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Childhood Vaccinations and Autism: Does the National Childhood Vaccine Injury Act Leave Parents of Children with Autism Out in the Cold with Nowhere to Go?

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CHILDHOOD VACCINATIONS AND AUTISM: DOES THE NATIONAL CHILDHOOD VACCINE INJURY ACT LEAVE PARENTS OF CHILDREN WITH AUTISM OUT IN THE COLD WITH NOWHERE TO GO?

A.J. was born on May 15, 1994, a healthy baby boy. Between May 1994 and December 1995, A.J. was administered standard childhood vaccines. When he was eighteen months old, A.J.’s development began to regress. He began to lose language and motor skills, and became withdrawn and non-interactive. In May 2001, seven years from the date of administration of his first vaccine, A.J. was diagnosed with disintegrative autism resulting from mercury toxicity. The mercury poisoning allegedly resulted from exposure to cumulative doses of thimerosal, a mercury-containing preservative used in vaccines previously administered to A.J. In May 2002, approximately six and one half years after the first manifestation of his symptoms, A.J.’s parents initiated a civil action to recover for their son’s vaccine-related injuries.

The current legislation governing such a claim is the National Childhood Vaccine Injury Act (“Vaccine Act”). This comment explores the interaction of various factors which will ultimately dictate the possible remedies available to A.J.’s parents and to the parents of other autistic children across the nation. Namely, the implications of the Vaccine Act are explored, including the interplay between the potential causal relationship between childhood vaccines and autism, the statute of limitations of the Vaccine Act, the development and import of the Omnibus Autism Proceeding and its effect on potential remedies available to parents of autistic children, and the constitutionality of the Vaccine Act’s provision regarding limitations of claims. Although, when it was enacted in 1986, the Vaccine Act seemed to adequately redress petitioners’ claims of vaccine-related injury, the relatively recent and marked increase in the prevalence of autism, potentially the consequence of childhood vaccinations, was not foreseen by the legislature, and, if such a causal association is determined,
it cannot be adequately redressed under the Vaccine Act's current statutory scheme.

AUTISM AND THE CAUSAL ASSOCIATION WITH CERTAIN CHILDHOOD VACCINATIONS

In order to fully appreciate the significance of the remedy limitation created by the Vaccine Act, it is first essential to understand certain underlying conditions and concepts, including autism, childhood vaccination, and thimerosal, which interact to fuel ongoing medical and legal debate regarding the appropriateness and fairness of the Vaccine Act.

Autism is a complex biological disorder that generally lasts throughout a person's life. It is considered a developmental disability because symptoms first manifest in the developmental period before age 3 and because it adversely affects many aspects of a person's growth and development. In the majority of cases, autism causes problems with a person's communication (both verbal and nonverbal), social interactions (both physical and verbal), and routines or repetitive behaviors, such as repeating words or actions over and over, and following routines or schedules for his or her actions. These characteristic symptoms may also be accompanied by sensory and motor dysfunctions, cognitive or other mental processing deficiencies, and other neurological abnormalities.

The symptoms of the disorder essentially disassociate people with autism from the world around them. For example, children with autism may not want their mothers to hold them, and adults with autism may not make eye contact with others. Some people afflicted


8. Id.

9. Id.; see also Kidd, supra note 6, at 292 (describing three symptom patterns of autism as "(1) the failure to use language for communication, (2) abnormal development of social reciprocity, and (3) desire for sameness, as seen in repetitive rituals or intense circumscribed interests").

10. Kidd, supra note 6, at 293.
with autism never learn to speak, making the lives of those who care for them very difficult.\textsuperscript{11}

Initial studies conducted in the 1960s indicated there were four to five cases of autism in every 10,000 people, leading medical professionals and researchers to believe it was a rare condition. While the exact prevalence of autism is not presently known, estimates range from one in 500 cases to one in 1000 cases of autism diagnosed in the United States every year. The dramatic increase in autism disorders clearly shows that the condition is not rare.\textsuperscript{12} In fact, some researchers suggest that autistic disorder (AD) and autistic spectrum disorder (ASD) are epidemics.\textsuperscript{13} Statistics also demonstrate that boys are three to four times more likely to be affected by autism than girls.\textsuperscript{14}

