

Decisions in the Omnibus Autism Proceeding

Enacted in 1986, the no-fault National Vaccine Injury Compensation Program (VICP) was designed to resolve a crisis in vaccine liability claims that threatened the continued availability of childhood vaccines nationwide. Between 1999 and 2007, more than 5,000 parents filed claims under VICP, alleging that vaccines had caused their children's autism. Because these claims were so numerous, the U.S. Court of Federal Claims, which administers VICP, created an Omnibus Autism Proceeding – similar to a class-action lawsuit – to resolve them. Each claim rested on one of three theories of causation: (Theory 1) that measles, mumps, and rubella (MMR) vaccines and thimerosal-containing vaccines can combine to cause autism; (Theory 2) that thimerosal-containing vaccines, by themselves, can cause autism; and (Theory 3) that MMR vaccine, by itself, can cause autism (this third theory was later abandoned).

In 2007, three Special Masters heard three test cases selected by the petitioners (i.e., the children whose autism was allegedly caused by MMR and thimerosal-containing vaccines and the children's parents/guardians) to represent the first theory of causation. Each Special Master was responsible for applying the evidence presented in the hearings to one of the three test cases. The Special Masters weighed exhaustive

evidence: The official record generated 5,000 pages of transcript and 700 pages of post-hearing briefs; 939 medical journal articles, 50 expert reports, and testimony from 28 experts were entered into evidence.

The Special Masters' decisions in the three test cases were issued on February 12, 2009. **In each of these cases, the decisions rejected the petitioners' causation theories.** All three of the Theory 1 test cases were appealed to regular judges of the Court of Federal Claims, and two were further appealed to the U.S. Court of Appeals for the Federal Circuit. In all of these appeals, the Special Masters' decisions were upheld. No further appeals are possible for the Theory 1 cases.

In 2008, the Court held hearings on the test cases for Theory 2, the claim that thimerosal-containing vaccines could act on their own to produce autism. **On March 12, 2010, after extensive proceedings, the Special Masters' decisions in each of the Theory 2 test cases rejected the petitioners' causation theories.** None of the petitioners in the Theory 2 test cases chose to appeal the Special Masters' judgments.

Here are a few key passages from the rulings. To read the complete decisions, go to www.uscfc.uscourts.gov/autism-decisions-and-background-information.

Theory 1 test cases

From Denise K. Vowell, Special Master, in the case of Colten Snyder, No. 01-162V:

"After careful consideration of all of the evidence, it was abundantly clear that petitioners' theories of causation were speculative and unpersuasive. Respondent's experts were far more qualified, better supported by the weight of scientific research and authority, and simply more persuasive on nearly every point in contention."

► See page 2: www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Vowell.Snyder.pdf

"Petitioners have not demonstrated by a preponderance of the evidence that Colten's condition was either caused or significantly aggravated by his vaccinations."

► See page 278: www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Vowell.Snyder.pdf

From George L. Hastings, Jr., Special Master, in the case of Michelle Cedillo, No. 98-916V:

"The petitioners in this case have advanced a causation theory that has several parts, including contentions (1) that thimerosal-containing vaccines can cause immune dysfunction, (2) that the MMR vaccine can cause autism, and (3) that the MMR vaccine can cause chronic gastrointestinal dysfunction. However,

as to each of those issues, I concluded that the evidence was overwhelmingly contrary to the petitioners' contentions.... Considering all of the evidence, I found that the petitioners have failed to demonstrate that thimerosal-containing vaccines can contribute to causing immune dysfunction, or that the MMR vaccine can contribute to causing either autism or gastrointestinal dysfunction. I further conclude that while Michelle Cedillo has tragically suffered from autism and other severe conditions, the petitioners have also failed to demonstrate that her vaccinations played any role at all in causing those problems."

► See page 2: www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Hastings-Cedillo.pdf

From Patricia E. Campbell-Smith, Special Master, in the case of William Yates Hazlehurst, No. 03-654V:

"[P]etitioners' experts tended to assign greater weight to speculative conclusions offered by the investigators involved in the studies than did the investigators themselves. Petitioners' experts also urged reliance on a few carefully selected sentences from particular articles which, when considered in the proper context of the referenced articles, did not support the propositions advanced by the witnesses. Moreover, because petitioners' experts relied on a number of scientifically flawed or unreliable articles for several important aspects of their causation theory, their testimony on those aspects of their offered theory could not be credited as sound or reliable. Finally, petitioners' experts

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made several key acknowledgments during testimony that rendered their proposed theory of vaccine causation much less than likely.”

