REDACTED OPINION

In the United States Court of Federal Claims

No. 03-103V
Filed: February 18, 2014
Redacted Version Issued for Publication: April 2, 2014[1]

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TODD SIMANSKI and JULIA SIMANSKI, as Parents and Next Friends of [O.A.S.], a minor,	*	**Motion for Review of Special Master's Decision; National Vaccine Injury Act, 42 U.S.C. 300aa-1 et seq.; Standard of Review; Spinal Muscular Atrophy with Respiratory Distress (SMARD); Guillain-Barré Syndrome (GBS); Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).**
Petitioners,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *	*	

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioners. With him was **Sylvia Chin-Caplan,** Conway, Homer & Chin-Caplan, P.C., Boston, MA.

Traci R. Patton, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent. With her were **Debra F. Begley**, Trial Attorney, **Lisa Watts**, Trial Attorney, **Rupa Bhattacharyya**, Director, Torts Branch, Civil Division, and **Stuart F. Delery**, Assistant Attorney General, Civil Division, Washington, D.C.

O P I N I O N

HORN, J.

On January 17, 2003, Petitioners Todd and Julia Simanski filed a timely Petition for compensation with the National Vaccine Injury Compensation Program, pursuant to

[1] This opinion was issued under seal on February 18, 2014. Although the parties had not filed a motion for redaction, on March 28, 2014 the court contacted the parties to determine whether redactions would be appropriate. Thereafter, Petitioners filed a proposed redacted opinion, asking to redact the minor child's name to initials only, and to omit the minor's birthdate.

the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, Title III, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 et seq. (2006)) (Vaccine Act), on behalf of [O.A.S.], a minor, as her parents and next friends. After several years of delay,[2] the Petitioners perfected their Petition pursuant to 42 U.S.C. § 300aa-11(c), by filing medical records, an affidavit of Petitioner, Ms. Julia Simanski, and expert reports by Dr. Paul Maertens and Dr. Yehuda Shoenfeld in support of their claim. Special Master Christian Moran,[3] however, deemed the Petition still insufficient for the Petitioners to pursue their case for compensation, and, on May 13, 2010, dismissed their case. See Simanski v. Sec'y of Health & Human Servs., No. 03-103V, 2010 WL 2292200 (Fed. Cl. Spec. Mstr. May 13, 2010), aff'd, 96 Fed. Cl. 588 (2010), rev'd and remanded, 671 F.3d 1368 (Fed. Cir. 2012). Subsequently, on June 14, 2010, the Petitioners moved this court to review the Special Master's decision to dismiss their case, pursuant to Rule 23 of the Rules of the United States Court of Federal Claims (RCFC) Appendix B (2013). On December 15, 2010, Judge Christine O.C. Miller, now retired,[4] of the United States Court of Federal Claims affirmed the Special Master's dismissal and denied Petitioners' Motion for Review. See Simanski v. Sec'y of Health & Human Servs., 96 Fed. Cl. 588 (2010), rev'd and remanded, 671 F.3d 1368 (Fed. Cir. 2012). The Simanskis appealed Judge Christine O.C. Miller's decision to the United States Court of Appeals for the Federal Circuit. On March 6, 2012, the United States Court of Appeals for the Federal Circuit reversed and remanded the case to this court, "with instructions for the special master to address the merits of the Simanskis' claim, either by applying appropriate summary judgment standards or by conducting a hearing and resolving the compensation claim on the merits." Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1385 (Fed. Cir. 2012).

On August 20, 2013, Special Master Moran issued a decision on remand. This time, after receiving evidence and holding hearings, the Special Master denied Petitioners' request for compensation for injury suffered by [O.A.S.], which Petitioners claimed was the result of the vaccinations received on January 26, 2001, when she was

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[2] The original Petition, filed in 2003, did not specify [O.A.S.]'s injury, but stated that "[a] fact-specific description of . . . the nature and extent of the injuries caused by the inoculation . . . will be set forth in affidavits which will be filed and is set forth in the medical records which, when filed, will be incorporated by reference herein." It appears that Petitioners first identified [O.A.S.]'s injury as Guillain-Barré Syndrome (GBS) in May 2005. Petitioners did not complete the filing requirements pursuant to the Vaccine Act, including not filing [O.A.S.]'s medical records and the expert report prepared by Dr. Paul Maertens, until 2008.

[3] Initially, the above-captioned case was assigned to Chief Special Master Gary Golkiewicz. On August 7, 2007, the case was reassigned to Special Master John Edwards, and, subsequently, on August 1, 2008, was reassigned to Special Master Christian Moran.

[4] On September 25, 2013, following the retirement of Judge Christine O.C. Miller, the above-captioned case was reassigned to the undersigned Judge.

two months old. See Simanski v. Sec'y of Health & Human Servs., No. 03-103V, 2013 WL 7017568 (Fed. Cl. Spec. Mstr. Aug. 20, 2013). Petitioners again filed a timely Motion for Review to this court pursuant to RCFC 23, Appendix B. Respondent filed a response to the Motion for Review, and the court held oral argument on November 18, 2013. At the oral argument, the Petitioners' counsel agreed with respect to the proceedings before the undersigned that "we're talking only about, for the purposes of this review, whether or not the SMARD conclusion by Special Master Moran is the correct one." Counsel for Petitioners also agreed at the oral argument and asserted in the Motion for Review that "there was no need to explore in detail . . . whether the vaccines could have adversely affected [O.A.S.]'s SMARD via the Althen test."[5]

FINDINGS OF FACT

[O.A.S.] was born in [2000] and weighed four pounds, twelve ounces. [O.A.S.] was diagnosed with intrauterine growth retardation (IUGR), and her Labor and Delivery Summary noted that she had a decreased muscle tone as a newborn. Otherwise, however, she seemed healthy. On January 26, 2001, when she was two months old, [O.A.S.] received a set of five vaccines.[6] Four days later, on January 30, 2001, she suffered an episode of respiratory arrest and was hospitalized at Mercy Medical Center in Des Moines, Iowa, for nearly one month, where she was intubated and placed on a ventilator. While at Mercy Medical Center, doctors detected a respiratory syncytial virus (RSV).[7] [O.A.S.] was diagnosed with bronchiolitis, and an x-ray indicated that [O.A.S.] had intermittent atelectasis[8] and lung collapse. [O.A.S.] was sedated because she was "fighting the ventilators."

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[5] The test established by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005) requires a Petitioner to show, by preponderance of the evidence, that the vaccination brought about his or her injury by 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." Id. at 1278.

[6] Specifically, [O.A.S.] received Diphtheria-Tetanus-acellular-Pertussis, Hepatitis B, Haemophilus influenza type B, inactivated polio, and pneumococcal conjugate vaccinations.

[7] The Respondent's filings include an excerpt from the website of the United States Centers for Disease Control and Prevention, which provides a definition for RSV as "a respiratory virus that infects the lungs and breathing passages . . . . RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under 1 year of age in the United States."

[8] According to Dorland's Illustrated Medical Dictionary, atelectasis is defined as "incomplete expansion of a lung or a portion of a lung." Dorland's Illustrated Medical Dictionary 171 (32nd ed. 2012).

On February 23, 2001, [O.A.S.] was transferred to the Mayo Clinic in Rochester, Minnesota. While at the Mayo Clinic, she underwent further testing, including a muscle biopsy, two electromyographies (EMGs),[9] on February 26, 2001 and March 6, 2001, respectively, including a phrenic[10] nerve study, and a cerebrospinal fluid (CSF) protein testing. Interpreting [O.A.S.]'s March 6, 2001 left phrenic nerve conduction study, Dr. Suresh Kotagal concluded that [O.A.S.] suffered from a demyelinating[11] process in her peripheral nerves.[12] From March 7, 2001 to March 10, 2001, [O.A.S.] underwent a treatment with intravenous immunoglobulin (IVIG), after which her health improved, so that on March 14, 2001, she was taken off the ventilator.

