



October 2015

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Recommended Citation

Bartholomew C. Wacek, *Taking Sides in the Vaccine/Autism Legal Battle*, 8 DePaul J. Health Care L. 305 (2004)

Available at: <https://via.library.depaul.edu/jhcl/vol8/iss1/8>

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TAKING SIDES IN THE VACCINE/AUTISM LEGAL BATTLE

*Bartholomew C. Wacek**

I. INTRODUCTION

Autism is a health disorder that affects children and is characterized by the impairment of normal neuronal development. In the United States, the prevalence of autism has increased remarkably as data shows that approximately one in 300 children had the disorder in the mid-1990s compared to one in approximately 2,500 children in the mid-1980s.¹ Epidemiological studies in 2001 suggest that autism may affect as many as one in 150 children in the United States.²

The etiology (or cause) of autism is not known. However, the biological picture of autism in the human body is very similar to that of mercury poisoning.³ Children may be exposed to mercury by a variety of sources (e.g., including eating fish that has high levels of mercury).⁴ Another potential source for toxic mercury exposure is childhood vaccines.⁵

Prior to 1999, childhood vaccines contained a preservative called thimerosal.⁶ Thimerosal is an organic mercury compound that was added to vaccines to prevent infections from fungus and bacteria.⁷ The level of thimerosal in one vaccine shot is low. However, children now receive as many as 18 vaccine shots in their first two years of life, and combining the thimerosal levels of all these shots means that a child might theoretically have mercury levels that slightly exceed the United States Environmental Protection Agency (EPA) guidelines.⁸

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¹ See David A. Grier and Mark R. Greir, *An Assessment of the Impact of Thimerosal on Childhood Neurodevelopmental Disorders*, 6 PEDIATRIC REHABILITATION 97, 97 (2003).

² S. Bernard, et al., *Autism: A Novel Form of Mercury Poisoning*, 56 MEDICAL HYPOTHESES 462, 462 (2001).

³ See Parris M. Kidd, *Autism, An Extreme Challenge to Integrative Medicine. Part 1: The Knowledge Base*, ALTERNATIVE MED. REV. 292 (2002).

⁴ *Experts to Re-examine Autism, Vaccine Debate* (Feb. 10, 2004), available at <http://www.cnn.com/2004/HEALTH/02/09/autism.vaccine.reut/> (last visited Oct. 7, 2004).

⁵ *Id.*

⁶ *The Truth About Thimerosal*, WALL ST. J., Dec. 5, 2002, at A18.

⁷ *Id.*

⁸ *Id.*

Because of this fact, the Academy of Pediatrics and the United States Public Health Service in 1999 recommended that thimerosal be removed from vaccines.⁹

Do vaccines that contain thimerosal cause autism? The scientific evidence to answer this question is inconclusive.¹⁰ In October 2001, the Institute of Medicine issued a report stating that there was no hard evidence that thimerosal caused autism, but the report also said it was “biologically plausible” for autism to be caused by mercury poisoning.¹¹ In February 2004, the Institute of Medicine said it would re-examine the autism/vaccine debate by studying the latest research in this area.¹²

While scientists continue to debate whether there is a link between childhood vaccines and autism, parents of autistic children have filed hundreds of lawsuits against vaccine makers.¹³ Parents of autistic children seek compensatory and punitive damages from vaccine makers in civil courts across the United States. By federal law, these petitioners must first file their claim in the United States Court of Federal Claims (“Vaccine Court”) as stipulated by the National Vaccine Injury Compensation Act (“NVICA”).¹⁴

The NVICA was enacted in 1986 by Congress and provides a no-fault remedial scheme for vaccine related injuries.¹⁵ A plaintiff needs only prove causation between the vaccine and the injury (and not negligence on the part of the vaccine maker) to be rewarded damages.¹⁶ The NVICA expressly prohibits filing a civil action for damages without first filing a petition with the Vaccine Court.

Parents of autistic children, however, would rather bypass the federal Vaccine Court because damages for pain, suffering, and death are capped at \$250,000.¹⁷ Attorneys for these parents state that awards would likely be higher if they could first try their cases in civil courts where juries have been known to award damages in the millions of dollars for medical injury cases.¹⁸ As a result, many attorneys for the parents of autistic children bypass the NVICA by characterizing their

⁹ Susan Warner, *New Vaccine Clause Angers Parents of Autistic; Amendment Buried in Homeland Security Law Restricts Right to Sue Makers of Drug Preservative*, WASH. POST, Dec. 9, 2002, at A03.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Experts to Re-examine Autism, Vaccine Debate*, *supra* note 4.

¹³ Warner, *supra* note 9, at A03.

¹⁴ *Shadie v. Aventis Pasteur, Inc.*, 254 F. Supp. 2d 509, 513 (M.D. Pa. 2003).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Warner, *supra* note 9, at A03.

¹⁸ *Id.*

claim as being about the link between the vaccine preservative thimerosal and autism, and not about the link between the vaccine itself and autism. Meanwhile, the federal Vaccine Court placed the parents of autistic children on a holding pattern because the Court issued a two-year stay so that scientific evidence concerning the possible link between vaccines and autism can be compiled.¹⁹

Another interesting wrinkle to this legal battle is that the United States executive and legislative branches seem to have taken sides. In the legal fight between parents of autistic children and vaccine makers, members of the federal government clearly support the vaccine makers. Two things solidify this advocacy for the vaccine makers: (1) the Bush administration asked the Vaccine Court to seal all documents from cases concerning whether childhood vaccines caused autism, and (2) Congress added a last-minute rider onto the Homeland Security Act that protected the vaccine maker, Eli Lilly, from vaccine-injury related lawsuits.²⁰

Therefore, the stage is set for a high-stakes showdown in the United States courts between parents of autistic children and vaccine makers. This article, in Part II, will examine the current scientific literature that is at the heart of each and every lawsuit. This article, in Part III, will examine the legal issues in the current vaccine/autism litigation, and also compare and contrast the different lawsuits seen in the federal court system versus those seen in the state court systems. Finally, this article, in Part IV, will discuss the current lawsuits in context of the United States executive and legislative branches actions that tend to favor the vaccine makers.

