July 1998

A Child's View of Recovery under the National Childhood Vaccine Act or "He Who Hesitates Is Lost"

Leonard D. Pertnoy
Professor of Law, St. Thomas University School of Law

Follow this and additional works at: http://scholarship.law.umt.edu/mlr

Part of the Law Commons

Recommended Citation
Available at: http://scholarship.law.umt.edu/mlr/vol59/iss2/5

This Article is brought to you for free and open access by The Scholarly Forum @ Montana Law. It has been accepted for inclusion in Montana Law Review by an authorized administrator of The Scholarly Forum @ Montana Law.
A CHILD'S VIEW OF RECOVERY UNDER THE NATIONAL CHILDHOOD VACCINE ACT OR "HE WHO HESITATES IS LOST"

Leonard D. Pertnoy

I. INTRODUCTION

The doctrine of statute of limitations, which acts as a bar to certain claims that are not timely filed, was developed to satisfy the public policy of preventing injustice and perpetual litigation, but often has inequitable results. These inequities are especially so in cases where a limitation on recovery has been placed upon children who might otherwise qualify for compensation under the National Childhood Vaccine Act of 1986 (Vaccine Act). This Article examines the application of the doctrine of Equitable Tolling to the Rights of Impaired Children to recover under the National Childhood Vaccine Act and traces the tremendous effects they can have on one child's life.

In understanding the context of the issues relative to the harsh application of the doctrine of the statute of limitations under the Vaccine Act, this Article will first look at the historical

---

* Professor of Law, St. Thomas University School of Law, A.B. 1964, University of Vienna; B.A. 1966, University of Louisville; J.D. 1969, University of Miami School of Law. I would like to extend special thanks to my research assistants, Aaron M. Cohen and Michael B. Senape, for all of their excellent work in preparing this article.

1. Statutes of limitations are statutes which set maximum time periods for which certain actions can be brought. After the time period elapses, which is set out in the statute or “as run,” no legal action can be brought even though the cause of action may have occurred. See BLACK'S LAW DICTIONARY 927 (6th ed. 1990).

2. “The doctrine of the law is that the dominion of things must not long remain uncertain, so as to disturb the peace of society by giving rise to numerous and perpetual litigation; and that, to prevent such serious evil, the laches of those who are dilatory in pursuing their just remedies, should be punished, and that those who are indolent shall impute to themselves the punishment.” HENRY F. BUSHWELL, THE STATUTE OF LIMITATIONS AND ADVERSE POSSESSION 7-8 (1991).

background of the Vaccine Act and its intended purpose. Next, the Article will examine one child's medical history and adverse experiences with the Vaccine Act. The Article will then explain the general and case-specific procedures of the Vaccine Act and its causation element. Finally, the Article will examine the differences between the doctrines of equitable estoppel and statute of limitations and provide an explanation of why the former should be applied in certain case brought under the Act.

II. BACKGROUND

A. The National Childhood Vaccine Act of 1986

In order to put this problem into perspective it is imperative to understand the background of the Vaccine Act. The Vaccine Act, which has a three-year statute of limitations, was enacted to provide an alternative method of compensation for vaccine-related injuries and to secure a constant supply of vaccines to help bolster federal immunization initiatives. The House Committee on Energy and Commerce created this alternative compensation system to supplement traditional civil tort law and settlement arrangements for injuries resulting from diphtheria.

4. See 42 U.S.C 300aa-16(a)(2).
5. "The consumption of vaccines is not a choice, but a requirement. All fifty states and the District of Columbia require virtually all children to be vaccinated for seven of the previously common childhood diseases--polio, measles, mumps, rubella, diphtheria, tetanus, and pertussis--before they are permitted to attend school." H. R. REP. No. 99-908, at 5; see also Randall B. Keiser, Deja Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986, 47 FOOD DRUG COSM. L.J. 15, 15 (1992). "All 50 states allow exemptions from vaccinations for medical reasons and all but West Virginia allow exemptions for religious reasons." Id. "Parents and children are not permitted to decide for themselves whether immunization is in their best interests. The state and federal governments have decided that immunization is necessary in the nation's war against disease. The federal government supports the mass immunization programs by testing and monitoring the vaccines and by informing the public of the benefits and dangers of the vaccines." Steel, supra note 3, at 144-45 (citing HARRIS L. COULTER & BARBARA L. FISHER, A SHOT IN THE DARK: WHY THE P IN THE DPT VACCINATIONS MAY BE HAZARDOUS TO YOUR CHILD'S HEALTH 199, 201-02 (1991)); see Okianer C. Dark, Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DPT Controversy?, 19 U. Tol. L. Rev. 799, 808-10 (1988).
7. Diphtheria is "an acute infectious disease caused by toxigenic strains of Corynebacterium diphtheria, acquired by contact with an infected person or a carrier of the disease, which is usually confined to the upper respiratory tract, and characterized by the formation of a tough membrane... attached firmly to the underlying tissue that will bleed if forcibly removed." DORLANDS ILLUSTRATED MEDICAL DICTIO-

http://scholarship.law.umt.edu/mlr/vol59/iss2/5
tetanus,\textsuperscript{8} and pertussis\textsuperscript{9} inoculations (DPT).\textsuperscript{10} Congress was concerned that injured children were not being properly compensated due to inadequacies in the tort system.\textsuperscript{11} However, the difficulty and expense in handling this type of litigation causes problems to arise when children that would otherwise be entitled to compensation under the Vaccine Act are unaware of their rights to compensation. This is due to the fact that medical research, until recently, did not support a causal connection between encephalopathy and the DPT inoculations given to children. Because of this lack of causation, injured parties had no other option than to file tort claims against the individual manufacturers.

Moreover, a strict reading of the statute of limitations provision of the Vaccine Act\textsuperscript{12} prevents a petition from being filed "if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than thirty-six months after the date of the administration of the vaccine."\textsuperscript{13} Accordingly, a healthy baby who is vaccinated and subsequently becomes ill may be barred from recovery if no medical data is uncovered within the three-year period to indicate a causal relationship.