On March 16, 2001, [O.A.S.] was transferred from the Mayo Clinic back to Mercy Medical Center. Her discharge diagnosis from the Mayo Clinic was "[p]robable post infectious demyelinating neuropathy." Upon her admission to Mercy Medical Center the record before the court indicates that [O.A.S.] "looked fairly improved compared to several weeks ago." A medical record dated March 21, 2001, stated that [O.A.S.] had "prob[able] G-B Synd [Guillain-Barré Syndrome or GBS]."[13] On March 28, 2001,

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[9] Dorland's Illustrated Medical Dictionary defines electromyography (EMG) as "a electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." Dorland's Illustrated Medical Dictionary 602.

[10] Dorland's Illustrated Medical Dictionary defines phrenic as "pertaining to the diaphragm of the body." Dorland's Illustrated Medical Dictionary 1442.

[11] Dorland's Illustrated Medical Dictionary defines demyelination as "destruction, removal, or loss of the myelin sheath of a nerve or nerves." Dorland's Illustrated Medical Dictionary 486.

[12] Dr. Kotagal also noted: "My colleague, Dr. [Nancy] Kuntz, informs me that the normal latency should be <2msec." Dr. Kotagal and Dr. Kuntz concluded that [O.A.S.] suffered from peripheral neuropathy, which could be characteristic of both GBS and spinal muscular atrophy with respiratory distress (SMARD). As discussed below, in 2003, when [O.A.S.] returned to the Mayo Clinic, Dr. Kuntz indicated the diagnosis was SMARD.

[13] Dorland's Illustrated Medical Dictionary defines GBS as

> rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face.

Dorland's Illustrated Medical Dictionary 1832.

[O.A.S.] was discharged from Mercy Medical Center in improved condition. At home, she remained extubated[14] and was bottle fed.

On March 30, 2001, [O.A.S.]'s pediatrician, Dr. Emily Gavin, examined [O.A.S.] and noted that she "was doing very well on room air without O2 [oxygen] supplementation until just 4-5 days ago when it was noted that she would drop her saturations when she got upset and a little bit at night when she was sleeping." Subsequently, however, on April 13, 2001, [O.A.S.] was readmitted to Mercy Medical Center for respiratory failure. She was placed on a ventilator and remained on one at the time of the Special Master's decision. On April 17, 2001, another EMG test was performed, which revealed deterioration from the previous EMG performed at Mayo Clinic. On April 24, 2001, [O.A.S.] was transferred to Johns Hopkins Hospital in Baltimore, Maryland. Her discharge report from Mercy Medical Center noted that the "lack of a definitive diagnosis has been a problem in addressing the extent of supporting the child." [O.A.S.]'s April 25, 2001 progress note from Johns Hopkins Hospital stated that [O.A.S.]'s diagnoses include "post-infectious demyelinating neuropathy vs. spinal muscular atrophy vs. degenerative vs. other NOS [not otherwise specified]" disorders. The April 26, 2001 Consultation Request and Report Form from Johns Hopkins Hospital indicated that [O.A.S.]'s "diagnosis (preliminary) includes a post-infectious GBS-like process, CIDP [chronic inflammatory demyelinating polyneuropathy[15]], and infantile spinal muscular atrophy (Werdnig-Hoffman)."[16]

Dr. Thomas Crawford at Johns Hopkins Hospital indicated in a Clinical Summary that [O.A.S.] previously had a "provisional diagnosis of infantile GBS," and concluded, after performing another EMG on April 26, 2001, that [O.A.S.]'s condition is "consistent with either a motor neuropathy or a sensorimotor axonal neuropathy." On May 3, 2001,

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[14] Dorland's Illustrated Medical Dictionary defines extubation as "the removal of a previously inserted tube." Dorland's Illustrated Medical Dictionary 665.

[15] According to Dorland's Illustrated Medical Dictionary, chronic inflammatory demyelinating polyneuropathy (CIDP) is "slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid. It occurs most commonly in young adults, and is related to Guillain-Barré syndrome." Dorland's Illustrated Medical Dictionary 1491.

[16] The Merck Manual of Diagnosis and Therapy indicates that there are four different types of spinal muscular atrophies. See The Merck Manual of Diagnosis and Therapy 1907 (Mark H. Beers et al. eds., 18th ed. 2006). Type 1, Werdnig-Hoffman disease, manifests itself in infants, by about six months of age; in type 2, intermediate, symptoms usually manifest between three months and fifteen months; type 3, Wohlfart-Kugelberg-Welander disease, usually manifests between age fifteen months and nineteen years; and, type 4, has an adult onset and manifests between ages thirty to sixty. Id. [O.A.S.]'s treating physicians only raised type 1 as a possible diagnosis for [O.A.S.].

[O.A.S.] was transferred from Johns Hopkins Hospital to the University of Iowa Hospitals and Clinics. A May 3, 2001 brief discharge summary sheet from Johns Hopkins Hospital identified [O.A.S.]'s principal diagnosis as "inflammatory and toxic neuropathies." At the University of Iowa Hospitals, [O.A.S.] had another EMG. Dr. Katherine Mathews, a neurologist, wrote a May 8, 2001 report about [O.A.S.]'s history, which indicated that [O.A.S.]'s "exam and findings are most suggestive of a peripheral neuropathy. . . . Her clinical picture is not compatible with spinal muscle atrophy (and DNA testing has been negative[[17]])." Dr. Mathews noted on June 30, 2001 that "[O.A.S.] is clearly getting stronger." Dr. Mathews also indicated that she consulted Dr. Sladky from Atlanta, Georgia, who "favors a diagnosis of an acute axonal neuropathy."

On August 20, 2001, [O.A.S.] was transferred back to Mercy Medical Center and on her admission, her diagnosis was indicated as "Flaccid Axonal Neuropathy."[18] On September 11, 2001, [O.A.S.] was discharged from Mercy Medical Center, and her discharge report indicated that an additional IVIG therapy for [O.A.S.] was "discussed but felt to be not useful at this time." The discharge report also stated that [O.A.S.] suffers from "[s]evere generalized muscular weakness secondary to peripheral neuropathy." On September 15, 2003, more than two years after her discharge from Mercy Medical Center, at the recommendation of her pediatrician, Dr. Gavin, [O.A.S.] returned to the Mayo Clinic. Her medical diagnosis on admission at the Mayo Clinic stated: "SMA [w] resp distress (SMARD)."[19] (brackets in original). On September 17, 2003, [O.A.S.] had another EMG, which was interpreted as showing "a severe, diffuse sensorimotor peripheral neuropathy characterized primarily by axonal loss. There has been significant progression of findings since the prior examination dated February 26, 2001." Dr. Kuntz at the Mayo Clinic subsequently concluded that:

> All of this suggests progressive motor and sensory neuronopathy or axonopathy. I believe that this is compatible with a recently described

[17] The comment about DNA testing is incorrect. [O.A.S.]'s mother, Julia Simanski, stated in her September 14, 2012 affidavit, submitted to the Special Master that the DNA "testing was never done nor was blood ever sent to Germany." The parent Petitioners ultimately decided not to pursue any genetic testing, claiming that genetic testing "was not going to alter [O.A.S.]'s treatment nor improve her condition," and, therefore, "[s]ince there is no benefit for [O.A.S.], we have decided not to seek genetic testing."

[18] The court notes that the diagnosis of "Flaccid Axonal Neuropathy" is inconsistent with the diagnosis of an "acute axonal neuropathy," discussed above, favored by Dr. Sladky.