II. SCIENTIFIC STUDIES ON THE POSSIBLE CONNECTION BETWEEN CHILDHOOD VACCINES AND AUTISM

Autism is a debilitating disorder that is characterized by repetitive behavior, abnormal movement, and social stigma.²¹ Physicians first described autism as strictly a behavioral problem in children, and therefore, it was initially studied primarily by the psychiatric community. However, while a biological cause for autism has not been

¹⁹ *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder v. Sec'y of Health and Human Services, 2002 U.S. Claims LEXIS 365, at *4 (Fed. Cl. Jul. 3, 2002).

²⁰ Fredrick Sweet, *Bush Blindsides Parents of Autistic Children*, INTERVENTION MAG., Dec. 1, 2002 at <http://www.interventionmag.com/cms/modules.php?op=modload&name=News&file=article&sid=254>

²¹ Bernard, *supra* note 2, at 462.

found, scientists in the medical community have been able to diagnosis a biological picture in the bodies of children stricken with autism. The medical consensus is that certain children have a genetic predisposition to getting autism, but that autism will only manifest if it is first triggered by an environmental factor.²² For example, it is hypothesized that autism might be triggered by toxic levels of mercury in the body.

Certain scientists in the medical community hypothesize that the source of toxic levels of mercury comes from childhood vaccines that contain the preservative thimerosal, which is a mercury-based compound.²³ The scientific evidence that childhood vaccines (through the preservative, thimerosal) cause autism is inconclusive. Several studies point to a link between childhood vaccines and autism, while an equal amount of studies point to no possible link between childhood vaccines and autism. The following gives a snapshot of the latest scientific evidence on whether thimerosal-containing childhood vaccines cause autism.

A. The Case FOR a Causal Relationship Between Childhood Vaccines and Autism

A study published in 2003 by the Genetic Centers of America noted that the prevalence of autism in United States children rose exponentially between the mid-1980s and the mid-1990s.²⁴ This study used mathematical models to calculate odds of getting a neurodevelopmental disorder (like autism) versus the dosage of mercury children typically received from a vaccine regiment that had thimerosal-containing vaccines.²⁵ Based on the mathematical statistics, the study concluded that the occurrence of neurodevelopmental disorders following a vaccine regiment that included thimerosal-containing vaccines was not coincidental.²⁶

Another study published in 2003 by SafeMinds examined levels of mercury in the first haircuts taken from children. Hair samples were obtained from 94 children with autism and compared to 45 age- and gender-matched controls.²⁷ Mercury levels in the hair were significantly different when autistic children were compared to the

²² Bernard Rimland, *Vaccines and Autism*, 33 LABORATORY MED. 708, 708 (2002).

²³ *Id.* at 711.

²⁴ Geier, *supra* note 1, at 101.

²⁵ *Id.* at 97.

²⁶ *Id.* at 101.

²⁷ Amy S. Holmes et. al, *Reduced Levels of Mercury in First Baby Haircuts of Autistic Children*, 22 INT'L J. OF TOXICOLOGY 277, 278 (2003).

control children.²⁸ The excretion pattern (or the ability of the body to rid itself of mercury) was significantly reduced in the autistic children.²⁹ In addition, mercury levels varied significantly between autistic children that were diagnosed as having either mild, moderate, or severe cases of autism.³⁰

A review study by ARC Research was published in 2001, which stated that exposure to mercury can cause immune, sensory, neurological, motor, and behavioral dysfunctions that were similar to the same dysfunctions seen in autistic children. This study also stated that the medical literature and United States government data suggested that many cases of autism are induced by early mercury exposure from thimerosal and that the genetic and environmental factors established that some children have a predisposition whereby thimerosal exposure leads to the adverse effects of autism.³¹

The Autism Research Institute published a review study in 2002. This study noted that autistic children had a particular immune profile, characterized by decreased immune indices, activation of the inflammatory immune system, and increased biological markers for autoimmunity.³² This review study noted that the immune profile for autistic children may be considered related to the similar immune profile a person has after prolonged mercury exposure.

Finally, research from Northeastern University has established an apparent link between exposure of certain neurodevelopment toxins (like the mercury-based thimerosal) and the possibility of developing neurodevelopment disorders (like autism).³³ This study is unique in that it looks at the precise molecular mechanism that leads the neurodevelopment toxin to cause the neurodevelopment disorder.³⁴ In this study, scientists found that certain molecules stimulate the neuronal cells and that compounds like thimerosal effectively shut down the pathway that leads to this neuronal stimulation.³⁵

²⁸ *Id.* at 280.

²⁹ *Id.* at 283.

³⁰ *Id.* at 280.

³¹ Bernard, *supra* note 2, at 462.

³² Rimland, *supra* note 22, at 709.

³³ *New Research Suggests Link Between Vaccine Ingredients and Autism, ADHD* (Feb. 3, 2004), available at http://64.41.99.118/vran/vaccines/mercury/research_link_mer.htm (last visited Nov. 29, 2004).

³⁴ *Id.*

³⁵ *Id.*

B. The Case AGAINST a Causal Relationship Between Childhood Vaccines and Autism

A 2003 study of data from the Danish Psychiatric Central Research Register examined the prevalence of autism in the Danish population between 1971 and 2000.³⁶ While the United States began to phase out thimerosal from childhood vaccines in 1999, Denmark had already done the same thing in 1992. This study examined if there was any difference in the rate of autism in Danish children before 1992 when thimerosal was in childhood vaccines and after 1992 when thimerosal was removed from childhood vaccines.³⁷ A total of 956 children in Denmark were diagnosed with autism between 1971 and 2000, and the researchers noted that the trend of a higher incidence of autism continued to occur after 1992, even though thimerosal had been removed from childhood vaccines.³⁸ In other words, the discontinuation of thimerosal had no effect on autism rates continuing to rise, thus suggesting that there is no link between childhood vaccines containing thimerosal and autism.³⁹

The Statens Serum Institute in Copenhagen administered a similar study in Denmark.⁴⁰ This study looked at 467,000 children born between 1990 and 1996.⁴¹ Similar to the previous study, it was able to compare children that received thimerosal-containing vaccines prior to 1992 against children that received non-thimerosal containing vaccines after 1992.⁴² This study again found that in the Danish population there was no difference in autism rates between those children who took thimerosal and those children who did not take thimerosal.⁴³

The Epidemic Intelligence Service Program (a division of the Centers for Disease Control) published a study in 2003 that showed no link between thimerosal-containing vaccines and autism.⁴⁴ In this study,

³⁶ Richard Reading, *Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data*, 30 CHILD: CARE HEALTH & DEVELOPMENT 90 (2004).

