IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

THERESA CEDILLO and **MICHAEL CEDILLO**, as Parents and Natural Guardians of **MICHELLE CEDILLO**,	*	
Petitioners,	*	No. **98-916V**
	*	Special Master **GEORGE L. HASTINGS, Jr.**
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	Judge **UNASSIGNED**
Respondent.	*	

PETITIONERS' MEMORANDUM IN SUPPORT OF MOTION FOR REVIEW OF THE SPECIAL MASTER'S DECISION OF FEBRUARY 12, 2009

DATED: March 16, 2009

Respectfully submitted,

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I. INTRODUCTION

On December 9, 1998, at four years of age, Michelle Cedillo ("Michelle") filed a petition in the Vaccine Program,[1] alleging that a measles, mumps, rubella ("MMR") vaccine harmed her. By 2001, Michelle and the respondent had each filed an expert report, and her case was ripe for hearing. In July of 2002, however, the chief special master initiated the Omnibus Autism Proceeding ("OAP").[2] He did so in response to a flood of

[1] The Vaccine Act, which established the National Vaccine Injury Compensation Program is located at 42 U.S.C. § 300aa-1 *et. seq*. For convenience, future references will be to the "Vaccine Act," the "Act" or the "Vaccine Program." Individual sections to the Act will include only the section number.

[2] *In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or Similar Neurodevelopmental Disorder, Various Petitioners v. Sec'y of HHS,*

petitions filed by autistic children.[3] Initially intending to file civil lawsuits against vaccine manufacturers,[4] these children were required by law to first process their claims in the Vaccine Program.[5] Michelle, who is autistic, joined the OAP.

In June of 2007, Michelle's evidence[6] was presented to a panel of three special masters ("The Panel").[7] She presented evidence that (1) she was born healthy; (2) she had normal development and met all milestones; (3) she received the recommended childhood vaccinations, including twelve (12) vaccines that contained thimerosal;[8] (4) the ethyl mercury damaged her immune system; (5) the MMR vaccine she received at 15 months further damaged her immune system; (6) she was unable

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General Order #1, July 3, 2002. The docket of the OAP, or "Autism Master File" is located at http://www.uscfc.uscourts.gov/node/2718.

[3] *See* OAP Autism Update of April 23, 2008, indicating that 4,900 autistic children have filed claims.

[4] The civil "tort" theory was that it was negligent for vaccine manufacturers to use thimerosal (ethyl mercury) as a preservative in childhood vaccines.

[5] *See* § 11(a)(3).

[6] Michelle's evidence consisted of her medical records, affidavits, written and oral opinions of a toxicologist, an immunologist, a gastroenterologist, a microbiologist, a molecular biologist, a pediatric neurologist, biochemists, and extensive scientific literature in support of these opinions.

[7] During the years 2002 through 2006, the OAP was managed by Special Master George L. Hastings, Jr. On January 11, 2007, however, the chief special master assigned two (2) additional special masters, Denise K. Vowell and Patricia E. Campbell-Smith, to assist Special Master Hastings. Subsequently, over Michelle's objection, the Panel decided it would hear and consider, as a group, all of the evidence in Michelle's case, but that only Special Master Hastings would write the decision. *See* OAP Autism Update, January 19, 2007.

[8] Thimerosal "is an organomercury compound (approximately 49% mercury by weight) used as an antiseptic and antifungal agent." WIKIPEDIA HOME PAGE, http://en.wikipedia.org/wiki/Thimerosal.

to clear the vaccine-strain measles virus ("MV") contained in the MMR vaccine due to her immune deficiency; (7) the MV persisted and replicated[9] in Michelle; (8) the MV caused her to suffer inflammatory bowel disease ("IBD"); and (9) the MV entered her brain, causing inflammation and autism.[10]

In response, the respondent presented the opinions of seventeen (17!) expert witnesses, all of whom denied that vaccines can cause autism.[11] Michelle, however, relies on the substantial concessions made by the respondent's experts and on circumstantial evidence contained in the hundreds of scientific

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[9] Replication: "Autoreproduction or duplication, as in mitosis or cellular biology." STEDMAN'S ELECTRONIC MEDICAL DICTIONARY (Lippincott Williams & Wilkens, 27th ed. CD-ROM, 2000), or *available at* http://www.stedmans.com/section.cfm/45.

[10] Simply put, it was Michelle's burden to show that the MMR vaccine harmed her. However, it was hoped that a decision in Michelle's case would have wide application to those other autistic children in the OAP. For this reason, Michelle chose a theory that implicated the thimerosal-containing vaccines ("TCV") as well as the MMR vaccine, which does not contain thimerosal. She alleged, credibly, that TCVs damaged her immune system. This, in turn, prevented her immune system from clearing the injected measles virus and allowed it to persist, replicate, and cause her IBD and autism. To meet her burden, Michelle did not need to prove that the TCVs harmed her. She needed only to show that her MMR vaccine harmed her. In this regard, as the Court of Federal Claims has noted, petitioners "are merely required to show that the vaccine in question caused them injury. . ." *Kelley v. Sec'y of HHS*, 68 Fed.Cl. 84, 100 (USCFC 2005). Michelle was also not required to show the precise mechanism of injury. *Knudsen by Knudsen v. Sec'y of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). She needed only to show a plausible medical theory, an appropriate temporal relationship between the vaccine and the injury, and the absence of a more likely cause of her injury. *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

[11] At a minimum, the respondent retained the following seventeen (17) experts: Dr. Jeffrey Brent, Dr. Edwin Cook, Dr. Eric Fombonne, Dr. Robert Fujinami, Dr. Michael Gershon, Dr. Diane Griffin, Dr. Stephen Hanauer, Dr. Christine McCusker, Dr. Brian Ward, Dr. Max Wiznitzer, Dr. Andrew Zimmerman, Dr. Stephen Bustin, Dr. Robert Rust (*Hazlehurst*), Dr. Thomas MacDonald (*Hazlehurst*), Dr. Michael McCabe (*Snyder*), Dr. Burton Zweiman (*Snyder*), and Dr. Bertus Rima (*Snyder*). Drs. Brent, Fombonne, Gershon, Griffin, Hanauer,

articles filed by the respondent. On February 12, 2009, a decade after she filed, Special Master Hastings dismissed her petition. In so doing, he "concluded that the evidence was overwhelmingly contrary to [Michelle's] contentions." *Cedillo v. Sec'y of HHS,* No. 98-916V (Spec. Mstr. February 12, 2009, page 2) ("Dec. ___.").

Michelle respectfully asks this Court to review this decision. She does so, first, because she has submitted preponderant evidence that her MMR vaccine harmed her. She also does so because the special master purposely turned a blind eye on her evidence, especially the substantial concessions by the respondent's expert witnesses. She does so because the special master abandoned his obligation to impartially weigh the evidence. She does so because, instead, the special master inappropriately assumed the respondent's role as protector of the integrity of vaccines. She does so because the special master has defied congress and the Federal Circuit. She does so because she has been denied the fundamental fairness compelled by Rule 7 of the Vaccines of the United States Court of Federal Claims. She does so because the special master abused his discretion, was arbitrary, capricious, and has issued a decision that is not in accordance with law.

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ward, Bustin, Rust, MacDonald, McCabe, and Rima have also received

II. CONGRESSIONAL INTENT

It is worth repeating congress' "principal findings" that required the establishment of the Vaccine Program in 1986. They were:

> 1. [t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities;
>
> 2. [t]he Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries; [and]
>
> 3. [p]rivate or non-governmental activities have proven inadequate in achieving either of these goals. . . .

H.R. Rep. No. 99-908, 99th Cong., 2d. Sess., page 5 (1986).

In sum, congress stated: "Thus, two overriding concerns have led to the development of this legislation:

> (a) the inadequacy--from both the perspective of vaccine-injured persons as well as vaccine manufacturers--of the current approach to compensating those who have been damaged by a vaccine; and
>
> (b) the instability and unpredictability of the childhood vaccine market. . . ."

Id. at 7.

To address these concerns, the Vaccine Program was established. Congress hoped the Vaccine Program would lessen the number of lawsuits against manufacturers. In so doing, it

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compensation from vaccine manufacturers for their services.

hoped the Vaccine Program would promote the "development of both new and improved vaccines. . . ." *Id*. at 4. It also hoped it would help to create "a new system for compensating individuals who have been injured by immunizations routinely administered." *Id*. at 3. Such awards, congress intended, would "be made to vaccine-injured persons quickly, easily, and with certainty and generosity." *Id*. at 18.

Prior to enacting the Vaccine Act, congress also recognized the uncertainty of the existing science about whether vaccines were even capable of causing serious injuries. However, congress realized, this "uncertainty" of the science did not stop civil lawsuits against vaccine-manufacturers. At the same time, congress was loath to pre-empt all rights to file civil litigation against vaccine manufacturers. For this reason, congress balanced these competing interests and established a standard of proof in the Vaccine Program that would allow meritorious causation cases to be resolved in the Vaccine Program. Thus, an excerpt from the legislative history of § 13:[12]

> The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide

[12] Section 13 of the Vaccine Act governs the standard of proof for non-Table injuries, including the injuries alleged by all claimants in the OAP.

> compensation to some children whose illness is not, in fact, vaccine-related.[13]

Shyface v. Sec'y of HHS, 165 F.3d 1344, 1351 (Fed. Cir. 1999) (citing H.R. Rep. No. 99-908 at 18).

III. FEDERAL CIRCUIT DECISIONS THAT INTERPRET THE VACCINE ACT

Several Federal Circuit opinions address the sufficiency of evidence necessary to prove a Vaccine Program claim. In *Knudsen by Knudsen v. Sec'y of HHS*, the Court defined the special master's role as:

> ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain. . . .Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and the nature of the vaccine compensation program. The Vaccine Act does not contemplate full-blown tort litigation in the Court of Federal Claims. The Vaccine Act established a 'compensation program' under which awards are to be 'made to vaccine injured persons quickly, easily, and with certainty and generosity.' House Report 99-908, *supra* at 3, 1986 U.S.C.C.A.N.at 6344. The program is supposed to be 'fair, simple, and easy to administer.' *Id*. at 7, 1986 U.S.C.C.A.N. at 6348.

35 F.3d 543, 549 (Fed. Cir. 1994).

In *Althen v. Sec'y of HHS*, the Court described a petitioner's burden as simply providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

[13] Due to this stated congressional intent, courts have held that "close questions of causation must be resolved in favor of the petitioners." *McClendon v. Sec'y of HHS*, 24 Cl.Ct. 329, 334 (USCFC 1991); s*ee also Althen v. Sec'y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." 418 F.3d at 1278 (Fed. Cir. 2005). Commenting on the quantity and quality of proof necessary, consistent with *Knudsen,* the Court stated: "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof [as to] how vaccines affect the human body." *Id*. at 1280. Indeed, the Court said, due to the very absence of direct scientific evidence in this field, Congress encouraged "the use of circumstantial evidence" and envisioned that "close calls regarding causation [would be] resolved in favor of injured claimants." *Id*.

In *Capizzano v. Sec'y of HHS*, the Federal Circuit once again commented upon the nature, quality, and quantity of proof necessary for a petitioner to be compensated under § 300aa-13. 440 F.3d 1317 (Fed. Cir. 2006). Reversing a special master's dismissal of a claim, the Federal Circuit ruled that he had "impermissibly" raised the petitioner's "burden under the Vaccine Act" by denying her the ability to prove her case with "'the use of circumstantial evidence [as] envisioned by the preponderance standard' (citing *Althen v. Sec'y of HHS*, 418 F.3d at 1280)." *Id*. at 1325. Next, the Court rejected the respondent's argument that proof of "a logical sequence" between the vaccine and the injury required solid scientific evidence.

Id. In this regard, the Court said, "'a logical sequence of cause and effect' means what it sounds like - the claimant's theory of cause and effect must be logical." *Id*. at 1326. *Capizzano* also commented on the evidentiary value of the recorded statements of a petitioner's treating physicians. In this regard, the Court determined:

> *Althen III* explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.' 418 F.3d at 1280; *see also* 42 USC §300aa-13(a)(1).

