



**U.S. Department of Justice**

**Office of Professional Responsibility**

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Washington, D.C. 20530

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**VIA E-MAIL & FIRST CLASS MAIL**

Robert F. Kennedy, Jr., Esq.  
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Children's Health Defense  
1227 North Peachtree Parkway  
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Peachtree City, GA 30269  
Attn: Lyn Redwood, President

Dear Messrs. Kennedy and Hazlehurst:

Children's Health Defense has made serious allegations of misconduct against Department of Justice attorneys who handled the Omnibus Autism Proceedings. The alleged misconduct reportedly had dire effects on the health of thousands of children who developed autism, and on the lives of the families who care for them. Although the allegations concern events and conduct that occurred more than ten years ago, the Office of Professional Responsibility (OPR) regarded those allegations as so serious and important that it initiated an inquiry to determine whether the Department attorneys performed their duties ethically and fairly. After a painstaking review, OPR has determined that the allegations are unfounded, and that no misconduct occurred. Specifically, Department attorneys did not suppress Dr. Andrew Zimmerman's opinion that in certain medical circumstances, the mercury-based measles, mumps, and rubella (MMR) vaccine can cause autism spectrum disorders, nor did the Department attorneys improperly use Dr. Zimmerman's earlier opinion that the MMR vaccine does not cause autism. OPR's finding are explained below.

**I. BACKGROUND**

In a September 20, 2018 letter to the Inspector General of the Department of Justice, which was referred to OPR, Mr. Kennedy and Mr. Hazlehurst alleged on behalf of Children's Health Defense that attorneys from the Constitutional and Specialized Tort Litigation Section (CSTL) of the Department's Civil Division committed fraud and obstructed justice during the course of litigation in the Omnibus Autism Proceedings (OAP) before the National Vaccine Injury Compensation Program. Their letter (Children's Health Defense Letter) leveled misconduct allegations against former Department attorneys Vincent J. Matanoski and Lynn E. Ricciardella.

The Children's Health Defense Letter alleged that the government retained Dr. Andrew Zimmerman, a pediatric neurologist, as an expert in *Cedillo v. Secretary of Health & Human*

*Services*,<sup>1</sup> the first of what was expected to be nine representative cases, drawn from among 5,400 children who claimed that mercury-based MMR vaccines caused the onset of their autism. Dr. Zimmerman rendered an expert opinion in *Cedillo* that the vaccine could not have caused Michelle Cedillo's autism. However, during a break in the *Cedillo* trial, Dr. Zimmerman allegedly advised Mr. Matanoski that his *Cedillo* opinion was case-specific and not intended to be a blanket opinion regarding other children.

In a subsequent case, *Poling v. Secretary of Health & Human Services*,<sup>2</sup> Dr. Zimmerman, who was Hannah Poling's treating physician, provided a written opinion stating that Hannah had an underlying condition of mitochondrial dysfunction<sup>3</sup> when the MMR vaccine was administered to her, and her autism was caused by the vaccine. The Children's Health Defense Letter alleged that the government settled the *Poling* case for lifetime payments that may amount to \$20 million, but at the government's behest, the case was sealed, preventing Dr. Zimmerman's opinion from being disseminated publicly, and preventing the *Poling* case from being used by other children whose autism was allegedly caused by the MMR vaccine.

Instead, the Children's Health Defense Letter alleged that under the unique rules of the vaccine court, Mr. Matanoski and Ms. Ricciardella continued to use Dr. Zimmerman's expert *Cedillo* opinion in other OAP cases, without petitioners' counsel being able to question Dr. Zimmerman, despite Dr. Zimmerman's direction that his opinion was case-specific and was not intended to be a blanket opinion regarding other children, and despite knowing that Dr. Zimmerman opined in *Poling* that the MMR vaccine caused Hannah Poling's autism. Mr. Matanoski, Ms. Ricciardella, and other unidentified Department attorneys allegedly maintained this position for years, and their allegedly deceptive and fraudulent misconduct caused thousands of children to be denied compensation under the vaccine program, and also affected the Supreme Court's decision in *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011) (holding that the National Childhood Vaccine Injury Act of 1986 preempted all design defect claims against vaccine manufacturers). Given the seriousness of the allegations, OPR initiated an inquiry into this matter, despite the fact that most of the underlying events occurred more than a decade ago, and despite the fact that neither Mr. Matanoski nor Ms. Ricciardella is currently a Department attorney.

OPR requested and received written detailed responses to the allegations of misconduct from Mr. Matanoski, from Ms. Ricciardella, and from the CSTL Section of the Civil Division. In addition, OPR interviewed Mr. Kennedy, Mr. Hazlehurst (whose son Yates was a representative

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<sup>1</sup> No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010).

<sup>2</sup> No. 02-1466V (Spec. Mstr. Fed. Cl.).

<sup>3</sup> "Mitochondrial diseases result from failures of the mitochondria, specialized compartments present in every cell of the body (except red blood cells). Mitochondria are responsible for creating more than 90% of the energy needed by the body to sustain life and support organ function. When they fail, less and less energy is generated within the cell. Cell injury and even cell death follow . . . . The parts of the body, such as the heart, brain, muscles and lungs, requiring the greatest amounts of energy are the most affected. Mitochondrial disease is difficult to diagnose, because it affects each individual differently. Symptoms can include seizures, strokes, severe developmental delays, inability to walk, talk, see, and digest food combined with a host of other complications." <https://www.umdf.org/what-is-mitochondrial-disease/>.

plaintiff),<sup>4</sup> Dr. Zimmerman, and Clifford Shoemaker and Renée Gentry, the attorneys who represented Hannah Poling in the OAP.<sup>5</sup> OPR also reviewed hundreds of pages of documents and on-line materials, including court and deposition transcripts, court filings and decisions, press releases, newspaper articles, and video presentations. Based on its analysis of these materials, OPR concluded that the Department attorneys did not suppress Dr. Zimmerman's opinion in *Poling*, and that they did not wrongfully use Dr. Zimmerman's *Cedillo* opinion in other vaccine court cases, and OPR has closed its inquiry.

## **II. FACTS**

### **A. The Vaccine Court and the Test Cases**

In the 1980s, Congress was faced with a reduction in the number of manufacturers willing to sell vaccines for childhood diseases, as a result of the cost of vaccine-related litigation. In response, Congress enacted the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 to 34 (Vaccine Act), which created the Office of Special Masters of the U.S. Court of Federal Claims (Vaccine Court), to facilitate compensation through a National Vaccine Injury Compensation Program for those claiming vaccine-related injuries, together with a no-fault compensation program. Petitioners who claim to have been injured by vaccines can receive compensation, without proof of a product defect or inadequate product labeling, as would be required in a common law tort action. Claims in the Vaccine Court are brought against the Secretary of the Department of Health and Human Services, not against vaccine manufacturers, and awards are paid from a fund created by an excise tax on vaccines.

Between 2002 and 2010, approximately 5,400 petitions were filed in Vaccine Court for compensation based on allegations of vaccine-induced autism from MMR alone or in combination with thimerosal-containing vaccines.<sup>6</sup> In late 2006, the Petitioners' Steering Committee for the OAP – a group of attorneys representing petitioners with autism claims – proposed a “test case” approach, allowing general causation evidence to be presented in the OAP. The first theory of causation to be litigated was whether thimerosal in the vaccines, working in combination with the MMR vaccine, causes or contributes to autism spectrum disorders. The Petitioners' Steering

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<sup>4</sup> Allegedly, it was not until 2018, as a result of treating Yates Hazlehurst, and serving as an expert witness in a Tennessee state court malpractice lawsuit against the health clinic and the doctor who had administered the MMR vaccine to Yates, that Dr. Zimmerman first learned that his *Cedillo* opinion had been used by the government in other OAP cases.

<sup>5</sup> OPR digitally recorded the interviews of Dr. Zimmerman and of Clifford Shoemaker and Renée Gentry. At his interview, Dr. Zimmerman was represented by counsel, who also recorded the interview.

<sup>6</sup> Thimerosal is a mercury-based preservative that was used for decades in the United States in multi-dose vials (vials containing more than one dose) of medicines and vaccines. According to the Centers for Disease Control, there is no evidence of serious harm caused by the low doses of thimerosal in vaccines. However, in July 1999, Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure. <https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html>.

Committee designated *Cedillo*, *Hazlehurst*,<sup>7</sup> and *Snyder*<sup>8</sup> as the three test cases for the first theory of causation.