Equitable tolling is often applied to a statute of limitations to suspend the application of the rule and provide a more equitable result. By suspending the application of a statute of limitations, a plaintiff who, despite all due diligence, is unable to obtain vital information bearing on the existence of a claim is safeguarded. Particularly, a plaintiff who does not show any symptoms of injury from a DPT inoculation until thirty-six months after the inoculation may still have a claim under the Vaccine Act. The application of equitable tolling is the only method avail-

\textsuperscript{8} Tetanus is "an acute, often fatal infectious disease caused by the anaerobic, spore forming bacillus Clostridium tetani; the agent most often enters the body through contaminated puncture wounds . . . physiological tetanus; a state of sustained muscular contraction without periods of relaxation caused by repetitive stimulation of the motor nerve trunk at frequencies so high that the individual muscle twitches are fused and cannot be distinguished from one another." \textit{Id.} at 1691.

\textsuperscript{9} Pertussis is "an acute, highly contagious infection of the respiratory tract most frequently affecting young children, usually caused by Bordetella pertussis." \textit{Id.} at 1268.

\textsuperscript{10} See H.R. REP. NO. 99-908, at 3-5; see also \textit{Patten}, 655 F. Supp. at 749; \textit{Naile}, supra note 6, at 657.


\textsuperscript{12} See 42 U.S.C. 300aa-16(a)(2).

\textsuperscript{13} \textit{Id.}
able for plaintiffs in such situations to correct injustices that would otherwise result from a strict interpretation of the Vaccine Act and ensure they are not denied compensation for DPT related, permanent, life-altering disabilities.

The case of Alex Chariff is a perfect example of the injustices described above. This Article will be a guide through the life and troubled times of Alex showing how strict application of the doctrine of statute of limitations has limited Alex’s recovery and resulted in a denial of compensation for Alex’s DPT related disabilities.

B. Facts of Alex’s Case

On April 28, 1986, at 9:36 a.m., Alexander “Alex” Chariff was born at Jackson Memorial Hospital in Miami. Alex’s mother carried him to full term and he was a healthy newborn. Upon his first examination doctors failed to notice any apparent abnormalities, or birth related injuries. Alex, a normal baby, was expected to grow up as any other healthy child would. He was required by law to receive four DPT vaccinations. On August 28, 1989, Alex received his fourth and final DPT vaccination from his pediatrician.

Within three days of Alex’s final DPT shot, he began to experience a very high fever and his parents noticed changes in his daily activities. Alex started to sway from his normal everyday actions and his behavioral changes were unusual for a boy of his age. Alex’s parents behaved as responsible parents and took him to the doctor for treatment.

Unfortunately, Alex’s condition continued to worsen and he suffered from almost constant cold-like symptoms and high temperature. Soon thereafter, Alex began to experience episodes in which he would just sit and stare motionless into space. The staring episodes were the beginning of what doctors later diagnosed as seizures. As a result of these seizure episodes, Alex encountered “drop attacks” where his eyes moved in circles and began to raise, eventually causing him to fall to the

14. See medical records on file with author.
15. See id.
16. See id.
17. See id.
18. See id.
19. See id.
ground. Additionally, Alex began drooling from the mouth and showed signs of oral discomfort, including extreme reddening and soreness of the throat. Doctors also noted that Alex was experiencing a decrease in muscle tone. This formerly healthy baby boy started to experience signs of paralysis and unresponsiveness to external stimuli, such as people passing by or talking to him.

Alex's motor skills weakened significantly during the period following his last inoculation and he developed facial ticks. The seizures progressed down to his lower body and he was eventually unable to control his lower body movements or functions. Alex became extremely hyperactive, unable to sit or stay motionless. Often he would lose momentary consciousness and pass out. Alex's actions also included bizarre periods of time in which he would howl at the moon. It was during this period of time that Alex shifted from left-handedness to right-handedness. Less than two months after the final inoculation, Alex began experiencing violent tremor-type seizures.

As a result of Alex's behavior and physical condition, he underwent numerous neurological examinations and tests at various hospitals throughout the United States. Alex's parents, in an attempt to diagnose their child's condition and determine what was causing this unusual change in their baby boy, took him to specialists throughout the country. These doctors tried to determine the cause of Alex's changed conditions and provide him with adequate and appropriate treatment. In early 1991, Alex was hospitalized and a Magnetic Resonance Imaging (MRI) scan of Alex's brain revealed "inflamed meningitis," which indicated to the doctors that Alex had some inflammation of the

20. See id.
21. See id.
22. See id.
23. Paralysis is the "loss or impairment of motor function in a part due to lesion on the neural or muscular mechanism also there can be an "impairment of sensory functions." DORLANDS ILLUSTRATED MEDICAL DICTIONARY 1227 (28th ed. 1994).
24. See medical records on file with author.
25. See id.
26. See id.
27. See id.
28. See id.
29. See id.
30. See id.
31. See id.
32. See id.
membranes of his brain. This swelling was potentially responsible for some of the problems with Alex's motor skills and behavior patterns, but there was insufficient data to draw any sort of conclusion. Subsequently, Alex was taken to Columbia Presbyterian Hospital where he was placed on steroids and Phenobarbital. This treatment helped relieve some of his discomfort and initially reduced the number and severity of the seizures.

Soon after, however, the seizures began again and Alex started to experience severe, violent seizures in addition to the drop attacks and staring spells. In response, doctors at the University of California ordered a Position Emission Tomography (PET). This procedure showed an area of abnormal brain tissue in his right temporal lobe. In order to alleviate this, Alex had a right temporal lobe resection. Unfortunately, neither this surgery, nor the post-operative medicines that the doctors prescribed, helped alleviate Alex's condition or control his seizures. Alex's condition continued to worsen and in September of 1992 Alex's mother took him to Johns Hopkins and Boston Children's Hospital for expert consultations. The doctors recommended a hemispherectomy and Alex's father, contacted an old friend, Dr. Aizik Wolf at the University of Maryland, for another opinion. Dr. Wolf concurred with the diagnosis and a right frontal lobe resection was performed at the University of Maryland Hospital. The operation apparently caused the drop attacks, from which Alex previously suffered, to cease.

However, the staring spells, which Alex had suffered since three days after the last injection, persisted.

