.gov/cber/vaccine/thimerosal/htm> (last accessed March 23, 2005) “FDA has been actively addressing the issue of thimerosal as a preservative in vaccines. Under the FDA Modernization Act (FDAMA) of 1997, the FDA conducted a comprehensive review of the use of childhood vaccines. Conducted in 1999, this review found no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions.”

³⁵ Anders Hviid, Michael Stellfeld, Jan Wohlfahrt and Mads Melbye, *Association Between Thimerosal-Containing Vaccine and Autism*, 290 JAMA 1763 (2003). This is the most significant prospective study comparing neurological outcomes in children who had received thimerosal containing vaccines with those in children who did not.

³⁶ SK Parker, B Schwartz, J Todd, and LK Pickering, *Thimerosal-containing vaccines and autistic spectrum disorder: a critical review of published original data*, 114 PEDIATRICS 793 (2004).

³⁷ Reuters, *MMR shot does not cause autism, large study says*, available at <http://www.msnbc.com/id/23001150/print/1/displaymode/10098> (last accessed February 5, 2008).

³⁸ Anders Hviid, Michael Stellfeld, Jan Wohlfahrt and Mads Melbye, *supra* note 35.

³⁹ *Daubert v Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). Bendectin, the only effective prescription drug for treatment of nausea and vomiting in pregnancy was removed from the United States market over twenty years ago. Bendectin remained on the market in Europe and Canada.

⁴⁰ NATIONAL VACCINE INJURY COMPENSATION PROGRAM (NVICP), NATIONAL CHILDHOOD VACCINE INJURY ACT (NCVIA) OF 1986, *supra* note 15.

If the tort claims in state court are preempted despite a plaintiffs' victory in the vaccine court, the case will stop at the vaccine court. But, the end results may be no funds left to compensate families for other injuries caused by other vaccines, vaccine manufacturers possibly leaving the U.S. market anyway, and another pyrrhic victory for personal injury attorneys at the expense of public health.

Health Law Perspectives (February 2008), available at:
<http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>.

⁴¹ *McDonald v. Lederle Laboratories*, 341 N.J. Super. 369 (N.J. Super.App.Div. 2001). (The plaintiff must file a Vaccine Compensation Act Claim before filing a tort claim in state court. Similar rulings have come out of state courts in other states, among them Texas).