While the exact cause of autism is unknown, there are several theories regarding its etiology\textsuperscript{15} that are being actively examined.\textsuperscript{16} For instance, there is almost certainly a genetic susceptibility or predisposition to autism.\textsuperscript{17} During the last 40 years, autism has also been linked to many different potential causes, including various inborn errors, genetic abnormalities including fragile X syndrome\textsuperscript{18}, rubella (caused by the rubella virus) and other pathogens, and many other factors. Genetic predisposition, metabolic abnormalities, and abnormalities of the gastrointestinal, hepatic, and immune systems all appear to be markedly involved.\textsuperscript{19} In addition, in recent years many

\begin{itemize}
  \item \textsuperscript{11} U.S. Dept. of Health and Human Services, \textit{supra} note 7.
  \item \textsuperscript{12} Id.
  \item \textsuperscript{13} Kidd, \textit{supra} note 6, at 295.
  \item \textsuperscript{14} U.S. Dept. of Health and Human Services, \textit{supra} note 7.
  \item \textsuperscript{15} Kidd, \textit{supra} note 6, at 298 (providing an overview of potential etiopathologic factors in the development of autism).
  \item \textsuperscript{16} U.S. Dept. of Health and Human Servicesalso Kidd, \textit{supra} note 6, at 298 (providing an overview of potential etiopathologic factors in the development of autism).
  \item \textsuperscript{17} J.A. Lamb, J. Moore, A. Bailey, & A.P. Monaco, \textit{Autism: Recent Molecular Genetic Advances}, 9 HUM. MOL. GENET. 861, 861 (2000).
  \item \textsuperscript{18} Fragile X Syndrome is a defect of the X chromosome which causes mild mental retardation. The disorder occurs more frequently and severely among males than females. The wide range of symptoms associated with the disorder include language delays, behavioral problems, autism or autistic-like behavior (including poor eye contact and hand-flapping), large or prominent ears, hyperactivity, delayed motor development and/or poor sensory skills. U.S. Dept. of Health and Human Services, National Institute of Child Health and Human Development, \textit{Families and Fragile X Syndrome}, at (last modified May 05, 2004).
  \item \textsuperscript{19} Kidd, \textit{supra} note 6, at 298-99 (providing an overview of potential etiopathologic factors in the development of autism); see also M.T. Acosta & P.L. Pearl, \textit{The Neurobiology of Autism: New Pieces of the Puzzle}, 3 CURR. NEUROL. NEURISCI. REP. 149 (2003) (stating that while multiple etiologies of autism are implicated, genetic
\end{itemize}
medical investigations have focused on the putative association between certain childhood vaccines, namely the measles-mumps-rubella (MMR) vaccine and vaccines containing the preservative thimerosal, and an increased risk of developing autism, autism spectrum disorder, or other neurological abnormalities.

The potential association between certain childhood vaccinations, particularly the MMR vaccine and thimerosal-containing vaccines, and an increased risk of developing autism is highly controversial and currently disputed in the medical and scientific community. There have been numerous studies conducted and review articles written to discern and clarify both the association between exposure to thimerosal and an increased risk of developing autism and the association between vaccination with the MMR vaccine and increased risk of developing autism. While the studies designed to address the potential link between childhood vaccination with the MMR vaccine and autism tend to refute such a link, the studies concerning thimerosal-containing vaccines do not definitively support or negate the existence of such a causal association.

In 2000, at the request of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), the Institute of Medicine (IOM) at the National Academy of Sciences began a review of the evidence linking MMR vaccine to autism. This independent panel reviewed completed and ongoing studies, as well as


published medical and scientific papers, and heard testimony from experts on vaccines and autism to determine whether there is a causal link between autism and the MMR vaccine.23 The IOM concluded that the evidence and testimony did not support an association between autism and the MMR vaccine.24 In addition, The American Academy of Pediatrics (AAP) held a conference on the MMR vaccine and autism in which parents, scientists, and practitioners presented information on this topic to a multi-disciplinary panel of experts.25 The AAP similarly concluded the available evidence does not support the notion that the MMR vaccine causes or contributes to autism or other related disorders.26

However, the conclusions reached by the IOM and The AAP are not universally accepted in the medical or scientific community. Some researchers still contend that the MMR vaccine is causally related to the increased prevalence of autism throughout the United States, particularly in California, a state which comprises 10 percent of the U.S. population.27 Those who advocate a connection note that sharp increases in autism prevalence in California and the United Kingdom roughly parallel increases in the number of MMR vaccination administered to children.28 Additionally, advocates note that the introduction of the MMR vaccine in California is linked to an important change in the pattern of onset of autism.29 According to the data collected since 1965 by the Autism Research Institute of California, prior to the early 1980s the majority of autism cases had onset at birth; however, since that period far more cases of autism began to manifest around 18 months of age, which corresponds to the time after birth when most children receive the MMR vaccine.30 These contentions, however compelling, generally are not accepted in the medical and scientific community. In fact, the majority of studies and review articles addressing the putative association between the MMR vaccine and autism have concluded there is no epidemiological data to support such an association.31