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Ed Edelson, *New Study Finds No Autism-Vaccine Link* (Sept. 30, 2003), available at <http://www.healthscout.com/template.asp?ap=1&page=newsdetail&id=515304> (last visited Nov. 29, 2004).

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Thomas Verstraeten et al., *Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases*, 112 PEDIATRICS, 1039, 1045 (2003).

researchers used computerized databases from two health maintenance organizations (HMOs) to search for a link between neurodevelopment disorders (like autism) and thimerosal exposure.⁴⁵ In all, the study examined records for 124,170 infants born between 1992 and 1999, and dosages of calculated mercury exposure from thimerosal-containing childhood vaccines did not correlate with relative risk factors of autism.⁴⁶

The same review study by the Autism Research Institute (discussed earlier) also noted that while immune profiles are similar in autistic children and those suffering from toxic mercury exposure, thimerosal by itself might not be the only source of mercury.⁴⁷ This review stated that nutritional status, food intolerances, concomitant infections, and other toxic influences also might play a role in the development of autism.⁴⁸ In addition, the study on mercury levels in hair (also discussed earlier) also stated that mercury levels in infants had a correlation to the fish consumption of their mothers.⁴⁹

The National Institute of Allergy and Infectious Disease stated that in a review of the scientific literature, it was shown that babies eliminate the mercury found in thimerosal within days. This data suggests that any mercury exposure for thimerosal is quickly excreted out of the body such that it is unlikely that the mercury is around long enough to cause any neurological damage.⁵⁰

C. Summary of the Scientific Literature

In summation, all the scientific studies concerning thimerosal-containing childhood vaccines and its possible causal relation to autism paint an inconclusive picture. The Institute of Medicine hoped to close the door on the issue back in 2001 when it issued a report that stated emphatically that there was no evidence that thimerosal-containing vaccines caused any harm.⁵¹ This report was based on the opinions of experts from the Centers for Disease Control, from Food and Drug Administration reports, and from numerous epidemiological studies.⁵² While the attempt might have been to give a conclusive statement that there was no link between thimerosal-containing vaccines and autism,

⁴⁵ *Id.* at 1044.

⁴⁶ *Id.* at 1042.

⁴⁷ Rimland, *supra* note 22, at 714

⁴⁸ *Id.*

⁴⁹ Holmes, *supra* note 27, at 278

⁵⁰ NIAID Research on Thimerosal (May 2004), available at <http://www.niaid.nih.gov/factsheets/thimerosal.htm> (last visited Nov. 29, 2004).

⁵¹ *Immune to Reason*, WALL ST. J., Oct. 23, 2001, at A26.

⁵² *Id.*

the report, in fact, did just the opposite when it also added that it was still “biologically plausible” that mercury exposure could have an effect on autism and therefore thimerosal should be removed from childhood vaccines.⁵³ In fact, the Institute of Medicine’s report simply fueled the flames of the debate, so much so, that it is now re-examining the issue less than three years after the publication of the original report.

III. LEGAL ISSUES AND CURRENT VACCINE/AUTISM LITIGATION

Congress created the NVICA to expedite lawsuits and to protect vaccine makers from excessive and costly litigation.⁵⁴ The purpose of this Act is to be beneficial to both the person suffering from a vaccine-related injury and to the manufacturer of the vaccine. It is beneficial to the person suffering a vaccine-related injury because the person needs only show causation between the vaccine and the injury and not negligence on the part of the vaccine maker.⁵⁵ It is also beneficial to the vaccine maker because damages are not awarded from the manufacturer’s pocket, but rather out of a federal fund that was generated by adding a cost of 75 cents to every vaccine shot issued.⁵⁶

However, many people who suffer vaccine-related injury (and especially the parents of children with autism), see the NVICA as a hindrance rather than being helpful. They find it a hindrance because the NVICA places a cap on damages for pain and suffering or emotional distress at \$250,000.⁵⁷ In addition to this cap on punitive damages, a person may also recover actual nonreimbursable medical and rehabilitation expenses, reduced earning capacity or lost wages, and reasonable attorneys’ fees and costs.⁵⁸ The NVICA is also considered a hindrance by parents of autistic children because it prohibits them from filing a lawsuit in a civil court where there are no caps on damages until after a petition has been filed first with the federal Vaccine Court.⁵⁹ Currently, all pending petitions regarding vaccine injury from thimerosal-containing vaccines have been issued a

⁵³ *Id.*

⁵⁴ *See* Shadie, 254 F. Supp. 2d, at 513.

⁵⁵ *Id.*

⁵⁶ Wagner, *supra* note 9, at A03 (As of the date of this reference, the NVICA had paid out \$1.4 billion dollars on 1,775 claims).

⁵⁷ *Id.*

⁵⁸ *See* Shadie, 254 F. Supp. 2d, at 513.

⁵⁹ *Id.*

stay while the court allows for scientific discovery (which as shown earlier the data are still inconclusive).⁶⁰

Therefore, the current legislation has set the stage where parents of autistic children prefer to have lawsuits decided in state civil courts and vaccine manufacturers prefer to have lawsuits decided in the federal claims court.⁶¹ What follows is a look at some of the current cases and current issues in the United States court system, and how the battle lines are being drawn on what jurisdiction the legal battle should take place.