440 F.3d at 1326.

IV. VACCINE PROGRAM DECISIONS

A. Introduction

During the past decade, the publicity afforded the issue of whether vaccines can cause autism has been intense. In Michelle's view, due to this publicity, both the respondent and the special master feared that a finding in her favor would drive down immunization rates. For this reason, to protect the integrity of vaccines, Michelle's case, a so-called "test" case, was treated far differently than other vaccine program petitioners. First, in 2001, the respondent was prepared to defend against Michelle's claim with only one expert. By 2007, however, after thousands of other autistic children had filed claims, and after years of intense public controversy over the

vaccine/autism connection, the respondent was permitted to present the opinions of *seventeen* experts to defeat Michelle's claim. In so doing, the special master treated Michelle far differently than other petitioners. In addition, disregarding the Federal Circuit's recent decisions in *Althen* and *Capizzano*, the special master instead invoked *Daubert*[14] and found all of Michelle's evidence unreliable. For him to do so, Michelle submits, was fundamentally unfair. She was entitled to equal treatment.

There is no direct scientific proof, Michelle concedes, that vaccines cause autism. As the Federal Circuit noted in *Althen*, the field is "bereft" of science in this area. 418 F.3d at 1278. However, she also submits, substantial *circumstantial* evidence, albeit indirect evidence, supports such a link. Indeed, Michelle says, similar circumstantial evidence, preponderant evidence, consisting of the statements of treating physicians in medical records, expert opinions, scientific literature, and concessions by the respondent's experts, has been sufficient to support compensating a wide variety of injuries in the Program. In this regard, Michelle is sure, each of the respondent's seventeen experts in her case would deny that vaccines are capable of causing any of the below-cited injuries. There is simply no scientific proof. None of these

[14] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

cases would survive a *Daubert* motion in a civil court. However, Michelle submits, all of the below petitioners were compensated in the Vaccine Program because of the Program's relaxed standards of proof. All were compensated because they, like she, presented preponderant evidence, legally sufficient evidence, that a vaccine injured them.

B. Past Vaccine Program Cases

Medical records, affidavits, expert testimony, and scientific articles, all based on circumstantial evidence alone, have established that vaccines have caused:

- Optic neuritis and acute-disseminated encephalomyelitis caused by tetanus vaccine;[15]
- Multiple sclerosis ("MS") caused by tetanus vaccine;[16]
- MS due to hepatitis B ("hep B") vaccine;[17]
- Transverse myelitis due to hep B vaccine;[18]
- Guillain-Barré Syndrome ("GBS") due to hep B vaccine;[19]
- Chronic inflammatory demyelinating polyneuropathy ("CIDP") due to hep B vaccine;[20]

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[15] *Althen v. Sec'y of HHS*, 418 F.3d 1274 (Fed. Cir. 2005).

[16] *Rogers v. Sec'y of HHS*, No. 94-89V (USCFC 2000).

[17] *Werderitsh v. Sec'y of HHS*, No. 99-310V, 2006 WL 1672884 (USCFC 2006).

[18] *Stevens v. Sec'y of HHS*, No. 99-594V, 2006 WL 659525 (USCFC 2006).

[19] *Peugh v. Sec'y of HHS*, No. 99-638V (USCFC Order dated April 21, 2006).

[20] *Gilbert v. Sec'y of HHS*, No. 04-455V, 2006 WL 1006612 (USCFC 2006).

- CIDP due to tetanus vaccine;[21]
- Intractable seizures due to DPT vaccine[22] and DTaP vaccine;[23]
- Death due to DPT Vaccine;[24]
- Scarring due to DPT;[25]
- Hemolytic anemia due to DPT;[26]
- Transverse myelitis due to DTaP.[27]

In one case relevant to Michelle, a special master determined that a DPT triggered familial hemophagocytic lymphohistiocytosis ("FLH"), an inherited immune deficiency.[28]

The MMR vaccine, special masters have found, was the legal cause of the following off-Table *neurological injuries*:

- Acute disseminating encephalomyelitis ("ADEM");[29]
- Transverse myelitis with resulting paraplegia;[30]
- Transverse myelitis;[31]

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[21] *Kelley v. Sec'y of HHS*, 68 Fed.Cl. 84 (USCFC 2005).

[22] *Andrews v. Sec'y of HHS*, 33 Fed.Cl. 767 (USCFC 1995).

[23] *Paulmino v. Sec'y of HHS*, No. 03-2190 (USCFC 2006).

[24] *Shyface v. Sec'y of HHS*, 165 F.3d 1344 (Fed. Cir. 1999).

[25] *Blankenship v. Sec'y of HHS*, No. 01-273V (USCFC 2002).

[26] *Brown v. Sec'y of HHS*, No. 99-044V, 2000 WL 1207255 (USCFC 2000).

[27] *Herkert v. Sec'y of HHS*, No. 97-518V, 2000 WL 141263 (USCFC 2000).

[28] *Gall v. Sec'y of HHS*, No. 91-1642V, 1999 WL 1179611 (USCFC 1996).

[29] *Tufo v. Sec'y of HHS*, No. 98-108V, 2001 WL 286911 (USCFC 2001).

[30] *Lodge v. Sec'y of HHS*, 92-697V, 1994 WL 34609 (USCFC 1994).

- GBS;[32]
- Seizure disorder;[33]
- Attention deficit disorder, encephalopathy, learning disabilities, and behavioral problems;[34]
- Mental retardation in a child who became autistic;[35]
- ADEM and resulting Pervasive Developmental Delay/Not Otherwise Specified ("PDD/NOS");[36]
- Autistic-like symptoms in a child with an underlying mitochondrial disorder;[37]

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[31] *Rodriguez v. Sec'y of HHS*, 67 Fed.Cl. 409 (USCFC 2005).

[32] *Tufo v. Sec'y of HHS,* No. 98-108V, 2001 WL 286911 (USCFC 2001).

[33] *Freeman v. Sec'y of HHS*, 01-390V, 2003 WL 22424999 (USCFC 2003).

[33] *Blanks v. Sec'y of HHS*, 91-0428V (USCFC 1997)(approved stipulation agreement).

[35] *Freeman v. Sec'y of HHS*, 01-390V, 2003 WL 22424999 (USCFC 2003).

[36] *Banks v. Sec'y of HHS*, No. 02-738V, 2007 WL 2296047 (USCFC 2007). In *Banks*, the special master ruled that PDD/NOS, unlike Pervasive Developmental Delay ("PDD") is not a condition on the autism spectrum. Instead, citing the Yale Child Study Center's Developmental Disabilities Clinic Webpage at http://www.med.yale.edu/chldstdy/autism/pddnos.html, he ruled, PDD/NOS is a condition in which some, but not all, features of autism are identified. It is referred to as "atypical autism." The condition encompasses "cases where there is marked impairment of social interaction, communication, and/or stereotyped behavior patterns or interests, but when full features of autism. . .are not met." *Id*. at 2, n. 4.

[37] In *Poling ex. rel. Poling v. Sec'y of HHS*, No. 02-1466V, 2008 WL 1883059 (USCFC 2008), the respondent reportedly agreed to compensate Hannah Poling, a child with an underlying mitochondrial disorder, because vaccines caused her autism. *See Vaccine Case Draws New Attention to Autism Debate*, located at: http://www.cnn.com/2008/HEALTH/conditions/03/06/vaccines.autism/. Although the Poling family has sought to make the details of the government's concession available to the public, especially to the thousands of autistic children in the OAP, the respondent has fiercely resisted the family's effort. *See Poling* Motion for Complete Transparency, March 4, 2008; Respondent's Response to Motion on March 21, 2008; Petitioner's Reply of

- Significant aggravation of an underlying, perhaps genetic, encephalopathy.[38]

In each of the above cases,[39] as in Michelle's case, the respondent's experts flatly denied that a vaccine was capable of causing the injury.[40] Certainly, Michelle agrees, there is no "general acceptance" in the medical community that vaccines can cause any one of the above-compensated injuries. Indeed, Michelle concedes, there is no direct or even persuasive scientific proof that any of these injuries were caused by a vaccine. However, each petitioner was successful. Like Michelle, each offered circumstantial, indirect evidence. Each offered preponderant circumstantial evidence. In Michelle's

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March 24, 2008; Respondent's Reply of April 2, 2008; Petitioner's Reply of April 8, 2008; and the special master's Order of April 10, 2008 deferring ruling on Motion for Complete Transparency. To date, the special master has not ruled on this motion. Michelle has cited the *Poling* case for several reasons. First, the respondent has purportedly conceded, at least in one case, that vaccines *can* cause autism. Second, the *Poling* case highlights the fears of both the respondent and the special masters on Michelle's Panel that releasing such information will undermine the integrity of vaccines, lower immunization rates, and cause preventable illnesses to return. Finally, the *Poling* special master's unprecedented refusal to release such government information evidences the **Panel's** overriding objective – to protect the integrity of the vaccines - and explains why Michelle was denied the fundamental fairness granted to other petitioners.

[38] *Wilkerson v. Sec'y of HHS*, 90-0822V, 1998 WL 106132 (USCFC 1998); *Zeller ex. rel. Zeller v. Sec'y of HHS*, No. 06-120V, 2008 WL 3845155 (USCFC 2008).

[39] Except in *Blanks v. Sec'y of HHS*, 91-0428V (USCFC 1997), where the parties entered into an approved court stipulation agreement.

[40] Indeed, Michelle once again states, in all likelihood, none of these petitioners would have survived a *Daubert* hearing in the civil arena. *Daubert* interprets the Federal Rules of Evidence, rules that do not apply, for policy considerations, in the Vaccine Program. *See* Vaccine Rules of the United States Court of Federal Claims, Rule 8(c).

view, each successful petitioner offered evidence similar to her evidence. She was well; she received a MMR vaccine; she suffered symptoms of a brain injury at a medically appropriate time thereafter; her treating physicians suspected that her MMR vaccine caused this injury; and no other likely cause of her injury has been identified.

In each of the above cases, the sufficiency of evidence was viewed by the special masters in the context of the precise words of the statute, that a petitioner sustained "any illness, disability, injury or condition not set forth in the Vaccine Injury Table" [§ 11(c)(1)(C)(ii)(I)], that he or she "has demonstrated by a preponderance of the evidence" that such injury was due to the vaccine [§ 13(a)(1)(A)], and that there "is not a preponderance of the evidence that the. . .injury . . .is due to factors unrelated to the. . .vaccine." § 13(a)(1)(B).

Due to the extraordinary publicity in her case, Michelle submits, she was not afforded the "fundamental fairness" required by the Vaccine Rules. Instead, she was sacrificed to protect the integrity of vaccines.

V. FACTS

The special master, once again, "concluded that the evidence was overwhelmingly contrary to [Michelle's] contentions." Dec. 2. He based his conclusion upon the

opinions of the respondent's seventeen (17) paid experts, none of whom ever examined Michelle. He based them on opinions offered more than eleven (11) years after her injury. In so doing, he rejected the objective opinions of Michelle's treating physicians who contemporaneously observed the changes in her health after the MMR vaccine. Michelle's MMR vaccine was administered on December 20, 1995 at the age of 15 months, 20 days. An examination of the facts during the early post-vaccination period, including the pre-filing period, is instructive.

Michelle was healthy when born on August 30, 1994. Petitioners' Exhibit 22, p. 21 ("Pet. Ex. ___, p. ___."); Pet. Ex. 28, p. 261. Michelle received an MMR vaccine on December 20, 1995. Pet. Ex. 50, p. 1. At that time, she had a good appetite and slept well. Pet. Ex. 8, p. 2; Pet. Ex. 32, p. 223. No problems were noted. *Id*. Seven days later, however, "[Michelle] developed a fever. . .that would spike up to 105 or over then come back down with Tylenol, and then go back up, come back down." *Cedillo v. Sec'y of HHS,* No. 98-916V Transcript of Proceedings, June 8, 11-15, 18-22, 25-26, 2007, page 227 ("Tr. ___."). Michelle's mother, Theresa, called the pediatrician and was told "a very bad flu [was] going around . . ." Tr. 227. Michelle's high fever returned. The January 6, 1996, pediatric notes stated, "105.7° today. Started with cough yesterday.