33. See id.
34. See id.
35. Steroids are used "mainly to promote growth and repair body tissues in senility, debilitating illness, and convalescence." DORLANDS ILLUSTRATED MEDICAL DICTIONARY 1579 (28th ed. 1994).
36. Phenobarbital is "a long-acting barbiturate, used as sedative, hypnotic and anticonvulsant, administrated orally." DORLANDS ILLUSTRATED MEDICAL DICTIONARY 1274-76 (28th ed. 1994).
37. See medical records on file with author.
38. See id.
39. See id.
40. See id.
41. See id.
42. See id.
43. See id.
44. See id.
45. See id.
46. See id.
47. See id.
ber, 1992 and November 1992, Alex underwent three more surgeries at the University of Maryland, all resulted in very little improvement.\footnote{See id.} Since the right frontal lobe resection was performed, Alex developed e. coli Meningitis and received intrathecal medication.\footnote{See id.} Alex’s seizures persisted and it was in September, 1993 that Alex had a total right hemispherectomy (functional) performed at Miami Children’s Hospital, whereby the right part of Alex’s brain was removed.\footnote{See id.} Despite all the surgeries, consultations and treatments, Alex continues to have staring episodes, where the left side of his face pulls upward. These do not appear to be associated with any apparent alteration in his level of consciousness, as Alex has no control over this strange occurrence.\footnote{See id.} Furthermore, there is no family history of epilepsy, febrile seizures, degenerative illness, retardation, or motor tics.\footnote{See id.} Initially, none of the doctors that examined Alex ever deduced or even contemplated that this condition was a result of the last DPT shot that Alex received on August 28, 1989.\footnote{See id.}

Throughout Alex’s care and treatment there were conflicting medical opinions as to the nature and cause of his condition. In some instances, the diagnosis used for treatment was Rasmussen’s Syndrome,\footnote{See id.} but the doctors at Duke University Hospital said that a Rasmussen’s Syndrome diagnosis was inconclusive.\footnote{See id.} In fact, up until March 2, 1994, no one suggested a connection between DPT and Alex’s condition.

The first indication that Alex’s condition might be related to DPT came in March of 1994 when his parents happened to see a television report on the newly discovered connections between DPT and conditions such as Alex’s.\footnote{See medical records on file with author.} Prior to 1994, there was

---

48. See id.
49. See id.
50. See id.
51. See id.
52. See id.
53. See id.
54. “Possible causes [of epilepsy partialis continua] include infarction, hemorrhage, tumor, and inflammation. Epilepsy partialis continua is the initial feature of a poorly defined entity of childhood called Rasmussen encephalitis . . . . Affected children have focal motor seizures that defy treatment and progress to affect first both limbs on one side of the body and then the limbs on the other side. Progressive hemiplegia and other neurologic deficits develop, and often they remain even after seizures have stopped.” Gerald M. Fenichel, Clinical Pediatric Neurology, A Signs and Symptoms Approach 32 (2d ed. 1993).
55. See medical records on file with author.
56. The 60 Minutes television report on March 2, 1994, followed the publication of the 1994 Institute of Medicine report, DPT and Chronic Nervous System Dysfunction, A New Analysis. See infra note 89.
no medically accepted causal connection between DPT inoculations and encephalopathy. The medical research community reconsidered its previous view and now supports the position that a DPT inoculation can be the triggering factor of chronic encephalopathy, commonly known as Rasmussen’s Syndrome.

It is evident that, prior to the airing of the television special, Alex’s parents had no indication that the DPT shot had any sort of relation to their son’s condition. At all times prior to this connection, neither the medical community, nor those treating Alex had any basis to connect Alex’s chronic, permanent condition with the DPT inoculations. Unfortunately, Alex’s parents were unable to allege such a connection within thirty-six months of the last inoculation, because, prior to the television report, the medical community limited DPT related injuries to acute encephalopathies.

In Alex’s case, during the time frame of the application of the statute of limitations, there was insufficient medical evidence to support a causal connection for recovery and Alex’s parents were unaware of the potential benefits of the Act. Subsequently, Alex’s parents became aware of their rights under the Vaccine Act and would have been entitled to compensation if the causal connection was made and a petition filed within the thirty-six months following the date of his final DPT inoculation. However, Alex was denied compensation and barred from recovery due to his failure to comply with the statute of limitations provided in the Vaccine Act. The harsh result in Alex’s case is only one example of the sort of injustices that can arise when courts strictly apply the statute of limitations provision of the Vaccine Act to undetected and unconnected medical conditions.

C. Recovery Under the National Childhood Vaccine Act of 1986

The first step in obtaining coverage under the Vaccine Act is the filing of a petition for compensation. This next section explains the general and case-specific procedures required by the Vaccine Act.

57. For a discussion of medical views on the causal connection between DPT inoculations of encephalopathy, see infra Part III.A.
58. See id.
1. General Procedure

In order to receive compensation for a vaccine-related injury, petitions for compensation must be filed with the Court of Federal Claims within thirty-six months of the last inoculation. These claims are heard and decided by a special master appointed by judges of the United States Claims Court. After the receipt and filing of a petition the chief special master will assign and designate a special master to review documents, listen to testimony and set forth a decision that includes "finding of fact and conclusions of law." Subsequently, the decision of the special master may be reviewed by the United States Claims Court upon a motion by the parties within thirty days of the issuance of the special master's decision.

2. Procedure and Ruling in Alex's Case

On March 20, 1995, a Petition on behalf of Alex was filed with the Court of Federal Claims. The petition alleged that Alex's final DPT vaccinations contained partial cell pertussis baceteris and as a result of this Alex contracted DPT-induced seizure disorders. The disorders, as previously explained in Part II(B), included high fever, encephalitis, and shock collapse. Therefore, compensation should have been available to Alex, because he first showed symptoms and the manifestation of onset of significant aggravation of illnesses after the vaccine inoculation, within the meaning of the vaccine injury table. "A table injury is an injury, disability, illness or condition listed on the Vaccine Injury Table." Alex's parents alleged that his exposure to the DPT vaccinations resulted in continued seizures affecting his motor skills, bodily functions, and everyday activities. Alex and his family have suffered tremendous pain, suf-

60. See 42 U.S.C. § 300aa-12(c)(1).
61. See 42 U.S.C § 300aa-12(d)(3)(a), 12 (e)(1).
63. See id.
64. See 42 U.S.C. § 300aa-14(a).

Published by The Scholarly Forum @ Montana Law, 1998
Fering, and emotional distress.67 Furthermore, the effects of the final DPT vaccination have required Alex to undergo several brain surgeries, including a hemispherectomy, during which large portions of his brain were resected and removed.68 Alex's parents contend that their son's life has been forever altered due to the DPT inoculation on August 28, 1989.