**B. The Cedillo Case**

The petitioners' theory in *Cedillo* was as follows:

- (1) The thimerosal-containing vaccines that Michelle [Cedillo] received during her first 16 months of life weakened her immune system;
- (2) That weakening of the immune system allowed the measles virus contained in the MMR vaccine to persist within Michelle's body;
- (3) The persisting vaccine-strain measles virus damaged Michelle's digestive system, causing her gastrointestinal difficulties; and
- (4) The persisting vaccine strain measles virus also damaged Michelle's brain, causing her autism, mental retardation, and seizures.<sup>9</sup>

Under the rules of the OAP, all general causation evidence submitted in *Cedillo*, the first test case, was applicable to the other two test cases, *Hazlehurst* and *Snyder*. The *Cedillo* case was tried from June 11, 2007 to June 26, 2007. Six medical experts testified for the petitioners; nine medical experts testified for the government. Dr. Zimmerman, a pediatric neurologist, was designated as one of the government's experts.<sup>10</sup> According to the CSTL section, Dr. Zimmerman was retained largely to counter the testimony of Dr. Marcel Kinsbourne, an expert called by the petitioners, who theorized that an aberrant immune reaction to the MMR vaccine can lead to an increase of pro-inflammatory cytokines (neuroglia) in the brain, resulting in brain dysfunction that manifests as autism. Dr. Kinsbourne's "neuroinflammation" theory was premised on a Johns Hopkins laboratory study co-authored by Dr. Zimmerman, but Dr. Zimmerman did not accept Dr. Kinsbourne's theory.

Mr. Matanoski explained to OPR that as with all the government's retained medical experts, at their initial meeting with Dr. Zimmerman, he and CSTL attorney Voris Johnson, whom Matanoski assigned to work on the neurological aspects of the representative cases, explained "what the OAP was and how [the] evidence they provided would be used. With regard to the general causation theory at issue in *Cedillo*, [Dr. Zimmerman and the other experts] were

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<sup>7</sup> *Hazlehurst v. Secretary of Health & Human Services*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010).

<sup>8</sup> *Snyder v. Secretary of Health & Human Services*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

<sup>9</sup> *Cedillo*, 2009 WL 331968 at \*15.

<sup>10</sup> Dr. Zimmerman is a prominent pediatric neurologist. At the time of the *Cedillo* and *Poling* cases, he was the Director of Medical Research of the Center for Autism and Related Disorders of the Kennedy Krieger Institute in Baltimore, and a professor at the Johns Hopkins University School of Medicine. His major research interest is in the role of the immune system in autism. He is the author or co-author of more than eighty peer-reviewed books, articles, case notes, and studies. He is now a professor of medicine at the University of Massachusetts Memorial Medical Center in Worcester, Massachusetts.

specifically advised that the OAP was designed to test the scientific validity of the proposition that thimerosal caused immune dysfunction[, which] allowed [the] measles virus from [the] MMR vaccine to persist, enter the brain, and cause autism. They were also advised that the evidence they provided would be used in all subsequent OAP cases alleging that same theory of causation.”

Dr. Zimmerman told OPR that initially, he met with Mr. Matanoski and another Department attorney at the Kennedy Krieger Institute in Baltimore for four hours. He stated that although the attorneys told him about the use of test cases in the OAP, he understood he was asked to review Michelle Cedillo’s medical records and provide his expert opinion only in her case. He did not recall whether, at this initial meeting, he mentioned the Poling case note, but said it was “out” and “clearly in the public domain.”

1. Dr. Zimmerman and the Poling Case Note

According to the CSTL, at a meeting with Dr. Zimmerman – either at the initial meeting or during a trial preparation session – Voris Johnson and other CTSL lawyers learned of Dr. Zimmerman’s co-authorship of a 2006 case note in the *Journal of Child Neurology*.<sup>11</sup> The case note describes a female child in whom mitochondrial dysfunction was found, who developed regression and autism following the administering of childhood vaccines. The Department lawyers regarded Dr. Zimmerman’s co-authorship of the case note as irrelevant to the initial test cases, because the mitochondrial mechanism described in the case note was not similar to Dr. Kinsbourne’s “neuroinflammation” theory.

2. Dr. Zimmerman’s Written Opinion in *Cedillo*

Dr. Zimmerman’s opinion in *Cedillo* was several pages long. In its salient paragraph, he stated:

There is no scientific basis for a connection between measles, mumps and rubella (MMR) vaccine or mercury (Hg) intoxication and autism. Despite well-intentioned and thoughtful hypotheses and widespread beliefs about apparent connections with autism and regression, there is no sound evidence to support a causative relationship with exposure to both, or either, MMR and/or Hg. Michelle Cedillo had a thorough and normal immunology evaluation by Dr. Sudhir Gupta, showing no signs of immunodeficiency that would have precluded her from receiving or responding normally to MMR vaccine.<sup>12</sup>

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<sup>11</sup> Jon S. Poling, Richard E. Frye, John Shoffner, and Andrew W. Zimmerman, “Developmental Regression and Mitochondrial Dysfunction in a Child With Autism,” 21 J. Child. Neurol. 170 (Feb. 2006). The authors wrote that their study of Hannah Poling (who was not identified) was “the first description of an autistic child with mitochondrial dysfunction, growth failure, and abnormal muscle histopathology without seizures or a defined chromosomal abnormality. This patient exemplifies important questions about mitochondrial function in autism and developmental regression.” The authors concluded there might be a link between vaccine immunizations and autism in children with mitochondrial disorders.

<sup>12</sup> Letter, Dr. Andrew Zimmerman to Office of Vaccine Litigation, April 24, 2007, at 4.

Significantly, Dr. Zimmerman wrote his opinion in *Cedillo* more than a year *after* he co-wrote the Poling case note, and thus he must have found no conflict between the suggestion in the case note that there might be a link between immunizations and autism in children with mitochondrial disorders and his opinion in *Cedillo* that “[t]here is no scientific basis for a connection between measles, mumps and rubella (MMR) vaccine or mercury (Hg) intoxication and autism.” Dr. Zimmerman’s written opinion was admitted into evidence in *Cedillo*, as were the written opinions of all the other experts.

Mr. Matanoski asserted that Dr. Zimmerman’s report was designed to be a response to the petitioners’ general theory of causation, and Dr. Zimmerman was advised that the evidence he provided would be used in all subsequent OAP cases alleging that theory of causation. Moreover, according to Matanoski, the Department would never have retained Dr. Zimmerman if the evidence he gave could be used only in the *Cedillo* case.

### 3. The Use of Dr. Zimmerman’s Opinion in Other Vaccine Cases

According to Children’s Health Defense:

[B]efore the DOJ lawyers used [Dr. Zimmerman’s written opinion] as evidence, Dr. Zimmerman specifically advised the DOJ attorneys representing HHS that his written opinion was a case specific opinion pertinent to Michelle Cedillo only. Dr. Zimmerman said that he did not intend his opinion to be a blanket statement as to all children and all medical science. Dr. Zimmerman further advised the DOJ that in his opinion vaccinations could, and in at least one of his patients, (Hannah Poling) did cause autism. Most importantly, he explained to DOJ how vaccines may cause autism in a subset of children with underlying mitochondrial disorder.

Dr. Zimmerman’s clarification of his opinion panicked DOJ attorneys. Matanoski and Ricciardella realized that, if Dr. Zimmerman’s true opinion became known to the petitioners, it would open the floodgates to all 5,400 autism cases and collapse the Defendants’ scheme to deny the autism link and keep claimants out of courts . . . . Instead of giving plaintiffs the benefit of the doubt, as the [Vaccine Act] requires, HHS and its attorneys were now actively conspiring and scheming to prevent brain injured children from obtaining their lawful remedies.<sup>13</sup>

This account is, in part, supported by an affidavit Dr. Zimmerman provided to Children’s Health Defense, which was submitted to OPR. In his affidavit, Dr. Zimmerman stated:

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<sup>13</sup> Children’s Health Defense Letter at 5-6.

6. On Friday June 15th 2007, I was present during a portion of the O.A.P. to hear the testimony of the Petitioner's expert in the field of pediatric neurology, Dr. Marcel Kinsbourne. During a break in the proceedings, I spoke with DOJ attorneys and specifically the lead DOJ attorney, Vincent Matanoski in order to clarify my written expert opinion.

7. I clarified that my written expert opinion . . . was a case specific opinion as to Michelle Cedillo [and] . . . not intended to be a blanket statement as to all children and all medical science.

8. I explained that I was of the opinion that there were exceptions in which vaccinations could cause autism.

9. More specifically, I explained that in a subset of children with an underlying mitochondrial dysfunction, vaccine induced fever and immune stimulation that exceeded metabolic energy reserves could, and in at least one of my patients, did cause regressive encephalopathy with features of autism spectrum disorder.

10. I explained that my opinion regarding exceptions in which vaccines could cause autism was based upon advances in science, medicine, and clinical research of one of my patients in particular.

11. For confidentiality reasons, I did not state the name of my patient. However, I specifically referenced and discussed with Mr. Matanoski and the other DOJ attorneys [who] were present, the medical paper, *Developmental Regression and Mitochondrial Dysfunction In a Child With Autism*, which was published in the Journal of Child Neurology and co-authored by Jon Poling, M.D. [Dr. Zimmerman, and others] . . . .

