THE OMNIBUS AUTISM PROCEEDING:

"There is No Vaccine-Autism Link. Case Closed."

RIGHT? WRONG.

By Mary Holland, Esq. and Robert Krakow, Esq.

On February 12, 2009, Special Masters of the Federal Court of Claims released long-awaited decisions in the first Omnibus Autism Proceeding (OAP) test cases. Over 5,000 petitioners, children with autism and their families, sued the federal government for damages, alleging that vaccines caused their autism. Although families had filed suits all over the country, a 2002 decision effectively forced almost all vaccine-autism cases into this "vaccine court" – the Vaccine Injury Compensation Program (VICP) – that Congress created in 1986. This proceeding was the most robust hearing on whether vaccines can cause autism in a U.S. courthouse to date.

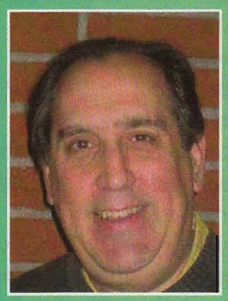
The Special Masters ruled that: 1) there is no plausible link between the mumps-measles-rubella (MMR) vaccine, acting with thimerosal (the mercury-containing vaccine preservative), and autism; and 2) the three "test case" petitioners for this MMR-thimerosal autism causation theory – Michelle Cedillo, Colten Snyder, and Yates Hazelhurst – deserve no compensation for vaccine injuries. The Special Masters did not stop at simply concluding that the science does not favor petitioners. Instead, they rejected and demeaned petitioners' scientific theories and the doctors who treated them and testified on their behalf.

Special Master Hastings proclaimed that the Cedillo case was "one-sided," that the doctors who advised Michelle Cedillo were ***"very wrong,"*** and that the physicians who found a link between Michelle's severe maladies and her vaccines "misled" the Cedillos and "are guilty. . .of gross medical misjudgment." Special Master Vowell, in the Snyder case, similarly characterized the petitioners as "victims of bad science" and suggested that "an objective observer would have to emulate Lewis Carroll's White Queen and be able to believe six impossible (or, at least, highly improbable) things before breakfast" to decide in petitioners' favor.

In short, the Special Masters decided that: 1) there is no reliable science supporting an MMR-thimerosal-autism link; 2) the petitioners' physicians are "guilty of gross medical misjudgment"; and 3) the parents who pursue vaccine injury treatments are "victims." Based on these decisions, it appears almost impossible that these same Special Masters will decide in petitioners' favor in the second set of OAP test cases, to be decided soon, on the theory that thimerosal alone causes autism. The Special Masters should soon release their decisions on these additional test cases that they heard in 2008 on the mercury-autism causation theory.

So, how should we understand these negative, even hostile, decisions? Should the autism community abandon vaccine-autism theories as the Special Masters suggest? Or, alternatively, should it reject the National Vaccine Injury Compensation Program, of which the OAP is part? We outline below the vaccine court background, how this forum prejudiced petitioners, and how the next round of vaccine-autism legal battles are shaping up outside this flawed court.

Mary Holland, JD is director of the Graduate Legal Skills Program at New York University School of Law. Educated at Harvard and Columbia Universities, Mary Holland has worked in international public and private law. Prior to joining NYU, Mary worked for six years at major U.S. law firms, with three years based in Moscow, Russia. She also worked at a major U.S. human rights advocacy organization, Human Rights First (then Lawyers Committee for Human Rights), as director of its European Program. After graduating law school, she clerked for a federal district court judge. She has taught international law courses at Columbia Law School and has served as a consultant to the Aspen Institute Justice and Society Program. Additionally, Mary researches and writes on legal issues related to autism and vaccines.



Robert Krakow, JD started his legal career with the New York Public Interest Research Group, a consumer advocacy organization. For nine years in the 1980s Bob was a prosecutor with the New York County (Manhattan) District Attorney's office, serving as Bureau Chief of the special narcotics prosecution division. Bob represents families of children with autism in a variety of venues, including insurance coverage disputes, vaccine exemption issues, IDEA education disputes with school districts, and claims by educational and medical neglect. Since 2002 Bob has served a the Board Chair of Lifespire, Inc., a 59-year-old not-for-profit organization that provides residential, day habilitation, occupational, educational and medical programs and supports for more than 6000 developmentally disabled adults and children. Bob was co-founder of Autism United, a founding board member of the National Autism Association and former board member of SafeMinds. In 2005, Bob co-founded Advocates for Children's Health Affected by Mercury Poisoning, now known as the Autism Action Network. Most recently, Bob co-founded of the Elizabeth Birt Center for Autism Law and Advocacy.

Vaccine Court Background

Congress created a vaccine compensation system under the National Childhood Vaccine Injury Compensation Act of 1986 (NVICA) to achieve two ends: 1) to provide a fair, expedited, non-adversarial, low-cost, no-fault forum for vaccine-injured petitioners; and 2) to insulate vaccine manufacturers from liability for unavoidable vaccine injuries. The idea was that a "vaccine court" would be a useful compromise between the public's interest in ensuring a steady vaccine supply and victims' interests in getting fair compensation. When the law passed, Congress intended that federal compensation would presume that a vaccine or combination of vaccines caused a child's injury if no other demonstrated cause existed. Congress recognized that some children who were not, in fact, vaccine injured might be compensated.