[19] Respondent suggests that "[w]hile [O.A.S.] does not suffer SMA, a condition separate and distinct from SMARD, it is clear from these records that she carried a presumed diagnosis of a genetic neuromuscular condition, rather than GBS or CIDP."

> entity[[20]] called spinal muscular atrophy with respiratory distress or SMARD.[[21]]

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[20] Dr. Richard Finkel testified for the Respondent at the February 2013 hearing that in 2003, an article on SMARD, Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719 (2003), authored by Dr. Katja Grohmann, was published, which brought SMARD to the attention of pediatric neurologists. According to his testimony, Dr. Finkel assumed that Dr. Kuntz of the Mayo Clinic, after becoming aware of the article and seeing [O.A.S.] again, changed her diagnosis to SMARD. The court notes, however, that the article was published in the December 2003 issue of the Annals of Neurology (made available online in October 2003), after Dr. Kuntz examined [O.A.S.] in September 2003. It is possible Dr. Kuntz already may have been aware of SMARD, as the lead author of Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719 (2003), Grohmann, et al., had previously published an article on SMARD in 2001. See Grohmann, et al., Mutations in the Gene Encoding Immunoglobulin μ-binding Protein 2 Cause Spinal Muscular Atrophy with Respiratory Distress Type 1, 29 Nat. Genet. 75, 76 (2001). Both the Special Master in his decision, and Dr. Finkel in his testimony cited to the 2001 article. Although both Dr. Finkel and the Special Master mark the line of demarcation for when SMARD was widely known with the publication of the 2003 Grohmann article, it is possible they are overstating its effect. The 2003 article has only been cited 75 times while the 2001 article has been cited over 200 times. The court also suggests that the 2003 article likely was not the first time SMARD had become more widely known as the 2001 article examined 29 infants with SMARD1.

[21] Although Dorland's Illustrated Medical Dictionary does not define SMARD, the National Institutes of Health's website defines SMARD as

> an inherited condition that causes muscle weakness and respiratory failure typically beginning in infancy. Early features of this condition are difficult and noisy breathing, especially when inhaling; a weak cry; problems feeding; and recurrent episodes of pneumonia. Typically between the ages of 6 weeks and 6 months, infants with this condition will experience a sudden inability to breathe due to paralysis of the muscle that separates the abdomen from the chest cavity (the diaphragm).

Genetics Home Reference, Spinal muscular atrophy with respiratory distress type 1, Nat'l Insts. of Health (Feb. 18, 2014), http://ghr.nlm.nih.gov/condition/spinal-muscular-atrophy-with-respiratory-distress-type-1. The National Institutes of Health's website also indicates that "SMARD1 appears to be a rare condition, but its prevalence is unknown. More than 60 cases have been reported in the scientific literature." Id. As noted in an exhibit offered by Respondent, SMARD's "clinical picture is characterized by initial respiratory insufficiency due to diaphragmatic palsy and often followed by distally pronounced weakness and wasting." See Rudnik-Schöneborn, et al., Long-Term Observations of Patients with Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 35 Neuropediatrics 174 (2004).

Dr. Kuntz recommended genetic testing, and continued: "I answered mother's questions regarding 4-amino pyridine treatment trials in adults with Guillain-Barre and diaphragmatic nerve pacing. Neither of those are applicable to [O.A.S.] at this time."

In January 2007, [O.A.S.] was a patient in the pediatric neurology clinic at Blank Children's Hospital in Des Moines, Iowa, where she was evaluated by Dr. Haidar Kabbani, a pediatric neurologist. Dr. Kabbani concluded that [O.A.S.] has "a clinical diagnosis of sensorimotor axonal neuropathy that also can be called spinomuscular atrophy with respiratory distress." He noted that "[t]here is very little known about this entity and it is believed to be progressive. The mechanical ventilation prolongs the life of these patients to anything between the first to the beginning of the second decade of life." Dr. Kabbani also stated: "Unfortunately, there is no well-defined treatment for those patients that I am aware of. Also, there is no further investigation that I have at this point to recommend."

Since September 2003, [O.A.S.]'s treating physicians have primarily referenced SMARD as [O.A.S.]'s diagnosis. For example, in a November 11, 2003 letter, Dr. Gavin, [O.A.S.]'s pediatrician, stated that [O.A.S.] has "a current working diagnosis of a recently described entity called spinal muscular atrophy with respiratory distress or SMARD." In February 2004, after [O.A.S.] returned to Mercy Medical Center, she was seen by Dr. Bala Napa, a pediatric intensivist, who indicated in his discharge report that [O.A.S.] has a "[k]nown neuromuscular disorder – SMA-RD type." In a letter to an insurance company, dated October 25, 2004, Dr. Gavin requested additional services for [O.A.S.] and stated: "One medical consultant has suggested she may have Spinal Muscle Atrophy with Respiratory Distress but this diagnosis has yet to be confirmed." Additionally, during an August 3, 2006 evaluation by Dr. Stuart Weinstein of the Department of Orthopedics at the University of Iowa Hospitals, Dr. Weinstein remarked that [O.A.S.] "has some form of spinal muscle atrophy." In October 2008, [O.A.S.] was evaluated by Dr. Ricardo Flores, a pediatric pulmonologist at the Blank Children's Hospital, who also concluded that [O.A.S.] "has Spinal Muscular Atrophy with Respiratory Distress." Moreover, an August 11, 2011 note written by Dr. Judy Walker of Blank Children's Hospital describes [O.A.S.] as a 10 year old girl with a history of spinal muscular atrophy. According to the record at the time of the Special Master's decision, [O.A.S.] still requires the use of a ventilator and a wheelchair, and is paralyzed from the neck down. She needs an indwelling catheter for continuous urinary drainage. She needs a feeding tube for proper nutrition and requires 24-hour attendant care. Nevertheless, [O.A.S.] attends school, and has an individualized education plan.

As noted above, on January 17, 2003, Petitioners filed a timely Petition for Compensation under the Vaccine Act, although the Petition was filed without the supporting medical records required by the Vaccine Act. See 42 U.S.C. § 300aa-11(c). After considerable delay, the Petitioners finally filed expert reports in 2008, which were deemed insufficient by Special Master Moran to meet the Petitioners' burden of proof. Therefore, on November 20, 2009, Special Master Moran issued an order to show cause, pursuant to 42 U.S.C. § 300aa-12(d)(B), requiring the Petitioners to demonstrate why Petitioners' case should not be dismissed, for failure to comply with his previous

orders of April 13, 2009 and June 26, 2009, which had required Petitioners to "obtain a supplemental report from Dr. Shoenfeld." Special Master Moran concluded that two expert reports prepared previously by Dr. Shoenfeld were inadequate "to meet the petitioners' burden of producing persuasive evidence" under the Althen test. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. In his order to show cause, Special Master Moran stated:

> A supplemental report from Dr. Shoenfeld is more likely to advance the litigation than not obtaining one. The undersigned reaches this conclusion based upon his experience, including adjudicating several cases in which Dr. Shoenfeld testified. In the undersigned's experience, Dr. Shoenfeld often introduces ideas, which have not been disclosed in his expert reports, while he is testifying. The response to this new idea theoretically can take one of two forms: either (a) Dr. Shoenfeld's new opinion is excluded on the ground that he failed to disclose the opinion, or (b) respondent is extended additional time to respond to Dr. Shoenfeld's new opinion and a second hearing is required. Because special masters are inclined to allow petitioners an opportunity to present their case, special masters rarely exclude an opinion on the ground that it was not disclosed previously. Thus, by process of elimination, special masters permit hearings to be continued to allow time to respond to a previously undisclosed opinion. A second hearing increases the work for everyone involved - petitioner's attorney, petitioner's expert, respondent's attorney, respondent's expert and the undersigned. Thus a second hearing should be avoided if possible.
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> If Dr. Shoenfeld disclosed all his opinions completely before trial, then the hearing would proceed more expeditiously. The Simanskis' delay in producing more information about Dr. Shoenfeld's opinion does not advance the litigation.