12. Shortly after I clarified my opinions with the DOJ attorneys, I was contacted by one of the junior DOJ attorneys and informed that I would no longer be needed as an expert witness on behalf of H.H.S.<sup>14</sup>

In a January 2019 press statement, Dr. Zimmerman stated:

In 2007, I wrote an affidavit for the US Department of Justice, in which I stated my opinion at that time, based on the 2004 Institute of Medicine (IOM) report, "Immunization Safety Review: Vaccines and Autism," that there was no scientific evidence that

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<sup>14</sup> Affidavit of Dr. Andrew W. Zimmerman, September 7, 2018 (Zimmerman Affidavit), at ¶¶ 6-12.

vaccines cause autism. I was prepared to testify to that effect at the Omnibus Autism Proceeding (OAP).

Three days before I was scheduled to testify, I spoke with DOJ attorneys about my revised opinion, that there *may be a subset of children* who are at risk for regression if they have underlying *mitochondrial dysfunction* and are simultaneously exposed to factors that stress their mitochondrial reserve (which is critical for the developing brain). Such factors might include infections, as well as metabolic and immune factors, and vaccines.

I was subsequently asked by the DOJ not to testify.

In the years since 2007, I was asked to testify in federal vaccine or civil courts on behalf of several children who had similar histories of developmental regression and ASD following immunizations and were later found to have mitochondrial disorders. During one of these cases, I learned that my original affidavit, based on the 2004 IOM report, had been used in court without the modification I refer to above.<sup>15</sup>

During his OPR interview, Dr. Zimmerman gave a fuller, and slightly different, factual account. He told OPR that he had been asked to attend the OAP hearing on June 15, 2007, to hear Dr. Kinsbourne's testimony. He saw the enormous media coverage of the OAP, and realized that more was at stake than Michelle Cedillo's case. He approached Voris Johnson, one of the CSTL attorneys, to say that he believed there was an exception to his opinion in *Cedillo* that vaccinations did not cause autism. His comment led to a lunchtime meeting, attended by Matanoski, Johnson, and other Department attorneys, in which Dr. Zimmerman described the Poling case note, and said that treating Hannah Poling had modified his opinion. He did not recall whether the CSTL lawyers at that meeting indicated that they had read the case note. Dr. Zimmerman told OPR that Matanoski seemed "concerned," and recalled him responding by saying something like, "We'll take that into consideration." At the end of the day, Dr. Zimmerman recalled briefly attending what he called a "wrap-up" conference, but he departed before it concluded. Dr. Zimmerman told OPR that the only issue he raised at the meetings was the exception for underlying mitochondrial disorders, and when asked specifically if he discussed the government's use of his *Cedillo* opinion in future vaccine cases, he responded, "Not at all," and "the subject did not even come up."

Mr. Matanoski did not recall any discussion with Dr. Zimmerman during the *Cedillo* trial. But he pointed out that the Poling case note had been published more than a year earlier, and everyone on the CSTL litigation team already knew that Dr. Zimmerman had written the Poling case note and that he believed there were exceptional cases in which vaccinations could cause autism. In addition, Dr. Zimmerman did not explain in his affidavit why his general statement that

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<sup>15</sup> Statement of Andrew W. Zimmerman, MD, Professor of Pediatrics and Neurology, University of Massachusetts Medical School, Jan. 15, 2018 [*sic*, 2019] (emphases in original).



“[t]here is no scientific basis for a connection between measles, mumps, rubella (MMR) vaccine or mercury (Hg) intoxication and autism” would be true for Michelle Cedillo but not for the other OAP test case petitioners, who also did not present with underlying mitochondrial dysfunction. Indeed, in his affidavit, Dr. Zimmerman never stated that his view of the validity of the petitioners’ general causation theory had changed.

#### 4. The Decision Not To Call Dr. Zimmerman To Testify

Dr. Zimmerman was not called to testify at the *Cedillo* trial.<sup>16</sup> During his OPR interview, Dr. Zimmerman stated that Voris Johnson called him on the evening of June 15, 2007, and said that the government had decided to prune its case, and that he was one of several experts who would not be called to testify. He said that was “fine” with him. Dr. Zimmerman told OPR, “If I were cross-examining me, I would [have asked], ‘Well, doctor, what about the *Poling* case? What about your publication last year? Are there not exceptions?’ and I would have [had] to say, ‘Yes. I don’t know how frequent[ly] they occur,’ and I still don’t know.” He concluded, “I did not want to be cross-examined about the *Poling* case. In a way, I was looking out for [the government].”

Mr. Matanoski recalled that he made the decision not to call Dr. Zimmerman based on concerns that developed during the preparation of Dr. Zimmerman for trial. According to Matanoski, Voris Johnson recommended that Dr. Zimmerman not be called to testify because Johnson was concerned that Dr. Zimmerman’s testimony about the *Poling* case note would be distracting, a “sideshow,” because it was not relevant to the causation theory at issue.<sup>17</sup> Mr. Matanoski decided not to call Dr. Zimmerman to testify, but kept his report in the record, figuring that if the report were withdrawn, it would suggest that Dr. Zimmerman was not called because he had changed his opinion.

As to the decision not to call Dr. Zimmerman to testify, the CSTL section informed OPR that Dr. Zimmerman attended the trial on June 15, 2007, to listen to Dr. Kinsbourne’s testimony. They recall that at a team meeting after court adjourned that day, which Dr. Zimmerman and several other experts attended, the Department attorneys agreed amongst themselves that the petitioners’ case-in-chief had not gone well and that there were gaps in the petitioners’ medical causation evidence. The CSTL attorneys discussed whether it made sense for the government to scale back its rebuttal case. The consensus at the meeting was that the petitioners might try to prove their case through cross-examination of the government’s experts, and it would be a smart litigation strategy to streamline the government’s presentation of evidence. The Department attorneys decided that it was unnecessary for Dr. Zimmerman to testify because his testimony would be redundant, given the expected testimony of other government experts; Johnson later contacted Dr. Zimmerman to advise him of their decision.

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<sup>16</sup> The government filed expert reports from three additional witnesses who did not testify during hearings: Robert Fujinami, Ph.D, an immunologist and microbiologist; Michael Gershon, M.D., a neurogastroenterologist; and Peter Simmonds, Ph.D, a virologist. *Cedillo*, 2009 WL 331968 at n.16.

<sup>17</sup> The government lawyers’ sense of what might have happened was supported by Clifford Shoemaker, the Polings’ lawyer, who told OPR that the petitioners’ attorneys were “all prepared to cross-examine him and see what the heck was going on,” but the petitioners did not know if Dr. Zimmerman’s opinion had changed during the course of the hearing, or what Dr. Zimmerman would testify about vaccines effecting mitochondrial function or causing mitochondrial disorder, since there was no evidence that Hannah Poling had a genetic mitochondrial function problem.

## 5. The Vaccine Court Decision in *Cedillo*

In his February 2009 *Cedillo* opinion, OAP Special Master George L. Hastings, Jr. found that

petitioners have *failed completely* to demonstrate that it is ‘more probable than not’ that the MMR vaccination can be a substantial factor in contributing to the causation of autism, in individuals suffering from regressive autism or any other type of autism. To the contrary, the evidence that I have reviewed makes it appear *extremely unlikely* that the MMR vaccine can contribute to the causation of autism.<sup>18</sup>

The Vaccine Court considered a massive record, which included 7,700 pages of Michelle Cedillo’s medical records, twenty-three expert reports, and sixteen testifying experts. The hearing transcripts total 2,917 pages.<sup>19</sup> A fair reading of the *Cedillo* opinion indicates that Dr. Zimmerman’s written opinion had little influence on the special master’s decision. Dr. Zimmerman is mentioned only twice, and in a footnote, the special master stated:

Another pediatric neurologist with extensive experience with autism, Dr. Andrew Zimmerman, also filed an expert report for respondent. Dr. Zimmerman stated the opinion that the evidence does not support the proposition that the MMR vaccine can cause autism. Thus, Dr. Zimmerman’s report certainly supports the result that I have reached in this case. However, because he did not testify at the evidentiary hearing, his opinion has been far less important than that of the respondent’s experts who did testify, in leading to my conclusion.<sup>20</sup>

### C. The Poling Case

On October 25, 2002, Terry and Jon Poling, the parents of Hannah Poling, filed a short-form autism petition pursuant to the Vaccine Act, electing to opt into the OAP. On September 17, 2007, the Petitioners’ Steering Committee designated the *Poling* case as a potential test case to be heard on the second theory of general causation. The second theory advanced in the OAP was whether thimerosal in the vaccines can cause autism. Clifford Shoemaker, the Polings’ lawyer, told OPR that the Poling case note was filed as an exhibit in the OAP on June 17, 2007.<sup>21</sup> Dr.

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<sup>18</sup> *Cedillo*, 2009 WL 331968, at \*94. The decision of the special master was affirmed in the Court of Federal Claims, 89 Fed. Cl. 158 (2009), and again in the Federal Circuit Court of Appeals, 617 F.3d 1328 (Fed. Cir. 2010).

<sup>19</sup> *Id.*, 2009 WL 331968 at \*14.