23. Id.
24. Id.
25. Id.
26. Id.
27. Kidd, supra note 6, at 308.
28. Id. at 307-08.
29. Id. at 308.
30. Id. (citing B. Rimland, The Autism Epidemic, Vaccinations, and Mercury, 10 J. NUTR. ENVIRON. MED. 261 (2000)).
31. E.g., Chen et al., supra note 21; C.P. Farrington, E. Miller, & B. Taylor, MMR and Autism: Further Evidence Against a Causal Association, 19 VACCINE 3632 (2001);
On the other hand, there is some support by medical professionals and the scientific community for the notion that exposure to thimerosal through vaccination is causally related to the development of autism. Thimerosal is a preservative that has been added to certain vaccines since the 1930's due to its effectiveness in killing bacteria and preventing bacterial contamination. When thimerosal is degraded or metabolized inside the body, it produces ethyl mercury. Another type of mercury, methyl mercury, which is the most common organic derivative of mercury, can accumulate in certain edible freshwater and saltwater fish. Methyl mercury can also accumulate in humans who eat these fish. Exposure to high levels of methyl mercury is toxic and can cause mental retardation, cerebral palsy, and seizures. The fetus is particularly sensitive to methyl mercury exposure and may suffer brain damage or even death if exposed to high levels. However, not much is known about the effects of ethyl mer-

Madsen et al., supra note 21; B. Taylor et al., Autism and MMR Vaccination in North London; No Causal Relationship, 7 MOL. PSYCHIATRY S7 (2002); B. Taylor et al., Autism and Measles, Mumps, and Rubella Vaccine: No Epidemiological Evidence for a Causal Association, 353 LANCET 2026 (1999). But see D.A. Geier & M.R. Geier, A Comparative Evaluation of the Effects of MMR Immunization and Mercury Doses from Thimerosal-Containing Childhood Vaccines on the Population Prevalence of Autism, 10 MED. SCI. MONIT. 33 (2004) (concluding there is a biological plausibility and epidemiological evidence showing a direct relationship between measles-containing vaccines and serious neurological disorders); A.T. Phelan, MMR and Autism: An Overview of the Debate to Date, 11 Br. J. Nurs 621 (2002) (after reviewing two major studies, the authors conclude that although epidemiological studies to date do not support a link between MMR and autism, the studies have been too imprecise to rule out the possibility that the MMR vaccine is involved in a small number of autism cases); K. Wilson et al., Association of Autistic Spectrum Disorder and the Measles, Mumps, Rubella Vaccine: A Systematic Review of Current Epidemiological Evidence, 157 ARCH. PEDIATR. ADOLESC. MED. 628 (2003) (stating that while the current literature does not suggest an association between ASD and the MMR vaccine, only limited epidemiological evidence exists to rule out a link between a rare variant form of ASD and the MMR vaccine). For further studies refuting an association between the MMR vaccine and autism, refer to Appendix 3.


33. U.S. Dept. of Health and Human Services, National Institute of Allergy and Infectious Disease, NIAID Research on Thimerosal, at (last modified May 18, 2004).

34. Id.

35. Id.

36. Id.

37. Id.

38. Id.
cury exposure in humans and how this compares to methyl mercury exposure.\textsuperscript{39} In addition, there are important known differences between methyl mercury exposure and thimerosal exposure.\textsuperscript{40} Namely, ethyl mercury is structurally different than methyl mercury and the timing and route of exposure are different for the two chemicals.\textsuperscript{41} More research is necessary to determine whether the guidelines for methyl mercury exposure can be appropriately applied to thimerosal exposure.\textsuperscript{42}

In July 1999, U.S. Department of Health and Human Services agencies, The AAP, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure and to reduce exposure to mercury from all sources.\textsuperscript{43} Today, all routinely recommended pediatric vaccines currently manufactured for the United States market are either free from thimerosal or contain markedly reduced amounts of the substance.\textsuperscript{44} However, thimerosal is still used in some vaccines that are administered to adults and adolescents, as well as in some pediatric vaccines not appearing on the Recommended Childhood Immunization Schedule.\textsuperscript{45}

**THE NATIONAL CHILDHOOD VACCINE INJURY ACT MANDATES A UNIVERSAL PROCEDURE FOR THE LITIGATION OF VACCINE-RELATED INJURY CLAIMS**

The Vaccine Act\textsuperscript{46} established a National Vaccine Injury Compensation Program ("Program") in 1986 in the U.S. Department of Health and Human Services "to achieve optimal prevention of infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."\textsuperscript{47} Congress enacted the Program for the dual purposes of reducing tort litigation against vaccine manufacturers and administrators, as well as to compensate individuals who may

\textsuperscript{39.} Id.

\textsuperscript{40.} U.S. Dept. of Health and Human Services, National Institute of Allergy and Infectious Disease, NIAID-Supported Studies on Mercury, Thimerosal, and Vaccine Safety, at (last modified May 20, 2004).