On May 13, 2010, after receiving Petitioners' response to the order to show cause, Special Master Moran concluded that "[t]he Simanskis have not presented evidence to fulfill their burden of proof and have declined the opportunity to present additional evidence," for which reason he dismissed Petitioners' case. See Simanski v. Sec'y of Health & Human Servs., 2010 WL 2292200, at *1.

As discussed above, the Simanskis subsequently filed a Motion for Review of the Special Master's dismissal in this court, claiming that Dr. Shoenfeld's expert reports were sufficient to establish causation and that the Special Master's dismissal of their case, before requiring the Respondent to submit an expert report to counter the Simanskis' evidence, was arbitrary, capricious, an abuse of discretion and not in accordance with the law. On December 15, 2010, Judge Christine O.C. Miller of the United States Court of Federal Claims affirmed the Special Master's dismissal and denied Petitioners' Motion for Review. See, generally, Simanski v. Sec'y of Health &

Human Servs., 96 Fed. Cl. 588.[22] The Simanskis then appealed to the United States Court of Appeals for the Federal Circuit on February 14, 2011. On March 6, 2012, the United States Court of Appeals for the Federal Circuit reversed and remanded the above-captioned case, "with instructions for the special master to address the merits of the Simanskis' claim, either by applying appropriate summary judgment standards[[23]] or by conducting a hearing and resolving the compensation claim on the merits." Simanski v. Sec'y of Health & Human Servs., 671 F.3d at 1385.[24]

On May 9, 2012, the Federal Circuit mandate was issued. Thereafter, on June 20, 2012, Petitioners filed [O.A.S.]'s updated medical records with the Special Master, as well as medical literature. In response to the immunological causation theories presented by Petitioners' immunologist expert, Dr. Shoenfeld, on December 14, 2012, Respondent filed an expert report prepared by Dr. Christine McCusker, a pediatric

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[22] Judge Christine O.C. Miller concluded that "the special master did not abuse his discretion by denying compensation when respondent had not submitted any rebuttal evidence." Simanski v. Sec'y of Health & Human Servs., 96 Fed. Cl. at 611. Moreover, noting that the Petitioners failed to "list[] their specific objections to the special master's findings," Judge Christine O.C. Miller sustained the Special Master's ruling. Id.

[23] Special Master Moran did not hold a hearing before his May 13, 2010 dismissal of the above-captioned case, but had conducted several informal telephonic status conferences. During an April 13, 2009 status conference, the Respondent indicated that "it intended to file a motion for summary judgment, arguing that petitioners had not met their burden as established by Althen v. Secretary of Health and Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005)." Although the Respondent did not file such a motion, the case was dismissed "for failing to comply with the show cause order, which required the Simanskis to produce sufficient evidence to meet the Althen prongs." See Simanski v. Sec'y of Health & Human Servs., 2010 WL 2292200, at *5.

[24] The Federal Circuit concluded: "[T]he special master should not have dismissed the petition as a sanction for the Simanskis' failure to comply with the orders to supplement Dr. Shoenfeld's report." Simanski v. Sec'y of Health & Human Servs., 671 F.3d at 1382. The Federal Circuit continued:

> if a Vaccine Act petitioner has produced what the petitioner believes is enough evidence to prevail, or at least to proceed to a hearing, the petitioner is normally entitled to a ruling on that question. If the petitioner cannot produce additional evidence in response to a special master's order—or chooses not to do so—the petitioner may be at risk of an adverse ruling on the merits, but that ruling should be based on the merits and not on the petitioner's failure to come forward with additional evidence.

Id.

immunologist. After the Petitioners filed a supplemental expert report by Dr. Shoenfeld, Dr. McCusker filed a second report.

On August 24, 2012, Special Master Moran requested that Petitioners file an updated, supplemental affidavit indicating Ms. Simanski's "understanding of the condition with which [O.A.S.]'s doctors have diagnosed her,"[25] in particular,

> Ms. Simanski shall state whether doctors have told her that [O.A.S.] suffers from Guillain-Barré syndrome. If so, Ms. Simanski shall state when the Guillain-Barré syndrome diagnosis was most recently communicated to her. Ms. Simanski shall state whether doctors have told her that [O.A.S.] suffers from SMARD. If so, Ms. Simanski shall state when the SMARD diagnosis was most recently communicated to her.
>
> In addition, Ms. Simanski shall state how her family responded to Dr. Kuntz's suggestion that there be genetic testing on [O.A.S.]. If the Simanskis decided not to have genetic testing, Ms. Simanski shall explain why the family reached that decision. If any member of the Simanski family had genetic testing, Ms. Simanski shall explain who was tested, when the test was conducted, and which doctor / facility conducted the test.

Petitioners filed Ms. Simanski's affidavit on September 18, 2012, in which Ms. Simanski indicated that genetic testing "was not going to alter [O.A.S.]'s treatment nor improve her condition," and, therefore, "[s]ince there is no benefit for [O.A.S.], we have decided not to seek genetic testing." Ms. Simanski also indicated that "virtually all the doctors" who evaluated [O.A.S.] in 2001 "supported a diagnosis" of GBS. Ms. Simanski's affidavit appears not to include a more recent diagnosis of GBS than from 2001.

Petitioners also filed a supplemental expert report on December 5, 2012,[26] prepared by Dr. Maertens, a pediatric neurologist, who stated that [O.A.S.] suffered from either GBS or CIDP. Respondent filed an expert report prepared by a pediatric neurologist, Dr. Richard Finkel, who indicated that [O.A.S.] suffered from SMARD, not GBS or CIDP. In response, Petitioners filed another supplemental report from Dr. Maertens on December 28, 2012, in which he challenged the diagnosis of SMARD, and discussed with more specificity why GBS and/or CIDP represents the correct diagnosis for [O.A.S.]. A final, supplemental expert report by Dr. Finkel was filed by Respondent on January 18, 2013.

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[25] Special Master Moran explained that "[i]n an affidavit dated May 20, 2004, Ms. Simanski stated that [O.A.S.]'s treating doctors had not yet offered a diagnosis for [O.A.S.]'s condition. Thereafter, Petitioners filed additional records indicating a possible diagnosis of spinal muscle atrophy with respiratory distress ('SMARD') and indicating requests for genetic testing."

[26] Dr. Maertens first submitted an unsigned version of his expert report and then, a day later, submitted a signed version, which appears otherwise to be identical.

Pursuant to the Federal Circuit's instructions on remand, Special Master Moran conducted evidentiary hearings between February 4 and 7, 2013, with a fifth day of testimony completed via videoconference on February 20, 2013. Petitioners called their two experts, Dr. Shoenfeld and Dr. Maertens, at the evidentiary hearing. Respondent also called their two experts, Dr. McCusker and Dr. Finkel, at the hearing.

In their post-hearing briefs submitted to the Special Master, the parties reiterated their differing positions with respect to [O.A.S.]'s condition. While Petitioners maintained that [O.A.S.] suffers from GBS/CIDP, Respondent challenged that position, and argued that [O.A.S.] suffers from a different neurologic problem, SMARD, which is caused by a genetic mutation. Respondent also asserted that even assuming that [O.A.S.] suffered from GBS or CIDP, Petitioners have not met their burden of establishing that the vaccines caused [O.A.S.]'s neurologic problem.