Gagging to the point of vomiting. Tylenol at 8:30 am. . . .[Assessment]: sinusitis vs. flu." Pet. Ex. 8, p. 1; Pet. Ex. 28, p. 266; Pet. Ex. 32, p. 222. The note also reports that Michelle "**had fever and rash last week, 1 week after MMR**." *Id*. (emphasis added).

On March 15, 1996, Michelle again was seen by her pediatrician, who stated: "Rash to face & neck [times] 2 ½ weeks. Walking, runs. **Talking less since ill in Jan[uary]**. Seems to hear well. Stools well. . . .Skin - face flushed ____ erythema rash on chin, around nose. [Questionable] staph vs ____. . . ." Pet. Ex. 8, p. 1; Pet. Ex. 28, p. 266; Pet. Ex. 32, p. 222 (emphasis added). At that visit, Michelle received her fourth Hib vaccine and a DTaP vaccine.[41] Pet. Ex. 50, p. 1.

During the subsequent months, Michelle did not improve. On May 2, 1997, at the age of 33 months, Michelle was examined by a neurologist, Dr. William Masland, who wrote:

> [Michelle's] neonatal period was unremarkable. She started crawling about nine months and walking at 16 months. She also was using single words at the time, **at 16 months she developed a fever of 105+, that lasted for four days. This occurred two weeks after immunization. The fever went down, stayed away for a week and then recurred to 104 to 105 degrees for three or four days. Since then she lost her ability to verbalize and has continued with repetitive movement**. When I saw her she was relatively unresponsive to verbal stimuli. . . .**It would appear that there was some neurological harm done at the time of the fevers.**

[41] In all, Michelle received 3 hep B, 3 DPT, 1 DTaP and 4 Hib vaccines, all of which contained thimerosal (i.e. ethylmercury). Pet. Ex. 101, pp. 3-4; Pet. Exs. 95, 97, 50.

> **Whether this was a post-immunization phenomenon or a separate occurrence, would be very difficult to say . . . .Given the overall history, it would appear the neurological problem now is dependent upon the febrile episodes and is not a structural or systemic problem, such as a chromosomal abnormality or one of the inborn errors of metabolism.**

Pet. Ex. 28, p. 207; Pet. Ex. 32, p. 227 (emphasis added).

Two weeks later, on May 20, 1997, Michelle was examined for suspected speech and/or language delay. The report stated:

> **Michelle was said to have reached the major developmental milestones on time up to the age of sixteen months when she received vaccinations for measles, mumps, and rubella. At that time, she suffered two high fevers.** At the time of this evaluation, Michelle was using a few words but her parents did not think Michelle was trying to communicate when she spoke. She was able to imitate voices on the TV and she liked to listen to music. When listening to people speak to her, Michelle wanted people to speak slowly and she watched the speaker's mouth. . . .SUMMARY AND RECOMMENDATIONS:. . . .It was recommended that Michelle continue with any needed speech/language therapy.

Pet. Ex. 6, p. 1 (emphasis added).

On July 21, 1997 Michelle was examined at Phoenix Children's Hospital by Karlsson Roth, Ph.D., a developmental psychologist. Dr. Roth recorded:

> She was discharged home at 24 hours of age, feeding and growing well. She has never had an episode of otitis media. She has been very healthy with the exception of one cold. **This child had a MMR at around 15 months of age, after which she had two separate bouts of high fevers from 103 to 105. This was then followed by a mild fever, after which the youngster began to cut eight teeth at once. This child also has had a rash around her mouth which followed this episode, and the parents got an air purifier and/or**

> **humidifier which seems to have helped. The child took only liquids for three weeks, and it was after this time that they noticed a complete change in her development. . . .Michelle appears to meet criteria for a diagnosis of Autism. . . .**[42]

Pet. Ex. 7, pp. 2-7 (emphasis added).

On August 6, 1997, Michelle's measles titer tested positive. Pet. Ex. 24, pp. 56-57; Pet. Ex. 28, p. 137. That day, Dr. Sudhir Gupta, an immunologist, observed:

> 3 [year old] young girl (1st child) born full term. Normal delivery 8 lbs, normal reflexes. **Developed normal. She received her MMR at 16 month - 2 days later fever of 105° F. No infection was found. This followed by rash on the face and trunk. Then she stopped talking. She became afraid of strangers. . . .** Impression: ? Autism. . . .

Pet. Ex. 3, pp. 1-2 (emphasis added).

The next day, August 7, 1997, Michelle was seen by Dr. Ira Lott, a pediatric neurologist. He wrote:

> **Until about 15 months of age, Michelle was described as entirely normal. At that time she had multiple single words, perhaps as many as 10. She then had an 'MMR immunization' followed by a viral illness with high fever. It was then noted that she had lost her words. . . .**

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[42] Autism: "A mental disorder characterized by severely abnormal development of social interaction and verbal and nonverbal communication skills. Affected individuals may adhere to inflexible, nonfunctional rituals or routine. They may become upset with even trivial changes in their environment. They often have a limited range of interests but may become preoccupied with a narrow range of subjects or activities. They appear unable to understand others' feelings and often have poor eye contact with others. Unpredictable mood swings may occur. Many demonstrate stereotypical motor mannerisms such as hand or finger flapping, body rocking, or dipping. The disorder is probably caused by organically based central nervous system dysfunction, especially in the ability to process social or emotional information or language." STEDMAN'S ELECTRONIC MEDICAL DICTIONARY (Lippincott Williams & Wilkens, 27th ed. CD-ROM, 2000), or *available at* http://www.stedmans.com.

Pet. Ex. 28, pp. 208-209; Pet. Ex. 31, pp. 19-20 (emphasis added).

On October 31, 1997, Dr. Gupta wrote to Michelle's parents:

> [W]e have done the immunological testing that shows that Michelle has almost normal immune functions. I do not see that it is necessary to do any genetic testing at this stage. . .As far as vaccination is concerned, vaccinations can be postponed based on the laboratory data that shows that Michelle has significant amounts of antibodies to various vaccines that she is supposed to get. **Based on that, she could get medical exception to the vaccination requirements of the school system**.

Pet. Ex. 24, p. 36 (emphasis added).

Catherine Brown of the San Diego State University Communications Clinic examined Michelle on May 28, 1998. She stated:

> **Mrs. Cedillo reported that Michelle showed typical development in motor skills and communication skills until about age 17 months. After her measles-mumps-rubella (MMR) vaccination at 17 months Michelle developed a high fever and was ill for some time. Following that incident, Michelle's behavior changed dramatically and communication development has not progressed since that time, according to Mrs. Cedillo. Mr. and Mrs. Cedillo noticed a change in Michelle's behavior beginning a few weeks after her illness following the MMR vaccination. Michelle became less interactive and affectionate with her family, and stopped using words and communicative behavior she previously produced**. . . .***Summary and Conclusions***[:] Michelle demonstrates a severe delay in both language comprehension and language production secondary to moderate-severe autism.

Pet. Ex. 28, pp. 211, 213 (emphasis added).

B.J. Freeman, Ph.D., performed a neuropsychiatry exam on May 13, 1999. The report stated:

> **The parents reported that language development was normal until approximately fifteen months of age. At that time, she received her 'MMR immunization' and soon after evidenced significant delays in language development including loss of single words previously obtained. Motor milestones were also reached within the normal range as Michelle crawled between the ages of six to ten months and walked at fourteen months of age. She does not have a significant history for ear infections, but as discussed she suffered significant infection following immunization. This included a high fever for four days, rashes, and gastrial intestinal distress. . . .**

Pet. Ex. 28, pp. 220, 224; Pet. Ex. 31, pp. 8, 12 (emphasis added).

Dr. Ramon Montes, a pediatric gastroenterologist, examined Michelle on May 22, 2000. He wrote: "Diagnostic impression is symptoms suggestive of possible gastroesophageal reflux disease . . . ." Pet. Ex. 28, p. 246; Pet. Ex. 44, p. 59. On January 31, 2002, Dr. Montes performed an esophagogastroduodenoscopy with biopsy and colonoscopy and ileoscopy with biopsies. Pet. Ex. 28, p. 190; Pet. Ex. 44, p. 13. His medical records noted:

> This is a seven-year-old autistic female with a history of erosive esophagitis and chronic constipation and diarrhea, in whom a followup esophagoscopy and an initial colonoscopy are being performed for diagnostic purposes. . . .POST PROCEDURE DIAGNOSES: 1. Rule out microscopic esophagitis. 2. Rule out lymphonodular hyperplasia of the colon. RECOMMENDATIONS: Wait for biopsy results.

Pet. Ex. 28, pp. 190-191; Pet. Ex. 44, pp. 13-14.

On January 31, 2002, a Unigenetics[43] lab report was **positive for measles virus**. Pet. Ex. 28, p. 179 (emphasis added).

VI. THE SPECIAL MASTER'S DECISION

Michelle, once again, offered the following theory as to how vaccines caused her bowel and brain injuries: (1) she was born healthy; (2) she had normal development and met all milestones; (3) she received all required childhood vaccinations, including 12 vaccines that contained ethyl mercury; (4) the mercury damaged her immune system; (5) the MMR vaccine she received at 15 months further damaged her immune system; (6) she was unable to clear the vaccine-strain MV contained in the MMR vaccine due to her immune deficiency; (7) the MV persisted and replicated in Michelle; (8) the MV caused her to suffer IBD; and (9) the MV entered her brain, causing inflammation and autism.

A hearing was conducted during the period of June 11, 2007 through June 26, 2007 in Washington, D.C. The special master, however, twenty (20) months later, found no evidence that Thimerosal-containing vaccines ("TCVs") can harm an infant's immune system (Dec. 22-34);[44] that, in any event, Michelle's

[43] Unigenetics is also known as "the O'Leary lab."

[44] The special master did agree, however, that proof of this contention is "essentially unnecessary" to Michelle's case. Dec. 21.

immune system was not "substantially abnormal" (Dec. 38; *see also generally* Dec. 35-40); that the O'Leary lab result was not reliable (Dec. 41-77); that even if measles virus was detected by the O'Leary lab, there is no proof it was vaccine-strain measles (Dec. 72); that there is no evidence that the MMR vaccine can cause autism or did cause Michelle's autism (Dec. 86); that autism is genetic "and the only non-genetic factors. . .are factors that influence development during the *early prenatal* period" (Dec. 88) (emphasis in original); that Michelle had "symptoms of autism *prior* to her MMR vaccination" (Dec. 127) (emphasis in original); that Michelle "did *not* experience an abrupt onset of autism symptoms shortly after her MMR vaccination" (Dec. 127) (emphasis in original); that epidemiology rejects the theory that the MMR vaccine can cause autism (Dec. 88); that Michelle "*failed completely*" to show MMR vaccine can cause autism (Dec. 126) (emphasis in original); that it is "*extremely unlikely* that the MMR vaccine can contribute to the causation of autism" (Dec. 126) (emphasis in original); that the MMR vaccine did not significantly aggravate an underlying condition (Dec. 134, n. 170);[45] that the MMR vaccine does not cause "chronic gastrointestinal dysfunction" (Dec. 140); that there is no evidence that Michelle has suffered "from any form

[45] The Vaccine Act provides for compensation if a petitioner shows a vaccine "significantly aggravated" an underlying condition. § 11(c)(1)(C)(ii) and § 33(4).

of chronic intestinal inflammation" (Dec. 146); and that "'autistic enterocolitis'. . .is *not* a medically recognized disease category" (Dec. 142) (emphasis in original).

