

# AUTISM AND THE COURTS

## WHAT DOES THE RECENT SETTLEMENT REALLY MEAN?

■ Elissa J. Taub, J.D.

### Abstract

*The US government recently agreed to pay a settlement to parents who claimed that vaccines had caused their daughter to develop autism. The rationale for the settlement was the US government's conclusion that vaccines the daughter received at 18 months of age significantly aggravated an underlying mitochondrial disorder, that manifested with features of autism spectrum disorder. This settlement is not legal precedent because it is not a conclusion by a judge or special master, as is the usual method to decide such cases in the context of the National Vaccine Injury Compensation Program. Instead, the federal government chose to settle this case out of court as it did not believe it could prevail. It is presently unclear how the present case will impact other cases of a similar nature, if at all.*

### Key Words

*autism, mitochondrial disorder, National Vaccine Injury Compensation Program, settlement, special master, Vaccine Court*

### Editor's note

*The number of conditions that fall within the realm of autism continues to increase. The subsequent increase in diagnoses may be real or a manifestation of increased sensitivity of the health and education community to such conditions. As optometrists who are in contact with these children/adults on a daily or weekly basis, it behooves us to be cognizant of the possible postulates concerning the causes of autism. One of these suggested causes is, what some believe, are unnecessary vaccinations. The case presented here is one that addresses this complex and continuing issue and is offered as evidence of how the legal system might address the alleged relationship between autism and vaccination.*

### INTRODUCTION

In a surprising move, the federal government settled a lawsuit with the parents of a girl named Hannah Polings. The Polings alleged that vaccines caused their daughter to develop autism. The federal government paid the family compensation for the child's injuries.<sup>1,2</sup> Once news of the settlement was leaked to the public, it became a lightning rod for those on both sides of the autism-vaccine debate. Those who believe vaccines cause autism immediately concluded that the settlement was proof positive of their theory. Those who believe that there is no definite link between vaccines and autism argued this to be a unique case.<sup>2</sup> What does this settlement mean? We must explore what this particular settlement says to answer that question. There is a legal process one must follow to present a case to the National Vaccine Injury Compensation Program (NVICP, also known in laymen's terms as the Vaccine Court). In addition, a plaintiff seeking compensa-

tion for a vaccine-related injury must satisfy specific proofs to be successful. This paper will discuss various aspects of this settlement.

The settlement document in this case describes the child's medical history in detail and ultimately recommends that the family be compensated.<sup>1</sup> It is important to analyze this settlement, both in terms of the medical history and in terms of how the law would have been applied to this medical history, if the case had gone to court.

### Medical history

Hannah Polings' medical history revealed a child who was meeting all of her developmental milestones until she reached 18 months of age. Prior to that time, Hannah had exhibited no adverse reactions to her vaccines. As an infant and young toddler Hannah experienced recurring ear infections, which caused her to be treated with tubes in both ears at age 20 months. Because of the ear infections she did not receive her regularly scheduled vaccinations at 12 and 15 months of age. Instead, her parents and doctor decided to give her all five shots at her 18-month checkup.<sup>1</sup> Two days after receiving the five vaccines, Hannah developed a fever and was lethargic, irritable and cried for long periods of time. Over the ensuing days, she continued to experience intermittent fevers and rashes, which the doctors attributed to normal vaccine reactions.<sup>2</sup> Over the next few months, she continued to experience fevers and behavioral changes, including reduced appetite, loss of previously acquired language skills, as well as deficits in her communication and social development skills. She also continued to experience auditory problems, including obstructions of the tubes in her ears and fluid accumulation behind the ear drum.

At the age of 23 months, a doctor noted that she had a possible speech delay.<sup>1</sup> Because of their concern about Hannah's communication difficulties, her parents sought a consultation with a pediatric neurologist at 25 months of age. The neurologist noted Hannah's loss of previously acquired language, eye contact and relatedness. He diagnosed her with regressive encephalopathy with features consistent with an autistic spectrum disorder, following normal development. The neurologist ordered genetic testing, a magnetic resonance imaging (MRI) and an electroencephalography (EEG). He also referred Hannah for an occupational therapy assessment. The occupational therapist concluded that Hannah was developmentally delayed and exhibited features of autistic disorder.<sup>1</sup>

The MRI and EEG were normal, but laboratory studies "strongly indicated an underlying mitochondrial disorder."<sup>1</sup> Subsequently, Hannah met with a specialist in neurogenetics who confirmed that her history was consistent with mitochondrial Progressive Pseudorheumatoid Dysplasia (PPD). Notably, the neurogeneticist also described how other children with Hannah's genetic profile exhibit normal development until sometime between the first and second year of life when they begin to regress developmentally. Hannah began to undergo treatment for mitochondrial dysfunction, including speech, occupational, physical and behavioral therapy. It should also be noted that, almost six years after receiving her vaccines, Hannah developed a seizure disorder, from which she continues to suffer.<sup>1</sup>

The US government concluded that the vaccines Hannah received at 18 months "significantly aggravated an underlying mitochondrial disorder, which ... manifested as a regressive encephalopathy with features of autism spectrum disorder," and recommended compensation.<sup>1</sup> The government also concluded that Hannah's seizure disorder was too remote in time from the administration of the vaccines and consequently, declined to provide compensation for that injury.