<sup>20</sup> *Id.*, 2009 WL 331968 at n.135 (internal citations omitted).

<sup>21</sup> Mr. Shoemaker told OPR that the attorneys on the Petitioners Steering Committee would have been aware of the Poling case note no later than when it was filed, and it may have been part of the rationale for making the *Poling* case a test case.

Zimmerman's expert report in the *Poling* case stated that thimerosal-containing vaccines can cause autism spectrum disorders in a child, such as Hannah Poling, who has a mitochondrial disorder. Coordinated trials to hear testimony in the three designated test cases on the second theory of general causation were scheduled for May 2008. The Petitioners Steering Committee was well aware of the *Poling* case note; it was one of the 213 medical journal articles the petitioners listed as evidentiary exhibits in the Vaccine Court.<sup>22</sup>

1. The Government Concedes *Poling* as a "Table Injury" Case

According to Children's Health Defense, the *Poling* case "was slated to be one of the remaining three test cases for HHS but crooked DOJ attorneys secretly conceded [it] and sealed it in 2007 when they realized they could not win it. By their acts, they fraudulently deprived 5400 petitioners of their rightful relief."<sup>23</sup> They added, "To block the public from learning of Zimmerman's true opinion, the DOJ lawyers Vincent Matanoski and Lynn Ricciardella secretly settled Hannah's case -- for lifetime payments that could exceed \$20 million. Working with Defendants, the two DOJ lawyers procedurally concealed the record which resulted in it remaining confidential. As a result, another much weaker case became the bellwether to the OAP."<sup>24</sup>

According to Mr. Matanoski, the Department lawyers reviewed the medical records in the *Poling* case and concluded that Hannah Poling had an encephalopathy,<sup>25</sup> which, in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii), was a presumptive MMR vaccine-related injury. None of the other potential test cases appeared to involve a presumptive injury. The Department of Health and Human Services medical experts also reviewed Hannah Poling's medical records and determined, as the government's "Rule 4 Report" indicates,<sup>26</sup> that the vaccines administered to her (the MMR and others) had "significantly aggravated an underlying mitochondrial disorder," leading to a regressive encephalopathy. In the Rule 4 Report, the government conceded that the Polings should be awarded compensation for an illness or injury caused or exacerbated by a vaccine, but denied that the onset of Hannah's complex partial seizure disorder, nearly six years after her vaccinations, was related to the vaccinations.<sup>27</sup> In his OPR interview, Clifford Shoemaker

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<sup>22</sup> "PSC [Petitioners Steering Committee] Master Reference List," Sept. 10, 2007, at 13.

<sup>23</sup> Children's Health Defense Letter at 4.

<sup>24</sup> *Id.* at 9.

<sup>25</sup> The term "encephalopathy" means brain disease, damage, or malfunction. Encephalopathy can present a broad spectrum of symptoms that range from mild, such as memory loss or subtle personality changes, to severe, such as dementia, seizures, coma, or death. In general, encephalopathy is manifested by an altered mental state that is sometimes accompanied by physical manifestations (e.g., poor coordination of limb movements). [https://www.medicinenet.com/encephalopathy/article.htm#what\\_causes\\_encephalopathy](https://www.medicinenet.com/encephalopathy/article.htm#what_causes_encephalopathy) (accessed May 20, 2019).

<sup>26</sup> A "Rule 4 Report" takes its name from Vaccine Rule 4(c), Appendix B, Rules of the Court of Federal Claims. A Rule 4 Report includes a detailed discussion of the petitioner's medical history as well as a discussion of the petitioner's claimed vaccine-related injury. The report may contain an evaluation of the petitioner's medical claim by one or more of the government's experts. Additionally, the report may include the concession of a claim by the government, together with an explanation for the position the government has taken. The report is signed by counsel for the Department of Justice.

<sup>27</sup> *Poling*, Case 1:02-w-01466-UNJ, Respondent's Rule 4 Report, Nov. 9, 2007, at 8.

pointed out that in its initial Rule 4 Report, the government conceded the case but did not assert it was a Table Injury case.<sup>28</sup> Significantly, autism itself is not a listed injury on the Vaccine Injury Table.<sup>29</sup>

At a status conference with the special master, the Polings' attorney stated that they intended to file an additional report from Dr. Zimmerman in support of their claim that Hannah Poling's complex partial seizure disorder was a sequela to her vaccine-related injury. In that report, Dr. Zimmerman wrote that the cause of the

regressive encephalopathy in Hannah at age 19 months was underlying mitochondrial dysfunction, exacerbated by vaccine-induced fever and immune stimulation that exceeded metabolic energy reserves. This acute expenditure of metabolic reserves led to a permanent irreversible brain injury . . . Epilepsy is a result of the original brain injury in Hannah. Its appearance was delayed but was part of the same pathogenesis that led to autistic encephalopathy. Its onset appeared earlier than is typical in autism, due to Hannah's history of mitochondrial dysfunction and the brain injury at age 19 months.<sup>30</sup>

Mr. Shoemaker told OPR that he believed, but was not certain, that he circulated Dr. Zimmerman's expert opinions in *Poling* to the other members of the steering committee, as was his practice for other medical expert reports. On February 21, 2008, the government filed a Supplemental Rule 4 Report, in which it conceded that Hannah should receive compensation for her seizure disorder as a sequela to her vaccine-injury, according to the Vaccine Injury Table. In another vaccine case, years later, a special master explained the nature of the government's concession in *Poling* that Hannah Poling met the Vaccine Injury Table requirements:

[T]he *Poling* case was compensated based on the presumption of causation that attaches when the Table injury requirements are met, *not on an actual causation or causation in fact basis*. Otherwise, the reference to an injury appearing on the Vaccine Injury Table is nonsensical, as the only injuries that appear on the Table are those for which entitlement to compensation is presumed, such as the MMR Table injury of encephalopathy.<sup>31</sup>

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<sup>28</sup> As the court explained in *Cedillo*, "In some cases, the petitioner may simply demonstrate the occurrence of what has been called a 'Table Injury.' That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the 'Vaccine Injury Table' corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination." *Cedillo*, 2009 WL 331968 at \*\*6-7.

<sup>29</sup> *Hazlehurst*, 2009 WL 332306 at \*15.

<sup>30</sup> Letter, Dr. Andrew Zimmerman to Clifford Shoemaker, Esq., Nov. 30, 2007, at 3.

<sup>31</sup> *R.K. v. Secretary of Health & Human Services*, 2015 WL 10911950, \*17 (Fed. Cl. Spec. Mstr. May 23, 2016)

## 2. The Polings' Request for an Order to Publicize the Facts of Their Case

According to Children's Health Defense, "The same DOJ lawyers who submitted and relied upon Dr. Zimmerman's written expert opinion in *Cedillo* secretly conceded *Poling v. HHS*. They then objected to the release of the information in *Poling*, in order to conceal this concession and the evidence of causation from other petitioners and the public." Children's Health Defense also alleged that the Department lawyers

unethically concealed [Dr. Zimmerman's] opinion, from the petitioners. DOJ and HHS conspired and acted to block Dr. Zimmerman's opinion in *Poling* from being released to the public. That secret concealing of the government's Hannah Poling concession which resulted in the substitution of a weaker case was the bait and switch that allowed DOJ to get away with representing to the special master, and subsequently, the [Federal Circuit], that no link had been found between vaccines and autism in any of the six test cases. That representation was fraudulent.<sup>32</sup>

After the government conceded the *Poling* case, on March 4, 2008, the Polings' attorneys filed two motions. The first was a motion for leave to disclose case-specific facts from the *Poling* case to the Petitioners Steering Committee. The next day, March 5, 2008, the Vaccine Court granted that motion.<sup>33</sup> The second motion filed by the Polings on March 4, 2008 was styled "Petitioner's Motion for Complete Transparency of Proceedings," in which they requested an order permitting the parties to freely discuss with anyone every aspect of the *Poling* case, including the government's concession that Hannah was entitled to compensation for her vaccine-related injuries, including her autism.

In the meantime, the government's Rule 4 Report had been leaked, and it was publicly available on the internet. The Rule 4 Report received a great deal of media attention, but official disclosure was proscribed by statute unless express written consent was obtained first. In her April 10, 2008 order, the special master regarded the "Petitioner's Motion for Complete Transparency of Proceedings" as moot because of the unauthorized disclosure, and deferred ruling on the motion to allow time for the parties to come to an agreement.<sup>34</sup>

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(emphasis added).

<sup>32</sup> Children's Health Defense Letter at 6, 10-11.

<sup>33</sup> *Poling*, Case No. 1:02-vv-01466-UNJ, docket report, entry no. 32, Motion for Leave to Disclose, March 4, 2008; *id.*, entry no. 34, Order Granting Motion for Leave to Disclose Case-Specific Facts to the Plaintiffs' Steering Committee, March 5, 2008.