On August 20, 2013, Special Master Moran issued a 72-page decision, denying the Petitioners' request for compensation. Special Master Moran concluded that "[a] preponderance of the evidence establishes that [O.A.S.] suffers from a spinal muscular atrophy with respiratory distress, not Guillain-Barré syndrome or chronic inflammatory demyelinating polyneuropathy." Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *42. Special Master Moran indicated that the parties' experts came to very different conclusions regarding [O.A.S.]'s case, but he determined that the evidence "overwhelmingly favors a finding that [O.A.S.] suffers from SMARD." Id. at *1. Because Special Master Moran concluded that [O.A.S.] appears to suffer from SMARD, the Special Master did not reach the issue of whether the vaccines [O.A.S.] received at two months could have caused her condition, making her eligible for compensation under the Vaccine Compensation Program, pursuant to the Althen test. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278.

Special Master Moran began his analysis by explaining his understanding of the etiology of GBS, CIDP, and SMARD, the diseases at issue in Petitioners' case. He dedicated multiple pages of his decision to a description of the "Structure of the Nervous System" and how each of the diseases implicated in this case, GBS, CIDP, and SMARD, impacts the nervous system. Id. at *4-8. Turning to GBS and CIDP, Special Master Moran wrote:

> Both GBS and CIDP are neuromuscular diseases involving sensory and motor nerves of the peripheral nervous system. The basic definitions of these conditions point to similarities and differences between them. GBS is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection." CIDP is a "slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs . . . usually with elevated protein in the cerebrospinal fluid. It . . . is related to Guillain-Barré syndrome."

Id. at *4.

The Special Master noted that both GBS and CIDP "seem to share a common pathway," as both are "demyelinating condition[s]." Id. at *5. He explained that "[d]octors generally believe that the substance that attacks the myelin is part of the person's immune system." Id. Special Master Moran stated: "Whether the immune system of newborns is sufficiently strong to damage myelin was a disputed point between the two immunologists, Dr. Shoenfeld and Dr. McCusker. E.g. compare Tr. 269-78 (Dr. Shoenfeld) with Tr. 345-53, 383-85 (Dr. McCusker)." Id. The Special Master added: "Dr. McCusker's view that a newborn's immune system is not robust enough to cause autoimmunity is in accord with the general incidence of autoimmune diseases, including GBS." Id. Special Master Moran also noted that according to the testimony of Petitioners' expert, Dr. Maertens, reports of GBS in infants less than three months old are very rare, and that "[t]here is some question whether GBS can occur in a newborn at all." Id.

Special Master Moran also discussed the symptoms, the diagnostic criteria and the types of tests used to identify GBS. Id. at *6. He noted that "GBS begins with 'paresthesias of the feet,'" and thereafter, "usually progresses quickly." Id. at *6. In contrast, he pointed out that CIDP is "usually 'slowly progressive.'" Id. at *7. Special Master Moran further stated that "[t]he Asbury criteria[[27]] establish the symptoms frequently used to diagnose GBS," including "elevated protein in the spinal fluid and response to IVIG treatment," and "'reduced or absent reflexes.'" Id. at *6. The Special Master also quoted from the testimony of Respondent's expert, Dr. Finkel, who explained that the "'reflexes are typically lost early in GBS/CIDP. That's a hallmark. That's one of the two main criteria of GBS.'" Id. The Special Master observed that Petitioners' expert, Dr. Maertens, agreed with Dr. Finkel's explanations, and stated, "'[i]n most cases, the reflex[es] are decreased or lost.'" Id. The Special Master further noted that "[t]he duration of GBS is a primary way of distinguishing it from chronic inflammatory demyelinating polyneuropathy." Id. The Special Master continued: "As the name implies, CIDP is a chronic condition, meaning it 'persists over a long period of time.' Unlike GBS, which resolves quickly, CIDP can be diagnosed only if the patient suffers symptoms for eight or more weeks." Id. Moreover, the Special Master observed that "[a]nother difference between GBS and the common presentation of CIDP concerns how the disease appears initially. People with GBS decline rapidly. In contrast, CIDP is usually 'slowly progressive.'" Id. at *7. The presenting symptoms for CIDP "'often

[27] The Asbury criteria reference is to an article originally published in 1990 in Annals of Neurology by Asbury, et al., Assessment of Current Diagnostic Criteria for Guillain-Barré Syndrome, 27 Ann Neurol 21 (1990), which established the diagnosis criteria for GBS. Dr. Maertens testified that the Asbury criteria is a generally accepted assessment guide in the medical community criteria, which describes the symptoms frequently used to diagnose GBS, including response to IVIG treatment. Dr. Finkel testified that the "Asbury Cornblath criteria . . . is still largely accepted as the general clinical means of making that [GBS] diagnosis."

include tingling or numbness of the digits, weakness of the limbs, hyporeflexia or areflexia, fatigue, and abnormal sensations.'" Id.

In his decision, Special Master Moran also discussed SMARD, which, he noted, is "'characterized by a sudden onset of respiratory distress within the first 13 months of life and initially distal and later generalized muscular weakness.'" Id. The Special Master indicated: "For SMARD, '[t]he clinical picture is characterized by initial respiratory insufficiency due to diaphragmatic palsy and often followed by distally pronounced weakness and wasting.'" Id. Special Master Moran added: "Most pediatric neurologists became aware of the distinction between SMA and SMARD in 2003, when the Annals of Neurology published an article on SMARD. Dr. Maertens testified that he first learned about SMARD in 2005 or 2006." Id. at *8. Special Master Moran explained that SMARD and SMA are different because they have different origins, as "[t]he basis for most cases of SMA is a genetic mutation, located on chromosome 5q, which was identified in 1995. In contrast, SMARD involves a different gene, known as IGHMBP2." Id.

The Special Master explained that "one way to distinguish the diseases implicated in this case (GBS, CIDP, and SMARD) is to determine what part of the peripheral nerve is damaged." Id. at *4. The Special Master indicated that while the two most common "demyelinating" forms of GBS, "Acute Motor Axonal Neuropathy" and "Acute Motor-Sensory Axonal Neuropathy" involve "the axon of the nerve," both SMA, spinal muscular atrophy, and SMARD, spinal muscular atrophy with respiratory distress, "are considered diseases of the anterior horn cell."[28] Id. at *8 n.13.

In his decision, the Special Master also provided a detailed chronology of the tests and treatments [O.A.S.] had received at various medical institutions, including references to medical opinions and [O.A.S.]'s test results. See, generally, id. at *8-25. Special Master Moran concentrated on the testimony of two of the experts, Dr. Maertens for the Petitioners and Dr. Finkel for the Respondent, and their respective interpretations of [O.A.S.]'s test results and opinions as to whether [O.A.S.]' conditions and symptoms, based on her test results, were more consistent with GBS/CIDP or with SMARD. See, generally, id. at *9-25.

[28] Special Master Moran cited to Kelley v. Secretary of Health and Human Services, 68 Fed. Cl. 84 (2005), Tompkins v. Secretary of Health and Human Services, No.10-621V, 2013 WL 3498652, at *27 (Fed. Cl. Spec. Mstr. June 21, 2013), and Torday v. Secretary of Health and Human Services, No. 07-372V, 2009 WL 5196163 (Fed. Cl. Spec. Mstr. Dec. 10, 2009), for the proposition that the issue "[w]hether GBS and CIDP are separate and distinct clinical entities or they belong on a spectrum of similar diseases is a difficult question that has appeared periodically in cases in the Vaccine Program." Id. at *7. The Special Master determined that "[a] resolution of that question, however, is not required in this case because, for the reasons explained below, [O.A.S.] has not suffered from either GBS or CIDP. Rather, she suffers from an entirely different disease, SMARD." Id.

