

**Commentary****Shoemaker On Vaccines**

By

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[Editor's Note: Clifford J. Shoemaker is a member of Shoemaker & Associates in Vienna, Va., where his practice includes vaccine injury law. He is co-author of "The Swine Flu Litigation" published in the 1981 Journal of the Section of Litigation of the American Bar Association. He received a Bachelor of Arts degree from the University of Iowa, a Master of Business Administration degree and J.D. from Drake University and an L.L.M. from George Washington University. Replies to this commentary are welcome. Reply to the author at [cliff@attorneyaccess.net](mailto:cliff@attorneyaccess.net). Copyright 2003, the author.]

Once again in this issue of Mealey's Reporter, we will look at the LAW, MEDICINE and POLITICS of Vaccine Litigation, and we will consider some Practice Tips.

**The LAW of vaccine litigation:** Congratulations to Sheila Ann Bjorklund of Minneapolis, Minnesota for the Opinion of Judge Bohdan A. Futey in the case of *Setnes v. HHS*, No. 02-791V (June 13, 2003). This is a landmark decision on the issue of the statute of limitations as it applies to autism cases in the NVICP. AJ Setnes was born on June 10, 1997 and seemed to be developing normally. AJ received all of his normal childhood vaccines, and on September 11, 1998, he received his 15-month vaccinations, including MMR, DtaP-Hib, Varicella and OPV. Following these vaccinations, his parents began noting significant changes in his behavior. He started making a constant humming noise and was doing a lot of babbling. He was slow to develop words and stopped responding to his name. His parents thought at first that he had a hearing problem, but it checked out as being normal. Sometime after these vaccinations, AJ also started to have temper tantrums where he would kick and scream. He also was observed eating the cardboard boxes that held videotapes. By age two (June of 1999), AJ was no longer a happy, smiling little boy who liked to play with his brother and interact with his parents. He was hitting and kicking his brother, and the family could not take him out in public because of this temper tantrums. He had also developed a vacant stare, and his development became more and more behind. The parents expressed their concern to the pediatrician. On July 16, 1999, the pediatrician noted AJ's lack of speech and development delays, and he noted that these impediments may be the result of PDD. He noted that the lack of eye contact was an abnormal physical finding, and he recorded that AJ had speech delays and poor social skills. After an evaluation on January 7, 2000, doctors for the first time referred to AJ's problems as probable PDD/autism. AJ was diagnosed with definite autism on March 3, 2000. The petition was filed on July 15, 2002, within 3 years of the July 16, 1999 pediatric visit, but more than three years after the first symptoms. A medical opinion filed from Dr. Donald Marks put the onset of symptoms within 3 months of the September 11, 1998 vaccinations. Special Master Millman concluded that: "Since the onset of AJ's alleged vaccine injury precedes 36 months before petitioners filed their petition, the undersigned has no subject matter jurisdiction over this petition, and the petition must be dismissed. Petitioner sought to have the decision reviewed by a Judge of the Claims Court, and the claim was assigned to Judge Futey. Judge Futey agreed that there is no equitable tolling in the NVICP, citing *Brice v. HHS*, 240 F.3d 1367 (Fed. Cir. 2001), cert. denied sub nom., 70 U.S.L.W. 3360 (U.S. Nov. 26, 2001)(No. 01-341). Judge Futey also recognized that the NVICP is a waiver of sovereign immunity: "The court proceeds with a full understanding that a "statute of limitations is a condition on the waiver of sovereign immunity by the United States,' and courts should be 'careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.'" (Citing *Brice*.)