A. The Need and Benefit of Putting a Stay on All Cases Pending Scientific Discovery

In July 2002, the Vaccine Court issued a general order that put all autism cases seeking damages from vaccine makers on hold.⁶² The Court noted that the hold was unusual because of the large number of cases being filed in a short period of time.⁶³ In July 2002, the Vaccine Court had more than 400 cases claiming a link between thimerosal-containing vaccines and the onset of autism.⁶⁴ Of these 400 cases, more than 300 of them were filed in the six months prior to the Court ordered stay.⁶⁵ In addition, the Court stated that even more civil suits were being filed around the country and that most of those courts were dismissing the claims with the instructions that all claims must be first filed with the Vaccine Court.⁶⁶ Hence, the Court recognized that the number of cases filed in the Vaccine Court was only going to grow exponentially. Therefore, the Court opinion stated that the large number of vaccine/autism cases would “stretch thinly the resources of both the court and the bar.”⁶⁷

In the name of efficiency, the Court held that there would be a stay on all vaccine/autism cases for two years, in which time there would be scientific discovery on the possible causation between thimerosal-containing childhood vaccines and the development of autism.⁶⁸ The Court opinion stated that “a uniform evidentiary record would assist in fairly and expeditiously resolving such claims.”⁶⁹ In

⁶⁰ See *In re* Claims for Vaccine Injuries, 2002 U.S. Claims LEXIS 365, at *16.

⁶¹ Warner, *supra* note 9, at A03.

⁶² See *In re* Claims for Vaccine Injuries, 2002 U.S. Claims LEXIS 365, at *16.

⁶³ *Id.* at *2.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *In re* Claims for Vaccine Injuries, 2002 U.S. Claims LEXIS 365, at *4.

⁶⁸ *Id.* at *11.

⁶⁹ *Id.* at *1.

other words, having a uniform evidentiary record would allow the Vaccine Court to make a ruling concerning causation between thimerosal-containing childhood vaccines and the development of autism in one broad stroke that would cover all pending and future cases before the Court.

At first glance, this ruling by the Vaccine Court seems detrimental to the parents of autistic children. For example, for the parents of autistic children, two years is a relatively long time for a case to sit in discovery. In fact, the purpose of the NVICA, which set up the Vaccine Court, was to give petitioners a relatively expedient route of obtaining relief.⁷⁰ However, the Court opinion issuing the two-year stay noted that it was often the attorneys of the parents of autistic children who were requesting the additional discovery time such that scientific proof could establish causation.⁷¹

The Office of Special Masters (OSM) oversees the collection of scientific discovery for the Vaccine Court.⁷² An Autism Master File will be compiled and put on record with the Court at the end of the two-year period.⁷³ The OSM has a two-step procedure, including conducting an inquiry into the general causation issue and applying the conclusions reached in the causation inquiry to all the individual cases before the Vaccine Court.⁷⁴

All attorneys of the parents of autistic children were not given a voice in the evidentiary proceedings; rather, a representative team of the petitioner's lawyers was selected to represent the interest of all the petitioners.⁷⁵ The Court proposed the bulk of the two years be used in the discovery portion (i.e., the first part of the two-step procedure) that would examine general causation.⁷⁶ The discovery process includes scientific experts from both sides.⁷⁷ In other words, the discovery includes scientists stating that there is causation between thimerosal-containing vaccines and autism, and scientists stating that there is no causation between these vaccines and autism. Finally, the Court appointed Special Master George Hastings to preside over the proceedings and to make any and all necessary rulings on whether there

⁷⁰ *Id.* at *13.

⁷¹ *Id.* at *12.

⁷² *See In re Claims for Vaccine Injuries*, 2002 U.S. Claims LEXIS 365, at *7.

⁷³ *Id.* at *13.

⁷⁴ *Id.* at *7.

⁷⁵ *Id.*

⁷⁶ *Id.* at *8.

⁷⁷ *See In re Claims for Vaccine Injuries*, 2002 U.S. Claims LEXIS 365, at *6.

is causation between thimerosal-containing childhood vaccines and the development of autism.⁷⁸

In January 2003, the United States District Court for the Eastern District of Louisiana in *Case v. Merck* also issued a stay on an individual case citing essentially the same reasons given by the Vaccine Court. The Court noted that the Vaccine Court, which handled hundreds of claims similar to the one particular claim in its court also issued a stay so that the issue of causation could be resolved; however, unlike the Vaccine Court, the District Court did not set a time-table as to how long the stay would be.⁷⁹

The Court held that a stay was justified because it “would economize the time of the Court, the counsel, and the litigants.”⁸⁰ The Court further reasoned that causation was an essential element in order to recover damages, and therefore, it was in the best interest of the plaintiffs to have the issue of causation settled in discovery.⁸¹ Because this fact of causation was both necessary and unresolved, the Court held that the plaintiffs (the parents of the autistic child) would not be prejudiced by a stay.⁸²

Case also had two additional rulings. First, the Court held that the petitioner can obtain a loss of consortium ‘award’ from a state court and also obtain compensation from a vaccine injury through the Vaccine Court (discussed more in detail below), and second, Eli Lilly was considered separate from the other defendant vaccine makers because of the special protection it received from the Homeland Security Act of 2002 (also discussed more in detail below).⁸³

B. An Examination of Vaccine/Autism Cases Actually Decided by the Vaccine Court

As mentioned, hundreds of cases sit before the Vaccine Court on whether a causal link between thimerosal and autism exists. Below is a snapshot of some of the decisions reached by the Vaccine Court concerning both legal issues and legal procedures.

Wood v. Secretary of The Department of Health and Human Services demonstrated that statute of limitation remains an important issue in vaccine/autism cases. The petitioners (parents of an autistic child) filed a claim in September 2002 relating to vaccines the child

⁷⁸ *Id.* at *8.

⁷⁹ *Case and Redding v. Merck*, 2003 U.S. Dist. LEXIS 770; CCH Prod. Liab. Rep, P16,589, at *9.

⁸⁰ *Id.* at *8.

⁸¹ *Id.*

⁸² *Id.* at *9.