Then, applying the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[46] the special master determined that none of Michelle's theories were generally accepted by the medical community and dismissed her petition. Dec. 4, 29 at n. 34, 122.[47]

VII. ARGUMENT

A. Introduction

In Michelle's view, the special master ignored Michelle's considerable, albeit circumstantial, evidence that a persisting vaccine-strain measles virus caused her IBD and her autism. Indeed, she submits, the special master even ignored the very substantial *concessions* by the *respondent's* experts tending to support her theories of injury. In Michelle's view, he did so

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[46] 509. U.S. 579 (1993).

[47] Congress intended the Vaccine Program to be a "less-adversarial, expeditious, and informal" alternative to the civil tort arena. § 11(d)(2)(A). For this reason, congress required special masters to use "flexible and informal standards of admissibility of evidence." § 11(d)(2)(B). In *Daubert*, the Supreme Court interpreted Rule 702 of the Federal Rules of Evidence ("FRE"). In the Vaccine Program, however, special masters are not bound by the FRE. Instead, they are required to consider "all relevant and reliable evidence governed by principles of fundamental fairness to the parties." Vaccine Rules of the United States Court of Federal Claims, Rule 8(c). In his decision, the special master noted that one Federal Circuit decision did state that special masters can use the *Daubert* factors to evaluate the reliability of scientific evidence in the Program. *See Terran ex. rel. Terran v. Sec'y of HHS*, 195 F.3d 1302, 1316

because of the intense national publicity her case has received. In Michelle's view, he did so to assure the American public that vaccines are safe. He did so because he views his role as a protector of the integrity of our nation's vaccines. However, Michelle submits, this is the role of the respondent, not a special master.

In an address to the Advisory Commission on Childhood Vaccines ("ACCV") in March of 2008, the U.S. Court of Claims Chief Special Master Gary Golkiewicz recognized that the interplay of various competing policy considerations play a considerable role in defining the Vaccine Program's causation standard. He stated:

> [D]epending on your respective goal, the standard of causation [in the Vaccine Program] could look very different. . . .it's important to understand whether you're promoting a policy based standard of causation or a traditional tort based standard. . .If you believe that the causation standards are correctly tort based, you may take issue with several of the recent Federal Circuit opinions discussing the appropriate causation standard to apply in vaccine cases. . .If you believe the causation standard should be policy based, you have to determine what your primary policy objective is. . . .
>
> We all know from the legislative history, Congressman Waxman, a primary architect of the program, stated at several Congressional hearings, the purpose of the Program is to promote receipt and production of vaccines by protecting manufacturers and administrators from liability, but also to compensate those who suffer a vaccine-related injury.

(Fed. Cir. 1999). The special master weighed Michelle's evidence in this light. Dec. 4.

> However, Congressman Waxman also articulated a competing policy concern. I call it protecting the vaccine's integrity, and that is that vaccine does not cause every injury that follows immunization. There's a tension between these two objectives, a tension that affects dramatically the litigation of the cases, the parties' arguments and ultimately who wins.

In Michelle's view, the special master, to protect vaccine integrity in a very public case, chose to impose upon Michelle an unattainable standard of proof. To protect the vaccine's integrity he rejected **all** of Michelle's credible evidence and blindly accepted the conclusions of the respondent's seventeen experts. In so doing, Michelle submits, the special master shirked his role as an impartial jurist, denied Michelle the fundamental fairness required by the Vaccine Rules, ignored congress' intent in establishing the Vaccine Program, and rejected the Federal Circuit's interpretation of that intent. For him to have done so was arbitrary and capricious, an abuse of his discretion, and not in accordance with law.

B. Numbered Objections

1. The Use of a Panel of Three Special Masters to Hear the "General Causation" Issue in Michelle's Case Was Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance With the Law

On January 9, 2007, the Petitioners' Steering Committee ("PSC") proposed that a "test case" be heard by Special Master George L. Hastings, Jr. *See* OAP Autism Master File, January 9, 2007: Petitioners' Proposed Conduct of General Causation

Hearing and Subsequent Effect of Ruling. In this regard, the PSC relied upon the fact that Special Master Hastings was uniquely qualified to hear such a case. He not only had served as a special master since the inception of the Program, he also had presided over a number of similar test cases that had the effect of resolving hundreds of cases.[48] Two days later, on January 11, 2007, the chief special master assigned two new, recently appointed special masters, Special Master Vowell and Special Master Campbell-Smith, to assist Special Master Hastings with the autism docket. *See* OAP Autism Master File, January 11, 2007: Notice Regarding Reassignment. In this regard, the chief special master stated, "the docket, which to-date has been overseen by Special Master George Hastings, will be divided roughly in equal numbers and assigned to the three special masters for further proceedings." *Id*. The chief special master further stated:

> With three special masters hearing and deciding the test cases, the OSM is confident that the special masters' decisions discussing the legal and medical issues will educate fully the Federal Circuit. . .to issue opinions that guide the special masters in the resolution of the remaining cases.

Id. at 2.

[48] For example, Special Master Hastings presided over the rubella/arthropathy omnibus hearing that resolved in excess of 100 cases. *See* Analysis of Recent Evidence Concerning general Rubella/Arthropathy Issue, December 13, 2002.

One week later, the Panel, including Special Masters Hastings, Vowell and Campbell-Smith announced that they would consider, *as a group*, the "general causation evidence" in Michelle's case,[49] but that Special Master Hastings would consider the case-specific evidence alone and make an independent decision as to whether Michelle is entitled to compensation. OAP Autism Master File, January 19, 2007, page 7. The PSC repeatedly objected to the appointment of the two additional special masters, stating that "multiple decisions by multiple Special Masters addressing nearly identical issues of law, fact, science and medicine. . .will generate significant confusion and delay at the appellate level, further slowing progress towards resolving claims in the omnibus." OAP Autism Master File, PSC Reply Brief, February 26, 2007, page 2.

Having now reviewed the decision of the special master in her case, as well as the decisions of the special masters in *Hazlehurst*[50] and *Snyder*,[51] Michelle submits that she had the burden of persuading not one but **three** special masters that her MMR vaccine can cause autism. No other petitioner in the

[49] At that time, Michelle's case had been selected as the first "test" case to be heard beginning on June 11, 2007. OAP Autism Master File, January 19, 2007, page 7.

[50] *Hazlehurst v. Sec'y of HHS*, No. 03-654V, (Spec. Mstr. Vowell: February 12, 2009).

[51] *Snyder v. Sec'y of HHS*, No. 01-162V, (Spec. Mstr. Campbell-Smith: February 12, 2009).

Program's History has been saddled with such a burden. It violates the "fundamental fairness" requirement of Vaccine Rule 8. For this reason, the special masters' decision to permit Special Masters Hastings, Vowell, and Campbell-Smith, as a panel, to hear the "general causation" evidence in Michelle's individual case was arbitrary, capricious, an abuse of the special masters' discretion, and not in accordance with law.

2. The Special Masters' Decision to Allow the Last-Minute Expert Reports and Testimony of Dr. Stephen Bustin Was Arbitrary, Capricious, and an Abuse of Their Discretion

Michelle's hearing was scheduled to begin on June 11, 2007. On the eve of trial, as Michelle was preparing for the direct testimony of her four (4) expert witnesses, as well as for cross-examination of the respondent's twelve (12) experts, the respondent filed three more expert reports, all prepared by Dr. Stephen Bustin. First, the respondent filed Respondent's Exhibit UU on May 31, 2007. This was a simple twelve (12) page report. Then, on June 7, 2007, the respondent filed two more reports. *See* Respondent's Exhibits XX and WW. These exhibits were vastly different from Respondent's Exhibit UU.

A paid expert for the vaccine manufacturers in the United Kingdom, Dr. Stephen Bustin had prepared Respondent's Exhibit XX on June 30, 2003 and Respondent's Exhibit WW on November 20, 2004. These reports, however, had been sealed by a United

Kingdom ("UK") court. Michelle invites the Court to review Respondent's Exhibit XX, a highly technical sixty-one (61) page scientific document, and Respondent's Exhibit WW, a highly technical sixty-two (62) page document, and Respondent's Trial Exhibit 13, Dr. Bustin's impossibly technical power-point presentation at the hearing.[52] Prior to the hearing, at a recorded status conference on Friday, June 8, 2007, Michelle's counsel angrily opposed the introduction of these exhibits. First, she argued, the reports addressed the reliability of the O'Leary lab, the single-most critical issue in the case. Next, they were filed without notice, on the eve of trial. Next, to permit these reports into evidence at that time was grossly unfair to Michelle, leaving her counsel no time to review the documents, let alone prepare for cross-examination. Clearly, Michelle's counsel needed more time to digest the contents of the 123-page highly technical reports.

The fact that Michelle was permitted to file supplemental post-hearing reports does not cure the inability to conduct an adequate cross-examination *ab initio*. In addition, the fact Michelle was given time to find UK counsel to seek to unseal other documents does not cure the prejudice. The playing field was not even. The respondent, for example, had unlimited

[52] To demonstrate the complexity of this material, Dr. Bustin asked Special Master Hastings at the hearing whether he understood the testimony. Special Master Hastings said "no." Tr. 2062.

financial resources, the full assistance of attorneys with the Department of Justice who could counsel them to obtain extra territorial documents, the consent of the vaccine manufacturers, and the ability to hire UK attorneys to unseal the Bustin reports. Even so, it took the respondent more than four (4) months to have a single UK expert report released. Even with all these resources, the first report was not emailed until Friday evening, less than seventy-two (72) hours before opening arguments.

In his reports, Dr. Bustin stated that during the UK litigation he had the opportunity to examine the O'Leary lab notebooks. In this regard, it is now clear that the laboratory notebooks formed the basis for the opinions of the three UK experts whose reports the Department of Justice eventually was successful in unsealing. *See also* Reports of Dr. Bertus Rima and Dr. Peter Simmonds, filed in *Snyder*. Since the laboratory notebooks have never been unsealed, one must question whether Dr. Bustin violated the UK statute by reproducing information contained within those notebooks, and whether Dr. Rima could testify about what he claims was a problem with the high copy numbers.

3. The Special Master Abused His Discretion By Discounting the Opinions of Michelle's Treating Physicians

Michelle's medical records demonstrate (1) she was born healthy; (2) she developed normally; (3) she received twelve (12) thimerosal-containing vaccines; (4) she then received an MMR vaccine; (5) the vaccine-strain measles virus persisted and replicated in her body; (6) she suffers from a gastrointestinal disorder and symptoms on the autism spectrum; and (7) no cause, other than Michelle's vaccines, has been identified for her gastrointestinal or autism symptoms. Michelle's medical records also demonstrate that several of her treating physicians associated her illness with her MMR vaccine. These physicians include: (1) Dr. Daniel Crawford her pediatrician (Pet. Ex. 8, p. 2); (2) Dr. William Masland, a neurologist (Pet. Ex. 28, p. 207); (3) Dr. Lisa Shigio, an audiologist (Pet. Ex. 6, p. 1); (4) Karlsson Roth, a developmental psychologist (Pet. Ex. 7, p. 8); (5) Dr. Sudhir Gupta, an immunologist (Pet. Ex. 3, p. 17); (6) Dr. Ira Lott, a pediatric neurologist (Pet. Ex. 31, p. 20); and (7) Dr. B.J. Freeman, a neuropsychologist (Pet. Ex. 31, p. 2).

The special master affords these records absolutely no probative value. In this regard, Michelle concedes that these doctors did not conclude that Michelle's MMR vaccine had caused

her autism. However, they should have been afforded significant probative weight. *Capizzano v. Sec'y of HHS*, 440 F.3d at 1326. The special master abused his discretion by affording no weight to the statements of treating physicians in Michelle's medical records.