\textsuperscript{41.} Id.

\textsuperscript{42.} U.S. Dept. of Health and Human Services, supra note 33.

\textsuperscript{43.} Id.

\textsuperscript{44.} Id.

\textsuperscript{45.} Id.


\textsuperscript{47.} Id. § 300aa-1.
have been harmed by vaccinations. In order to achieve this end, the Program mandates that:


[no person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with [42 USCS § 300aa-16], for compensation under the Program for such injury or death. . . .

Congress designed the Program as an alternative to tort litigation against vaccine manufacturers and administrators, intending that each Program petitioner be able to obtain an evaluation of his or her claim of vaccine-related injury. While Congress certainly hoped that a claimant receiving a Program award as a result of such an evaluation would accept the award and forego the option of a tort suit, Congress also hoped that many claimants who were denied Program awards would nevertheless be satisfied with their day in court. As such, Congress did not make the Program the exclusive remedy for vaccine-related injuries.

Congress instead designed the Program to give any claimant who was dissatisfied with the size of a Program award or who failed to obtain a Program award the option of rejecting the Program verdict and pursuing a civil action against the vaccine manufacturer or administrator. Specifically, in order for a petitioner to directly sue a vac-

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48. Stewart v. Sec'y of HHS, 2002 U.S. Claims LEXIS 363, at *21 (Fed. Cl. Dec. 30, 2002). See also Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4, 1994 U.S App. LEXIS 5477 (1st Cir. 1994) (stating that "an important federal purpose of the [Vaccine] Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market" and that "[t]he Act seeks to achieve its cost-reducing purpose, not by denying compensation to victims . . ., but by reducing the litigation and insurance costs related to lengthy, complex tort procedures and random large tort awards"); McDonald v. Lederle Labs., 775 A.2d 528, 530 (N.J. Super Ct. App. Div. 2001), aff'd in part and rev'd in part on other grounds, 841 A.2d 948 (N.J. Super. Ct. App. 2004). (the Program was established "to protect the vaccine supply from market instability created by an increasing number of vaccine-related personal injury lawsuits").


50. Stewart, 2003 U.S. Claims LEXIS 275, at *43.

51. Stewart, 2003 U.S. Claims LEXIS 275, at *43; see also 42 U.S.C. §§ 300aa-11(a), 300aa-21(a).

52. Stewart, 2003 U.S. Claims LEXIS 275, at *43-44; see also 42 U.S.C. §§ 300aa-11(a), 300aa-21(a).
cine manufacturer or administrator for a vaccine-related injury one of
two things must occur at the conclusion of a proceeding with respect
to a petition filed under the Program: (1) the Court of Federal Claims
must have issued a judgment on such petition, and the petitioner must
have filed an election declining to accept that judgment and choosing
instead to proceed with a suit against the vaccine manufacturer or
administrator or (2) the petitioner must have elected to withdraw the
Program petition under section 300aa-21(b) of the Vaccine Act. The
filing of a petition under the Program for a vaccine-related injury or
death stays the running of the statute of limitation with respect to a
civil action brought for such injury or death beginning on the date the
petition is filed and ending on the date the petitioner either files an
election declining to accept the judgment rendered by the Federal
Claims Court or elects to withdraw the petition.

There are two different means of establishing entitlement to com-
pensation under the Program. First, if an injury specified in the Vac-
cine Injury Table, occurred within the time period after vaccination
prescribed in that Table, then the injury is presumed to qualify for
compensation. If a person qualifies under this presumption, he is
said to have suffered a Table Injury. Alternatively, compensation
may be awarded for injuries not listed in the Table; however, entitle-
ment in such cases is dependent upon proof that the vaccine actually
caused the injury. Although Congress correctly anticipated that
most petitions would involve Table Injury claims when it published the
initial Vaccine Injury Table, in recent years, most Program cases,

53. Stewart, 2003 U.S. Claims LEXIS 275, at *15-16; see 42 U.S.C. §§ 300aa-
11(a)(2)(A)(i)-(ii); see also Ashton v. Aventis Pasteur, Inc., 2004 PA Super. 202, ¶ 7,
851 A.2d 908 (stating that "[t]he language of the Act relative to wherein jurisdiction
lies is clear: a claimant's exhaustion of the Act's statutory remedy is a condition
precedent to subject matter jurisdiction of a state or federal court to resolve the merits
of a claim filed by an individual seeking damages for a vaccine-related injury").
54. See 42 U.S.C. § 300aa-16(c).
56. The vaccines included in the Vaccine Injury Table include (1) DTP, P, DTP/
Polio combination, or any other vaccine containing whole cell pertussis bacteria,
exttracted or partial cell bacteria, or specific pertussis antigen(s), (2) measles, mumps,
rubella, or any vaccine containing any of the foregoing component, DT, Td, or tetanus
toxoid, (3) polio vaccines, and (4) inactivated polio vaccine. 42 U.S.C. § 300aa-14(a).
57. Stewart, 2003 U.S. Claims LEXIS 275, at *46; see 42 U.S.C. §§ 300aa-
59. Stewart, 2003 U.S. Claims LEXIS 275, at *46; see 42 U.S.C. §§ 300aa-13(a)(1),
300aa-11(c)(1)(C)(ii).
including autism\textsuperscript{60} cases, have involved non-Table claims of actual causation.\textsuperscript{61}