⁸³ *Id.*

received in 1996 and 1997.⁸⁴ The respondents (vaccine makers) asked for a dismissal contending that the petition was untimely filed.⁸⁵ Therefore, the statute of limitation had run, thus meaning that the case should be dismissed.⁸⁶ The Vaccine Court noted that petitioners actually filed two separate claims: (1) that vaccines received in 1996 and 1997 caused the autism, and (2) that vaccines received in April 2000 “significantly aggravated” the autism.⁸⁷ The Court held that the NVICA allows for a petition to be filed within “36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.”⁸⁸ Therefore, the Vaccine Court held that the petition concerning vaccines in 1996 and 1997 was not timely filed, but the petition concerning the aggravation of vaccine-related injury in 2000 was timely filed.⁸⁹

In *Kuehn v. Secretary of the Department of Health and Human Services*, petitioners (parents of an autistic child) did not receive the same result as petitioners in *Wood* when challenging dismissal of a petition based on the statute of limitation. Petitioners asked for a reversal of a dismissal order claiming that a strict application of the NVICA violated their constitutionally protected right of due process and right to have a jury resolve their state common law claim as protected by the Seventh Amendment.⁹⁰ The Vaccine Court denied the petitioners’ request, holding that the Court did not have the authority to resolve constitutional questions.⁹¹ In addition, the Vaccine Court cited that the Federal Circuit refused to apply equitable tolling to NVICA cases.⁹² This strict ruling on not allowing tolling of the statute of limitations can be a serious roadblock to parents of autistic children because often times the autism is not diagnosed until well beyond the time of vaccinations. It is important to note that a child might have autism develop over a slower period of time; therefore, just because clinical symptoms are not diagnosed does not mean that a child is not suffering from the autistic disorder.

⁸⁴ *Wood v. Secretary of Health and Human Serv.*, 2003 WL 23218062 (Fed. Cl.), at *1.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *See Wood*, 2003 WL 23218062 (Fed. Cl.), at *1.

⁹⁰ *Kuehn v. Sec’y of the Dep’t of Health and Human Serv.*, 2003 WL 22416683 (Fed. Cl.), at *1.

⁹¹ *Id.* at *3.

⁹² *Id.* at *2.

Tebecherani v. Secretary of the Department of Health and Human Services determined that when considering if a vaccine injury occurred, judgment should be akin to deciding a motion for summary judgment in that all the evidence should be viewed in the light that is most favorable to the petitioner. This case was remanded because the Special Master compiling the evidence failed to consider school records which were relevant to the issue of whether the child in question exhibited an onset of injuries within a 72-hour time after her vaccination.⁹³ A credible demonstration of injuries in this 72-hour time period can be considered prima facie proof of a vaccine-related injury; however, a petitioner may still prevail by demonstrating a preponderance of evidence that the vaccine significantly aggravated an injury.⁹⁴ The former scenario described here is atypical of an autism case (although the child in question here did have autism) because the development of autism is seen often well into a child's first or second year of life and not as an immediate reaction to a vaccine shot.⁹⁵ The Special Master in this case placed great weight on the child being diagnosed early with autism, and therefore, denied recovery of damages mostly based on whether there was an acute injury following a vaccination shot.

Finally, another atypical case of a petitioner seeking relief is a vaccine/autism case is seen in *Stewart v. Secretary of the Department of Health and Human Services*. In this case, the parent of a child with autism essentially asked the Vaccine Court to allow a short-form petition that would result in a Court ruling despite a stay being ordered for scientific evidence to be gathered. The parent of the autistic child bases this claim on the literal wording of the NVICA that says a decision on a petition must be made within 240 days of the petition being filed (with an allowance for a 180-day extension).⁹⁶ This wording is within the scope of what Congress intended when it passed the NVICA because Congress was mindful it did not want petitioners to be locked indefinitely in the Vaccine Court.⁹⁷ In fact, Congress conceived the NVICA on the principle that petitioners should have access to expedient relief for vaccine-related injuries.⁹⁸ Naturally, the vaccine makers asked the Vaccine Court to deny this short-form petition

⁹³ *Tebecherani v. Sec'y of the Dep't of Health and Humans Serv.*, 55 Fed. Cl. 460, 463 (2003).

⁹⁴ *Id.* at 472.

⁹⁵ *Id.* at 473.

⁹⁶ *Stewart v. Sec'y of Health and Human Serv.*, 2003 WL 22300298 (Fed. Cl.), at *5.

⁹⁷ *Id.*

⁹⁸ *Id.*

because the Court should not be making any definitive ruling while the issue of general causation was still being considered under the Vaccine Court's order. The Vaccine Court agreed with the vaccine makers holding that the stay issued by the Court essentially trumps the 240-day provision written into the NVICA.⁹⁹

Even though the Vaccine Court had a two-year timetable to gather scientific evidence concerning causation for vaccine/autism cases, it is unknown whether any kind of consensus regarding causation will be reached at the conclusion of those two years. In fact, the Institute of Medicine which supposedly gave a definitive report in 2001 stating there was no link between thimerosal-containing vaccines and autism decided to reexamine the issue less than three years later.¹⁰⁰ Therefore, any consensus that the Vaccine Court may make at the end of the two-year period might not be considered credible in light of the Institute of Medicine decision to re-examine the issue once again.¹⁰¹ The danger for parents of autistic children is that the Vaccine Court might extend this two-year stay, in which case the potential of parents getting locked into the Vaccine Court indefinitely (as discussed in Stewart) might become a reality.

C. Comparing and Contrasting Federal and State Jurisdiction for Vaccine/Autism Lawsuits

In *Shadie v. Aventis Pasteur*, the parents of an autistic child brought action in a state court against numerous vaccine manufacturers claiming the injury their child suffered as a result of taking vaccines was covered by state laws for strict product liability, negligence, and fraud.¹⁰² The vaccine manufacturers removed the case to a federal court and moved for dismissal.¹⁰³ Parents moved to remand case back to the state court.¹⁰⁴ The United States District Court for the Middle District of Pennsylvania held in favor of the parents stating that (1) the NVICA did not completely preempt state law, (2) interpretation of what made up "vaccine-related injury within the meaning of the NVICA was insufficient to confer federal question jurisdiction, and (3) there was not complete diversity between the defendants and the plaintiffs.¹⁰⁵

The important element to this case is whether a federal act equates to a federal question thus necessitating the case be removed to

⁹⁹ *Id.* at *7.

¹⁰⁰ See *Experts to Re-examine Autism, Vaccine Debate*, *supra* note 4.