Concluding that "the dispute over the correct diagnosis is a critical issue in this case," and that "[t]he parties agree that determining [O.A.S.]'s injury is the first step in determining whether the vaccinations harmed her,"[29] the Special Master proceeded to analyze "whether the evidence preponderates in favor of either GBS/CIDP or SMARD," citing Moberly ex rel. Moberly v. Secretary of Health and Human Services, 592 F.3d 1315, 1322 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 2010), Hodges v. Secretary of the Department of Health and Human Services, 9 F.3d 958, 962-63 (Fed. Cir. 1993), and Bunting v. Secretary of the Department of Health and Human Services, 931 F.2d 867, 873 (Fed. Cir. 1991). Id. at *3, *25 (capitalization removed).

Indicating that "[O.A.S.] presented normal and abnormal behaviors," consistent and inconsistent, with both SMARD and GBS/CIDP, and that the parties' experts came to very different conclusions regarding [O.A.S.]'s case, Special Master Moran focused on twelve data points in his discussion, representing symptoms that he found were pertinent to the determination of etiology and nature of [O.A.S.]'s injury.[30] Id. at *25. At the February 2013 hearing conducted by the Special Master, he asked both Dr. Finkel and Dr. Maertens "to analogize [O.A.S.]'s signs and symptoms to pebbles[[31]] and then

[29] The Petitioners "acknowledge that this is such a case," in other words, a situation in which the Special Master must first determine the type of disease or injury at issue. Petitioners, however, "assert the evidence contained in the medical records and literature filed in this case unequivocally demonstrate that [O.A.S.] does not have SMARD, but suffered GBS as a result of her January 26, 2001 vaccinations."

[30] It appears the Special Master's analysis that [O.A.S.]'s condition was consistent with SMARD closely resembles the analysis conducted by the Respondent's expert, Dr. Finkel. In his September 28, 2012 expert report, Dr. Finkel provided a chart, which summarized his interpretations of the data included in [O.A.S.]'s medical records. Dr. Finkel's "[d]ata items" included: "Intrauterine Growth Retardation (IUGR)"; "[r]espiratory failure – acute onset, as the presenting symptom, with early right hemi-diaphragm eventration"; "[r]espiratory failure presenting at age 2 months, 3 weeks"; "[p]rogression to permanent ventilation support within one month of onset of respiratory failure"; "[w]eakness in limbs, trunk, neck muscles – onset within days to few weeks of respiratory failure (RF)"; "[w]eakness: distribution of lower>upper limbs, distal>proximal, symmetric"; "[n]erve conduction and EMG findings – length-dependent axonal sensorimotor polyneuropathy, without focal or segmental changes. (May have slowing of conduction initially that raises the consideration of GBS or CIDP)"; "[s]ural nerve biopsy"; "[c]erebrospinal fluid (CSF) profile"; "[l]ow serum creatinine (0.1) upon admission 1/20/00, suggestive of chronic muscle wasting (non-specific as to etiology)"; "[s]low decline in motor function over years, following the initial acute deterioration"; "[e]xcessive sweating (diaphoresis)"; "[n]o apparent therapeutic benefit from IVIg or prednisolone Rx."

[31] A search of published decisions by this court and the Office of Special Masters indicates the unusual "pebble" analogy approach has not been used before to evaluate the strength of evidence in a vaccine case. The pebble analogy, however, was not used consistently by the experts who testified in [O.A.S.]'s case, nor did the Special

place each pebble on a scale," one side of the scale representing SMARD, and the other side representing GBS/CIDP. Id. The Special Master noted that Dr. Finkel ranked his pebbles by size[32] (one to five with five being the most weighty) according to the amount of weight he thought should be attributed to each symptom. The Special Master explained that this "process allowed the undersigned [Special Master Moran] to weigh the evidence supporting and opposing a particular diagnosis." Id.

Special Master Moran's analysis included evaluation of the following data points in the discussion section of his decision:

1. Intrauterine Growth Retardation (IUGR)
2. Acute Respiratory Failure as a Presenting Sign
3. Onset of Respiratory Failure at 12 Weeks
4. Weakness Pattern and Reflexes
5. Progression to Permanent Ventilator Support
6. Sural Nerve Biopsy
7. Cerebrospinal[33] Fluid (CSF) Protein
8. Creatinine Levels
9. EMG Tests and Nerve Conduction Studies
10. Response to IVIG Treatment
11. Treating Doctors and
12. Comparison of Experts: Dr. Maertens and Dr. Finkel[34]

Master continue to push for the experts to use the pebble scale throughout the case or the hearing. Moreover, the pebble analogy also was abandoned by the Special Master in his decision after his discussion on the first three data points.

[32] Only Dr. Finkel ranked his pebbles by size. Dr. Maertens did not engage in pebble ranking, but described three items as "toss" (on neither side of the scale).

[33] Dorland's Illustrated Medical Dictionary defines cerebrospinal as "pertaining to the brain and spinal cord." Dorland's Illustrated Medical Dictionary 333.

[34] While Petitioners' expert, Dr. Maertens, and Respondent's expert, Dr. Finkel, concentrated on [O.A.S.]'s diagnosis, Petitioners' expert, Dr. Shoenfeld, an immunologist, and Respondent's expert, Dr. McCusker, a pediatric immunologist, offered opinions mainly on the issue of causation. Special Master Moran indicated in his decision that the Petitioners "elicited no testimony on direct examination from either Dr. Shoenfeld or Dr. Maertens [Petitioners' experts] about [O.A.S.]'s vaccinations having played a causal (or aggravating) role under the assumption that [O.A.S.] has SMARD," and, therefore, there was no need to discuss the issue of causation in his decision. Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *41. For that reason, while evaluating the expert testimonies, Special Master Moran considered mainly the testimony of Dr. Maertens and Dr. Finkel, the pediatric neurologists, who testified about [O.A.S.]'s diagnosis. The Special Master's focus on Dr. Maertens and Dr. Finkel is discussed further below.

A chart summarizing key findings by the Special Master regarding his conclusions as to whether the various symptoms and tests results for [O.A.S.] were consistent or inconsistent with each disease at issue was included on page 41 of the Special Master's decision. Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *41. The chart included by the Special Master, however, is not entirely consistent with the data points addressed by the Special Master in his discussion section. The chart includes only ten of the twelve data points addressed at greater length in the discussion section of the Special Master's decision. Moreover, although included on the chart, [O.A.S.]'s health before her respiratory arrest is not listed as a separate data point in the Special Master's discussion section of his decision. He addressed [O.A.S.]'s health before the respiratory arrest in the discussion of his second data point ("Acute Respiratory Failure as a Presenting Sign"). The Special Master's chart also does not reflect the treating doctors' opinions or the comparisons of experts included in the Special Master's discussion. For reference, the Special Master's chart is included below. The dots on the chart represent the Special Master's conclusion whether the particular data point was consistent, neutral or inconsistent with each of the three diseases implicated in the case, GBS, CIDP, or SMARD.

GBS/CIDP			Data Point	SMARD		
Consistent	**Neutral**	**Inconsistent**		**Inconsistent**	**Neutral**	**Consistent**
	•		**IUGR**			•
•			**Health before Respiratory Arrest** (some dispute whether [O.A.S.] had a weak cry)			• (weakly)
		• (extremely rare)	**Age of Onset**			• (strongly)
		• (strongly – absent reflexes are diagnostic criteria)	**Reflex and Weakness Pattern**			•
		• (but not impossible)	**Permanent Ventilator Support**			• (strongly)
		• (strongly)	**Sural Nerve Biopsy Showing No Demyelination**			•
		• (but not impossible)	**CSF Protein – Normal**			•
	•		**Creatinine Levels** (results varied; a question about Mayo results)			• (weakly)
		• (weakly – better response to 2d and 3d dose is expected)	**Response to IVIG**		•	
		• (strongly)	**EMG and Nerve Conduction Studies** (showing axonal damage, not demyelination)			• (strongly)

Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *41. (emphasis in original).