In response to the Chariffs suit, the Secretary of Health and Human Services,69 filed a motion to dismiss.70 The special master who presided over the case, granted the motion to dismiss with "prejudice for lack of jurisdiction."71 The special master ruled that Alex's mother failed to inquire into her legal rights until after the statute of limitations expired, therefore waiving her right to now bring suit, and that she had ample opportunities in 1989 to question attorneys as to the feasibility of filing a claim for compensation pursuant to the Vaccine Act.72 The special master, reasoning that under an objective standard a reasonable parent would have inquired into her legal rights, ultimately stated that a reasonable parent would have sought legal options after seeing such drastic changes in her son's condition.73 In order to pursue federal monies under the Vaccine Act,74 a claim must be filed in the federal claims court within thirty-six months75 of the last vaccination.76 This statute of limitations is set in stone and has no equitable consideration, regardless of

---

67. See id.
68. See id.
69. See Tandy, supra note 11, at 31 (stating that "the U. S. Government, specifically the Secretary of the Department of Health and Human Services" is the respondent in vaccine compensation cases).
70. See Motion on file with author.
72. See id.
73. See id.
74. See 42 U.S.C § 300aa-16(a)(2). "In the case of a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this subpart, 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." Id.
75. In Alex's case, a telephone status conference was conducted before Special Master Laura D. Millman, in Court of Federal Claims, in which she heard argument on behalf of both parties. At that time, the special master stated that, based upon the submitted petition and supporting documentation, Alex Chariff would have been eligible for benefits had he filled his petition within thirty-six months of the first symptom or manifestation of injury after receiving the DPT vaccination. But because the statute of limitations barred Alex from bring suit, he was unable to receive relief.
76. See 42 U.S.C § 300aa-16(a)(1).
what medical complications or uncertainties of causation were present at the time. The special master dismissed the action stating that the application of equitable tolling in such a case might result in an indefinite statute of limitations.

Alex's parents asserted in their petition for compensation that, up until 1994, there was no recognized medical data supporting the connection between Alex's encephalopathy and the last DPT inoculation. The Institute of Medicine (IOM) and the medical community received first noticed that compensation for chronic permanent nervous system dysfunction would be permitted under the Vaccine Act. The IOM report is important because it states that the Act provides for independent and impartial examination of health related subjects that are complex, lacking in definitive date, or subject to differing opinions of reputable science. It is clear that, in Alex's case, neither his doctors, his parents, nor the medical community as a whole, realized that there could be a causal connection until the IOM report was issued. Consequently, the Vaccine Act's statute of limitations should not have started to toll until March 2, 1994, the date when Alex's parents made the connection between the vaccine and Alex's condition.

There have been situations where inequities have resulted due to strict compliance with the statute of limitations and a reluctance to allow equitable tolling. Such an example occurred

77. See Smith v. Secretary of Health and Human Servs., 26 Cl. Ct. 116 (1992); Alex's claim was filed on March 20, 1995, sixty-seven months after the last shot.
79. The original petition is on file with the author.
80. The Institute of Medicine, was "chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public," and act as an adviser to the federal government. INSTITUTE OF MEDICINE, COMMITTEE TO STUDY NEW RESEARCH ON VACCINES, DPT VACCINE AND CHRONIC NERVOUS SYSTEM DYSFUNCTION: A NEW ANALYSIS ii (Kathleen R. Stratton et al. eds., 1994) [hereinafter IOM].
81. See id. at 3.
82. See id. "The study was mandated by Section 312 of Public Law 99-660, the National Childhood Vaccine Injury Act of 1986, which called for specific reviews of the adverse consequences possibly associated with Pertussis and Rubella vaccinations. The Act specifically requested that the Institute of Medicine carry out these reviews, since the IOM is well prepared to examine health related subjects that are of interest to the executive and legislative branches, that have implications for a large segment of the population, and that are difficult to resolve because of their complexity or lack of definitive date or where reputable science may have differing opinions, and the judgment of an independent, impartial, a multi disciplinary body would be helpful." Id.
in *Melendez v. Secretary of Health and Human Servs.*, where the United States Court of Federal Claims held that the discovery rule would not be applied to the statute of limitations in the Vaccine Program and that the Petitioner, once aware of the child's injury, had a duty to inquire as to whether there were legal remedies available. This strict interpretation of the law puts an incredible burden upon parents. If all parents of sick children followed this decision, they would want to call their attorneys each time their child shows some abnormal behavior. Only absurd results could come of such a duty.

In Alex's case, the court ruled that "a lack of knowledge of one's rights is not enough to toll the statute of limitations." Alex's parents do not refute this point as this is not the case in Alex's situation. His parents made a good faith effort and exercised due diligence in attempting to discover the causes of Alex's injuries. Why would Alex's parents thought to pursue legal remedies if they did not even have evidence to prove a causal relationship between his injuries and the vaccination?

Additionally, Alex's case is different from those claimants who allege having no knowledge of the requirements of the Vaccine Act, prior to the expiration of its statutorily provided limitations period. Prior to 1994, Alex had no medical data to support his claim for compensation, but after the limitations period for Alex's potential claim under the Vaccine Act expired, the medical community altered its position regarding the DPT vaccine. The medical community, including Alex's doctors, indicated that there is a causal connection between DPT and Alex's type of encephalopathy. Indeed, if Alex had sought relief from the Court prior to 1994, with the original medical data, his petition would have been summarily dismissed. Up until 1994, neither Alex's parents, nor his doctors, had any proof or medical data to support a contention that his encephalopathy was caused by, and the result of, his DPT vaccine. Since there was no evidence to support such a claim, Alex's parents did not seek relief under the Vaccine Act within the statutory limitations period.

---

83. No. 94-103V (Fed. Cl. Jan. 6, 1995).
84. Id.
85. Dion v. United States, 137 Ct. Cl. 166, 167 (1956).
86. See medical records on file with author.
87. See id.
III. ESTABLISHING THE CAUSAL LINK BETWEEN INOCULATIONS AND ENCEPHALOPATHY

The causation element is the key factor in obtaining recovery under the Vaccine Act. The next section discusses what is required, under the Vaccine Act, to establish causation and the adverse affects that may occur once causation is established.