The reality of vaccine court has not lived up to the intent of Congress. More than two-thirds of all petitioners lose. It took almost ten years for the court to hear OAP claims – and even then they were not heard individually but in the aggregate. While there is some precedent to consolidate claims, there is no precedent for the OAP as a kind of class action case using test cases on different causation theories before three Special Masters. And these test cases were anything but non-adversarial. On the contrary, the government vociferously argued that decisions for petitioners would undermine the national vaccine program and defeat the public interest. By all appearances, the Special Masters embraced that view.

Ten Problems with the OAP

The Special Masters spent over a month in hearings and reviewed copious materials to reach their decisions. There is every reason to think that they did so conscientiously and in good faith. But was this forum fair to Michelle, Colten, Yates, their families, and the other petitioners whose cases hinge on theirs? Here are some of the many problems with "vaccine court" that the OAP showcased.

1. Special Masters' Inadequate Independence. Special Masters, who have wide discretion and whose decisions merit deference in higher courts, serve for four-year terms. Unlike judges in ordinary federal courts, who serve with life tenure and whose salaries may not be reduced, these court officers do not remotely enjoy that kind of professional and financial independence. It is hard to imagine that these Special Masters enjoy the requisite independence to make decisions in cases like the OAP that have the potential to affect federal vaccine policy.

2. Lack of Equality between the Government's and Petitioners' Lawyers and Witnesses. The lawyers for the Department of Justice, representing the Department of Health and Human Services (HHS), were privileged in these proceedings. This privilege was starkest in financial terms. The government lawyers work on salary and have almost unlimited budgets for expert witnesses and trial preparation. By contrast, the court pays petitioner lawyers' fees – but generally only **after** proceedings are over. So, petitioners' lawyers must fund all trial preparation for many years on their own and pay expert witnesses after the court reaches its decision, which is often years later. In the OAP, petitioners' lawyers and witnesses were not paid for their services for years whereas the government lawyers and witnesses were. The financial playing field has a steep tilt in the government's favor.

3. Lack of Adequate Access to Existing Science. Petitioners' lawyers had inadequate access to government scientific information to show that the MMR-thimerosal theory is plausible. During the pendency of this proceeding, HHS failed to make the Vaccine Safety Datalink (VSD) available to petitioners or to fund federally recommended studies on potential autism-vaccine links. The Department of Justice, by contrast, presumably had access to government-sponsored science, including the VSD. The VSD, created with taxpayer funds in 1990, draws together many large-scale health databases to monitor and track adverse events to vaccines. Availability of existing science was unequal.

4. Absence of Essential Science. The deplorable lack of science on vaccine safety was the most troubling realization of the OAP. Despite the fact that the U.S. currently recommends 36 doses of 14 vaccines before children turn five, there are no serious studies comparing health outcomes between unvaccinated and vaccinated individuals. The Centers for Disease Control say it should be done, but it has not.

Similarly, there is no government authorized level for exposure to ethylmercury. While there are guidelines and studies on methylmercury exposure, there is nothing comparable for ethylmercury. Yet thimerosal, which contains ethylmercury, has been used in childhood vaccines since the 1940's. As Dr. Bernadine Healey, former director of the NIH, recently stated on the *Larry King Live* show about the vaccine-autism link, the lack of research is "inexcusable. . .I really don't believe that this is a closed case from a research point of view."

5. Lack of Transparency and Perception of Arbitrariness. While the OAP was in process, government lawyers settled the claim of one potential test case petitioner, Hannah Poling. HHS elected to compensate this case because it agreed that vaccines triggered her underlying mitochondrial condition, causing autism. HHS did not publicize this settlement; on the contrary, it required the signers to enter a nondisclosure agreement to keep the settlement quiet. The public learned of the Hannah Poling concession only because a journalist leaked it to the press, and the Polings then elected to talk about something that was already in the public domain. The Poling concession and cases like the Bailey Banks case for vaccine-induced acute disseminated encephalomyelitis (ADEM) (Bailey has an autism spectrum disorder diagnosis but received compensation for ADEM) show that the government acknowledges a vaccine-autism link by different names. Semantics and secrecy erode public confidence.

6. Lack of Adequate Discovery. One of the most important aspects of civil litigation is discovery, which is the ability of the parties to acquire documents and testimony from the other side before trial. Although the Special Masters may permit discovery, they allowed little in this case. Petitioners' lawyers were unable to examine internal vaccine manufacturer documents or to take testimony from drug company employees. That evidence might be critical.