Turning to the first data point in the discussion section of Special Master Moran's decision, he noted that [O.A.S.], who weighed only four pounds, twelve ounces at birth, was diagnosed with IUGR. The Special Master, in reviewing the trial testimony of Respondent's expert, Dr. Finkel, and Petitioners' expert, Dr. Maertens, and their expert reports and accompanying literature, concluded that "[O.A.S.]'s IUGR supports a diagnosis of SMARD." Id. at *26. Specifically, Special Master Moran cited to Dr. Finkel's supplemental expert report, which relied on a study "showing that approximately three-quarters of patients with SMARD have intrauterine growth retardation." Id. During his testimony, Dr. Finkel also discussed a study which found that IUGR was 48% sensitive[35] and 77% specific for SMARD. When asked by the Special Master to "place the IUGR pebble on the scale," Dr. Finkel stated that IUGR was a medium sized pebble for SMARD, a size three.

Dr. Maertens, on the other hand, wrote in his expert report that IUGR is associated with conditions other than SMARD1. Therefore, according to him, "'at best, IUGR is neither supportive nor inconsistent with a diagnosis of SMARD1.'" Id. Special Master Moran did not give much weight to Dr. Maertens' opinion, however, noting that, "at trial, it became apparent that Dr. Maertens was using 'consistent' unusually," and that, although during his testimony Dr. Maertens agreed that IUGR was "'consistent with'" SMARD, Dr. Maertens maintained that IUGR is not a prerequisite for SMARD. When asked by the Special Master to decide where IUGR should be placed on the hypothetical scale, Dr. Maertens stated that [O.A.S.]'s IUGR did not go to either side of the scale. Instead of placing it on one of the scales, Dr. Maertens stated that it would be a "toss." The Special Master's analysis of his first data point in his discussion section included a single footnote reference to GBS, explaining that "Dr. Maertens did not provide any testimony regarding any connection between IUGR and GBS/CIDP." Id. at *26 n.35. Based on Dr. Finkel's testimony and the literature introduced into the record, after considering both experts and the information in the record, the Special Master found Dr. Finkel's opinion persuasive.

As a second data point, Special Master Moran examined whether [O.A.S.]'s January 30, 2001 acute respiratory failure was "consistent with a diagnosis of SMARD." Id. at *27. He noted that there was "consensus that respiratory failure is typically not a presenting symptom for GBS/CIDP," however, both parties "strenuously disputed whether [O.A.S.]'s presentation at Mercy [Medical Center] for respiratory failure is consistent with a diagnosis of SMARD."[36] Id. Special Master Moran also indicated that

[35] Dr. Finkel explained during his testimony that "sensitive" means "what percentage of patients have that feature."

[36] The Special Master discussed separately, in a section identified as "Respiratory Arrest and SMARD," whether respiratory failure is consistent with a diagnosis of

Petitioners' expert, "Dr. Maertens opined that the acute onset of respiratory arrest was consistent with SMARD," and that Respondent's expert, Dr. Finkel also "linked an acute presentation of respiratory problems with SMARD." Id. at *27-28. The Special Master noted that despite this seeming consensus of the experts, the Petitioners "challenged Dr. Finkel on cross-examination," and stated in their post-hearing brief that based on the literature, '"every child who was diagnosed with SMARD with a known gene mutation had the onset of symptoms prior to presentation of respiratory arrest,'" while [O.A.S.] was basically healthy before her respiratory arrest. Id. at *27. The Special Master rejected the Petitioners' arguments, pointing out "two flaws" in their position: "The first problem stems from the Simanskis' assertion of what happens in all cases of SMARD. The second problem concerns what happened to [O.A.S.]." Id. With regards to the first issue, the Special Master noted that "[i]t is difficult to accept the proposition that absolutely every child with SMARD has been noted to suffer some relatively benign symptoms before presenting to a doctor with respiratory arrest." Id. Special Master Moran noted that Dr. Finkel refuted a similar argument made by the Petitioners' counsel at the hearing, although stating, "I don't think we went through every case that was in every report. We went through certain cases that you selected and you wished to address, but let's be clear here. We didn't go through every case in every report." Id. Special Master Moran also noted that the medical literature "seems to indicate more variability in presentation" of SMARD, and quoted an article in the record, Yiu, et al., Genetic Axonal Neuropathies and Neuronopathies of Pre-Natal and Infantile Onset, 17 J. Periphe. Nerv. Sys. 285, 289 (2012), which stated that "[e]arly-onset respiratory distress is the cardinal feature, presenting between 1 and 6 months of age, although a weak cry, inspiratory stridor,[37] or foot deformities *may* have been noted earlier." Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *27. (emphasis in original). Special Master Moran also noted that despite the Petitioners' assertions that [O.A.S.] was healthy before her respiratory arrest, there was contrary evidence in the record, including Dr. Finkel's interpretation of the December 28, 2000 video of [O.A.S.] that she had a weak cry. Id. at *28.

Indicating that "although Dr. Finkel assigned [O.A.S.]'s respiratory arrest as a strong pebble on the side of SMARD, a size four; the Simanskis have effectively cast some doubt on this point," Special Master Moran determined that "whether these pieces of information favor SMARD or GBS/CIDP depends upon the other side of the hypothetical scale," whereupon he proceeded to the analysis of "Respiratory Arrest and GBS/CIDP." Id. The Special Master examined Dr. Maertens' expert report, and his determination that "[a]cute respiratory failure is a frequent complication in patients with severe neuromuscular disease." Id. The Special Master concluded that Ito, et al., Phrenic Nerve Conduction in the Early Stage of Guillain-Barre Syndrome Might Predict the Respiratory Failure, 116 Acta Neurol. Scand. 255 (2007), and Stojkovic, et al.,

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SMARD, and, in a section identified as "Respiratory Arrest and GBS/CIDP," whether respiratory failure is consistent with a diagnosis of GBS/CIDP. Id. at *27-29.

[37] Dorland's Illustrated Medical Dictionary defines stridor as "a harsh, high-pitched breath sound." Dorland's Illustrated Medical Dictionary 1785.

Phrenic Nerve Palsy as a Feature of Chronic Inflammatory Demyelinating Polyradiculoneuropathy, 27 Muscle & Nerve 497 (2003), two studies referenced in Dr. Maertens' expert report, "provide at least some support for Dr. Maertens's statement that patients with severe neuromuscular diseases can develop respiratory problems as a 'complication' to their disease." Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *28. The Special Master indicated, however, that based on the medical records, [O.A.S.]'s presentation was different than the presentation described in the Stojkovic article, because [O.A.S.]'s respiratory arrest was not "progression" of a disease, but rather her "first significant problem." Id. The Special Master also noted Dr. Maertens' opinion that "[O.A.S.]'s January 30, 2001 respiratory arrest did not mark the beginning of her neurological problem," but rather that [O.A.S.]'s "Guillain-Barré syndrome probably came on" after [O.A.S.] started to recover from her RSV infection. Id. The Special Master, therefore, concluded: "Given that Dr. Maertens did not argue that [O.A.S.]'s presentation for acute respiratory failure was part of her demyelinating neuropathy, this particular piece of information does not support the diagnosis of GBS/CIDP." Id. at *29. Therefore, because "Dr. Finkel believed that [O.A.S.]'s presentation with acute respiratory failure strongly favored SMARD . . . [and] Dr. Maertens stated that it was a 'toss up finding' that should not be placed on either side of the scale," Special Master Moran found that the "more persuasive evidence suggests that the presentation with respiratory failure is more common in SMARD, than in GBS/CIDP." Id. The Special Master, therefore, concluded that [O.A.S.]'s acute respiratory failure "slightly favors" the SMARD diagnosis. Id. On his chart, however, the Special Master indicated that [O.A.S.]'s health before respiratory arrest, which the Special Master discussed under his second data point in the discussion section, was consistent with GBS/CIDP, but only weakly consistent with SMARD.