4. The Special Master Abused His Discretion By Ignoring Concessions By the Respondent's Expert Witnesses

a. Introduction

In the end, the respondent used seventeen (17) experts to attack Michelle's theories of causation. Although Michelle did object to the gross unfairness of permitting the highly prejudicial, last-minute, technical materials submitted by Dr. Bustin, she did not - and does not - object to the number of presentations of the many highly qualified scientists retained by the respondent. Indeed, Michelle's trial strategy was to meet her burden of proof based on the opinions of the respondent's experts *alone*. In this regard, Michelle says, in general, experts for the respondent are honest scientists who strongly disagree with the conclusions of the petitioners' experts. This is because there is no direct scientific proof that vaccines can cause any serious injury. In the Vaccine Program, however, a petitioner is not required to show direct proof. A petitioner is only required to show *legal* proof – a preponderance of *circumstantial* evidence. For this reason,

Michelle welcomed the opportunity to cross-examine the respondent's experts, who invariably conceded important aspects of Michelle's case. The special master, however, relied solely upon the number of the respondent's experts, their obvious qualifications, and their *conclusions* to find against Michelle.[53] However, in so doing, the special master chose to ignore the many concessions of the respondent's experts that supported Michelle's case. In this case, apparently, the special master found the respondent's experts' conclusions *reliable*, but their concessions *unreliable*. For him to have done so was arbitrary, capricious, and an abuse of his discretion,

b. Dr. Stephen Hanauer's Concessions

Michelle alleges that the persisting vaccine-strain measles virus from her MMR caused her to suffer IBD. The special master, however, determined that she does not suffer from this condition. Dr. Stephen Hanauer,[54] however, the respondent's

[53] In this regard, Michelle points out, the Supreme Court has stated with respect to expert testimony, it is the "methodology underlying the testimony" that must be "scientifically valid. . . ." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. at 592-593. Thus, "[t]he inquiry envisioned . . .is, we emphasize, a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission. . . .not on the conclusions that they generate." *Id*. at 594-595.

[54] Dr. Hanauer has testified in 50 medical malpractice and toxic tort cases. Tr. 2179. He has served as consultant for a pharmaceutical company, Centocor, Inc. Tr. 2181. He has received grants from Asahi, Centocor, Elan, Genetech, Otsuka, Protein Design Labs, Prometheus, Targicept, and Therakos. He has also served as a consultant to Abbott labs, Amgen, Asahi, USB Pharma or Celltec, Centocor, Elan, Genetech, GlaxoSmithKline, Novartus, Otsuka,

expert gastroenterologist, provided significant support for Michelle's argument. While denying that Michelle has IBD, he reluctantly conceded that she has significant bowel symptoms. Tr. 2143, 2144. He also agreed that Michelle has aphthous ulcers, which can evolve into IBD, specifically Crohn's disease, and that the ulcers are often the first sign of Crohn's disease. Tr. 2125-2126. Dr. Hanauer also agreed that Michelle has elevated OmpC and that OmpC is elevated in 60% of Crohn's patients. Tr. 2131. He agreed that diarrhea frequently occurs after measles vaccine. Tr. 2145. He agreed that Michelle's lower abdominal symptoms persisted after her measles vaccine. Tr. 2154-2155.

Dr. Hanauer testified that IBD, a chronic condition, is caused by both genes and environmental triggers. Tr. 2164. However, he denied that viruses can cause chronic gastrointestinal disease. Tr. 2161. Dr. Hanauer, however, was confronted with the following statement from his own 2006 article,

> [r]egardless of the underlying genetic predisposition, a growing body of data implicates a dysfunctional mucosal immune response to commensal bacteria in the pathogenesis of IBD, especially [Crohn's disease]. Possible triggers include a chronic inflammatory response precipitated by infection with a particular pathogen or virus.

Protein Design Labs, Targicept, Teva and Therakos. Tr. 2183; *see also* Petitioners' Trial Exhibits 12 and 13.

Petitioners' Trial Exhibit 10, page 1. At that point, Dr. Hanauer conceded that the ability of a virus to trigger a chronic inflammatory response is "the hypothesis we are currently working on." Tr. 2165.

Dr. Hanauer also conceded:

> In particular, it's difficult to discriminate ulcerative colitis from other forms of colitis including Crohn's disease, and there seems to be a growing overlap of pathophysiologic processes between ulcerative colitis and post-infectious irritable bowel syndrome. . . .Patients who remain indeterminate between ulcerative colitis and Crohn's disease also continue to be a diagnostic challenge.

Tr. 2168-2169; Petitioners' Trial Exhibit 11, page 1.

Dr. Hanauer also conceded that Michelle suffers from arthritis and eye problems, both of which, he agreed, are associated with IBD. Tr. 2173. He also conceded that Michelle's present gastroenterologist, Dr. Ziring, treats Michelle with Humira, a medication used for IBD. Tr. 2178; *see also* Petitioners' Trial Exhibit 14, Humira prescription for "Crohn's Disease."

c. <u>Dr. Diane Griffin's Concessions</u>

Dr. Diane Griffin, an immunologist and virologist, conceded that measles is one of the most infectious of all viral diseases. Respondent's Exhibit V, page 2. She conceded, a "target organ" of the measles virus is the gastrointestinal tract. *Id*. In addition, she has observed, even the attenuated

measles vaccine can cause progressive fatal respiratory disease or neurological disease in immunocompromised individuals. Respondent's Exhibit V, page 10. She agreed that measles virus affects many components of the immune system. Tr. 2802. She agreed the measles virus causes immunosuppression that continues for months after the period of viremia. Tr. 2798. She agreed that measles virus skews T cells, and that when Th1 and Th2 are not in balance the body's ability to clear viruses will be impaired. Tr. 2804-2805. She agreed that the measles vaccine, like the wild virus, causes lymphopenia.[55] Tr. 2809. She agreed that "you can definitely identify changes [in antibodies] that are occurring as part of the induction of the immune response to the vaccine." Tr. 2812-2813. She agreed that Michelle's first fever after the MMR vaccine was related to the MMR vaccine. Tr. 2816. She agreed measles can cause neurologic disease. Tr. 2820.

Dr. Griffin also agreed that the risk of viral persistence increases in an immunosuppressed person. Tr. 2821. She agreed that viruses can persist in the human body. Tr. 2820. Indeed, in one of her own studies, Dr. Griffin stated that the presence of a virus' RNA indicated to her that "viral protein may

[55] Lymphopenia: "A reduction, relative or absolute, in the number of lymphocytes in the circulating blood." STEDMAN'S ELECTRONIC MEDICAL DICTIONARY (Lippincott Williams & Wilkens, 27th ed. CD-ROM, 2000). Lymphocyte: "A white blood cell formed in lymphatic tissue throughout the body. . . ." *Id*.

continue to be made, providing the impetus for the continued presence of [virus]-specific B cells in the brain." Tyor, Respondent's Exhibit V, Tab 64, page 4016.[56]

Dr. Griffin agreed with the following quote from the literature:

> The three foundations upon which the understanding of persistent infection rests are, first, that the host's immune response. . .fails to purge virus from the infected host. Thus, viral persistence is synonymous with evasion of the host immunologic surveillance system. Recent advances have shed light on the cellular and molecular players involved. Second, viruses can acquire unique components or strategies of replication. That is, viruses can regulate expression of both their own genes and host genes to achieve residence in a non-lytic state within the cells they infect. Third, the type of diseases that persisting viruses cause are often novel and unexpected. . . .The continuous replication of a viral, i.e., foreign gene in a differentiated cell can selectively disorder the functions of that cell without destroying it. [There are] [s]everal examples [of] viruses that interfere with the ability of neurons to make neurotransmitters . . . .The result is a disturbance in the host's biologic equilibrium. Thus, one important direct effect of persistent virus replication is to disorder the normal homeostasis of the host and thereby cause disease without destroying the infected cell.

Oldstone, Pet. Ex. 61, Tab VV, pp. 111-112; Tr. 2844-2846.

Dr. Griffin agreed that the PCR technique used by the O'Leary lab is commonly used to detect viral RNA. Respondent's Exhibit V, page 6.

[56] In her case too, Michelle submits, the presence of measles RNA in her gut tissue suggests that protein is being manufactured and the virus is replicating.

While Dr. Griffin denied that the detection of the measles virus RNA in Michelle's gut tissue implied the presence of the protein necessary for the disease to replicate and persist, or implied the presence of infectious disease in Michelle, Dr. Griffin's opinion is belied by her own literature. In the Permar article (Pet. Ex. 112, Tab L), co-authored by Dr. Griffin, the investigators, using the PCR technique, detected measles RNA in the blood of immunodeficient children long after exposure to the virus. The authors wrote, "***we believe the presence of measles virus RNA represents continued measles virus replication, not simply the persistence of measles virus RNA after cessation of viral replication. This is supported by detection of measles virus RNA from multiple clinical sites***." Permar and Griffin, Pet. Ex. 112, Tab L, p. 535 (emphasis added).

Dr. Griffin has written that a measles vaccine should not be given to an immunosuppressed child. *Snyder* Pet. Ex. 205, p. 439. She agreed at the hearing that evidence of a persisting, replicating measles virus is "an important observation" and "should definitely be followed up" by a physician. Tr. 2285.

d. Dr. Brian Ward's Concessions

Dr. Ward, however, also provided support for Michelle's petition. First, he agreed that wild measles virus causes a skewing towards a Th2 response, which happens to occur during

the period of maximum viremia (1-2 weeks after exposure or immunization). *See* Tr. 1880, lines 9-15. He agreed this skewing of the Th2 response causes immunuosuppression and allows the development of opportunistic infections. Tr. 1889-1890. Dr. Ward agreed that measles vaccine can cause a skewing towards a Th2 response, like wild type measles can. Tr. 1889-1890. Asked if a measles vaccine can presumptively cause the same illnesses as the wild measles virus, Dr. Ward said that opportunistic infections can occur after the wild virus, but denied that this could occur after the measles vaccine.[57] Tr. 1893.

Dr. Ward agreed that the measles virus can persist. Tr. 1921. He also agreed that Dr. Oldstone is one of the most respected virologists in North America. Tr. 1922; *see* Oldstone, Pet. Ex. 61, Tab VV. He agreed that Dr. Oldstone has spent virtually his entire professional career studying viral persistence. Tr. 1922. He agreed that Dr. Oldstone has written many articles on viral persistence, and that a review article involves reviewing the literature and summarizing what is

[57] Indeed, his testimony is in marked contrast to that of his co-expert Dr. McCusker, also from McGill University, who testified in *Tosches v. Sec'y of HHS*, No. 06-192V. In *Tosches*, Dr. McCusker testified that if a wild virus causes a certain adverse reaction, it is presumed that the vaccine-strain can also cause the reaction, and it is reportable as an adverse event to the Canadian version of VAERS. *See* Pet. Ex. 127, Transcript of Proceedings, February 12, 2007; *see also* Pet. Ex. 128: Stratton, *et. al.*, *Adverse Events Associated with Childhood Vaccines Other Than Pertussis and Rubella*, where the Institute of Medicine ("IOM") presumes biologic plausibility between a vaccine and an injury if the wild virus can cause the injury.

present in the literature. Tr. 1922-1923. Dr. Ward agreed the literature states: "'[T]he three foundations upon which the understanding of persistent infection rests are: First, that the host immune response fails to form or fails to purge virus from the infected host. Thus, viral persistence is synonymous with evasion of the host's immunologic surveillance system.'" Tr. 1923-1924. He also agreed that:

> 'Recent advances have shed light on the cellular and molecular players involved. Second, viruses can acquire unique components or strategies of replication; that is, viruses can regulate expression of both their own genes and host genes to achieve residence in a nonlytic state within the cells they infect.'

Tr. 1924-1925.

Dr. Ward agreed that: "'The type of diseases that persisting viruses cause are often novel and unexpected.'" Tr. 1925. He agreed that "'The result is a disturbance in the host's biologic equilibrium. That's one important direct effect of persistent virus replication is to disorder the normal homeostasis of the host and thereby cause disease without destroying the infected cell.'" Tr. 1926-1927.