A. Discovery of the Causal Link

Alex's condition was not diagnosed by physicians as there was no knowledge of a causal connection between the DPT shot and the new condition, until the doctors reversed their position in an IOM publication,88 in mid-1994.89 As of 1991, the IOM was aware of a British study which was investigating the long-term effects of DPT vaccines.90 However, prior to 1991, the studies were inconclusive as to any causal link between DPT and chronic seizure syndrome.91 In 1994, the IOM decided to re-investigate the findings of the British study and concluded that there was evidence to support a causal connection between the administration of the DPT vaccine and resulting chronic seizure disorders.92 As indicated earlier in this article, the study subsequently conducted by the IOM affirmed that the new evidence showed a causal relationship between vaccine with DPT and Acute Encephalopathy.93 The committee found that the excess risk is estimated to range from 0.0 to 10.5 per million DPT immunizations. However, the same IOM Committee also found, in 1991, that the evidence was insufficient to support a causal relationship between DPT and permanent neuralgic damage. Because the evidence showing a causal relationship between the DPT and acute encephalopathy has been so limited, and because of the ten-year follow up to the National Childhood Encephalopathy Study, the United States Public Health Service asked the IOM to study the new data and, “if warranted, reevaluating the causal relationship between DPT and Chronic Nervous System Dysfunction.”94

The National Vaccine Program95 was established on No-
The government apparently was aware of the adverse effects that some vaccinations might have upon children, as evidenced by the implementation of the Vaccine Act. It was not until 1994 that the IOM gave the first notice to the general medical community and potential claimants (such as Alex) that such a condition might be related to the DPT and therefore compensable. Up until this point, Alex's parents were not aware of any connection between the child's symptoms and the inoculation. Additionally, none of the doctors who examined Alex was able to make a causal connection between the DPT shots and his condition. It would have been futile for Alex to petition for benefits previously, since his condition was not described as having a relationship to DPT vaccinations.

As of 1991, the IOM committee concluded that the evidence was inadequate to establish a causal relationship between DPT and permanent neurologic damage. In contrast, the 1994 IOM report stated, "the relation between DPT and chronic nervous system dysfunction had not been studied in a rigorous scientific manner until recently;" currently "the balance of evidence is consistent with a causal relation between DPT and the forms of chronic nervous system dysfunction." Therefore it was not until the 1994 report that the general medical community or Alex's parents would have been aware of the updated results. The original committee had concluded there was not enough evidence to indicate a relationship between the DPT and febrile seizures, febrile seizures or epilepsy. In December of 1993, in light of the new data from the National Childhood Encephalopathy Study (NCES), the IOM was enlisted to study the relationship between DPT inoculations and permanent nervous system damage which resulted in the finding of a causal relationship was between the DPT inoculations and permanent ner-

---

98. 42 U.S.C. § 300aa-11(a) allows for compensation under the National Vaccine Act for vaccine-related injuries.
99. This refers to a chronic, permanent nervous system dysfunction.
100. Medical records are on file with author.
101. See id.
102. See IOM, supra note 80, at 3.
103. Id. at 1.
104. Id. at 2.
105. See id. at 3.
vous system dysfunction.\textsuperscript{106}

The NCES was a "case-control study" of serious acute neurologic illnesses in children living in Great Britain.\textsuperscript{107} In 1993, the NCES published its results from a ten-year follow-up study. In this report the NCES determined that some areas of dysfunction can be detected by parents and even teachers upon examination of the child.\textsuperscript{108} The NCES concluded that these areas were "quite broad" and could include children's neurologic reactions, motor skill, sensory perception, behavior, such as howling, and self-care dysfunctions.\textsuperscript{109} The new data from the follow-up study indicated that children who experience "a serious acute neurologic illness are at risk for chronic nervous system dysfunction," similar to the condition afflicting Alex.\textsuperscript{110} The NCES data indicates that there is a strong possibility that some children, without underlying brain or metabolic abnormalities, could come to suffer and experience serious acute neurologic illness within seven days after receiving DPT.\textsuperscript{111} "Acute illness could have chronic nervous system sequelae."\textsuperscript{112} The NCES data also supports the notion that some children with underlying brain or metabolic abnormalities "might go on to develop Chronic Nervous System Dysfunction due to a DPT-triggered acute illness."\textsuperscript{113} Therefore the Committee's findings are conclusive evidence that there is a causal relation between DPT and Chronic Nervous System Dysfunction in those children who experience a serious acute neurologic illness within seven days after receiving DPT vaccine.\textsuperscript{114} Children such as Alex, who receive DPT and later come to suffer serious acute neurologic illness, might be expected to either experience chronic, permanent nervous system dysfunction or die.\textsuperscript{115}
B. Applications of the Causal Link

1. General Causation Scenarios

By utilizing the IOM's findings, a petitioner in Alex's position--where the acute neurologic illnesses that follow the DPT may be related to Chronic Nervous System Dysfunction--can now make a claim under three scenarios. The findings of this new study open the door for compensation for litigants like Alex. Before these three scenarios can be discussed, it is important to note that the NCES data does not permit any distinctions to be drawn between the three scenarios.\(^1\) Hence, any conclusions based upon any one of these scenarios might be the "true" explanation.\(^2\) The IOM Committee's conclusions indicate that they do not support any of these scenarios over the others. The first scenario stated by the NCES involves situations where "DPT administration might cause a serious acute neurologic illness and subsequent chronic nervous system dysfunction in children who otherwise might not have experienced either an acute neurologic illness or chronic dysfunction in the absence of DPT."\(^3\) If this were the sole explanation of whether DPT and Chronic Nervous System Dysfunction were causally related, the committee would have concluded that the relation is causal and that DPT increases the risk of Chronic Nervous System Dysfunction in children.\(^4\)

However, the second scenario indicated that "DPT might trigger (and thereby be an immediate or proximate cause [of] . . . ) an acute neurologic illness and subsequent chronic nervous system dysfunction in children with underlying brain or metabolic abnormalities."\(^5\) These abnormalities might make the children react adversely to stimuli such as fever, infection, and vaccines that children without such abnormalities might tolerate.\(^6\) "Thus, these children might have experienced chronic nervous system dysfunction even in the absence of DPT administration . . . ."\(^7\) It is possible that some other, non-DPT-related, acute event might have triggered the illness.\(^8\)