¹⁰¹ *Id.*

¹⁰² See *Shadie*, 254 F. Supp. 2d 509, at 511.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

a federal jurisdiction.¹⁰⁶ The “well pleaded complaint rule” is the standard the court uses to determine if there is a presence or absence of a federal question.¹⁰⁷ This rule provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff’s well pleaded complaint.¹⁰⁸ However, mere presence of a federal issue does not automatically confer jurisdiction to the federal level.¹⁰⁹ The vaccine makers argued that the NVICA created an exclusive remedy in the Vaccine Court and any claims brought under state laws must only be brought after remedies were exhausted through the Vaccine Court. The United States District Court rejected both these arguments by holding that the NVICA did not completely preempt state law because it only made it a prerequisite to file first with the Vaccine Court prior to filing any state law claims (such as product liability, negligence, and fraud).¹¹⁰ In other words, the wording of the NVICA does not shut the door to those wishing to file a complaint in state court; rather it just states that a claim must first be filed with the Vaccine Court prior to any filings under state law.¹¹¹

Additionally, a state case may be removed to a federal court if there is complete diversity.¹¹² Complete diversity exists when the plaintiffs and all the defendants are from different states.¹¹³ In this case, the plaintiffs lived in Pennsylvania and two defendants (Aventis and GlaxoSmithKline) were considered citizens of Pennsylvania as well.¹¹⁴ Defendants argued that these two companies were fraudulently added to defeat diversity.¹¹⁵ The Court, however, stated that this theory was suspect because it asked the Court to extend the fraudulent joinder too far in light of the Supreme Court’s opinion that all doubts regarding removal are to be resolved in favor of remand.¹¹⁶

Likewise, the vaccine manufacturers in *Case* sought a dismissal because they claimed all vaccine injury cases must first be filed in the Vaccine Court. In fact, in this particular case, the defendant vaccine makers were mistaken in that the plaintiffs had previously filed a claim in the Vaccine Court. The Court in *Case* was similar to the holding in

¹⁰⁶ *Id.* at 515.

¹⁰⁷ *See* Shadie, 254 F. Supp. 2d 509, at 516.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *See* Shadie, 254 F. Supp. 2d 509, at 518.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

Shadie in that it recognized that the NVICA did not prohibit parents of autistic children from bringing civil suits in state courts. The only prerequisite to filing a claim in a state civil court is that a claim be filed first with the Vaccine Court, which was consistent with the facts in *Case*. Specifically, the Court held that a parent of an autistic child could recover a loss of consortium award from a state court and *also* receive compensation from the Vaccine Court for a vaccine-related injury (emphasis added).¹¹⁷

The *Case* and *Shadie* cases represent wins for the parents of autistic children who wish to have their lawsuits tried in a state court; however, it has yet to be decided if a state court will in fact find proof of product liability, negligence, or fraud on the part of the vaccine manufacturers.¹¹⁸ However, these cases do demonstrate that parents of autistic children tend to feel that their best chance of winning damages are in state courts, and the vaccine makers in turn are equally vehement in their desire to have cases in the federal courts where their likelihood of success is greater.

IV. THE EXECUTIVE AND LEGISLATIVE BRANCHES TAKE SIDES IN THE VACCINE/AUTISM DEBATE

While the courts have issued stays to allow for scientific discovery into whether thimerosal-containing vaccines cause autism, the executive and legislative branches of the federal government have taken affirmative actions that have the intent to limit these kinds of lawsuits. The executive branch in November 2002 asked the Vaccine Court to seal from the public all of its documents concerning whether thimerosal-containing vaccines cause autism.¹¹⁹ Meanwhile, the legislative branch in the same month attached a last-minute rider to the Homeland Security Act that essentially gave immunity to Eli Lilly (the company that invented thimerosal) from being sued for any vaccine-related injury.¹²⁰ The following discussion will examine both of these actions by the government and their intended effect on vaccine/autism lawsuits.

A. Sealing the Vaccine Court Documents

Department of Justice attorneys in the George W. Bush Administration requested that the Vaccine Court seal all documents on autism cases

¹¹⁷ See *Case*, U.S. Dist. LEXIS 770, at *8.

¹¹⁸ See *Shadie*, 254 F. Supp. 2d at 509.

¹¹⁹ Sweet, *supra* note 20.

¹²⁰ Warner, *supra* note 9, at A03.

that are part of the NVICA proceedings.¹²¹ A Justice Department spokesman stated that the goal of sealing the documents was to protect the Department of Health and Human Services, which is the opposing party to the parents of autistic children in all vaccine/autism suits filed under the NVICA.¹²² The reasoning is that the Department of Health and Human Services has the authority to decide when to release evidence on whether thimerosal-containing vaccines cause autism.¹²³ Therefore, the Justice Department argued that the autonomy of the Department of Health and Human Services to release this information would be compromised if the public already had access to the discovery documents from the Vaccine Court.¹²⁴ However, opponents of this argument suggest that if the Department of Health and Human Services goal is to issue a statement on whether thimerosal-containing vaccines cause autism then the Justice Department's action infringes on this goal by restricting the fact-finding process.¹²⁵

Attorneys for parents of autistic children retort that the real reason behind the Justice Department's request is a clever attempt to keep the information out of state civil courts, where jury awards might be extremely large against the vaccine makers.¹²⁶ These attorneys argue that the request to seal documents is, in effect, a way to punish the parents of autistic children who file suit because it would require them to incur the extra time and expense of having to regenerate the evidence that was sealed in the Vaccine Court.¹²⁷ To make this point, an attorney that represents hundreds of families with autistic children stated that this policy really favors a lawyer like himself because it allows him to bill more for unnecessary research because the government blocked access to information.¹²⁸ Hence, the increased legal costs that a parent of an autistic child may incur from the records being sealed would act as a deterrent from pressing on with a civil lawsuit after a decision from the Vaccine Court.¹²⁹

The Justice Department answered this argument by saying that parents with autistic children that choose to forgo federal compensation from the NVICA and take their cases to civil court should not have the

¹²¹ Sarah Lueck, *Administration Asks for Seal on Autism Case Documents*, WALL ST. J., Nov. 27, 2002, at D3.

¹²² *Id.*

¹²³ Sweet, *supra* note 20.

¹²⁴ *Id.*

¹²⁵ Lueck, *supra* note 121, at D4.