Finally, Dr. Ward was confronted with Dr. Oldstone's statement that an important direct effect of persistent virus replication might be a "'virally caused neurotransmitter defect of neurons altering cognitive learning and yielding behavioral

disorders.'" Tr. 1927. Asked whether this example sounds like autism, Dr. Ward said he is not an autism expert, but agreed that it would "describe some of the children with ASD." Tr. 1927-1928.

e. Dr. Robert Fujinami's Concessions

The respondent's expert Dr. Robert Fujinami failed to appear at the hearing, thus depriving Michelle of the opportunity to cross-examine him about his report. Nevertheless, Michelle says, Dr. Fujinami provided significant evidence in support of her case. He has known for decades, for example, that **measles** virus can persist in human cells, injure tissues, and cause a potentially damaging autoimmune response. *See* Michael Oldstone and Robert Fujinami, *Virus Persistence and Avoidance of Immune Surveillance: How measles viruses can be induced to persist in cells, escape immune assault, and injure tissues*, 33rd Symposium of the Society for General Microbiology, 185-202 (Mar. 1982), filed as Pet. Ex. 132.

f. The Respondent's Experts' Concessions Concerning the O'Leary Lab

Dr. Bustin's testimony actually supports Michelle's position regarding the reliability of the O'Leary lab. In this regard, at the hearing, Dr. Bustin attempted to show that another laboratory (Dr. Finbar Cotter) in London was unable to replicate the O'Leary lab's results (i.e. detecting measles RNA

in samples) using the O'Leary primers. However, as Dr. Bustin's power point presentation showed, Dr. Cotter's lab *was* able to replicate the O'Leary results using the O'Leary primers for *high copy numbers*. High copy numbers are considered accurate because the detection of RNA occurs at a lower cycle number, in other words, earlier in the experiment, and makes them inherently reliable. Dr. Bustin acknowledged this in his testimony. He also agreed that his dispute was only with the O'Leary lab's low copy numbers (Tr. 2042), and he conceded that Michelle had high copy numbers (Tr. 2061).

Next, in *Snyder*, the respondent introduced a letter from Dr. Michael Oldstone. *Snyder* Respondent's Exhibit AA. In his letter, Dr. Oldstone revealed "[i]n the early 2000s" he reviewed the O'Leary lab's protocols for detecting measles virus with PCR, and found them "to be sound." *Id*. In addition, Dr. Oldstone stated, Dr. O'Leary's test results agreed with his own in 80% of the samples he sent to the O'Leary lab. *Id*. Dr. Oldstone also indicated that there was concordance between the two laboratories on high copy numbers. In other words, the high copy numbers detected by the O'Leary primers were confirmed by the Oldstone laboratory using its primers. Thus, there was

concordance among three separate laboratories for high copy numbers of MV RNA.[58]

Michelle also relies on portions of the testimony of the respondent's expert Dr. Rima. Dr. Rima conceded that the O'Leary lab used allelic discrimination to attempt to distinguish between vaccine-strain and wild measles viruses.[59] *Snyder v. Sec'y of HHS*, No. 01-162V, Transcript of Proceedings, November 5th-9th, 2007, page 855 ("*Snyder* Tr. ___."). Dr. Rima agreed that if measles virus RNA is present, the virus may be replicating. *Snyder* Tr. 911. He agreed that the Uhlmann paper indicated that the O'Leary lab had detected measles protein using immunohistochemistry. *Snyder* Tr. 916. He agreed that the respondent's expert Dr. Griffin, in her 2001 paper,[60] using PCR technology, did find positive measles RNA in samples of immuno-suppressed children taken 60-90 days after exposure to the measles virus. *Snyder* Tr. 912.

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[58] The special master used Dr. Rima's testimony in *Snyder* to reject this argument. In *Snyder*, Dr. Rima testified that the O'Leary lab's copy numbers for Colten Snyder were "[t]oo high to be believed." *See Snyder* Transcript of Proceedings, page 932. Michelle has filed the affidavit of Dr. Ronald Kennedy, who explains that Dr. Rima's opinions in *Snyder* with respect to high copy numbers were based upon a *gross mathematical computation error*. *See* Pet. Ex. 138. Dr. Kennedy then uses Dr. Rima's properly corrected formula to calculate Michelle's copies and concludes that her copies, like those of Colten Snyder, were "very plausible." Pet. Ex. 138, p. 1.

[59] *See* Pet. Ex. 130: O. Shiels, *et al.*, *Development of an 'allelic discrimination' type assay to differentiate between the strain origins of measles virus detected in intestinal tissue of children with ileocolonic lymphonodular hyperplasia and concomitant developmental disorder.*

[60] Pet. Ex. 112, Tab L.

5. The Special Master Abused His Discretion By Simply Ignoring Other Important Aspects of Michelle's Evidence

a. Reliability of the O'Leary Lab Test Results

As Michelle argued in objection 4 above, the special master abused his discretion by ignoring major concessions by Dr. Bustin concerning the reliability of Michelle's O'Leary lab test results. For example, the special master ignored the fact that Dr. Bustin's objections to the O'Leary results involved only those with low copy numbers. Tr. 2045. He ignored Dr. Bustin's testimony that Michelle had high copy numbers and that high copy numbers are considered accurate because they appear with a lower number of cycles. Tr. 2044, 2047.

The special master also ignored evidence that when scientists conduct experiments, controls are run in tandem with the experiments to confirm that the results are reliable and not the result of contamination.[61] Dr. Bustin agreed, for example, that when the positive control is positive and the negative control is negative, then the experiment is considered valid, for it is only when the negative control is positive can contamination be present. Tr. 1939, 1941. Interestingly, despite having access to the O'Leary laboratory notebooks, Dr.

[61] A control would consist of a known positive sample and a known negative sample. If the positive control is negative and/or the negative control is positive, the experiment is invalid. In cases where the negative control is positive, the positive control, which should be negative, reflects contamination.

Bustin could not point to one specific instance where a negative control was positive as evidence that the results of any of the O'Leary lab's low copy numbers was contaminated. Dr. Bustin could point to only **one** page in one O'Leary laboratory notebook that indicated **one** episode of contamination.[62] Tr. 2036. In this regard, as Drs. Ward (Tr. 1841), Bustin (Tr. 2036) and Rima (*Snyder* Tr. 926) all acknowledged, contamination is known to occur in **every** laboratory and every laboratory has procedures in place to eradicate the contamination.

In addition, as the special master stated, the parties agree that replication among laboratories is the recognized method by which scientists validate their results. Dec. 55. The special master here, however, ignored evidence that the Cotter laboratory, as well as the Oldstone laboratory, did replicate the O'Leary lab's results with respect to high copy numbers. In this regard, at the hearing, attempting to discredit the O'Leary lab, Dr. Bustin inadvertently provided support for the O'Leary lab. In his power point presentation at the hearing, Dr. Bustin compared the findings of the O'Leary lab with those of Dr. Cotter, who had attempted to reproduce the O'Leary lab's findings.[63] *See* Respondent's Trial Exhibit 13.

[62] Incredibly, the special master used this testimony to characterize the contamination in the O'Leary lab as "rampant." Dec. 50. However, not one witness ever made such a statement, and there is no evidence in the record to support this preposterous conclusion concerning a critical issue in the case.

Dr. Bustin's presentation demonstrated, however, that the two labs **agreed** with respect to high copy numbers. *See* Respondent's Trial Exhibit 13, page 17. In sample B11, the only "high copy number" sample on the page, each lab detected the measles virus after a low, but similar, number of cycles.

Further evidence of the reliability of the O'Leary lab's high copy numbers was elicited in *Snyder*. Dr. Ronald Kennedy testified that the disagreement between the O'Leary and Oldstone labs was limited to samples with "***low*** copy numbers." *Snyder* Tr. 338 (emphasis added). In this regard, he said, the group of scientists who studied the discrepancies between the labs unanimously concluded that O'Leary's findings with respect to ***high*** copy numbers were absolutely reliable. *Snyder* Tr. 346. In addition, Dr. Kennedy testified, Dr. Cotter, a molecular biologist and PCR expert eventually had replicated the O'Leary laboratory work *with respect to the high copy numbers*. *Snyder* Tr. 347-349.

Dr. Bustin did speculate that contamination might explain the high copy numbers. Respondent's Exhibit XX, page 8. However, Dr. Karin Hepner, who has herself replicated the O'Leary lab's findings, stated that the possibility of contamination of Michelle's sample is highly unlikely. In her opinion, "[t]he high copy number found in Michelle Cedillo's

[63] Michelle, of course, had no access to this allegedly "sealed" evidence.

biopsy sample is simply inconsistent with a spontaneous contamination event." Pet. Ex. 120, p. 6. In addition, as Dr. Hepner indicated, the high measles virus copy number found in Michelle supports the proposition that the virus remains active in her. Pet. Ex. 63, p. 6.

The respondent also argues that the high copy numbers are too high, even "higher than what would occur at the peak of a wild-type measles virus infection." Respondent's Post-Hearing Brief, filed January 11 2008, page 57. However, as Dr. Kennedy explained, while a properly functioning immune system clears the measles virus, in Michelle's case:

> [T]here's an IgG antibody response. . .that is not effective at clearing, resolving the infection. So you're getting an amplification of the measles virus RNA to higher copy numbers than you would anticipate just through a natural infection because it's amplifying and replicating. . . .[T]he measles virus enzyme is making more.

Tr. 829-830.

In addition, Dr. Kennedy explained, the O'Leary lab obtained, "[t]he copy numbers from biopsy [] material where inflammation is ongoing. . . .When you look for copy numbers in a natural measles virus infection, you are not going to a specific cite where it's inflamed." Tr. 830. Neither Dr. Griffin or Dr. Rima, both of whom testified after Dr. Kennedy, disputed this explanation. Indeed, Dr. Oldstone, who carefully

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from the UK litigation.

studied the O'Leary lab's results, did not find the copy numbers to be implausibly high. The special master, however, either ignored or discounted this important evidence.

b. Evidence Concerning Allelic Discrimination

The special master also determined that Michelle had failed to prove that the measles virus RNA, if detected at all, was vaccine-strain measles virus.[64] Dec. 71. In this regard, Michelle points out, the process of "allelic discrimination" is the method used by scientists to determine whether a virus in question is of wild origin or of vaccine-strain origin. In this regard, Michelle says, the special master ignored and discounted Michelle's direct evidence that the O'Leary lab used allelic discrimination and that the RNA recovered in her test sample was vaccine-strain measles virus. *See* Pet. Ex. 130. In addition, as Dr. Kennedy stated, the O'Leary lab's substitution of one amino acid in a base pair, an accepted method within molecular biology to distinguish between wild type and vaccine strain measles, was not challenged by any of the respondent's experts. *See* Pet. Ex. 121.

c. Evidence Concerning Persistent Measles Virus and Replication

Dr. Griffin, the respondent's expert virologist, discounted the results of Michelle's gut biopsy that reflected high copy

[64] Michelle's medical records indicate that she has never been exposed to wild measles.

numbers of measles virus RNA in her gut tissue. She indicated that the presence of measles virus RNA was not indicative of disease because **protein** was required for the virus to replicate. During cross-examination, however, she acknowledged that she had not reviewed the Uhlmann article (Pet. Ex. 63, Tab U) that formed the basis for Michelle's contentions that the O'Leary laboratory engaged in good and accepted practices. Dr. Griffin was thus unaware that the O'Leary laboratory had found protein via the process of immunohistochemistry and that the Uhlmann article reflected that finding under Figure 4E. *See* Pet Ex. 63, Tab U.