Lastly, DPT inoculations might cause an illness in children

\(^{116}\) See id. at 14.
\(^{117}\) See id.
\(^{118}\) Id.
\(^{119}\) See id.
\(^{110}\) Id.
\(^{111}\) See id.
\(^{112}\) Id.
\(^{113}\) See id. at 14.
with underlying brain abnormalities that would have eventually have led to chronic nervous system dysfunction even in the absence of an acute neurologic illness. The essence of this third connection is that the presence of underlying brain abnormalities might predispose a child to react adversely to the DPT with an acute neurologic illness. In this situation it is the "underlying abnormality that is the cause of the chronic nervous system dysfunction, not the acute illness." The NCES data suggests that the first scenario is consistent with a "causal" relationship between DPT and Chronic nervous System Dysfunction, while the third scenario is not. The NCES is not clear on whether the second scenario is consistent with a causal connection between DPT and Chronic Nervous System Dysfunction. The IOM concluded, based on its studies and the NCES follow up report, that if a child had not experienced an acute neurologic illness other than one which occurred within seven days after receiving the final DPT inoculation and then the child experiences Chronic Nervous System Dysfunction, the evidence is consistent with a causal relation between DPT and the Chronic Nervous System Dysfunction. In response to the above findings, the IOM changed its position and now accepts a "causal" relationship between DPT and chronic nervous system dysfunction. The IOM now also recognizes that children who previously received DPT inoculations but did not have underlying brain or metabolic abnormalities, might, after receiving DPT, suffer serious acute neurologic illness and "could have chronic nervous system sequelae."

2. Legal Implications of the Causation Scenarios

In rendering the ruling in Alex's case, Special Master Millman pointed out that she was not bound by the IOM. Indeed, the National Vaccine Act does not require special masters to accept IOM reports as dispositive on the issue of claim brought under the vaccine act. To the contrary, the Act affords the special master considerable discretion to weigh evidence oth-

---

124. See id.
125. Id. (emphasis in original).
126. See id. at 15.
127. See id.
128. See id.
129. Id.

Published by The Scholarly Forum @ Montana Law, 1998
er than the IOM reports. 131 Estep v. Secretary of Health and Human Services, 132 a United States Court of Federal Claims opinion, decided June 25, 1993, clarifies that the special master may place varying weights on the IOM report and the NCES, even finding differently in different cases on the same issue. 133 “The court is aware that in previous decisions, special masters have reached varying conclusions as to the probative value of the IOM report and the NCES.” 134 In Estep, the special master found the IOM report unpersuasive. However, in Cucuras v. Secretary of Health and Human Services, 135 the same special master was presented with conflicting evidence. 136 One party offered into evidence the IOM report while the other offered the NCES report with the testimony a doctor. 137 In Cucuras, the special master came to the opposite conclusion from that in Estep. 138 He concluded that the IOM report was more persuasive, than the doctor’s testimony. 139

It is the author’s view that the IOM report is persuasive and should be given more credence than Special Master Millman allowed for in Alex’s case. The Petitioners in Alex’s case requested that the court place heavy weight upon the 1994 IOM report and recognize that the information available to the medical community was recently updated to include its findings. 140 The IOM has been empowered with the ability to revise and update the eligibility for benefits under the National Vaccine Acts and has done so. 141 Indeed, this alone is enough to illustrate the power the IOM. Therefore, the deference the judges should give

132. 28 Fed Cl. 664 (1993).
133. See id.
135. 26 Cl. Ct. 537 (1992), aff’d, 993 F.2d 1525 (Fed. Cir. 1993).
136. See Cucuras, 26 Cl. Ct. at 543.
137. See id.
138. See id.
139. See id. at 543, 545-46.
140. Complaint on file with author.
141. See Rules and Regulations Department of Health and Human Services Public Health Service, 60 Fed. Reg. 7679 (“After weighing all the varied opinions expressed at the June meeting, as well as the written comments received from two commissions members, the Department has decided that a final rule which is a revised and refined version of the proposed rule published in 1992 will reflect best as scientific evidence.”).
One of the objectives of the Vaccine Act\textsuperscript{43} is to ensure that the vaccine injury table is updated periodically to ensure scientific knowledge is reflected.\textsuperscript{44} The Department of Health and Human Services has carefully reviewed the IOM's conclusions regarding DPT vaccine and Chronic Nervous System Dysfunction.\textsuperscript{45} The Department concluded that despite the uncertainty regarding causation, the final rule is consistent with IOM report and conclusions regarding the Miller Study.\textsuperscript{46} This new rule allows for "a presumption of causation if the DPT vaccine recipient shows signs of injury, within the applicable period, the injury meets the description of an acute encephalopathy, and the chronic encephalopathy persists for more than six months beyond the date of vaccination."\textsuperscript{47} Hence, the final rule is consistent with the IOM's conclusions that some children, like Alex, have been shown to have experienced an acute encephalopathy following vaccine administration and then have gone on to develop chronic neurologic dysfunction.\textsuperscript{48}

In the instant case, Alex demonstrated appropriate manifestations of a DPT related injury within the specified time provided in the injury table set forth in the Vaccine Act. However, since Alex's injury is a chronic, permanent neurological dysfunction, based upon the strict wording of the 1991 IOM Report, Alex would have not been eligible to receive benefits because the DPT was causally related by the IOM only to acute encephalopathies. It was not until 1994 that the IOM made public its findings, which expanded the causal relationship definition to the chronic permanent conditions experienced by Alex.

The special master who ruled on Alex's case claimed that children suffering from chronic encephalopathy were routinely granted benefits; however, a review of the literature reveals cases in which the "acute" criteria was strictly enforced.\textsuperscript{49} For

\begin{itemize}
  \item \textsuperscript{142} See id.
  \item \textsuperscript{143} This program was released by the National Vaccine Program Office/OASH.
  \item \textsuperscript{144} See Rules and Regulations Department of Health and Human Services Public Health Service, 60 Fed. Reg. 7685.
  \item \textsuperscript{145} See id.
  \item \textsuperscript{146} See id.
  \item \textsuperscript{147} Id.
  \item \textsuperscript{148} See 1994 Institute of Medicine Report Executive Summary 1-3 (1994).
  \item \textsuperscript{149} See Yeoman v. Secretary of Health and Human Servs., No. 90-1049V, 1994 WL 387855 (Fed. Cl. July 11, 1994).
\end{itemize}
example, the court in *Yeoman v. Secretary of Health and Human Services*, the court stated,

Summarizing, Dr. Kinsbourne's testimony appears to be that the parent's testimony are credible and that Hillary suffered from the vaccine-related residual seizure disorder after the first shot.