First, to maintain an action against the government for Program compensation, individuals must demonstrate that their claim meets the filing prerequisites of the Vaccine Act.\textsuperscript{62} Section 11(a) of the Vaccine Act is the gate-keeping provision of the statute which sets forth the general rules describing when a vaccinee may petition for compensation.\textsuperscript{63} Sections 300aa-11(c)(1)(A)-(E) of the Vaccine Act are the specific provisions describing qualified Vaccine Court litigants.\textsuperscript{64}

**The Statute of Limitations of the National Childhood Vaccine Injury Act and Equitable Tolling**

Individuals seeking relief under the Vaccine Act must also act within the prescribed statute of limitations. Section 300aa-16(a)(2) dictates that in the case of

a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury . . . .\textsuperscript{65} (emphasis added)

Congress is currently scrutinizing the statute of limitations for claims under the Vaccine Act and a strong possibility exists that the limitations period may be extended to six years.\textsuperscript{66} However, under the current statutory scheme, a qualified petitioner under the Vaccine Act

\textsuperscript{60} Autism does not appear in the Vaccine Injury Table as an "[illness, disability, injury, or condition covered" for the purpose of receiving compensation under the Program. 42 U.S.C. § 300aa-14(a).
\textsuperscript{61} Stewart, 2003 U.S. Claims LEXIS 275, at *46.
\textsuperscript{63} Id; see Amendola v. Sec'y of HHS, 989 F.2d 1180, 1182-83 (Fed. Cir. 1993); see also Klahn v. Sec'y of HHS, 31 Fed. Cl. 382, 385 (1994) ("The court's jurisdiction involves compliance with [these] gate-keeping provisions . . . .").
\textsuperscript{64} Cheskievicz, 2004 PA Super 40, ¶ 12, 843 A.2d at 1263. The requirements are that a petitioner: (1) received a vaccine set forth in the Vaccine Injury Table, (2) in the United States, (3) sustained an injury caused by the vaccine, (4) suffered residual effects for more than six months after the date of vaccination, died as a result of administration of the vaccine, or suffered illness or injury from the vaccine which resulted in inpatient hospitalization, and (5) has not previously received compensation. 42 U.S.C. §§ 300aa-11(c)(1)(A)-(E).
\textsuperscript{65} 42 U.S.C. § 300aa-16(a)(2).
\textsuperscript{66} Setnes v. United States, 57 Fed. Cl. 175, 178 (2003).
must not only satisfy those prerequisites listed in § 300aa-11(c)(1), but also file a claim with the Vaccine Court within three years from either the date of (1) the occurrence of the first symptom or (2) the manifestation of onset of injury experienced as a result of vaccination. Either event triggers the running of the statute of limitations and courts should apply the standard appropriate for the facts of each case.67

Because autism is a disorder with no dramatic or obvious onset, determining the first symptom of an autistic disorder is a question of fact that is quite complex in many cases.68 Many of the initial symptoms of autism are subtle and can be easily confused with typical childhood behavior.69 Therefore, in Vaccine Act claims based on autism or other conditions where there is no clear start to the injury, a court addressing the statute of limitations should not hinge its decision on the occurrence of the first symptom standard.70 Instead, where the symptoms of autism develop insidiously over time and the child's behavior cannot be readily associated with an injury or condition, the court should rely on the child's medical or psychological evaluations for guidance in ascertaining when the manifestation of onset occurred.71

Although the standard of determining the first symptom of or manifestation of onset of autism appears to favor petitioners under the Program, the court's stance on equitable tolling72 is less forgiving. The court in Weddel v. Secretary of Health and Human Services, held that equitable tolling of the limitations period is not available for claims arising under section 16(a)(1) of the Vaccine Act, which applies to vaccines administered prior to the effective date of the Act ("pre-Act cases").73 Along the same lines, in Brice v. Secretary of Health and

