



# COUGHLIN DUFFY LLP

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## Vaccines Appear Vindicated in the Debate over the Causes of Autism: U.S. Federal Claims Court Finds No Link Between Thimerosal-Containing Vaccines In Combination With The MMR Vaccine And Autism In Children

Recently, the United States Court of Federal Claims, Office of Special Masters, vindicated certain vaccines in the debate over the causes of autism. The special masters assigned to hear the test cases filed before the National Vaccine Injury Compensation Program (the "Program"), ruled that there is no link between thimerosal-containing vaccines, when combined with the measles-mumps-rubella vaccine (MMR), and autism.

The court issued three rulings on test cases of the more than 5,000 claims filed through the government's Program. Petitioners blame the MMR vaccine and a mercury-containing preservative called thimerosal for causing autism or autism-like symptoms in their children. Due to the case volume and complexity of the so-called Omnibus Autism Proceeding, the court previously ordered separate trials based on three distinct theories of liability under the Program: (1) a combination of thimerosal containing vaccines and MMR can cause autism; (2) thimerosal-containing vaccines alone can cause autism; and (3) MMR vaccines alone can cause autism. The recent decisions address the first theory and roundly reject the notion that the MMR vaccines and thimerosal-containing vaccines can combine to cause autism.

The key component to the petitioners' claims was that the children afflicted with autism were developmentally normal prior to the receipt of the combination of thimerosal-containing vaccines and the MMR vaccine during their first one and one-half year of life. They contend that the vaccinations impaired the functioning of each child's immune system, and that the MMR vaccine caused immunosuppression, permitting the measles component of the MMR vaccine to persist in the children's bodies. It was the petitioners' contention that the persistent measles virus caused chronic inflammation in the neurological and gastrointestinal tissues eventually leading to a neurological injury that manifested as autism.

In *Cedillo v. Secretary of Health and Human Services*, a special master held that the evidence presented was "overwhelmingly contrary to the petitioners' contentions" and that the Cedillo family failed to demonstrate that the vaccinations at issue played any role in the child's autism. In *Hazlehurst v. Secretary of Health and Human Services*, the special master held that the combination of the thimerosal-containing vaccines and the MMR vaccine is not a causal factor in the development of autism, and could not have contributed to the development of autism. Finally, in *Snyder v. Secretary of Health and Human Services*, a third

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special master held that the Synder family failed to show by a preponderance of evidence that their child's autism was caused or significantly aggravated by a vaccine, adding that it was "abundantly clear that petitioners' theories of causation were speculative and unpersuasive."

Under the Federal Vaccine Act, the petitioner does not need to establish that the vaccination was the sole cause, or even the predominant cause of the injury or condition. Rather, demonstrating that the vaccination was a "substantial factor" in causing the condition and was a "but for" cause is sufficient for recovery. Notwithstanding, in the *Synder* case, Special Master Denise K. Vowell made clear that "courts, whether they deal with vaccine injuries, medical malpractice claims, toxic torts, or accident reconstruction, must base their decisions on reliable evidence."

In reviewing cases filed under the Program, a special master may determine the reliability of a medical theory by considering the framework established by the federal court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Despite the relaxed burden of proof to sustain a claim under the Federal Vaccine Act, the special masters found that the petitioners' theory is not generally accepted as required under the *Daubert* standard. In fact, in the *Synder* case, Special Master Denise K. Vowell found that there "is virtually no evidence that the wild-type measles virus can cause ASD ['autism spectrum disorder'], either directly, through some action of the pathogen on the brain, or indirectly, by creation of a disease, or symptoms such as inflammation, that triggers the onset of ASD." The *Synder* court made clear that petitioners are required to demonstrate "more than merely a medical theory;" they must "offer a biologically plausible medical theory."

The strong tone of all three opinions clearly indicates that the special masters, although sympathetic and cognizant of the special needs of autistic children and their

families, were not persuaded by the scientific and medical evidence advanced by petitioners. In fact, the special masters were harsh in their criticism of the scientific and medical community in advancing theories of a correlation between vaccination and autism. In one of the cases, Special Master George L. Hastings declared that although he did not doubt that the Cedillo parents were sincere in their belief that the MMR vaccine was a cause of their daughter's autism, "unfortunately, the Cedillos have been misled by physicians who are guilty, in my view, of gross medical misjudgment." Similarly, in *Synder* the special master stated that "petitioners in this litigation have been the victims of bad science, conducted to support litigation rather than to advance medical and scientific understanding of ASD."

Undoubtedly, these recent rulings do not end the debate over the link between vaccines and autism. Though litigation continues regarding the causal link of other vaccines to autism, the rulings in *Cedillo*, *Synder* and *Hazlehurst* only affect those who claim the interaction of the MMR vaccine and thimerosal-containing vaccines cause autism. The court has yet to rule on separate claims that thimerosal or MMR alone caused autism symptoms, but the recent rulings signaled skepticism. Moreover, the outcome of the three "test cases" is not formally "binding" on any other case. Indeed, petitioners in subsequent cases may submit additional "general causation" evidence that was not presented in a test case. Therefore, though vaccines appear to have been vindicated for now, the debate linking vaccines and autism in children is likely far from over.

Should you have any questions about this decision, please do not hesitate to contact us.