... Dr. Joel Herskowitz, a board-certified pediatric neurologist testified that Hillary presently suffers from a seizure disorder and a chronic encephalopathy. Her conditions, however, were not caused by the DPT vaccinations and do not fall within the Vaccine Injury Table.

Similarly, in Alex's case medical science did not draw a causal link between his DPT shot and his chronic encephalopathy until 1994. Accordingly, Alex should not be barred from recovery for having failed to make a claim at a time when, based on the available medical information, his claim would have been denied.

IV. EQUITABLE ESTOPPEL VERSUS STATUTES OF LIMITATION

Special Master Millman in her decision stated that, "[t]he purpose of a statute of limitations is the promotion of justice by preventing presentation of claims which have been dormant and are later revived when 'evidence has been lost, memories have faded, and witnesses have disappeared.'" According to the United States Supreme Court, "The theory is that even if one has a just claim it is unjust not to put the adversary on notice to defend within the period of limitation and that the right to be free of stale claims in time comes to prevail over the right to prosecute them." Special Master Millman continued by saying that "ignorance of one's legal rights does not toll the statute of limitations." Specifically, Millman pointed to the National Childhood Vaccine Injury Act and found that "She [Alex's mother] was under a duty to seek legal counsel before she saw a television program in 1994." To support her conclusion, Millman pointed to three cases.

151. *Id.*
155. *Id.* at *3.
Millman first relied on Cragin v. United States, where the court dismissed the Cragins' complaint due to their failure to comply with the two-year statute of limitations. The plaintiffs, the Cragins, had a duty to ask about their legal recourse before the statute of limitations expired. The duty to inquire is based on an objective, not a subjective, standard. Even if a doctor would not have disclosed the cause of the victim's injuries, the duty to inquire is not the same as the duty to disclose. The court held that plaintiffs did not exercise reasonable diligence in inquiring into the cause of the victim's injuries.

It is important to understand the distinction between Cragin and Chariff. In Alex's case his parents did not have the knowledge that the Cragin family had. The special master in Alex's case seems to have missed this distinction or, at a minimum, felt that there was adequate evidence for the Chariff family to have proceeded: "Yet petitioner asserts that the symptoms she alleges Alex suffered were not compensable before the IOM report in 1994 and moreover, are symptoms of a chronic condition. Petitioner's assertion is not credible."

As to equitable tolling in Alex's case, the court found that "there was no justification for applying equitable tolling."

The Order further stated:

Petitioner had ample opportunity in 1989 to query attorneys as to the feasibility of presenting claim. If the facts were as she alleges them, i.e., within three days of his fourth DPT, Alexander had encephalitis, shock, high fever, loss of muscle tone, paralysis, and unresponsiveness to external stimuli, a reasonable parent, if viewed using the objective standard, would have inquired into her legal rights . . . . A passive petitioner has no equitable right to toll the statute of limitations indefinitely until a fortuitous media even prompts her to take action.

Once again, the court rejected the Alex's contention that the statute of limitations should not apply in this case because of equitable tolling, in that Alex's injury was unknowable until

---

156. 684 F. Supp 746 (D. Me. 1988), aff'd, 873 F.2d 1433 (1st Cir. 1989).
157. See id. at 750.
158. See id. at 752-53.
159. See id. at 754.
160. See id. at 755.
161. See id. at 753 (quoting Pertnoy, 1995 WL 579827, at *6).
163. Id. at *4.
164. Id.
after the statute of limitations had expired.\textsuperscript{165} 

V. APPLYING THE EQUITABLE ESTOPPEL ARGUMENT TO ALEX'S CASE

The doctrine of equitable tolling allows a plaintiff who, despite having exercised all due diligence, is unable to obtain vital information bearing on the existence of the claim, to avoid a statute of limitations.\textsuperscript{166} This doctrine will be applied when "an accrual date has been ascertained but plaintiff does not know of his claim."\textsuperscript{167} The standard for equitable tolling has often been repeated within the Federal Circuit, which has stated that equitable tolling can apply when the plaintiff shows that their injury "was 'inherently unknowable' at the accrual date,"\textsuperscript{168} such as in Alex's case.

In cases brought before the United States Supreme Court, the Court instructed that the principles of equitable tolling fully apply to cases brought against federal governments.\textsuperscript{169} In \textit{Irwin v. Department of Veterans Affairs},\textsuperscript{170} the Supreme Court held that the same rebuttable presumption of equitable tolling applicable to suits against private defendants should be applied to suits against the United States. Additionally, Judge Plager of the United States Court of Appeals for the Federal Circuit noted the importance of the \textit{Irwin} decision\textsuperscript{171} and stated that federal courts no longer attempt to discern, on a case-by-case basis, which statutory time limits may be waived and which are deemed to be "jurisdictional."\textsuperscript{172} Judge Plager added that Con-

\begin{footnotesize}
\textsuperscript{165} See id.

\textsuperscript{166} The doctrine of equitable tolling relates to the situation when a cause of action has accrued, but the plaintiff cannot obtain information necessary to decide whether the injury is due to wrongdoing and is so, due to wrongdoing by the defendant. See Stevens v. Secretary of Health and Human Servs., 25 Cl. Ct. 12, 23 (1994).


\textsuperscript{170} 498 U.S. 89 (1990).

\textsuperscript{171} See Wood-Ivey Sys. v. United States, 4 F.3d 961, 964 n. 4 (Fed. Cir. 1993).

\textsuperscript{172} "It is no longer necessary for courts to offer unconvincing explanations as to why some statutory time limits are waivable and some not. It is now presumed that Congress intends traditional waiver to be available, unless Congress expressly specifies otherwise." Id. at 969 n.3.
\end{footnotesize}
gress may, if it chooses, “make a specified time limit jurisdictional and unwaivable, but it must do so unmistakably.”

Clearly, Alex and others like him are barred from recovery if the statute of limitations is strictly enforced. The United States Court of Appeals for the Federal Circuit acknowledged that equitable tolling may well be available under the National Childhood Vaccine Act. In the *Gilbert* case, which involved a petitioner’s untimely election to accept a final judgment, the Federal Circuit Court held that the requirements for equitable tolling were not satisfied under the facts of the case and noted that whether the doctrine applies is an open question.