<sup>34</sup> *Poling*, Case No. 1:02-vv-01466-UNJ, docket report, entry no. 33, Motion for Complete Transparency, March 4, 2008; *Poling*, 2008 WL 1883059, Order Deferring Ruling on Petitioners' Motion for Complete Transparency of Proceedings, April 10, 2008 (Campbell-Smith, Special Master). On July 21, 2010, a special master found that the Polings were entitled to compensation under the Vaccine Program and awarded damages. *Id.*, 2011 WL 678559, Attorneys' Fees and Costs Decision, Jan. 28, 2011.

The petitioners later withdrew their motion, although Mr. Shoemaker, who filed the motion as well as the motion to withdraw it, told OPR that he could not recall why. Shoemaker told OPR that he wanted the initial Rule 4 Report to be publicly available so the Petitioners Steering Committee could “sit down” with the government and come up with criteria to compensate similarly-situated children the same way. However, by “belatedly” treating *Poling* as a Table Injury case, it was no longer seen as a test case, and the concession by the government was a “one off” (the only one of its kind).<sup>35</sup>

Ms. Ricciardella informed OPR that the government sought permission from the Poling family to discuss Hannah’s medical condition publicly so that the government could disclose why it had conceded the case, but the Polings refused to consent. Instead, in negotiations over the motion for complete transparency, the Polings offered to allow public discussion of Hannah’s medical condition only if the court ruled that Rule 4 Reports are not subject to the proscriptions against disclosure in § 12(d)(4)(A),<sup>36</sup> and that the initial leaked disclosure of the Rule 4 Report had been proper. The government refused those terms, Ricciardella asserted, because it took the position that § 12(d)(4)(A) applied to information submitted by both parties in a Vaccine Act case and not just information submitted by petitioners. Ricciardella insisted the government’s position “had nothing to do with an attempt to ‘conceal’ anything about the concession or the record,” and, in fact, “the Rule 4 Report had already been publicly disclosed.” Ricciardella asserted that “to this day, the Poling family has never given consent for [the government] to discuss Hannah’s medical records or medical condition.” Finally, Ricciardella pointed out that because the petitioners in the *Poling* case filed Dr. Zimmerman’s report, under § 12(d)(4)(A) of the Vaccine Act, Dr. and Mrs. Poling had to consent to the disclosure of the report before it could be released.

For his part, Dr. Zimmerman told OPR that he was unaware of any effort by any Department attorney to suppress his opinion in *Poling*, and that no one from the government had ever asked him not to share or discuss it with anyone else. He was aware of four or five mitochondrial cases brought in the Vaccine Court after *Poling*, but he did not know if the government had submitted his *Cedillo* opinion in any of those cases.

#### **D. The Hazlehurst Case**

On March 26, 2003, Rolf and Angela Hazlehurst, the parents of Yates Hazlehurst, filed a short-form petition pursuant to the Vaccine Act, and then filed an amended petition on June 13, 2007, alleging that the MMR vaccination Yates received on February 8, 2001, or a combination of the MMR vaccination and the thimerosal-containing vaccinations he received during his first twelve months of life, caused him to develop regressive autism.<sup>37</sup> The theory at issue, according

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<sup>35</sup> *Poling*, Case No. 1:02-vv-01466-UNJ, docket report, entry no. 86, Motion to Withdraw Previously Filed Motion, July 20, 2009; *id.*, entry no. 92, Order, Aug. 20, 2009 (granting motion to withdraw motion for complete transparency). Children’s Health Defense asserted that the Motion for Complete Transparency “has never been decided,” suggesting incorrectly that it is still pending. Children’s Health Defense Letter at 13.

<sup>36</sup> Pursuant to section 12(d)(4)(A) of the Vaccine Act, information submitted to a special master in a case may not be disclosed without the express written consent of the party who submitted the information. 42 U.S.C. § 300aa-12(d)(4)(A).

<sup>37</sup> *Hazlehurst*, 2009 WL 332306 at \*3-4.

to Special Master Patricia Campbell-Smith, was “the claim that thimerosal-containing vaccines in combination with the MMR vaccine can cause autism in children who have received these vaccinations.”<sup>38</sup> The *Hazlehurst* hearings occurred on October 15-18, 2007, four months after the *Cedillo* trial.<sup>39</sup> As in *Cedillo*, the record in *Hazlehurst* was enormous, and included all the medical records, expert opinions, and medical literature pertaining specifically to Yates Hazlehurst, as well as the general causation evidence introduced in the two other test cases, *Cedillo* and *Snyder* (including the transcripts of the hearings in those cases and all the expert reports). All told, the parties filed 1,085 medical literature exhibits and fifty medical expert reports; the petitioners called seven medical experts to testify; and the government responded with fourteen testifying medical experts.<sup>40</sup>

Children’s Health Defense acknowledges that the “OAP’s peculiar rules allowed any evidence concerning the ‘general causation issue’ entered in one test case to be considered as evidence in the other test cases and the remaining 5,400 cases. The DOJ attorneys were therefore able to keep Zimmerman’s expert opinion in *Cedillo* in evidence and use it as general causation evidence against the petitioners in all subsequent cases.”<sup>41</sup> Dr. Zimmerman’s written opinion in *Cedillo*, which Children’s Health Defense characterized as “key” evidence, was one of the fifty expert reports in the *Hazlehurst* case. According to Children’s Health Defense, “Thanks to DOJ’s act of conceding and sealing the *Poling* case,” the petitioners in the *Hazlehurst* case “had no idea that DOJ was misrepresenting Dr. Zimmerman’s opinion.”<sup>42</sup> Children’s Health Defense claims that while the CSTL attorneys were

able to keep Zimmerman’s expert opinion in *Cedillo* in evidence and use it as general causation evidence against the petitioners in all subsequent cases . . . none of the petitioners against whom DOJ deployed his opinion were aware of Dr. Zimmerman’s opinion [in *Poling*] of how vaccines can cause autism. In the hands of the DOJ attorneys Dr. Zimmerman’s misrepresented opinion became a powerful weapon that denied compensation to almost every one of the 5,400 vaccine-injured children whose cases were in the OAP.<sup>43</sup>

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<sup>38</sup> *Id.* at \*4.

<sup>39</sup> *Id.* at \*5.

<sup>40</sup> *Id.* at \*6.

<sup>41</sup> Children’s Health Defense Letter at 7; *Hazlehurst*, 2009 WL 332306 at \*5 (“To ensure that the developed record in each test case includes the most comprehensive evidence, each special master has filed into the record of her or his particular test case, with the permission of the parties, the medical and scientific literature, the general causation expert opinions, and the corrected hearing transcripts from the other two test cases for consideration by the special master in deciding the general causation issue of whether thimerosal-containing vaccines and the MMR vaccine, in combination, can cause autism.”).

<sup>42</sup> Children’s Health Defense Letter at 13.

<sup>43</sup> *Id.* at 7. The Children’s Health Defense Letter goes on to state, “In the remaining trials, HHS and DOJ continued to fraudulently misrepresent Dr. Zimmerman’s opinion as evidence in the OAP despite the fact that Dr. Zimmerman advised the DOJ attorneys and HHS that his opinion in *Cedillo* was case specific and was never intended to be a blanket opinion regarding all children and all medical science.” *Id.* at 9.

In his closing argument in *Hazlehurst*, Mr. Matanoski referred to Dr. Zimmerman and his opinion in *Cedillo*. He argued to the court:

I did want to mention one thing about an expert, who did not appear here, but his name has been mentioned several times, and that was Dr. Zimmerman. Dr. Zimmerman actually has not appeared here, but he has given evidence on this issue, and it appeared in the *Cedillo* case. I just wanted to read briefly because his name was mentioned several times by Petitioners in this matter. What his views were on these theories [was] . . . , “There is no scientific basis for a connection between measles, mumps and rubella MMR vaccine or mercury intoxication in autism despite well-intentioned and thoughtful hypotheses and widespread beliefs about apparent connection with autism and regression. There’s no sound evidence to support a causative relationship with exposure to both or either MMR and/or mercury.”<sup>44</sup>

In his affidavit, Dr. Zimmerman stated that it was “highly misleading” for the Department attorneys to “continue to use [his] original written expert opinion, as to Michelle Cedillo, as evidence against the remaining petitioners in the O.A.P. in light of [what he told them on June 15, 2007] while omitting the caveat regarding exceptions in which vaccinations could cause autism.”<sup>45</sup> Dr. Zimmerman stated that Matanoski’s comments in closing argument about his expert opinion were “highly misleading and not an accurate reflection of [his] opinion,” because he had told Matanoski that his opinion was limited to Michelle Cedillo; that his opinion “was not intended to be a blanket statement as to all children and all medical science;” and that he had explained to Mr. Matanoski and the other Department attorneys that there were exceptions when vaccinations could cause autism.<sup>46</sup> Children’s Health Defense alleged that Matanoski “baldly lied” in his closing argument comments, and that his comments were “an extraordinary example of chutzpa[h] and shameful and fraudulent deceit.”<sup>47</sup>

As Ms. Ricciardella pointed out, however, the *Hazlehurst* case was tried in October 2007, one month *before* the government conceded the *Poling* case, and thus the government could not have concealed anything from the petitioners in *Hazlehurst*. Moreover, the general causation theory at issue in *Hazlehurst* – whether thimerosal, together with the MMR vaccine, caused or contributed to the development of autism – “had nothing whatsoever to do with an alleged relationship between mitochondrial disorders and autism [as in *Poling*]. None of the [petitioners’] expert witnesses for [the first general causation theory] ever mentioned mitochondrial disorders and their alleged relationship to autism.” Ms. Ricciardella was unaware that Dr. Zimmerman’s

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<sup>44</sup> *Hazlehurst*, Case No. 03-654V, Oct. 18, 2007, Trial Transcript at 95-96.