67. Id. at 179.
68. Stewart, 2002 U.S. Claims LEXIS 363, at *9; see also Setnes, 57 Fed. Cl. at 179.
69. Setnes, 57 Fed. Cl. at 179.
70. Id.
71. Id. at 181 (rev'd Setnes v. Sec'y of HHS, 2003 U.S. Claims LEXIS 30 (Fed. Cl. Jan. 31, 2003), which held that the Vaccine Act does not require that a symptom be diagnosed in order for the statute of limitations to start to run in causation in fact cases); see also Kuehn v. Sec'y of HSS, 2003 U.S. Claims LEXIS 286, at *13 (Fed. Cl. July 23, 2003) (applying the holding in Setnes v. United States in declaring that a medical diagnosis of autism is a clear indication of the time of onset of a child's autism).
72. If equitable tolling were to be allowed, the running of the statute of limitations would be delayed until a petitioner actually discovers that the vaccine caused the injury. Vessels v. Sec'y of HSS, 2002 U.S. Claims LEXIS 286, at *8 (Fed. Cl. Sept. 25, 2002).
73. 100 F.3d 929 (Fed. Cir. 1996).
the court held that equitable tolling is also not available for claims arising under section 16(a)(2) of the Vaccine Act, which applies to vaccines administered after the effective date of the Vaccine Act ("post-Act cases").

In Brice, this determination was based on two decisive factors. First, the Vaccine Act includes a specific exception to the limitations period for a petition improperly filed in state or federal court. Specifically, such a petition must be dismissed from the court in which it was improperly filed, but the date such dismissed action was filed is, for the purposes of the limitations of actions, considered to be the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action. When an Act includes specific exceptions to a limitations period, the court is "not inclined to create other exceptions not specified by Congress." Second, the legislative history of the Vaccine Act emphasizes the importance of quick resolution of claims. The limitations period is part of a detailed statutory scheme that includes other strict deadlines. For example, the special masters who preside over Vaccine Act claims are required to issue decisions within 240 days of the filing of the petition and may suspend proceedings for no more than a total of 150 days. According to the court in Brice, to allow equitable tolling would conflict with the principle of quick claim resolution fostered by the Vaccine Act because it "invites prolonged and wasteful collateral litigation concerning the running of the statute of limitations."

In upholding the Brice decision, the court in Lemire v. Secretary of Health and Human Services held that "the Federal Circuit in Brice did not distinguish between Table and off-Table cases in holding that equitable tolling is inapplicable in Vaccine Act cases." This case involved a non-Table causation in fact claim where petitioner asserted that, because a causation in fact case has the traditional tort burden and is a lengthier proceeding than a Table case, an off-Table case cannot be

75. Id.
76. Id. at 1373.
77. Id.
79. Brice, 240 F.3d at 1373.
80. Id.
81. Id.
84. Brice, 240 F.3d at 1373.
speedy and equitable tolling should apply. However, the court reasoned that “applying equitable tolling to causation in fact cases would lengthen their resolution even further in direct opposition to congressional intent.”

Another issue arising as a result of the Vaccine Act’s statute of limitations period is whether a subsequent civil action is barred by the Act where a judgment of dismissal is entered by the United States Federal Claims Court due to the petitioner’s failure to file a claim petition within the 36 month period. The Federal Claims Court has determined that a petitioner’s failure to prosecute and file a timely petition under the Vaccine Act precludes such petitioner from pursuing a subsequent state tort action on behalf of a child suffering a vaccine-related injury. In making this determination, the court states that the Act “expressly warns that a victim’s traditional tort claim will not be saved by a state statute of limitations that extends beyond the limitations period proscribed by the Act, if a claim is not filed with the Program within its time restrictions.”

DEVELOPMENT AND IMPORT OF THE OMNIBUS AUTISM PROCEEDING

In 2002 the Office of Special Masters (“OSM”) issued the Autism General Order #1 (“Order”) to address the growing concern in recent years that certain childhood vaccinations might be causally related to the apparent increase in the diagnosis of autism spectrum disorder. Specifically, it has been alleged that autism or other similar neurodevelopmental disorders may be caused by MMR vaccinations; by the thimerosal ingredient contained in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or some combination of the two. At the time of publication of the Order, over 400 cases alleging a causal relationship between these vaccinations and autism disorders had been filed in the Vaccine Court. Additionally, numerous civil lawsuits against vaccine manufacturers were filed around the country, alleging Thimerosal caused autism. A recent