Turning to the statute, Judge Futey stated: "In pertinent part, the Vaccine Act provides that the statute of limitations runs upon the '[1] occurrence of the first symptom or [2] manifestation of onset' of the injury. 42 U.S.C. § 300aa-16(a)(2)." Concluding that the clear Congressional intent was for these two statements to mean something different, the Court rejected the Respondent's argument that the occurrence of the first symptom and manifestation of onset mean the same thing. In hindsight, Dr. Marks was able to piece together the puzzle and conclude that the occurrence of the first symptoms occurred within three months of the vaccinations, but that does not mean that the **manifestation of onset of the injury** occurred then. "'Manifest' is defined as 'evident to the senses . . . obvious to the understanding, evident to the mind, not obscure or hidden, and is synonymous with open, clear, visible, unmistakable, indubitable, indisputable, evident, and self-evident.'" Judge Futey recognized that the onset of autism can be insidious, and it often does not become manifest until there is enough evidence for the doctors to put together the pieces of the puzzle. The manifestation of onset does not occur when a mother observes her child humming, babbling, kicking and screaming, etc. "Based on the contemporaneous medical evaluations and notations, AJ's onset of autism became evident between July 16, 1999, and January 7, 2000." Therefore, the case was timely filed, and Special Master Millman's decision was reversed and the case remanded. Once again, congratulations to Sheila.

**The MEDICINE of vaccine injuries** continues to evolve. One piece of evidence that can be critical in proving causation involves evidence of positive rechallenge. The best example of this type of evidence is the famous article by Pollard and Selby about a man who developed GBS shortly after receiving a tetanus vaccination. When they took his history, it turned out that he had developed GBS after another tetanus vaccination ten years earlier. This single case report was used by the Institute of Medicine to conclude that it is likely that tetanus vaccination can cause GBS. This IOM conclusion does not just apply to cases where someone develops GBS after tetanus vaccination twice; it applies to all cases of GBS occurring shortly after a tetanus vaccination. Dr. Wise and others also used positive rechallenge evidence in an article about alopecia after vaccinations.<sup>1</sup> They distinguished between two different types of positive rechallenge cases — ones where there was complete recovery between episodes (referred to as "clear" cases) and ones where the patient does not completely recover but experiences a significant worsening after a second dose (referred to as "possible" cases). For hepatitis b vaccination cases, this type of evidence will be critical for proving causation. In the next installment, we will look at a couple of cases that have followed and expanded upon the *Stevens* case — *White v. HHS*<sup>2</sup> and *Althen v. HHS*.<sup>3</sup>

**The POLITICS of vaccine litigation** is going nowhere fast. It is amazing that Congress continues to ignore the obvious problems in this program. The members of Congress who are truly concerned about doing something are few and far between, and the Republican leadership in the Senate seems intent on protecting industry at all costs, with very little regard for the victims who seek relief in the program. In 1999, I testified for the first time before Congress, asking for three simple fixes:

1. Extending the statute of limitations, so that our country doesn't continue to thumb its nose at thousands of American children;
2. Providing interim fees and costs, so that claimants can afford to hire the experts necessary to prove causation in an expeditious manner; and
3. Changing the burden of proof to make it easier to prove causation. The simplest way to do this would be to make it clear that the program is a remedial compensation program and not a waiver of sovereign immunity.

There are other issues to be addressed, but at the very least, Congress needs to address these concerns.

**Practice Tips:**

1. In addition to keeping track of your own time and expenses, it is important that you advise your clients to keep careful track of their own expenses with regard to pursuing the claim. Clients are entitled to recover any advances made for experts, collecting medical records, etc. In addition, they should keep track of phone bills, copying charges, postage, mileage and other travel expenses for evaluations that are strictly for the claim (as opposed to regular visits to treating doctors), etc.
2. Whenever you have questions about upcoming hearings in your cases, or about motions that have been filed, or about things you have been told in status conferences, don't hesitate to ask people who have been in the program. Petitioners' attorneys need to share information; Respondent's attorneys certainly do.

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**ENDNOTES**

1. Wise, et al, "Hair Loss After Routine Immunizations," JAMA, Vol. 278, No. 14 (October 8, 1997).
2. No. 98-426V, 2002 WL 1692537.
3. No. 00-170V, 2003 WL – June 3, 2003 (to be published). ■