► See page 19: www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Campbell-Smith_Hazlehurst_Decision.pdf

“The weight of the presented evidence that is scientifically reliable and methodologically sound does not support petitioners’ claim.”

► See page 200: www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Campbell-Smith_Hazlehurst_Decision.pdf

Theory 2 test cases

From Patricia Campbell-Smith, Special Master, in the case of William P. Mead, No. 03-215V:

“The underpinnings for the opinions of petitioners’ experts are scientifically flawed, and in the absence of a sound basis for the offered opinions of causation, those opinions cannot be credited.... Based on the developed record in this proceeding, the undersigned is unpersuaded that the thimerosal content of the prescribed childhood vaccines contributes to the development of autism as petitioners have proposed under this theory of general causation.”

► See page 165: www.uscfc.uscourts.gov/sites/default/files/opinions/Campbell-Smith%20Mead%20Autism%20Decision.pdf

From Denise K. Vowell, Special Master, in the case of Colin R. Dwyer, No. 03-1202V:

“In essence, petitioners propose effects from mercury in TCVs [thimerosal-containing vaccines] that do not resemble mercury’s known effects on the brain, either behaviorally or at the cellular level. To prevail, they must show that the exquisitely small amounts of mercury in TCVs that reach the brain can produce devastating effects that far larger amounts experienced prenatally or postnatally from other sources do not. In order to account for this dichotomy, they posit a group of children hypersensitive to mercury’s effects, but the only evidence that these children are unusually sensitive is the fact of their ASD [autism spectrum disorder] itself. In an effort to render irrelevant the numerous epidemiological studies of ASD and TCVs that show no connection between the two, they contend that their children have a form of ASD involving regression that differs from all other forms biologically and behaviorally. World-class experts in the field testified that the distinctions they drew between forms of ASD were artificial, and that they had never heard of the ‘clearly regressive’ form of autism about which the petitioners’ epidemiologist testified. Finally, the causal mechanism petitioners proposed would produce, not ASD, but neuronal death, and eventually patient death

as well. The witnesses setting forth this improbable sequence of cause and effect were outclassed in every respect by the impressive assembly of true experts in their respective fields who testified on behalf of respondent. Therefore, I hold that petitioners have failed to establish their entitlement to compensation, and their petition is denied.”

► See page 3: www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Vowell.Dwyer.FINAL.pdf

From George L. Hastings, Jr., Special Master, in the case of Jordan King, No. 03-584V:

“...I conclude that the evidence is overwhelmingly contrary to the petitioners’ contentions. The expert witnesses presented by the respondent were far better qualified, far more experienced, and far more persuasive than the petitioners’ experts, concerning the key points. The numerous medical studies concerning the issue of whether thimerosal causes autism, performed by medical scientists worldwide, have come down strongly against the petitioners’ contentions. Considering all of the evidence, I find that the petitioners have *failed* to demonstrate that thimerosal-containing vaccines can contribute to the causation of autism. I further conclude that while Jordan King has tragically suffered from autism, the petitioners have also failed to demonstrate that his vaccinations played any role at all in causing that condition.”

► See page 2: www.uscfc.uscourts.gov/sites/default/files/opinions/Hastings.King%20Decision.pdf

Conclusion

It is important to realize that the six test cases were those that, in the petitioners’ judgment, presented the clearest and strongest arguments for the proposition that vaccines had caused autism. It is therefore unlikely that any of the thousands of other Omnibus cases contain facts or circumstances that would lead to decisions different from those already rendered by the Special Masters and reviewing judges.

Many of the remaining Omnibus petitioners are expected to voluntarily exit the Omnibus Autism Proceeding program. Having completed the VICP process, they may now elect to file civil suits outside the program. Such suits, however, would be subject to more stringent burdens of proof, and the expenses of pursuing them would be borne by the plaintiffs, not by the VICP. To date, no such filings have been reported. Any petitioners who choose not to exit the program will have to develop novel theories of causation, for which they will be required to produce expert testimony and evidence. The Court has not released any information about potential alternative theories having been offered.