<sup>45</sup> Zimmerman Affidavit at ¶ 20.

<sup>46</sup> *Id.* at ¶ 17.

<sup>47</sup> Children’s Health Defense Letter at 9, 14.



opinion was introduced into evidence in any case other than the three test cases involving the first theory of causation, and she noted that the Children's Health Defense Letter cited no other case.

In his affidavit, Dr. Zimmerman stated that he has

reviewed extensive genetic, metabolic and other medical records of William 'Yates' Hazlehurst. In my opinion, and to a reasonable degree of medical certainty, Yates Hazlehurst suffered regressive encephalopathy with features of autism spectrum disorder as a result of a vaccine injury in the same manner as described in the DOJ concession in *Poling v. H.H.S.*, with the additional factors that Yates Hazlehurst was vaccinated while ill, administered antibiotics and after previously suffering from symptoms consistent with a severe adverse vaccine reaction.<sup>48</sup>

However, Dr. Zimmerman told OPR that he made his findings within the past two years, since becoming Yates Hazlehurst's treating physician. As a test case in the early 2000s, Yates Hazlehurst was not diagnosed, or presented at trial, as having regressive encephalopathy caused by an underlying mitochondrial disorder.<sup>49</sup> In fact, Dr. Zimmerman told OPR that Dr. Richard Frye first discovered that Yates had an underlying mitochondrial dysfunction long after the *Hazlehurst* case in the OAP had concluded. Thus, when the *Hazlehurst* case was tried, the Poling case note was in evidence and, in all probability, petitioners' counsel knew of Dr. Zimmerman's opinion in *Poling*, but they would not have realized the relevancy of those materials to Yates Hazlehurst's condition.

### 3. The Vaccine Court's Decision in *Hazlehurst*

In the 196-page decision in *Hazlehurst*, the Vaccine Court determined that the MMR vaccine and thimerosal in combination do not cause autism. The special master wrote that the "petitioners offered no reliable scientific evidence supporting their claim that mercury exposure through thimerosal-containing vaccines causes immunosuppression in vaccinees, facilitating the development of autism," and concluded, "The combination of the [thimerosal] and the MMR vaccine are not causal factors in the development of autism and therefore, could not have contributed to the development of [Yates]'s autism."<sup>50</sup>

Dr. Zimmerman's report is mentioned only in a single footnote, in which the special master identifies the four experts, including Dr. Zimmerman, whose reports were introduced into evidence but who did not testify at the hearing. The special master noted that she had reviewed and considered Dr. Zimmerman's report from *Cedillo*, that it and the reports of the other three experts who did not testify "len[t] support" to her conclusions about the invalidity of the first causation theory, but that she had relied "more heavily on the testimony and reports of the experts who were

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<sup>48</sup> Zimmerman Affidavit at ¶ 17.

<sup>49</sup> See *Hazlehurst*, 2009 WL 332306 at \*\*15, 108-16.

<sup>50</sup> *Id.*, 2009 WL 332306 at \*\*115, 122.

observed and heard during the hearings.”<sup>51</sup> Even a cursory review of the *Hazlehurst* opinion reflects the detailed, nuanced, and careful consideration the Vaccine Court gave to the testimony and the publications of the testifying experts, over more than one hundred pages.

#### 4. The Hazlehurst Appeal

On the appeal of *Hazlehurst* to the Federal Circuit, the court of appeals in oral argument asked Ms. Ricciardella about the developing science and medicine regarding whether vaccines can cause autism. She responded, “Well, there’s a lot to your question, Your Honor, but I would say at this stage we’re not even at the stage where it’s medically or scientifically possible.” Children’s Health Defense characterized this statement as “extremely consequential and profoundly fraudulent,” particularly in light of the fact that Ms. Ricciardella had signed and submitted the Rule 4 Report conceding that Hannah Poling suffered autism as a result of a vaccine injury, and that she knew Dr. Zimmerman and other doctors believed, when the case was argued in 2009, that in certain cases, vaccines can cause autism.<sup>52</sup>

The court of appeals judge asked Ms. Ricciardella about the “unknowns” of science, questioning whether the court should await further studies, and whether the government placed too much confidence in existing studies. The judge asked, “Would it suffice or should it suffice at this stage if it is shown to be medically, therapeutically, scientifically possible as one proceeds to develop the causal relationship?” Ms. Ricciardella focused, she said, on the word “possible,” and replied that science had examined the purported causal relationship between vaccines and autism, and that “we’re not even at the stage where it’s medically or statistically possible.” Ms. Ricciardella stated that she “used the word ‘possible’ in that moment because that is the word the judge used.” In retrospect, she regarded her response as slightly inaccurate, “not because of anything to do with Dr. Zimmerman, [or] the *Poling* case,” but rather because she now “appreciate[s] that science does not work in absolutes. Anything is ‘possible’ in science.” She maintained, however, that “the hypothesized link between vaccines and autism has been studied across many countries, and all credible studies have arrived at the same result: no causal association between vaccines and autism has been found.”

Ms. Ricciardella also noted that when she appeared before the court of appeals in 2009, the Department of Health and Human Services had conceded the *Poling* case as a Table Injury, which meant that causation was presumed, but there was no finding of actual causation. Moreover, after the *Poling* case, Department lawyers canvassed doctors with expertise in mitochondrial disease, and learned that most did not accept the theory that there is a causal relationship between mitochondrial disorders and autism. As a result, the government began to retain medical experts to rebut any case in which the petitioners asserted that vaccines aggravate mitochondrial disorders and cause autism. In fact, she informed OPR that Dr. Zimmerman has testified for petitioners in autism cases, alleging that there is a connection between mitochondrial disease and autism, but that his opinion has not been found persuasive by the special masters.<sup>53</sup>

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<sup>51</sup> *Id.* at \*6 n.16.

<sup>52</sup> Children’s Health Defense Letter at 18.

<sup>53</sup> *See Reed v. Secretary of Health & Human Services*, No. 08-650V, 2018 WL 684458 (Fed. Cl. Spec. Mstr. Dec. 4, 2018) (petitioners alleged that I.R. “suffered a significant aggravation of a preexisting condition, a

### E. The Snyder Case

Children's Health Defense made no allegations regarding the use of Dr. Zimmerman's opinion in the *Snyder* case. Presumably, as it did in *Hazlehurst*, Children's Health Defense would assert that the government should not have used Dr. Zimmerman's *Cedillo* opinion, at least without disclosing that Dr. Zimmerman believed there were exceptions to his opinion. But, as in *Cedillo* and *Hazlehurst*, the special master in *Snyder* referred to Dr. Zimmerman's written opinion only briefly, and relied on it only in evaluating the merits of the various interpretations of his findings:

In evaluating matters contained in expert reports filed by witnesses who did not testify, I have considered the experts' qualifications, as reflected in all of their filed curricula vitae ["CV"], the extent to which the experts' opinions were supported by other evidence or testimony, the bases for their opinions, and the nature of their opinions offered in determining how much weight to accord the proffered opinions. I have also considered that the witness was not available for cross-examination or to answer questions posed by me or another of the special masters, recognizing that there is no right of cross examination in Vaccine Act cases . . . . [With regard to Dr. Zimmerman specifically,] I relied on his report in considering the relative merits of various interpretations of his research findings.<sup>54</sup>

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mitochondrial disorder, causally related to the [MMR] vaccine" which caused I.R.'s illnesses, including "features of autism spectrum disorder;" Dr. Zimmerman filed two reports and testified at the hearing; nevertheless, the special master found that I.R.'s "autism began to manifest by the time he reached 12 months of age, prior to the vaccinations alleged to have caused his injuries," that there was no preponderant evidence that I.R. suffered from mitochondrial dysfunction, and that he did not experience a post-vaccination regression; and the special master concluding, "Dr. Zimmerman's opinion is not persuasive in this regard"); *Madariaga v. Secretary of Health & Human Services*, No. 02-1237V, 2015 WL 6160215 (Fed. Cl. Spec. Mstr. Sep. 26, 2015) (petitioners alleged that A.A. had an underlying mitochondrial disorder that made her vulnerable to the inflammatory effects of the MMR vaccine, which overwhelmed A.A.'s already impaired mitochondrial function and caused her to experience an acute regression and to develop autism; Dr. Zimmerman testified to that effect, but the special master noted that "he was unable to set forth a theory connecting vaccines to either mitochondrial dysfunction or autism. Indeed, he testified that he could not directly attribute autistic regression to the MMR immunization or any resulting inflammation;" the special master concluded that A.A. did not become ill as a result of her MMR vaccination).