86. Id. at *14-15.
87. Id. at *15.
88. McDonald, 775 A.2d at 529.
89. Id.
90. Id. at 534.
92. Id.
93. Id. at *2.
94. Id.
ruling determined as a matter of law that such claims against vaccine manufacturers must be dismissed and brought as Program claims. As a result of the influx of Program claims and the potential for many more such claims, the OSM, through a series of meetings and discussions with an informal advisory committee, developed a procedure to resolve these cases within a reasonable time frame. The advisory committee included petitioners’ counsel representing many current and potential Program claimants and legal and medical representatives of the Secretary of Health and Human Services. The OSM adopted a two-step procedure. First, the OSM will inquire into the general causation issues involved in these cases (i.e., whether the vaccinations in question can cause autism and/or similar disorders, and if so under what circumstances); and second, the conclusions reached in that general inquiry will be applied to the cases of the individual claimants. This general inquiry (called the “Omnibus Autism Proceeding”) will, after a period of discovery, a designation of experts for each side, and an evidentiary hearing, ultimately result in a special master’s ruling on the general causation issues. Then, these conclusions regarding causation issues will be applied to individual cases. The OSM did mandate that its “decision on the causation issues shall be rendered within two years after the filing of this General Order.” Although it is presently more than two years after the filing of the Order, the OSM has yet to rule on the causation issues. Therefore, all petitioners who seek relief under the Program must wait until such a ruling is made before the option of a civil suit becomes available.

The most recent update to the Autism Master File was filed on October 28, 2004. On this date, more than 4,400 petitions in autism cases had been filed, and more than 4,250 remain pending, stayed until the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed regularly. There is no indication from the most recent update to the Autism Master File that a decision on the

95. Id. at *1 (citing Owens v. American Home Products Corp., 203 F. Supp. 2d 748 (S.D. Tex. 2002)).
96. Id. at *3-4.
97. Id. at *7.
98. The documents filed in the Omnibus Autism Proceeding are contained in a special file known as the “Master Autism File,” which can viewed on the United States Court of Federal Claims website at
100. Id. at *4.
CHILDHOOD VACCINATIONS

general causation issues will be forthcoming anytime in the near future.102

THE CONSTITUTIONALITY OF THE NATIONAL CHILDHOOD VACCINE INJURY ACT WITH REGARD TO AUTISM AS A VACCINE-RELATED INJURY REMAINS UNDETERMINED

In addition to the regulations and standards prescribed by the Vaccine Act described above, section 11(a)(6) imposes a further roadblock to receiving compensation for a vaccine-related injury under the Program. This section provides that “[i]f a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under [the Vaccine Act] for such injury or death.”103 The effect of this provision is to bar the filing of a Vaccine Act petition for compensation if a civil action for damages was filed after November 15, 1988, if the vaccine-related injury allegedly associated with a vaccination occurred before this date.104 Although this provision has little effect on parents of autistic children seeking redress for such vaccine-related injury today (because the statute of limitations of the Vaccine Act would bar such a claim), past petitioners have argued that this statutory provision violates the equal protection clause of the Constitution.

In Greider v. Secretary of Health and Human Services,105 the petitioner filed a civil action in state court against the administrator and manufacturer of a polio vaccine several months before filing a vaccine petition.106 On April 5, 1991, the Special Master issued an order dismissing the claimant’s petition as in violation of section 11(a)(6) of the Vaccine Act. In response, petitioner argued that the Special Master’s interpretation of section 11(a)(6) violated the equal protection clause of the Constitution because the Act treats similarly situated persons differently and constitutes “arbitrary and irrational discrimination.”107

In response, the court first noted that, while Congress did establish different rules based upon the date of the vaccine-related injury, it was “not at liberty to change a statute enacted by Congress” and that because “the language of the statute is crystal clear and is supported

102. Id.
105. Id. at 349.
106. Id.
107. Id. at 350.
by the legislative history, the court must defer to its clear meaning.”

Second, the court also held that it had no jurisdiction to hear claims grounded in the due process or equal protection guarantees of the Fifth Amendment of the Constitution because these provisions do not obligate the federal government to pay money damages. Third, the court stated that petitioner’s argument lacked a rational basis because those persons with pre-Act injuries who filed a civil action before November 15, 1988 had no option to pursue a remedy under the Vaccine Act at the time they filed their civil actions. However, those persons with pre-Act injuries who filed a civil action after November 15, 1988 clearly had a choice of forum. Therefore, the two different groups of claimants, according to the court, are not similarly situated and petitioner’s equal protection argument is unavailing.

Since Greider, other petitioners have asserted that the prevailing interpretation of limitations of actions under the Vaccine Act render its provisions unconstitutional. In Kuehn v. Secretary of Health and Human Services, petitioners, who are the parents of a boy allegedly injured by a series of thimerosal-containing vaccines, argue that the Vaccine Act’s statute of limitations, namely section 300aa-16(a)(2), violate their equal protection rights “due to the insidious nature of the onset of autism compared to the more clear and dramatic onset of other vaccine related injuries.” However, the court did not reach the substance of this argument because the Vaccine Act, which is the source of the special masters’ authority, does not give the special master the power to address the constitutionality of the Act’s provisions.