### How to seek compensation from the NVICP

The NVICP provides compensation to individuals injured by certain childhood vaccines that include but are not limited to: DTaP (diphtheria, tetanus, and pertussis), DTP-Hib (diphtheria, tetanus, pertussis and the Hib bacteria), MMR (measles,

mumps and rubella), OPV (oral polio vaccine), IPV (inactivated polio vaccine), Hepatitis B, Chicken Pox (Varicella), Rotateq, the flu shot and pneumococcal conjugate. See Table 1. To be eligible to file a claim, a person's alleged injuries must meet at least one of three requirements:

- 1) the injury lasted for more than six months after the vaccine was given,
- 2) the injury resulted in a hospital stay and surgery; or
- 3) the injury resulted in death.<sup>3</sup>

If these requirements are met, the injured individual (or his or her parents, legal guardian or legal representative) may file a claim with the NVICP to obtain compensation.

A claim with the NVICP begins with a petition that is a statement of the facts that arguably entitle the individual to compensation, including:

- Who was injured by the vaccine;
- Which vaccine caused the injury;
- When the vaccine was administered;
- Where the vaccine was administered;
- The type and nature of the injury;
- When the first symptom(s) of the injury appeared; and
- How long the injury lasted.

In addition, the petition must be accompanied by documentary evidence of the injury, such as medical records.<sup>5</sup>

Once the case is filed, the Department of Justice reviews the facts and assigns the case to a special master for adjudication. The special master is a lawyer who is appointed by the judges of the Federal Court of Claims to make both the factual and legal conclusions necessary to determine if the individual is entitled to compensation.

The government chose the Polings' claim as a test case in the context of the wider ongoing autism-vaccine litigation in the Federal Court of Claims. Upon review of the evidence, the government decided to settle out of court. Consequently, a special master never had the opportunity to make a legal or factual conclusion. However, if the settlement had not been reached, the case would have been tried in court sometime in the near future.

When a vaccine injury case proceeds to trial before a special master, the person bringing the claim (the plaintiff) must submit the required evidence to obtain compensation. Ultimately, the plaintiff must address two major issues:

- 1) proof of the required link between the vaccine and the injury and

- 2) providing enough evidence of the link to persuade the special master to award compensation.

As to the first issue, there are three types of causes upon which a plaintiff may rely to prove a link between a vaccine and the claimed injury. In the petition, a plaintiff may present one cause as the basis for the claim, or a plaintiff may argue all three types of causes alternatively.

First, a plaintiff could show that the injured person received a vaccine listed on the Vaccine Injury Table and that the adverse events occurred within the specified time period.<sup>3</sup> See Table 1.

Second, a plaintiff could show that the vaccine definitively caused the injury. This is most often proved through expert testimony and through ongoing scientific research. Third, a plaintiff could show that the vaccine caused an existing illness to be significantly aggravated. This is the basis upon which the government decided to settle the Poling case.<sup>4</sup>

Once the plaintiff sets forth evidence of the link between the vaccine and the injury, the special master must determine that there is enough evidence to award compensation. The federal Vaccine Court is a civil court and not a criminal court. This means that a plaintiff does not have to prove the case beyond a reasonable doubt. Instead, the standard of proof is a "preponderance of the evidence."<sup>6</sup> This means that it is "more likely than not" that the vaccine caused the injury; however, the plaintiff must also show that the injury would not have occurred "but for" the vaccine.<sup>7</sup> If the plaintiff is able to meet this burden of proof, then the government must show that there is "not a preponderance of the evidence that the [injury] is due to factors unrelated to the administration of the vaccine."<sup>7</sup> In other words, the government has to show that there might be reasons for the injury other than the vaccine.