During his OPR interview, Dr. Zimmerman acknowledged that: (1) many doctors have questioned his conclusion in *Poling*; (2) other doctors in the Vaccine Court have denied that mitochondrial disorders increase what he called "a liability to vaccine reaction;" and (3) the issue of whether vaccines given to children with mitochondrial dysfunction causes autism "absolutely" is still much in debate in the medical community. The fact that the Vaccine Court has refused to compensate children with mitochondrial disorders who developed autism after vaccination seems to vitiate the Children's Health Defense claim that Dr. Zimmerman's November 30 letter in the *Poling* case was "critical" because he recognized that "a previously undetected and possibly otherwise harmless mitochondrial disorder . . . made [Hannah Poling] susceptible to vaccine injury and that her autism was triggered by a vaccine-induced temperature spike . . . . Dr. Zimmerman's new revelations threatened to open the vaccine court floodgates to children with autism." Children's Health Defense Letter at 8-9.

<sup>54</sup> *Snyder*, 2009 WL 332044 at \*9, 16.

### III. ANALYSIS

#### A. Department Attorneys Did Not Suppress Dr. Zimmerman's Opinion in *Poling*

Children's Health Defense claims that the government "buried" Dr. Zimmerman's opinion in the *Poling* case by settling the case as a Table Injury case. This assertion is meritless, because Dr. Zimmerman's opinion was not hidden from anyone. The *Poling* case note was published the year before; it was public information; and it was actually known to the petitioners.

The case note that Dr. Zimmerman co-authored with Dr. Poling was published in the February 2006 *Journal of Child Neurology*, and was introduced into evidence by the petitioners in the theory 1 test cases. The case note concerns a then-unnamed child who experienced a developmental regression and loss of skills following vaccination, and who was later diagnosed with autism and a mitochondrial disorder. In the case note, Drs. Poling and Zimmerman hypothesized that other children with autism spectrum disorders might also have underlying mitochondrial disorders. The case note was not only public information, but also was introduced into evidence in all three theory 1 test cases. The petitioners' attorneys did not rely on or even refer to the case note, apparently because the note, involving the study of only a single patient, lacks the persuasive power of a more broad-based or epidemiological study, and more importantly, because the other test cases did not involve the mitochondrial dysfunction that underlay the *Poling* case note.<sup>55</sup>

Moreover, the fact that Dr. Zimmerman had co-authored the *Poling* case note, which the petitioners introduced into evidence in the other test cases, indicates that the petitioners' attorneys were well aware that Dr. Zimmerman believed there was a subset of autism spectrum cases in which the MMR vaccine was a substantial contributing factor in causing autism. In addition, the Department attorneys, like the petitioners' attorneys, already knew of Dr. Zimmerman's reservation, and Dr. Zimmerman did not have to tell Mr. Matanoski or the other CSTL lawyers on June 15, 2007 that he had come to believe there might be exceptions to his opinion in *Cedillo* that vaccines did not cause autism.

In the *Poling* case itself, Dr. Zimmerman provided an expert opinion consistent with the hypothesis of the case note. As a result of the Vaccine Court's March 5, 2008 Order granting the motion for leave to disclose case-specific facts from the *Poling* case to the Petitioners Steering Committee, Clifford Shoemaker believes he disseminated Dr. Zimmerman's two written opinions in *Poling* to the petitioners' attorneys.<sup>56</sup> Moreover, the facts of, and the opinions rendered in, the *Poling* case were already public knowledge, as they had been leaked and were widely disseminated

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<sup>55</sup> Years later, Dr. Zimmerman himself used the *Poling* case note in the *Madariaga* case. *Madariaga*, 2015 WL 6160215 at \*5 n.11.

<sup>56</sup> *Poling*, docket report, entry no. 32, Motion for Leave to Disclose, March 4, 2008; *id.*, entry no. 34, Order Granting Motion for Leave to Disclose Case-Specific Facts to the Plaintiffs' Steering Committee, March 5, 2008. Shoemaker told OPR that all the lawyers on the steering committee were aware of the facts and opinions in all of the test cases, and that the steering committee lawyers shared the information with other, non-test case petitioners, if their own clients consented.

over the internet, as shown by the fact that the Vaccine Court regarded the petitioners' motion for "complete transparency" as moot as a practical matter.<sup>57</sup>

The dissemination of Dr. Zimmerman's expert opinions in *Poling* was prohibited by statute without the agreement of the proffering party, pursuant to 42 U.S.C. § 300aa-12(d)(4)(A), and the evidence suggests that it was the Polings, not the government, who prevented the disclosure of the opinions. In a recent vaccine case, the petitioners filed as an exhibit Dr. Zimmerman's expert report in *Poling* – which shows that it was not "buried" – and the government moved to strike the exhibit on the grounds, *inter alia*, that its use violated section 12(d)(4)(A) of the Vaccine Act. The special master stated he "would allow the exhibit to remain in the record if [the petitioners] obtained a current, written consent from the petitioners in the *Poling* case specific to this case. Petitioners did not do so, however, even after being given multiple opportunities, and therefore [the special master] granted [the government's] motion."<sup>58</sup>

For his part, Dr. Zimmerman told OPR that he was unaware of any effort by any Department attorney to suppress his opinion in *Poling*, and that no one from the government had ever asked him not to share his opinion with anyone else. He was aware of four or five mitochondrial cases brought in the Vaccine Court since *Poling*, but did not know if the government had submitted his *Cedillo* opinion in any of them. The fact that Dr. Zimmerman has been called to testify in other vaccine cases, where the children allegedly had mitochondrial disorders caused or exacerbated by MMR vaccines, also demonstrates that his opinions have not been suppressed by the government.

Finally, there was nothing improper about the decision made by Mr. Matanoski and the other CSTL lawyers not to call Dr. Zimmerman to testify in the *Cedillo* case; their tactical litigation decision cannot be seen as "suppressing" Dr. Zimmerman's opinion in *Poling*. Children's Health Defense alleges that the government did not call Dr. Zimmerman to prevent the petitioners from learning through cross-examination that Dr. Zimmerman believed there were exceptions to his opinion in *Cedillo*. However, the petitioners already knew there were exceptions, because they were aware of the *Poling* case note. The government did not need Dr. Zimmerman's testimony, and his testimony about a "mitochondrial exception" would have been irrelevant to the general causation theory at issue in *Cedillo*.

For all these reasons, OPR determined that the Department attorneys in the OAP litigation did not suppress Dr. Zimmerman's opinion in the *Poling* case for use in other vaccine injury cases.

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<sup>57</sup> *Poling*, 2008 WL 1883059, Order Deferring Ruling on Petitioners' Motion for Complete Transparency of Proceedings, April 10, 2008.

<sup>58</sup> *Murphy v. Secretary of Health & Human Services*, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. April 25, 2016) at 58 n.70 (internal citation omitted), *aff'd*, 128 Fed. Cl. 348 (2016).

**B. Department Attorneys Did Not Improperly Use Dr. Zimmerman's Cedillo Opinion**

**1. The Use of Dr. Zimmerman's Cedillo Opinion in Other OAP Cases**

Even though Dr. Zimmerman's *Cedillo* opinion was only one of the fifty expert reports admitted in *Hazlehurst*, and Dr. Zimmerman did not testify in *Hazlehurst*, Children's Health Defense nevertheless characterized his *Cedillo* opinion as "key" evidence. Children's Health Defense claimed that the "petitioners in the *Hazlehurst* case had no idea that DOJ was misrepresenting Dr. Zimmerman's opinion." They also claimed that "none of the petitioners against whom DOJ deployed his opinion were aware of Dr. Zimmerman's opinion of how vaccines can cause autism. In the hands of the DOJ attorneys Dr. Zimmerman's misrepresented opinion became a powerful weapon that denied compensation to almost every one of the 5,400 vaccine-injured children whose cases were in the OAP."<sup>59</sup>

In his affidavit, Dr. Zimmerman claimed that he told Mr. Matanoski during a break in the *Cedillo* trial that his opinion in that case – that vaccines do not cause autism – was subject to certain exceptions, notably when a child had a mitochondrial disorder, and he referred to the 2006 Poling case note. During his OPR interview, Dr. Zimmerman stated that he spoke with CSTL attorney Voris Johnson, not Mr. Matanoski, which is consistent with the other evidence OPR has gathered in this matter. More important, Dr. Zimmerman stated in his affidavit that he told the Department attorneys that his *Cedillo* opinion should be clarified, and used only with the clarification, because of scientific advances (specifically, the Poling case note).<sup>60</sup>

During his OPR interview, however, Dr. Zimmerman acknowledged that when he first met the CSTL attorneys, they told him about the use of test cases in the OAP, and he could not excuse his own "naiveté" for thinking that his expert opinion was meant for use only in the *Cedillo* case. Dr. Zimmerman acknowledged that he was told that his opinion in *Cedillo* would also be used as general causation evidence in *Hazlehurst* and *Snyder*. In addition, Dr. Zimmerman acknowledged that the *only* issue he raised during the June 15, 2008 meetings with the CSTL lawyers was the exception for underlying mitochondrial disorders. When asked specifically if he discussed the government's use of his *Cedillo* opinion in future vaccine cases, he said that "the subject did not even come up." In other words, he never told the Department attorneys not to use the *Cedillo* opinion in *Hazlehurst* or *Snyder*, and he never told them that his opinion had changed.

