

A Neverending Story

Even as researchers report once again that there is no link between a vaccine preservative and the way kids develop, parents of children with autism continue to press their cases against drugmakers. A coming wave of lawsuits?

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Despite mounting scientific evidence to the contrary, thousands of families still ardently believe that vaccines containing the mercury-based preservative thimerosal are the cause of their children's autism. A study published Wednesday in *The New England Journal of Medicine* concluding that there is no correlation between thimerosal and neuropsychological development in young children is unlikely to dissuade them. And two articles accompanying the new study, including one that sounds the alarm about a coming onslaught of civil lawsuits against vaccinemakers by autism families, will hardly defuse the emotionally charged issue. Together, the three journal pieces highlight the the tangle of scientific, medical and legal strands underlying one of our most enduring and complicated public-health controversies.

The new study examined the relationship between thimerosal exposure from vaccines given in the first seven months of life, and neuropsychological development between the ages of 7 and 10. A total of 1,047 children provided a range of thimerosal exposures—from 0 to nearly 200 micrograms, or the most any child would get if they took all of the thimerosal-containing vaccines at the prescribed time. Researchers found no significant effect on speech, verbal memory, fine motor coordination, attention, behavior or general intelligence. "We consider this a reassuring study," says lead author William Thompson, a scientist with the Centers for Disease Control and Prevention (CDC). "Most of the 42 outcomes we measured were not associated with thimerosal exposure and the links we did find were on the order of what you would expect by chance." (Over the last 10 years, thimerosal has been removed from all childhood vaccines, except for some influenza vaccines.)

Thompson's study is the third since 2004 to examine the link between thimerosal and neuropsychological development. Five additional studies have focused on a possible link between thimerosal and autism, and another 10 studies have tested the relationship between autism and the MMR (Measles, Mumps and Rubella) vaccine. The MMR vaccine does not contain thimerosal, but some families believe it plays a role in autism. All of these studies have reached similar conclusions, but none of them have been enough to stem the tide of litigation.

Families claiming illness or injury due to a vaccine are required to file their claims with the federal Vaccine Immunization Compensation Program (VICP), otherwise known as vaccine court, which was created in 1988. VICP cases are decided by one of three federally appointed special masters—attorneys who essentially act as judges. Compensation is awarded from a "vaccine trust fund," established with vaccine taxes derived from a patient fee of 75 cents per inoculation. The fund currently holds more than \$2 billion. Since 2001, nearly 5,000 families have filed complaints with the VICP alleging that a vaccine caused their child's autism, but to date, the VICP has never ruled in favor of a family claiming an autism-vaccine link. Still, the load of autism cases has turned standard VICP procedures on their head. According to court documents obtained by NEWSWEEK, for example, autism plaintiffs are no longer required to file medical records with their claims, because the VICP clerk's office does not have the space to accommodate such massive amounts of paper records.

Approximately 300 of the autism cases have been rejected outright. Nearly 1,000 families have opted out of the VICP system—which is permitted if the case is unresolved after 240 days, or if the VICP rules against a claim—and taken their cases to civil court, where they are suing the vaccine manufacturers directly. None of those cases have been decided yet. "The autism-thimerosal suits are different than anything that's ever happened," says Paul Offit, chief of infectious disease at Children's Hospital in Philadelphia, whose essay on the decision to remove thimerosal from vaccines despite a lack of scientific evidence showing the potential for harm was published Wednesday in the NEJM. While the scientific evidence is unequivocal, he says, the sheer number of cases alleging a link between thimerosal and autism, combined with the organization and political support that plaintiffs have garnered, is forcing scientists and legal experts to take notice. "The decisions pending now could have an enormous impact on the future of vaccine litigation."

Since its inception, the VICP has reviewed approximately 7,000 non-autism-related claims, including nearly 4,000 cases alleging injury or death from the DTP (Diphtheria-Pertussis-Tetanus) vaccine. (The court was originally created to handle DTP cases.) Nearly a third of those non-autism cases have won average settlements of \$850,000. But to win in vaccine court, the scientific evidence has to be on your side. The merit of a given case is largely determined by a simple table—established by a scientific advisory panel—that lists which medical conditions can be attributed to which vaccines. That table currently lists more than a dozen vaccines with medically recognized potential side effects, including paralytic polio from the live-virus polio vaccine and encephalitis from the MMR vaccine. Autism is not listed as a potential adverse outcome for any of the vaccines on the table.

Many legal experts worry that despite a higher standard of proof in civil court, autism cases may fare better there. "Jurors eyes gloss over when you start talking epidemiology," says Stephen Sugarman, a law professor at the University of California, Berkeley, who wrote about vaccine litigation for the NEJM: "Experience tells us that jurors don't trust or necessarily understand science and they are likely to make a decision completely independent of it."

Although most researchers suspect a combination of genetic and environmental factors, no one can say for certain what causes autism spectrum disorders. But the impaired social and communication skills associated with this condition tend to manifest themselves between 1 and 3 years of age—the same time during which most childhood vaccines are administered. For many parents whose children developed the devastating neurological condition shortly after receiving their shots, the link seems clear—no evidence is more powerful than their personal experience. "There are a lot of people who strongly believe in this connection, and no amount of science is going to dissuade them," says Sugarman. "They are organized. They have congressmen and celebrities on their side. And they have a group of lawyers who have now made thimerosal litigation their specialty."

The politicization of the thimerosal issue has led researchers to take unprecedented measures. Unlike previous studies, the current study included more than a dozen outside consultants, including at least one advocate for families of children with autism. "We have really tried to make the entire process—from experiment design to manuscript review—as transparent as possible," says Thompson. But that effort may not have made a difference in the long run. Sally Bernard, executive director of Safe Minds, a nonprofit parents' organization that focuses on the role of mercury in neurodevelopment disorders, consulted on the study but still takes issue with its findings. "All the studies, including this one have certain limitations in their design and their methodology," she says.

In a new study, Thompson and his colleagues are taking another look at thimerosal exposure and autism. But for many, the question has been resolved. "This study is the third one of its kind. When the autism one comes out, it will be the sixth of its kind. They've all shown the same thing—that there is no significant correlation," says Offit. "Meanwhile, the thimerosal question has diverted attention and resources away from the search for more promising leads on what causes autism. How many more studies will it take?"

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