7. Lack of Adequate Procedural Safeguards. Vaccine court has relaxed rules of evidence and civil procedure. Congress intended this informality to help petitioners. But in these test cases, the lack of clear rules allowed the government to introduce

prejudicial evidence about petitioners' experts and theories that civil courts most likely would have excluded. For example, the government introduced information about a key petitioner expert's departure from a job over twenty years ago. It also made information about certain individuals, particularly Dr. Andrew Wakefield (who was not testifying before the court), central to their efforts to discredit petitioners' theories. In civil court under clear procedural rules, this information would likely have been deemed irrelevant and inadmissible.

8. The Government's Lack of Burden to Prove Alternative Causation. The Special Masters ruled that the petitioners did not meet their burden to show: 1) a plausible medical theory connecting the vaccination and the injury; 2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and 3) a close relationship in time between the vaccination and injury. Because they found that petitioners did not reach this threshold, they did not require the government to explain their theory about what happened to these children. Presumably the government would have said that petitioners' injuries were genetic and that these children would have had the same developmental regression and associated medical problems even if they had not had vaccines. But the Special Masters never required the government to present an alternative theory. This proceeding did not honor Congress' intent to afford children a presumption of injury unless the government can demonstrate a more compelling alternative.

9. Lack of a Jury of Peers. Vaccine Court contemplates no juries, prejudicing petitioners' interests. While the legality of vaccine court has withstood previous constitutional challenges, petitioners do not enjoy the right to trial by a jury of other citizens. Congress considered this issue in arriving at the 1986 statute and believed it struck an appropriate compromise between the vaccine industry and those who assert injury. Most individuals claiming injury, however, dispute the fairness of the compromise that has evolved over time.

10. Inappropriately Short Statute of Limitations. Petitioners have only three years from the time of injury to file a claim. Because the theory of vaccine-induced autism is in dispute and new, and symptoms do not necessarily appear immediately, thousands of affected families are not now eligible to file claims, even if they want to.

This forum has not been friendly to those who claim vaccine injuries. So what other options are available? What other courts might be available to hear these claims?

Beyond Vaccine Court

In November 2008, the Georgia Supreme Court unanimously held in *American Home Products v. Ferrari* that the National Vaccine Injury Compensation Act (NVICA) does not preclude cases in state civil court for vaccine design defects. They ruled that the law Congress passed in 1986 protects vaccine manufacturers from liability for *unavoidable* vaccine injuries, but not for *avoidable* ones. Indeed, the Georgia Court argues that if there were no recourse to civil court and vaccine court were the only available forum, vaccine manufacturers would have "blanket tort immunity for design defects" and no incentives to make their products safer.

The Georgia Supreme Court decided *Ferrari* after a string of other federal and state courts ruled the other way – that the NVICA does bar all design defect claims against vaccine manufacturers. The Third Circuit Court of Appeals sharpened this split of views in its March 2009 decision in *Bruesewitz v. Wyeth*. In the first case interpreting NVICA after *Ferrari*, the Third Circuit said it did not find "the *Ferrari* court's reading to be compelling." Wyeth has already submitted a petition to the U.S. Supreme Court in *Ferrari*; it may seek to have the Supreme Court review *Bruesewitz*, as well.

Another important background factor is the Supreme Court's recent decision in *Wyeth v. Levine*. Although not about autism, that case decided the question whether a state may require a drug manufacturer to include a stronger warning than the Food and Drug Administration (FDA) does. The Supreme Court, 6 to 3, decided that the FDA's approval of Wyeth's drug warning did not preempt Vermont from requiring a more stringent one. The Supreme Court upheld the basic idea that federal and state laws on drugs are complementary, not mutually exclusive, and that "manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." The Third Circuit wrote that vaccines are different than other drugs. Levine is likely to appeal this ruling to the entire Third Circuit, arguing that the initial panel got it wrong.

The scene is now set for further legal battles about the meaning of NVICA and whether Congress intended for petitioners to be able to bring lawsuits outside of vaccine court for design defects. It seems quite possible that the Supreme Court may weigh in on this issue within the next year or so.

Conclusion

Michelle Cedillo, Colten Snyder, Yates Hazlehurst, and thousands of other children who assert that vaccines caused their autism and other injuries have not yet found justice. While the OAP, to its credit, offered the fullest hearing so far for the claims of vaccine-induced autism, it does not end the debate. On the contrary, it highlighted the inadequacy of the research on vaccine safety and the inadequacy of vaccine court to adjudicate claims that have far-reaching consequences for the national vaccine program. The OAP underscored the fundamental, structural problems with vaccine court for gaining information about vaccine injury, let alone for compensating it. Vaccine court presents serious inadequacies in the areas of judicial independence, financial parity, access to information, transparency, and procedural fairness.

To do justice in vaccine injury cases, the country needs impartial, comprehensive vaccine science and a fair forum. Until these scientific and legal preconditions are met, the government leaves at grave risk the very national vaccine program it seeks to protect.

To do justice in vaccine injury cases, the country needs impartial, comprehensive vaccine science and a fair forum. Until these scientific and legal preconditions are met, the government leaves at grave risk the very national vaccine program it seeks to protect.