The evidence is clear that all the parties were aware of the Poling case note, including the Petitioners Steering Committee, which received it from Mr. Shoemaker, and introduced it into evidence in the OAP. The other OAP cases in which Dr. Zimmerman's *Cedillo* opinion was used, *Hazlehurst* and *Snyder*, involved the same general theory of causation as *Cedillo*, without an underlying mitochondrial disorder, rendering Dr. Zimmerman's *Cedillo* opinion just as valid in the other OAP cases as it was for Michelle Cedillo. Indeed, the special masters in *Hazlehurst* and *Snyder* considered Dr. Zimmerman's opinion for the same purpose as the special master had in *Cedillo*. His opinion was not offered as "a blanket statement as to all children and all medical

<sup>59</sup> Children's Health Defense Letter at 13, 7.

<sup>60</sup> Zimmerman Affidavit at ¶¶ 9-11.

science,” because the Poling case note – which was also in the record, and which petitioners knew all about – clearly indicated that Dr. Zimmerman believed that in certain circumstances, vaccines can cause autism.<sup>61</sup>

Finally, despite the claim that Dr. Zimmerman was the government’s “star expert witness” and the “world’s top pediatric neurologist in the field of autism research,” it is clear from the Vaccine Court decisions in *Cedillo*, *Hazlehurst*, and *Snyder* that Dr. Zimmerman’s opinions were not critical to the defense of those cases. Indeed, in all three “Theory 1 decisions,” Dr. Zimmerman and his *Cedillo* opinion were scarcely mentioned, and given little weight. The assertion that Dr. Zimmerman’s *Cedillo* opinion was a “weapon that denied compensation to almost every one of the 5,400 vaccine-injured children” whose cases were in the OAP, is pure fallacy.

## 2. Matanoski’s Closing Argument in *Hazlehurst*

In his closing argument in *Hazlehurst*, referring to Dr. Zimmerman and his opinion in *Cedillo*, Mr. Matanoski argued to the court:

Dr. Zimmerman actually has not appeared here, but he has given evidence on this issue, and it appeared in the *Cedillo* case. . . What his views were on these theories [was], “There is no scientific basis for a connection between measles, mumps and rubella MMR vaccine or mercury intoxication in autism despite well-intentioned and thoughtful hypotheses and widespread beliefs about apparent connection with autism and regression. There’s no sound evidence to support a causative relationship with exposure to both or either MMR and/or mercury.”<sup>62</sup>

In his affidavit, Dr. Zimmerman characterized Mr. Matanoski’s comment as “highly misleading and not an accurate reflection of [his] opinion,” because he told Matanoski (actually, he told Johnson) that his opinion was limited to Michelle Cedillo’s case, and that his opinion was not intended to be “a blanket statement” that was applicable to other cases, since there were exceptions in which vaccinations could cause autism.<sup>63</sup> Children’s Health Defense alleged that Matanoski “baldly lied” in his closing argument, and that his comments were “an extraordinary example of chutzpa[h] and shameful and fraudulent deceit.”<sup>64</sup>

The petitioners in *Hazlehurst* alleged that thimerasol and the MMR vaccine caused autism, which was the same general causation theory at issue in *Cedillo*, and Dr. Zimmerman acknowledged that he knew that an opinion introduced in one of the OAP cases would be introduced, and could be used, in another OAP case. The language from Dr. Zimmerman’s report

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<sup>61</sup> Zimmerman Affidavit at ¶ 7.

<sup>62</sup> *Hazlehurst*, Case No. 03-654V, Oct. 18, 2007, Trial Transcript at 95-96.

<sup>63</sup> Zimmerman Affidavit at ¶ 17.

<sup>64</sup> Children’s Health Defense Letter at 9, 14.

that Mr. Matanoski quoted in his closing argument dealt with Dr. Zimmerman's overall view of the validity of the petitioners' general causation theory. As presented by the petitioners, the *Hazlehurst* case did not implicate mitochondrial dysfunction, and Dr. Zimmerman's belief that there were exceptions in which vaccines might cause autism was not implicated. Moreover, because the petitioners knew about the Poling case note, counsel for the Hazlehursts was free to argue that Dr. Zimmerman believed there were exceptions to the general rule that vaccines do not cause autism, if that would have helped the case. Accordingly, there was nothing improper about Matanoski's use of Dr. Zimmerman's opinion in *Cedillo* in his closing argument in *Hazlehurst*.

### 3. The Hazlehurst Appeal

On appeal to the Federal Circuit, when asked in oral argument about the developing science and medicine regarding whether vaccines can cause autism, Ms. Ricciardella responded, "I would say at this stage we're not even at the stage where it's medically or scientifically possible." Children's Health Defense characterized this statement as "extremely consequential and profoundly fraudulent," in light of the fact that Ms. Ricciardella had signed and submitted the Rule 4 Report conceding that Hannah Poling suffered autism as a result of a vaccine injury, and she knew that Dr. Zimmerman and other doctors, when the case was argued in 2009, believed that in certain circumstances, vaccines can cause autism.<sup>65</sup> However, as Ms. Ricciardella pointed out in her response to OPR, when the government conceded the *Poling* case as a Table Injury, causation was presumed, and there was never a finding of actual causation.

OPR concluded that Ms. Ricciardella made a mistake in representing to the court of appeals that "we're not even at the stage where it's medically or scientifically possible" that vaccines can cause autism. Ms. Ricciardella acknowledged to OPR that "[a]nything is 'possible' in science." Having worked on vaccine cases for years, she should have been more circumspect in characterizing the state of scientific knowledge, and not make an absolute statement regarding the science, especially when she knew that some respected doctors, including Dr. Zimmerman, believed that in certain circumstances, vaccines can cause autism spectrum disorders. However, her misstatement was a mistake, not poor judgment or misconduct, because it was made in the tense and unrehearsed atmosphere of an appellate oral argument, without time to carefully prepare her remarks.

### 4. The Supreme Court's Decision in *Bruesewitz*

Children's Health Defense alleges that "[t]he unethical acts by DOJ and HHS directly influenced the Supreme Court of the United States decision in *Bruesewitz v. Wyeth*, a decision that continues to adversely affect millions of vaccine-injured children."<sup>66</sup> In *Bruesewitz*, parents of a minor child sought compensation for an injury to their child allegedly caused by a vaccine. The Supreme Court held that the Vaccine Act preempted the parents' state law design-defect products liability claim.<sup>67</sup>

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<sup>65</sup> Children's Health Defense Letter at 18.

<sup>66</sup> Children's Health Defense Letter at 1.

<sup>67</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).



Children's Health Defense conceded that *Bruesewitz* interprets a different provision of the Vaccine Act and that *Bruesewitz* was not an OAP case.<sup>68</sup> Children's Health Defense seemed to argue, however, that if CSTL attorneys had not introduced Dr. Zimmerman's *Cedillo* opinion in the other OAP cases, the petitioners would have prevailed or, even if they had not prevailed, the Supreme Court would have adopted what is now the dissenting opinion in *Bruesewitz*, and allowed design defect claims to be brought in civil actions against vaccine manufacturers. This argument is wholly speculative and highly dubious.

Dr. Zimmerman's *Cedillo* opinion had little, if any, influence on the special masters' decisions in the OAP cases, and it is difficult, if not impossible, to conclude that the result in any of the OAP cases would have been different without it. In addition, since the OAP cases, Dr. Zimmerman has testified for petitioners in cases where the afflicted children allegedly had underlying mitochondrial dysfunction, but his theory has not been accepted by the special masters in those cases. Moreover, the Supreme Court's holding in *Bruesewitz* was based on statutory interpretation of the Vaccine Act, and the Court did not even refer to the OAP cases in its opinion.

### CONCLUSION

After carefully considering the Children's Health Defense allegations of misconduct by Mr. Matanoski, Ms. Ricciardella, and other, unidentified Department attorneys, and reviewing voluminous materials relating to this matter, OPR determined that the Department attorneys did not exercise poor judgment or commit professional misconduct, and has closed its inquiry.

OPR appreciates you bringing this matter to the Department's attention.

Sincerely,



Corey R. Amundson  
Director & Chief Counsel

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Children's Health Defense Letter at 20-21.