In another case involving the time limit of filing a petition by parties who had an action pending in state court when an Act went into effect, the Federal Circuit Court again noted, but did not decide the equitable tolling issue. The court went on to explain that they “need not decide if equitable tolling would be available in such a situation, even if, as the Claims Court has held, equitable tolling generally is not available under the Vaccine Act because the limitations period contained in the Act is a statute of repose.”

Although there is some authority indicating that equitable tolling may not be available under the Vaccine Act, in Alex’s case this authority should not be followed. First, the Federal Circuit has refused to endorse the position of these trial courts, which indicate that equitable tolling should not be allowed, even when presented with the opportunity to do so. This suggests that the appellate court has some doubts on the question of whether to apply equitable tolling to cases such as Alex’s. Furthermore, the Claims Court cases on equitable tolling involve the deadline for pre-Act vaccinations. These courts note that the legislative history for those claims mandates that there be no equitable tolling under that provision.

173. Id.
174. *See* *Gilbert* v. Secretary of Health and Human Servs., 51 F.3d 254, 255 (Fed. Cir. 1995).
175. “*Gilbert* invokes the doctrine of equitable tolling to avoid the time bar of 21(a). Assuming without deciding that the doctrine sometimes may be used to do that . . .” *Id.* at 257.
176. *See* *Weddel* v. Secretary of Health and Rehabilitation Servs., 23 F.3d 388, 397 (Fed. Cir. 1994).
177. *Id.* (citations omitted); *see also* Widdoss v. Secretary of Health and Human Servs., 98 F.2d 1170, 1179 (Fed. Cir. 1993) (Newman, J., dissenting) (notice to review special master’s decision which is filed one day late is subject to equitable tolling).
However, during Alex's case, the government presented no evidence as to post-Act vaccinations which would have rebutted the Irwin presumption that equitable tolling is available. Furthermore, the aforementioned trial level cases tend to speak of the filing requirements as being "jurisdictional." For example, in Stevens v. Secretary of Health and Human Services, the court stated that "the filing deadlines included in the Vaccine Act are jurisdictional and cannot be waived for any petitioner by this court, even in a compelling case." All of the different opinions taken together, including the Supreme Court opinion in Irwin, the suggestions by the Federal Circuit Court, and the lack of legislative intent involving post-Act vaccinations and time bar restraints, indicate the doctrine of equitable tolling should be available to people in Alex's situation.

(1994); Smith v. Secretary of Health and Human Servs., 26 Cl. Ct. 116 (1992); Massard v. Secretary of Health and Human Servs., 25 Cl. Ct. 421, 425-26 (1992) ("The special master in his analysis of Section 16(a)(1) concluded that the 4-month extension authorized in the 1990 amendments clearly was intended to serve as a cutoff for the filing of retrospective cases.")

179. Another Claims Court case finding no equitable tolling under the Act involved yet a different provision not at issue here: the provision (42 U.S.C. § 300aa-16) that a petition for compensation must be filed within twenty-four months after the death of a person receiving a vaccination. See Anderson v. Secretary Health and Human Servs., No. 92288V, 1993 U.S. Claims LEXIS 207 (Fed. Cl. Feb. 19, 1993); Fuentes v. Secretary of Health and Human Servs., No. 92-162V, 1993 U.S. Claims LEXIS 204 (Fed. Cl. Feb. 11, 1993).

180. 31 Fed. Cl. 12, 24 (1994).

181. Nevertheless, as explained in Judge Plager's concurrence in Wood-Ivey Sys. Corp., 4 F.3d 961, 969 n.3 (Fed. Cir. 1993): "Since Irwin, compliance with statutory time limits is no longer jurisdictional, in the old sense that when a Congressionally specified time limit had expired a court had no power to entertain the case. The presumption is now to the contrary. The court has jurisdiction to entertain the suit and to determine on the merits if equitable relief from the time bar is warranted."

182. Equitable tolling can also apply where the defendants concealed its acts with the result that the plaintiff was unaware of their existence. This was not apparent in Alex's case but rather, based on medical science, no one knew that Alex's condition was within the parameters of the Vaccination Act. In Anderson v. Secretary of Health and Human Servs., No. 92388V, 1993 U.S. Claims LEXIS 207 (Fed. Cl. Feb. 19, 1993) and Fuentes v. Secretary of Health and Human Servs., No. 92-162V, 1993 U.S. Claims LEXIS 204 (Fed. Cl. Feb. 11, 1993), Special Master Hastings described equitable tolling as being dependent upon concealment by the defendant. As stated, this is not correct. The Federal circuit cases cited in this text explain that "Plaintiff must either show that defendant has concealed its acts with the result that plaintiff was unaware of their existence, or its must show that is injury was 'inherently unknowable' at the accrual date." Catawba Indian Tribe, 982 F.2d at 1571 (quoting Japanese War Notes Claimants Ass'n v. United States, 373 F.2d 356, 359 (Ct. Cl. 1967)) (emphasis added); See Welcker v. United States, 752 F.2d 1577, 1580 (Fed. Cir. 1985).

183. See Hearing on S. 2117 Before the Senate Comm. on Labor and Human Resources, 98th Cong. 98-1060 (1985); Hearing on S. 827 Before the Senate Comm. on
VI. CONCLUSION

The National Vaccine Act has resulted in confusion and inappropriate results. The fact that the medical community was not aware of a connection between Alex's symptoms and his DPT inoculation should not bar him from subsequent recovery. The bottom line is that nobody knew.

Currently, the statute of limitations starts to run at the time the DPT injection is given. For cases such as Alex's the statute should start to run from the discovery of a connection between a disease and its cause. Under the current time bar if you do not make the connection it is good-bye and good luck. This is not right and that is why the doctrine of equitable tolling should be applied to all cases where a connection could not have been detected.

Although compensation may still be obtained through going after the drug companies for the defective lots of DPT, there remains a need to afford assistance to parents and children who have this disease. The government has done this by establishing the National Vaccine Act. However, for full recovery to occur, the Act must make allowances for children and their parents who had no possible way of knowing or detecting a connection or when the medical community, as a whole, did not accept a causal connection position. If Alex's case proves anything, it is that severe injustice can come from a strict interpretation of the National Vaccine Act's statute of limitations and "he who hesitates is lost."

---