¹²⁶ Sweet, *supra* note 20.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

advantage of having the entire discovery from hundreds of cases at their disposal. Federal law seals most documents generated in individual cases; however, the sealing of documents has never been applied to a procedural order by the court (in this case, the procedural order to generate one discovery process to be applied to all vaccine/autism cases).¹³⁰

Finally, it is argued by scientists that the sealing of these documents may have an effect on the scientific community as well as the legal community.¹³¹ This argument goes that if the court documents show the link between thimerosal-containing vaccines and autism is not strong then scientists would be more inclined to devote their resources to other needed areas of research.¹³² In contrast, if, in fact, the court documents showed a strong link between thimerosal-containing vaccines and autism, then scientists may benefit from the release of evidence because it would help focus their resources on the mechanisms involved, which might lead to a possible cure.¹³³ Therefore, the argument goes that the sealing of evidence hurts the scientific process no matter what. In fact, keeping information secret is antithetical to the basic philosophy of science where all the data of the past is used as a foundation for future hypotheses and research.

Whether the intent to seal the vaccine/autism documents before the Vaccine Court is intended to protect the Department of Health and Human Services autonomy or to punish parents of autistic children who bring lawsuits, there is no question that the request drapes the vaccine/autism debate into a shroud of secrecy.¹³⁴ This shroud of secrecy is even more evident considering the request came the same week that the last-minute rider was added to the Homeland Security Act.¹³⁵

B. Protecting a Vaccine Maker through the Homeland Security Act

The Homeland Security Act of 2002 was a massive 500-page document that Congress passed in response to protecting the United States from

¹³⁰ Todd Zwillich, *US Government Asks Court to Seal Vaccine Records* (Nov. 26, 2002), available at <http://www.researchprotection.org/infomail/1191/27.html> (last visited Oct. 5, 2004).

¹³¹ *Autism – And the Hits Just Keep on Coming. P.L.A. - A Journal of Politics, Law and Autism* (Nov. 24, 2002), available at http://pla.bologspot.com/2002_11_24_pla_archive.html (last visited Oct. 5, 2004).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ Lueck, *supra* note 121, at D4.

¹³⁵ *Id.*

terrorist acts.¹³⁶ Language that acted as a shield for vaccine makers mysteriously appeared as a last minute rider.¹³⁷ The rider did not have an author so it is not known if it originated with the President or with a particular member of Congress.¹³⁸ This last minute provision specifically protected the pharmaceutical company Eli Lilly, who invented thimerosal and who used this preservative in their vaccines all the way through the 1980s.¹³⁹ President George W. Bush appointed Chairman and CEO of Eli Lilly, Sidney Taurel, to the Homeland Security Advisory Board; however, a spokesman for Eli Lilly expressly denied that the company had any role in pushing the last-minute change.¹⁴⁰

A group of moderate Republican Senators (Olympia Snowe (R-ME), Susan Collins (R-ME), and Lincoln Chafee (R-RI)) were able to get the Eli Lilly provision removed from the Act in January 2003, approximately two months after the Act had passed.¹⁴¹ As seen in the *Case* lawsuit mentioned above, this relatively short period of time was sufficient for Eli Lilly to make a motion for the court to use this Act as a way to protect it from product liability in a state civil court. Eli Lilly was one of five vaccine makers that were named as defendants in *Case*, and it was the only one of these defendants that was able to seek dismissal of the lawsuit by citing the Homeland Security Act.

The moderate Republican Senators who were responsible for the last-minute Eli Lilly provision being reversed did not state that they objected to Eli Lilly and other vaccine makers receiving protection, rather their objection was the “cloak of night” addition of the provision into the Homeland Security Act with no debate or discussion.¹⁴² Furthermore, the addition of this provision clearly questions the connection between thimerosal-containing childhood vaccines and homeland security?¹⁴³ Also, in line with the moderate Republican Senators objections, if the provision was to be added to the bill why should there not be any congressional hearings before denying parents of autistic children the opportunity to file a lawsuit?¹⁴⁴

¹³⁶ *Thimerosal Immunity to Pork*, *Scientific America* (Feb. 2003), available at <http://www.mindfully.org/Health/2003/Thimerosal-Homeland-SecurityFeb03.htm> (last visited Nov. 30, 2004).

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ Warner, *supra* note 9, at A03.

¹⁴⁰ *Id.*

¹⁴¹ *Those Immoderate “Moderates,”* WALL ST. J., Jan. 20, 2003, at A14.

¹⁴² Albert R. Hunt, *The Mushy Moderates*, WALL ST. J., Dec. 5, 2002, at A19.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

Defenders of the provision protecting Eli Lilly (as seen in newspaper editorials and not by any actual member of Congress) state it was good law because tort lawsuits have the potential to bankrupt vaccine makers.¹⁴⁵ As an example, one particular lawsuit is seeking \$30 billion in damages alone.¹⁴⁶ These editorials in favor of the provision continue their argument by stating that now only four companies devote funds to researching new vaccines and that a large portion of the money dedicated to vaccines are entangled in fighting lawsuits.¹⁴⁷

Additionally, supporters of this Eli Lilly provision argued that the fear of thimerosal injuries is greatly exaggerated.¹⁴⁸ This argument stated that the combined levels of thimerosal from a full vaccination schedule would only theoretically put mercury levels at the EPA mercury guideline for safety and does not address the fact that mercury can be excreted from the body over the course of the two years that children receive their initial vaccines.¹⁴⁹ The argument also noted that scientists for the EPA stated that the cutoff level as to what is safe and what is unsafe is unusually low, and therefore, thimerosal being taken out of vaccines was done more to quell parents fears rather than because of any actual safety issue.¹⁵⁰

However, what is not argued in these editorials is that much of the research to develop vaccines are funded by the United States government and not by individual pharmaceutical companies who shy away from this research because it has low profit margins. In addition, none of these editorials ever answer the question of why it was necessary to have this specific provision be attached to a bill concerning homeland security?

Also quiet on the issue of how thimerosal-containing vaccines are connected to homeland security are all elected members of Congress.¹⁵¹ House Republican leader Dick Armey (R-TX) said the provision “was something that the White House wanted”; however, neither Armey nor anyone in the White House took credit for it.¹⁵² Although the author of the provision is not known, Eli Lilly is a very strong campaign contributor to both President George W. Bush and many Republican members of Congress.¹⁵³

¹⁴⁵ See *Those Immoderate “Moderates,” supra* note 141.

¹⁴⁶ *Id.*

¹⁴⁷ See *The Truth About Thimerosal, supra* note 6.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ See *The Mushy Moderates, supra* note 142.