### The implications of the Polings' settlement

At its core, the Polings' settlement means that the government felt that it could not mount a strong enough defense to avoid compensation. In fact, Julie Gerberding, head of the US Centers for Disease Control and Prevention (CDC) stated, "This does not represent anything other than a very special situation,"<sup>22</sup> and the CDC has cautioned that this case should not be relied upon to evaluate the risks of vaccines for

**Table 1.  
National Childhood Vaccine Injury Act Vaccine Injury Table<sup>9</sup>**

<b>Vaccine</b>	<b>Adverse Event</b>	<b>Time Interval</b>
I. Tetanus toxoid-containing vaccines (e.g., DTaP, Tdap, DTP-Hib, DT, Td, TT)	A. Anaphylaxis or anaphylactic shock B. Brachial neuritis C. Any acute complication or sequela (including death) of above events	0-4 hours 2-28 days Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, Tdap, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of above events	0-4 hours 0-72 hours Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of above events	0-4 hours 5-15 days Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis B Any acute complication or sequela (including death) of above event	7-42 days Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A Thrombocytopenic purpura B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient C Any acute complication or sequela (including death) of above events	7-30 days 0-6 months Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio --- in a non-immunodeficient recipient --- in an immunodeficient recipient --- in a vaccine assoc. community case B. Vaccine-strain polio viral infection --- in a non-immunodeficient recipient --- in an immunodeficient recipient --- in a vaccine assoc. community case C. Any acute complication or sequela (including death) of above events	0-30 days 0-6 months Not applicable 0-30 days 0-6 months Not applicable Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of above event	0-4 hours Not applicable
VIII. Hepatitis B antigen- containing vaccines	A. Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of above event	0-4 hours Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines)	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Vaccines containing live, oral, rhesus-based rotavirus	A. Intussusception B. Any acute complication or sequela (including death) of above event	0-30 days Not applicable
XIII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIV. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary of Health and Human Services	A. No condition specified for compensation	Not applicable

other children.<sup>2</sup> It also appears that not all the research is in regarding whether a vaccine can cause the aggravation of a mitochondrial disorder, however, for purposes of this case, the government determined compensation was appropriate.

Legally speaking, and despite what laypeople in the media might say or think, this settlement is *not* legal precedent, because it is not a conclusion by a judge, special master or jury. This means that in future cases, judges or special masters likely will not allow plaintiffs to cite this case in support of their claims. There is however, precedent for this settlement in that the Vaccine Court has awarded compensation in another recent case where the administration of vaccines aggravated an underlying condition leading to an autism-like disorder.<sup>2,8</sup>

It seems possible that this case was not the best one to use as a test because Hannah Polings was never specifically diagnosed with typical Autism Spectrum Disorder in accordance with the rubric set forth in the DSM IV. In fact, her medical records,

as reported in the settlement, reveal that her underlying disorder made her prone to the symptoms that she now exhibits.<sup>1</sup> In the coming months and years, the special masters of the Vaccine Court will address tens of thousands of pending autism cases. It remains to be seen how the science and the law will converge on this issue.

## References

1. Age of Autism Child v. Secretary of Health and Human Services-Settlement, <http://www.ageofautism.com/2008/02/full-text-autis.html> Last accessed 5/5/08
2. "Vaccine settlement no landmark, officials say," <http://www.msnbc.msn.com/id/23519029/> Last accessed 5/5/08
3. Health Resources and Services Administration-National Childhood Vaccine Injury Act Vaccine Injury Table. [www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf](http://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf) Last accessed 5/5/08
4. Health Resources and Services Administration-National Vaccine Injury Compensation Program, "Persons Eligible to File a Claim," [http://www.hrsa.gov/vaccinecompensation/persons\\_eligible.htm](http://www.hrsa.gov/vaccinecompensation/persons_eligible.htm) Last accessed 5/5/08
5. Health Resources and Services Administration-National Vaccine Injury Compensation Program, "Filing a claim with the VICP," [http://www.hrsa.gov/vaccinecompensation/persons\\_eligible.htm](http://www.hrsa.gov/vaccinecompensation/persons_eligible.htm) Last accessed 5/5/08

6. 42 U.S.C. § 300aa-13(a)(1). [http://straylight.law.cornell.edu/uscode/html/uscode42/uscode42\\_00000300--aa013-notes.html](http://straylight.law.cornell.edu/uscode/html/uscode42/uscode42_00000300--aa013-notes.html) Last accessed 5/5/08
7. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).
8. *Banks v. Secretary of HHS*, No. 02-0738V (Ct. Fed Claims July 20, 2007).
9. [www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf](http://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf) Effective Date: 2/1/07. Last accessed 5/5/08

Corresponding author:

Elissa J. Taub, JD  
6731 Garden Oaks Drive  
Memphis, TN 38120  
[etaub@visalaw.com](mailto:etaub@visalaw.com)

Date accepted for publication:  
May 27, 2008

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