The special master, however, did not need the presence of protein to support a finding that the measles virus was replicating. Dr. Griffin, herself, had found replication of measles virus, *in the absence of protein*, in one of her publications. *See* Pet. Ex. 112, Tab L. In this article, Dr. Griffin and her colleagues were able to recover measles RNA from the blood, urine and trachea of HIV positive patients 30 –60 days post-immunization. In her article, she declared that recovery of measles RNA from multiple sites from different patients was indicative that measles virus was persistent and replicating. The special master, however, ignored this evidence. Thus, the special master ignored multiple sources of

information that supported petitioners' belief that the measles RNA found in Michelle's gut tissue was not inert, but multiplying in her gut tissue and causing harm.

d. Evidence Concerning Dr. Arthur Krigsman's Diagnosis

The special master reserved special venom for Michelle's treating gastroenterologist and expert witness, Dr. Arthur Krigsman, a board-certified gastroenterologist, accusing him of "gross medical misjudgment." Dec. 173. In fact, the special master's attack is grossly unfounded.[65] In response, Michelle points out, at the time of her hearing, Dr. Krigsman had evaluated the gastrointestinal tracts of a thousand autistic children. At the hearing, he testified of his initial skepticism that autistic children had bowel symptoms. He testified that he conducted a history and physical of the initial eight (8) patients referred to him, and when appropriate, ordered non-invasive testing. When that testing revealed no abnormalities, he declined to treat them further. Only when shown an article by a prominent gastroenterologist in

[65] The special master has relied heavily upon the disciplinary action instituted by Lenox Hill against Dr. Krigsman for attacking his credibility. What he failed to relate was that the hospital, in violation of its own medical staff by-laws, attempted to curtail Dr. Krigsman's privileges, without due process, to prevent him from conducting further colonoscopies of autistic children. The hospital paid damages, and the parties went their separate ways. The "Texas matter," as the special master noted, involved an administrative error, and the "Florida proceeding" involved a failure to fulfill a special continuing education requirement of the Florida Board. None of these proceedings concerned the competence of Dr. Krigsman as a physician or gastroenterologist.

a textbook he had used in medical school did Dr. Krigsman reconsider his original thinking. He offered to conduct additional evaluations of the original patients. All parents agreed. What the special master does not acknowledge is that most parents will not allow a physician to conduct invasive procedures on their child unless the symptoms are chronic and unremitting, causing physical and emotional distress to their child, where they have been non-responsive to traditional treatment. All eight of Dr. Krigsman's original patients ultimately underwent colonoscopies. In all eight patients, he saw the same findings as was described in the journal article. In all eight, the pathology department at the hospital where the procedures were performed found colitis as reported in the article. *See generally* Tr. 408-491.

The special master, however, ignored the fact that Theresa Cedillo, Michelle's mother, only sought Dr. Krigsman after Michelle's treating gastroenterologist had refused to transfer her to the hospital where he practiced, despite the fact that she was dehydrated and had lost 25 pounds. He ignored the fact that Dr. Krigsman obtained a proper history, conducted a proper physical exam, ordered appropriate testing and only after doing so arrived at a diagnosis. He ignored Dr. Krigsman's testimony that the diagnosis of Michelle's IBD was based on all the evidence available to him, evidence that included Michelle's

history, her physical examination, results of diagnostic testing that included positive serological marker for IBD (+ Omp-C), elevated inflammatory markers (C-reactive protein ("CRP")) and the presence of aphthous ulcers (pre-Crohn's lesion). Further, the special master ignored the fact that Michelle had both uveitis and arthritis, commonly associated disorders of IBD. The special master especially ignored the fact that Michelle had responded to treatment with Remicade, an anti-inflammatory agent used for the treatment of IBD. Even worse, he ignored the findings of Michelle's current treating gastroenterologist, Dr. David Ziring, who had no doubt that Michelle had inflammatory bowel disease (Pet. Ex. 137, p. 7),[66] and who ordered Humira for it, specifically noting on the prescription that it was for "Crohn's Disease." *See* Petitioners' Trial Exhibit 14. The special master also ignored evidence of the consensus statement formulated by a renowned body of specialists in autism and pediatric gastroenterology convened by Autism Speaks on the "appropriate diagnostic evaluation and treatment of GI symptoms in children with ASD [autistic spectrum disorder]." *See* Petitioners' Trial Exhibit 6. He ignored the fact that Dr. Krigsman was an invited participant, and that the evaluation that was subsequently deemed proper and appropriate, mirrored

[66] The records of Dr. Ziring, Michelle's current treating gastroenterologist, were not available at the time of hearing and were filed in support of a motion for reconsideration which was denied by the special master.

the evaluation he had provided for Michelle. *See* Petitioners' Trial Exhibit 5.

Rather, the special master credited the testimony of Dr. Hanauer, the government's paid witness, an adult gastroenterologist who does not evaluate pediatric patients, who has never looked at the gastrointestinal tract of an autistic child, and who has never examined Michelle. In fact, Dr. Hanauer's conclusion that Michelle does not have IBD is limited to the fact that inflammation was not found in Michelle's pathology slides. He asserted that IBD could not be diagnosed in its absence. Yet Dr. Hanauer admitted Michelle had significant bowel problems. He did not deny that she had aphthous ulcers, nor did he deny that aphthous ulcers are the precursor to Crohn's Disease. He did not deny that her positive serology (Omp-C) was supportive of a diagnosis of Crohn's disease now that her inflammatory markers (CRPs) were elevated. He did not deny that Michelle had uveitis and arthritis and that both inflammatory diseases are commonly associated with IBD. Dr. Hanauer knew that Michelle's current treating pediatric gastroenterologist, Dr. Ziring, was ordering Humira, the most current treatment available for IBD, because he read the prescription into the record. Despite this evidence, Dr. Hanauer claims Michelle does not have IBD because inflammation was not noted in her pathology slides.

Dr. Hanauer, however, was forced to admit that he had previously authored an article in which he acknowledged that "[p]ossible triggers [of IBD] include a chronic inflammatory response precipitated by an infection with a particular pathogen or virus. . . ." Petitioners' Trial Exhibit 10. He was also forced to acknowledge that it can be "difficult to discriminate ulcerative colitis from other forms of colitis including Crohn's Disease," and that there was a "growing overlap of pathophysiologic processes between ulcerative colitis and post-infectious irritable bowel[.]" Petitioners' Trial Exhibit 11. In other words, a spectrum of inflammatory bowel disease exists, and "[p]atients who remain indeterminate between ulcerative colitis and Crohn's Disease continue to be a diagnostic challenge." *Id*. What both Dr. Hanauer and the special master did not acknowledge was that treatment, especially successful treatment, such as what was noted in Michelle after she began Remicade, could have been responsible for the lack of inflammation noted on the pathology slides. While the special master, most certainly can be excused for this oversight and for focusing on the absence of one factor in Michelle's history to support his denial of compensation, Dr. Hanauer, however, does not enjoy that deference.[67]

[67] As a physician, Dr. Hanauer must know that a diagnosis is not solely based on pathology slides. If so, then his role as a gastroenterologist would be superfluous. Dr. Hanauer knows that a proper diagnosis is based

e. Evidence of Neuroinflammation

As noted in the special master's decision, the respondent's experts did not deny "that inflammation may be present in the brains of autistic persons, and may possibly play a causal role in autism." Dec. 91, n. 109. The special master conceded as much. *Id*. He asserts, however, that Michelle failed to establish that measles caused the persistent neuroinflammation. *Id*. Once again, the special master ignored relevant evidence to arrive at this conclusion.

It is undisputed that persistent measles infection does occur and has resulted in two recognized brain disorders, subacute sclerosing panencephalitis ("SSPE") and measles inclusion body encephalitis. ("MIBE"). It also is undisputed that both disorders have a prolonged latency period after exposure before the onset of symptoms. Both disorders are associated with wild type measles. Vaccine-strain measles, however, was also recovered from the brain of one child with MIBE. *See* Pet. Ex. 61, Tab K. Clearly, if wild type measles can cause a latent inflammation of the brain, it is reasonable to believe that the attenuated measles vaccine, which is simply a weakened version of the live measles virus, can also cause a

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upon all the evidence elicited from the patient history, the physical and available test data, along with response to treatment, a process which both Michelle's treating gastroenterologists, Dr. Krigsman and Dr. Ziring engaged in, and which led both to diagnose inflammatory bowel disease and to order appropriate treatment.

latent infection of the brain. Lastly, as the special master is well aware, if encephalitis occurs in a child 5-15 days after measles immunization, it constitutes a Table injury and it is presumed that the vaccine is the cause of the encephalitis. Encephalitis is an inflammation of the brain. Thus, it is difficult to fathom how the special master could state that it is unproven that measles can cause neuroinflammation.

In Petitioners' Motion for Reconsideration, several chapters were included from the text edited by Dr. Andrew Zimmerman, one of respondent's expert pediatric neurologists. Those chapters support petitioners' theory that autism is caused by neuroinflammation. These chapters are authored by the very same physicians who Michelle cited in support of her theory at hearing.

The special master also ignored the findings of Dr. Oldstone who has spent his career studying persistent viral infections. *See* Pet. Ex. 61, Tab VV. Dr. Oldstone states:

> The three foundations upon which the understanding of persistent infection rests are, first, that the host's immune response fails to form or fails to purge virus from the infected host. Thus, viral persistence is synonymous with evasion of the host[']s immunologic surveillance system. . . .Second, viruses can acquire unique component(s) or strategies of replication. That is, viruses can regulate expression of both their own genes and host genes to achieve residence in a non-lytic state within the cells they infect. Third, the type of diseases that persisting viruses cause are often novel and unexpected. . . .The result is a disturbance in the host's biologic equilibrium. Thus,

> one important direct effect of persistent virus replication is to disorder the normal homeostasis of the host and thereby cause disease without destroying (killing) the infected cell. For example, a virally caused neurotransmitter defect of neurons altering cognitive learning and yielding behavioral disorders.

Pet. Ex. 61, Tab VV, pp. 111-112.

Dr. Oldstone also describes how a virus, including measles, can persist, and explains the biologic mechanism by which the host's immune system is dysregulated by the persistent virus. He details numerous incidences of how viral persistence causes alterations in cell functions without destruction of the cell and comments that:

> In all instances, the anatomy of the persistently infected tissues and cells with specific function . . .was normal by low and high resolution microscopy[68]. . . .Thus, conceptually, the virus caused disease by altering a selective function of each specialized cell type without destroying any cell. At the same time, the virus disordered the host immune system so that the foreign (viral) content of an infected cell was not recognized and the spread of infection was not curtailed.

Id. at 114. Dr. Oldstone concludes by noting that "[s]mall differences in either viral or host genes seem to profoundly influence the course of infection and the resultant disease state." *Id*. at 117.

[68] Michelle's brain MRIs were normal, but specialized tests, such as those performed by the Zimmerman group, are needed to detect cellular dysfunction at the molecular level. Those tests were never ordered for Michelle.

f. Evidence Concerning Michelle's Immune System Dysfunction

In addition, as noted in Petitioners' Motion for Reconsideration, the special master discounted the testimony of Dr. Vera Byers when she testified that the results of Michelle's immune workup indicated the presence of a dysfunctional immune system. Dr. Zimmerman's text includes a chapter by Dr. Paul Ashwood, who discusses the immune abnormalities noted in autistic children. *See generally* Pet. Ex. 134: Chapter 12. Michelle suffered from several of the abnormalities listed by Dr. Ashwood. In this regard, Michelle has relied upon the work of Dr. Ashwood, in part, in support of her theory that Michelle suffers from immune dysfunction.

Further, the special master ignored evidence submitted by the respondent's expert, Dr. Fujinami that some autistics suffer from a Th2 skewing of the adaptive immune system. Such skewing would affect a person's ability to eliminate viruses from the body. He relied on testimony from Dr. Christine McCusker, based upon her fabricated pediatric lab value range that Michelle's immune system was normal. Dr. Fujinami did this despite the fact that Dr. McCusker acknowledged, "there's a significant problem with trying to find normal ranges; and most studies will not provide a normal range. . . .[s]o you are limited by what is available in the literature." Tr. 2255, lines 11-13, 15-18.

Thus, Dr. McCusker was forced to retreat from her initial position that pediatric normal values existed and were well recognized. In addition, despite declaring that pediatric values should have been used in assessing Michelle's immune panel, she acknowledged that one of her "supportive" articles indicates that "[i]t's recommended that [one should] stick to [one's] own validated lab values." Tr. 2261, lines 3-4. Further, the special master ignored Dr. McCusker's waffling on the issue of the pediatric lab values, as well as her ignorance of what was stated in articles that she represented as being supportive of her position that, in fact, contradicted other portions of her testimony. *See* Tr. 2259 (lines 12-25); Tr. 2260 (lines 1-7).

g. Evidence Concerning Mercury and Immune Dysfunction

Clearly, for persistent measles infection to occur, immune dysfunction must be present. That fact is not in dispute. For instance, it is known from Dr. Griffin's work that measles virus RNA can be recovered from various sites in HIV infected children for a minimum of 30-61 days post onset of measles rash. Pet. Ex. 57, Tab F, p. 532. In this regard, Michelle presented evidence that the mercury contained in numerous vaccines received by Michelle affected her immune system and allowed measles to persist in her gut long after it should have been eliminated from her body.