In Cheskiewicz v. Aventis Pasteur, Inc., the parents of an autistic boy who was diagnosed with disintegrative autism resulting from mercury toxicity seven years after he was administered his first vaccine claimed on appeal that “an interpretation of the Act barring [their] claim from proceeding in state court renders its provisions unconstitutional in violation of equal protection, due process, and their right to a jury trial.” The petitioners initially brought an action to recover for their son’s vaccine-related injuries in the Philadelphia Court of Com-

108. Id.
111. Id. at 351.
112. 2003 U.S. Claims LEXIS 286, at *3.
113. Id. at *8-9.
114. 2004 PA Super 40, ¶ 3, 843 A.2d at 1261.
115. Id. at ¶ 8, 843 A.2d at 1262.
They filed the petition approximately six and one-half years after the first manifestation of his symptoms and three and one-half years after the expiration of the Vaccine Act statute of limitations. The trial court dismissed the petitioners' claim pursuant to the Vaccine Act's requirement that claimants "first exhaust the remedies provided by the Act" and rejected petitioners' claims that the Act's statute of limitations was unconstitutional "as lacking supporting authority." On appeal, as in Kuehn, the court did not address the constitutionality of the Vaccine Act's provisions, but held that because "[p]arents do not have a right to bring an action in state court until they have exhausted their administrative remedies," the Vaccine Court "is the appropriate forum in which to raise the constitutional issues." In this regard, it must be noted that "the Vaccine Act does not provide any textual authority to the special masters to determine the [c]onstitutionality of its provisions" and because the Act is the source of the special masters' authority, the Vaccine Court may not "entertain claims outside its statutorily created jurisdictional authority." However, under section 300aa-12(f), the Vaccine Act allows for appeal from the United States Federal Claims Court (the Vaccine Court) to the Federal Circuit, "where a constitutional challenge can be entertained." Therefore, petitioners not only must file a claim in the Vaccine Court when they know such claim will be unavailing because of the statute of limitations, but must also appeal the denial of this claim for the constitutionality of the Act's provisions to be properly addressed by the court. No claims challenging the constitutionality of the Act's limitation on civil actions have been adjudicated in the Federal Circuit on appeal from rulings of the Federal Claims Court. The decisions of the Federal Claims Court, such as in Kuehn and Cheskiewicz, do not indicate whether constitutional challenges to the Vaccine Act would prevail on appeal to the Federal Circuit. However, the...
fact that a strong possibility exists that the statute of limitations of the Vaccine Act may be extended to six years is indicative of Congress' awareness that the Act's limitation on actions treats children who allegedly developed autism as a result of vaccinations unfairly due to the insidious nature of the onset of autism in comparison to the more immediate onset of other vaccine-related injuries.

CONCLUSION

The prevalence of autism has increased dramatically in recent years, causing well-founded concern among many parents and prospective parents. Some researchers even suggest that autism has become epidemic. While the exact cause of autism is unknown, many factors are implicated in its etiology, including exposure to certain childhood vaccinations, particularly those containing the preservative thimerosal. The National Vaccine Injury Compensation Program, established under the Vaccine Act, functions both "to achieve optimal prevention of infectious disease" through the use of immunization and "to achieve optimal prevention against adverse reactions to vaccines." Parents of children who allegedly developed autism as a result of childhood vaccination must, under the Program, seek redress first with the Federal Claims Court within the prescribed statute of limitations and have no right to maintain a traditional civil tort suit against the vaccine manufacturer. For most petitioners under the Program, this limitation does not negate their ability to be adequately redressed for their children's vaccine-related injuries. However, due to the insidious nature of the onset of autism, the resulting difficulty and delay in its diagnosis, and the fact that only recently has a putative association between thimerosal and autism been recognized, parents of children with autism are placed at a distinct disadvantage under the current statutory scheme of the Vaccine Act. Additionally, because the special masters of the Federal Claims Court are not conferred with the authority to address constitutional challenges to the Vaccine Act, the issue of whether the limitations of actions provisions in the Vaccine Act are unconstitutional, particularly with regard to equal protection violations, has not been determined. The OSM, through the Omnibus Autism Proceeding, will hopefully render a determination on the issue of thimerosal's causal connection to the development of autism so that

127. *Kidd*, *supra* note 6, at 295 (providing an overview of potential etiopathologic factors in the development of autism).
the thousands of petitioners with claims pending in the Federal Claims Court can either receive the appropriate compensation or, in the event that an adverse ruling results, be able to pursue a civil tort remedy.
APPENDIX 1


APPENDIX 2


B. Taylor et al., Autism and MMR Vaccination in North London; No Causal Relationship, 7 MOL. PSYCHIATRY S7 (2002).

APPENDIX 3


Katherine Marie Bulfer