¹⁵² *Id.*

¹⁵³ *Id.*

Since no one has claimed to have authored the provision that protected Eli Lilly from lawsuits coming from parents of autistic children, no one is stating the only possible connection to homeland security is that vaccines may be necessary in the event of a bioterrorism attack. The argument is very tenuous at best because the provision specifically singled out protection from a childhood vaccine and not from any vaccine that may be necessary in the face of a bioterrorism attack.

In the end, the last-minute provision was most likely business as usual for Congress, which is known to add unrelated riders onto major bills that are helpful to their friends (e.g., campaign contributors).¹⁵⁴ Thankfully for the parents of autistic children who wish to continue their lawsuits, there was enough of a public uproar that ultimately the provision was removed.¹⁵⁵ The removal of this provision was another small “win” for the parents of autistic children, but it may be a win that foreshadows an ominous picture.¹⁵⁶ The vaccine makers, like Eli Lilly, have friends in high places, and the executive and legislative branches of the federal government have appeared to taken the side of the vaccine maker and against the parents of autistic children in the vaccine/autism debate.¹⁵⁷

V. DISCUSSION

The scientific process is a slow process as exemplified by the amount of autism research over the last 40 years that has yet to discover what causes the disorder. In contrast, the NVICA was designed by Congress to be a fast process to provide relief to those that suffered from vaccine injuries. When these two processes collided in the case of whether thimerosal-containing vaccines caused autism, the slower scientific process ultimately won out. Despite the NVICA being designed to give petitioners expedient relief, the Vaccine Court decided to issue a two-year stay on all vaccine/autism cases such that scientific discovery could be completed. However, two years does not appear to be enough time to clarify all the scientific questions on whether thimerosal-containing vaccines cause autism.¹⁵⁸ In fact, the Institute of Medicine, which in 2001 declared that there was no link between thimerosal-containing childhood vaccines, decided in 2004 to reexamine this issue

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ See *The Mushy Moderates*, *supra* note 142.

¹⁵⁷ See Thimerosal Immunity to Pork, Scientific America, *supra* note 136.

¹⁵⁸ See *Experts to Re-examine Autism, Vaccine Debate*, *supra* note 4.

in light of new scientific evidence that pointed to the possibility there was a link between childhood vaccines and autism.¹⁵⁹

While there are several new studies that indicate that there may be a link between thimerosal-containing childhood vaccines and autism, there are equally as many new studies which reiterate that there is no link between the vaccines and autism.¹⁶⁰ All of which means that parents of autistic children are on a holding pattern while the Vaccine Court weighs the merit of these new and increasing inconclusive scientific studies.

The “hurry up and wait” nature of these vaccine/autism cases leaves parents in an uncomfortable dilemma because on one hand, their own attorneys are asking for time to compile scientific evidence that should be favorable to their clients; and on the other hand, these parents often need immediate relief to help pay for the medical costs of caring for their autistic children. In addition, the Vaccine Court is only the first step for parents of autistic children if they wish to try and go after the “big bucks” which may be found in the state civil courts.

Finally, for parents of autistic children it seems as if not only are the super-wealthy pharmaceutical companies against them but so are the executive and legislative branches of the federal government. The Bush administration and the Republican-led Congress have taken affirmative steps that would cut off vaccine/autism petitioners at the knees.¹⁶¹ In effect, the White House and Congress, by requesting that documents be sealed and by successfully adding a rider (since removed) to the Homeland Security Act that shields Eli Lilly from vaccine-injury lawsuits, are essentially saying to the parents of autistic children that they should not even have their day in court.¹⁶² The ultra-powerful trinity of the White House, Congress, and pharmaceutical companies (as big campaign contributors) provides what would seem to be an insurmountable force in the face of parents with autistic children who seek relief through the court system.¹⁶³

As silly as it may initially seem, on the other side of the debate is the opinion that pharmaceutical companies actually need protection from the federal government. Vaccines have served the public well, yet partially because of the expense of litigation, many pharmaceutical companies have stopped making vaccines. In fact, the number of vaccine makers in the United States has shrunk to only four.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ See *Blindsides Parents of Autistic Children*, *supra* note 20.

¹⁶² *Id.*

¹⁶³ *Id.*

In the particular case of thimerosal and whether it leads to autism, vaccine makers correctly note that the reason that thimerosal was removed from childhood vaccines had more to do with appeasing parents who might have unnecessary fears of the reports of a possible link to autism. The American Academy of Pediatrics and the United States Public Health Service recommended the removal of thimerosal from childhood vaccines because they feared that if it remained in vaccines, parents would opt to not vaccinate their children at all.¹⁶⁴

Protecting vaccine makers from frivolous lawsuits would then also serve the public because it would encourage more companies to research and produce better vaccines.¹⁶⁵ This idea was the genus behind the NVICA. Vaccine makers could be free of litigation because any non-frivolous lawsuit would be settled in the Vaccine Court with damages being provided from a federal fund and not from the vaccine makers.

Of course, the NVICA did not let vaccine makers off the hook completely because the Vaccine Court was only a required first step for petitioners seeking relief from vaccine-related injuries. The NVICA provided that petitioners could forgo their federally funded relief and then take their cases to the state civil courts where the pharmaceutical companies would be on the hook if a jury awarded damages for product liability and/or negligence. Because medical costs continue to increase and because the Vaccine Court has a cap on damages, parents of autistic children almost always seek to forgo the federal court in favor of the state courts where the rewards would be richer.¹⁶⁶

VI. CONCLUSION

The only conclusive thing about the scientific evidence concerning thimerosal-containing vaccines and its link to autism is that it will be studied for a long time to come. Likewise, the lawsuits will continue as long as some evidence points to a possible link between these childhood vaccines and autism. It is unknown whether an evidentiary ruling by the Vaccine Court will provide an end-game for either the vaccine makers or provide the will to fight on in a state civil court for parents of autistic children.

¹⁶⁴ See *Immune to Reason*, *supra* note 51.

¹⁶⁵ *Id.*

¹⁶⁶ See *New Vaccine Clause Angers Parents of Autistic; Amendment Buried in Homeland Security Law Restricts Right to Sue Makers of Drug Preservative Warner*, *supra* note 9.