In discussing the evidence that he claims defeated petitioners' assertion of mercury induced immune dysfunction, the special master again ignored evidence that contradicted his conclusion. In a lengthy cross-examination of Dr. Jeffrey Brent, the respondent's toxicologist (*see* Tr. 2445-2457) of the hearing transcript, Dr. Brent conceded the following. He admitted that a large body of literature exists on the effects of mercury on the immune system. Tr. 2447. He agreed that both organic and inorganic mercury affects both arms of the immune system. Tr. 2446. He agreed that there was a hierarchy of susceptibility to mercury in the immune system with the monocytes affected the quickest, followed by the lymphocytes, B cells (antibodies), and the T cells. Tr. 2443. He admitted that even if mercury does not kill the cell, that it could significantly affect the function of the cell. Tr. 2445. He acknowledged that if no monocytes are present, the effect of mercury on the immune system is greater than in the presence of monocytes (Tr. 2448), that the effect of organic mercury on the immune system is five times more potent than inorganic mercury, (Tr. 2449); that "mercury containing compounds are immunomodulatory" and toxic at very low exposure levels to T-cells (Tr. 2449); that exposures to low concentrations of heavy metals, including mercury, causes 'silent' clinical symptoms which upon long term follow-up reveals "clear evidence of tissue

or organ dysfunction," (Tr. 2450-2451), and that low doses of mercury can have an inhibitory effect on human T-cells. Tr. 2453-2455.

Dr. Brent further acknowledged that while lymphocytes, a more mature white cell, showed minimal mercury effect at 1-4 hours of exposure, cell death was apparent after 24 hours of exposure. However, monocytes, a more immature white blood cell experienced the greatest effect during the early exposure period. Tr. 2457. In addition, Dr. Brent acknowledged that mercury also affects the immune forming cells in the spleen and thymus. Tr. 2452. The special master ignored all this testimony and instead focused on the Goth (Pet. Ex. 55, Tab Q) and Agrawal (Pet. Ex. 55, Tab A.) studies. He criticized the Goth study for being an *in-vitro* study that evaluated the effect of thimerosol rather than ethyl mercury. The Agrawal study, while an *in vivo* study, was still deficient since it too studied thimerosal. In making these statements, he ignored the entire body of literature that Dr. Brent alluded to in his testimony that demonstrated that mercury, both organic[69] and inorganic, had a detrimental effect on all elements of the immune system with organic mercury having a stronger effect than inorganic mercury.

[69] The parties agreed that the both methyl mercury and ethyl mercury are organic forms of mercury which over time, become inorganic mercury or mercuric mercury.

As Petitioners' Motion for Reconsideration demonstrates, Dr. Zimmerman's text acknowledges that autistic children have numerous documented immune system deficiencies that cause immune system dysfunction. As the text noted, the immune system and the nervous system are interconnected. The cytokines and chemokines released by the immune system in response to an infection affect brain development and plasticity. The chronic neuroinflammation noted by the Zimmerman group reflects a dysfunctional neuroimmune response. It was error for the special master to ignore the vast body of evidence regarding the effects of mercury on the immune system, and then declare that Michelle had failed to prove that mercury exposure can lead to a dysfunctional immune system.

6. The Special Master Abused His Discretion By Refusing to Consider Significant Post-Hearing Evidence[70]

Michelle asked the special master to reconsider his decision of February 12, 2009 dismissing her petition.[71] She did so in light of new evidence not available at the time of the hearing in June of 2007. This evidence, Michelle stated, is based upon the research of leading scientists in the field of autism, including the respondent's expert pediatric neurologist,

[70] On March 16, 2009, the special master denied Michelle's Motion for Reconsideration as both untimely filed and without "a good reason" for reconsideration. Order Denying Motion for Reconsideration, page 3.

[71] *See* Petitioners' Motion for Reconsideration.

Dr. Andrew Zimmerman. In sharp contrast to critical findings by the special master, this evidence demonstrates that:

- Postnatal environmental triggers may impact the immune system during the development of the brain, disrupt the normal development of the brain, and cause autism.[72]
- Regressive autism is not purely genetic and may be caused by postnatal environmental factors.[73]
- Scientists now accept the concept of gastrointestinal inflammation in autistic children.[74]
- There is a strong relationship between the immune system, gastrointestinal disorders, and autism.[75]
- Michelle has inflammatory bowel disease.[76]
- The O'Leary lab's primers are reliable in detecting measles RNA.[77]
- Dr. Bertus Rima's testimony in *Snyder*, a critical factor in the special master's rejection of Michelle's O'Leary lab result, was based upon a gross mathematical error.[78]

In Michelle's view, this new evidence significantly affects many critical aspects of the special master's decision. Given the familiarity of the special master with the science in Michelle's case, and given the limited nature of this new

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[72] Pet. Ex. 134, Chapter 15, p. 329.

[73] Pet. Ex. 134, Chapter 20, p. 443.

[74] Pet. Ex. 134: Chapter 20, pp. 430-431, 437.

[75] Pet. Ex. 134: Chapter 20, pp. 430-431, 437.

[76] Pet. Ex. 137, p. 7.

[77] Pet. Ex. 136, Hornig Article.

[78] Pet. Ex. 138, p. 1.

evidence, the special master should have been able to quickly decide if this new evidence is worthy of consideration. In light of the significance of the evidence, and in light of the impact of this decision upon thousands of autistic children in the Program, his failure to do so was an abuse of his discretion.

7. The Special Master's Decision Was Not in Accordance With the Law

As legal support for his determination that Michelle's evidence is unreliable, and that her theories are not generally accepted in the scientific community, the special master relies on the Supreme Court's decision in *Daubert v. Merrill Dow Pharmaceuticals, Inc.*,[79] (509 U.S. 579) and a 1999 Federal Circuit decision, *Terran ex. rel. Terran v. Sec'y of HHS*,[80] (195 F.3d 1302 (Fed. Cir. 1999)), that indicates that *Daubert* plays some role in Vaccine Program proceedings. Michelle submits, once again, *Daubert* refers only to the *methods* scientists use, not to the expert's *conclusions.* In this regard, Michelle says, the special master improperly applied *Daubert* to her experts *conclusions* and improperly ignored the teachings of recent Federal Circuit decisions.

[79] In his decision, the special master cites *Daubert* on eleven (11) occasions. *See* Dec. at 4, 29 at n. 34, 56, and 122.

[80] The special master cited *Terran* on six (6) occasions. *See* Dec. at 4, 122, and 125.

In *Althen v. Sec'y of HHS*, once again, the Court described a petitioner's burden as providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." 418 F.3d at 1278. Commenting on the quantity and quality of proof necessary, the Court stated: "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof [as to] how vaccines affect the human body." *Id*. at 1280. Indeed, the Court said, due to the very absence of direct scientific evidence in this field, congress encouraged "the use of circumstantial evidence" and envisioned that "close calls regarding causation [would be] resolved in favor of injured claimants." *Id*.

In *Capizzano v. Sec'y of HHS*, once again, the Federal Circuit recognized the ability of a petitioner to prove her case with circumstantial evidence and rejected the respondent's argument that proof of "a logical sequence" between the vaccine and the injury required solid scientific evidence. In this regard, the Court said, "a 'logical sequence of cause and effect' means what it sounds like-the claimant's theory of cause and effect must be logical." *Capizzano*, 440 F.3d at 1326.

Next, in *Pafford v. Sec'y of HHS*,[81] the Federal Circuit reaffirmed the principles set forth in *Althen* and *Capizzano* and provided strong support for Vaccine Program petitioners. First, in *Pafford* the Court once again recognized that a petitioner "must prove by preponderant evidence both that her vaccinations were a substantial factor in causing the illness. . .and that the harm would not have occurred in the absence of the vaccination" (citing *Shyface v. Sec'y of HHS*, 165 F.3d at 1352). 451 F.3d at 1355. *Pafford* also cited with approval the Federal Circuit's "recently articulated. . . alternative three-part test. . . .(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3). . .a proximate temporal relationship between the vaccination and the injury." *Id*. In this regard, the Court stated:

> Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis. *See Capizzano*, 440 F.3d at 1326 (finding medical opinions that explain how a vaccine can cause the injury alleged coupled with evidence demonstrating a close temporal relationship 'are quite probative' in proving actual causation).

Id. at 1358.

[81] 451 F.3d 1352 (Fed. Cir. 2006).

Has Michelle satisfied the *Althen* factors? Clearly, she has a medical theory. Her evidence is overwhelming that the MMR vaccine is capable of causing a wide variety of brain injuries, including autism. Next, there was a logical sequence of cause and effect between her MMR vaccine and her injury. She was healthy, received an MMR vaccine, and as her several treating physicians attest, she was never again the same. There is no question that her symptoms first occurred within an appropriate time after her MMR vaccine. This fact is supported by Michelle's medical records and by the respondent's expert Dr. Griffin. It is even supported by the Vaccine Injury Table that lists "5-15" days after the MMR vaccine as the appropriate time frame for the onset of symptoms of brain damage. *See* § 14.

Finally, once a petitioner presents a *prima facie* case, the Federal Circuit has held, the burden of proof shifts and the government must prove that the "'injury. . .described in the petition is due to *factors unrelated to the*. . .*vaccine*.' 42 U.S.C. § 300aa-13(a)(1)(B)." *Knudsen by Knudsen*, 35 F.3d at 547. In so doing, the Court has said, the government must not merely prove the existence of an alternative etiology. *Id*. at 549. Rather, it must prove that the alternative actually caused the injury. *Id*. In addition, the government must affirmatively show that the vaccine did not cause the injury. *Walther v.*

Sec'y of HHS, 485 F.3d 1146, 1151 (Fed. Cir. 2007). The respondent has failed to do so.

Instead, the respondent argues, autism is purely genetic. In this regard, Michelle submits, genetic susceptibility plays a role in all vaccine injuries. Frequently, non-vaccine environmental factors also contribute to the injury. However, when concurrent forces cause a single harm, the Federal Circuit has held, the burden is on the *governmen*t to show that the alternative cause is so predominant that the vaccine is insignificant. *See Shyface*, 165 F.3d at 1352. Therefore, the Court has stated, if evidence establishes equally plausible etiologies for an injury then the petitioner should prevail. *See Knudsen*, 35 F.3d at 550. In such cases, the government must eliminate the vaccine as a substantial contributing factor. *See Shyface*, 165 F.3d at 1353.

In this case, Michelle submits, it is not her burden to rule out all potential causes of her injury. As the Federal Circuit pointed out in *Walther*, "the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm." *Walther*, 485 F.3d at 1151. Michelle's burden, therefore, is to prove a *prima faci*e case that her vaccines were a substantial contributing factor to her injury. She believes she has done so. In these

circumstances, the burden has shifted to the government to show that Michelle's genetic predisposition, or some other factor, was so predominant that it rendered her vaccines insignificant. *Id*. at n. 4 (citing *Shyface*, 165 F.3d at 1352-1353). In Michelle's view, the respondent has failed to do so.

The special master improperly used *Daubert* as a clout to dismiss Michelle's petition. In so doing, the special master deprived Michelle of the benefit of these recent Federal Circuit decisions that correctly described her Vaccine Program burden. For the special master to have done so was not in accordance with law.

VIII. CONCLUSION

Michelle respectfully requests that the Court rule that she has satisfied her burden as a matter of law, that she is entitled to compensation, and that her case be remanded to the special master to assess appropriate compensation.

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Respectfully submitted,

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