As a third data point in his discussion section, Special Master Moran considered whether [O.A.S.]'s acute presentation of respiratory arrest at twelve-and-one-half weeks after [O.A.S.]'s birth was more consistent with SMARD or GBS/CIDP. Special Master Moran referenced the testimony of Dr. Finkel, who stated that [O.A.S.]'s respiratory failure at her age was consistent with SMARD, but inconsistent with GBS and CIDP, and the articles cited by Dr. Finkel: Grohmann, et al., Mutations in the Gene Encoding Immunoglobulin μ-binding Protein 2 Cause Spinal Muscular Atrophy with Respiratory Distress Type 1, 29 Nat. Genet. 75, 76 (2001), and Pierson, et al., Infantile-Onset Spinal Muscular Atrophy with Respiratory Disress-1 Diagnosed in a 20-Year-Old Man, 21 Neuromuscular Disord. 353 (2011) in support. Dr. Finkel also testified that "[O.A.S.]'s manifestation at six weeks to six months would be a size five pebble for SMARD." Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *29. Dr. Finkel further indicated that "'GBS can occur at all ages but is decidedly uncommon in infants.'" Id.

Special Master Moran noted that "Dr. Maertens's opinion regarding [O.A.S.]'s age of onset [of her disease] varied." Id. In his December 5, 2012 supplemental expert report, Dr. Maertens disagreed that GBS is highly unlikely to occur at two months of age and noted that "GBS occurs at all ages," citing a case report of a one-month-old girl the authors described as having GBS. Id.; see also Gilmartin, et al., Guillain-Barré

Syndrome with Hydrocephalus in Early Infancy, 34 Arch. Neurol. 567 (1977). Subsequently, however, at the hearing, Dr. Maertens testified that it is "'extremely rare'" to have the age of onset be two months in GBS, but that the onset of respiratory failure at two months could occur with SMARD. See Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *30. Based on the evidence presented, Special Master Moran concluded that the onset of SMARD could be consistent for a child of [O.A.S.]'s age, and determined that "on the whole, [O.A.S.]'s age of onset tends to favor SMARD, not GBS/CIDP." Id.

As a fourth data point in his discussion section, Special Master Moran analyzed whether [O.A.S.]'s weakness pattern, including weakness in her diaphragm and in her distal[38] extremities, as well as whether her "absent" reflexes, were more consistent with SMARD or GBS. Special Master Moran cited Dr. Finkel's testimony that, "[t]he clinical diagnostic criteria for GBS are weakness in one or more limbs and lack of reflexes." The Special Master also noted similar testimony by Dr. Maertens, who indicated that "in most cases [of GBS], the reflex[es] are decreased or lost." Additionally, Special Master Moran quoted Dr. Finkel's testimony, who stated that "'absent reflexes [are] not a necessary feature for SMARD.'" Id. Dr. Maertens was not asked to comment on reflexes in SMARD cases and did not offer testimony in this regard.

Special Master Moran noted that, according to [O.A.S.]'s discharge report prepared by Dr. Napa from Mercy Medical Center on March 28, 2001, [O.A.S.] "'continue[d] to have normal reflexes.'" Id. Subsequently, however, when [O.A.S.] was at Johns Hopkins Hospital, on April 26, 2001, "Dr. Crawford tested her tendon reflexes" and he "found that they were absent." Id. Finally, when [O.A.S.] was at the University of Iowa Hospitals, the medical report on May 16, 2001 indicated that her reflexes had improved. Id. Special Master Moran observed that when:

> Dr. Maertens was asked to address [O.A.S.]'s reflexes during her first hospitalization at Mercy, his response was an indication of 2+ reflexes, which is a normal result, 'makes no sense.' Dr. Maertens 'just [could not] believe that [Dr. Narawong was] right' about [O.A.S.]'s reflexes. In reference to Dr. Napa's March 28, 2001 discharge report about [O.A.S.] maintaining her reflexes, Dr. Maertens said that this data point does not favor either SMARD or GBS/CIDP.

Id. Special Master Moran agreed with Dr. Finkel that "the preservation of [O.A.S.]'s reflexes . . . makes the diagnosis of GBS/CIDP less likely." Id. He also noted that [O.A.S.]'s weakness in her diaphragm is "helpful in distinguishing SMARD from

[38] According to Dorland's Illustrated Medical Dictionary, distal means "remote; farther from any point of reference; opposed to proximal." Dorland's Illustrated Medical Dictionary 555.

GBS/CIDP" because "[d]iaphragmatic eventration[39] is consistent with SMARD." Id. at *31.

As a fifth data point in his discussion section, Special Master Moran considered whether [O.A.S.]'s permanent need for assistance with her breathing is more consistent with SMARD or GBS/CIDP. Considering whether progress to permanent ventilator support within one month of respiratory failure is consistent with SMARD, the Special Master noted Dr. Finkel's opinion that all "SMARD patients require ventilator support." Id. The Special Master cited a 2011 study, in which "researchers reported the results of a long-term study of 11 children with SMARD who survived their first year of life. The authors state that by nine months, all children 'were mechanically ventilated.'" Id. Special Master Moran also noted that "Dr. Maertens agreed that [O.A.S.]'s progression to permanent ventilator support 'would probably go more towards SMARD.'" Id. The Special Master acknowledged, however, Petitioners' argument that "[O.A.S.] did not require ventilator support until more than 30 days after her initial episode of respiratory arrest on January 30, 2001," and that [O.A.S.] "could breathe on her own" for one month, which, "makes [O.A.S.]'s case inconsistent with SMARD and consistent with a relapsing case of GBS/CIDP." Id. Special Master Moran noted that "Dr. Finkel acknowledged the reasonableness of the Simanskis' point." Id.

Turning to the discussion on GBS/CIDP, Special Master Moran noted that "Dr. Finkel stated that permanent ventilator support was inconsistent with GBS and highly inconsistent with CIDP." Id. Dr. Maertens' clinical experience was consistent with Dr. Finkel's opinion, as Dr. Maertens testified that, "[a]mong his pediatric patients with GBS," probably "one" remained permanently ventilated. Id. Nevertheless, the Special Master noted, "Dr. Maertens maintained that progression to permanent ventilator support 'occurs with GBS and persists in CIDP if the patient is unresponsive to IVIG and/or steroids.'" Id. Special Master Moran also noted that "Dr. Finkel, too, recognized that GBS can lead to long-lasting respiratory problems," and, in two articles cited by Dr. Finkel in support, "approximately 20 percent of people with GBS have respiratory problems." Id. at *31 (citing Halawa, et al., Guillain-Barré Syndrome as a Prominent Cause of Childhood Acute Flaccid Paralysis in Post Polio Eradication Era in Egypt, 15 Eur. J. Paediatric Neurol. 241, 242 (2011) (stating "[r]espiratory failure is the most life threatening complication and mechanical ventilation has been reported to be needed in about 20-30% of patients"), and DiMario Jr., et al., Autonomic Dysfunction in Childhood Guillain-Barré Syndrome, 27 J. Child Neurol. 581, 585 (2012) (noting respiratory failure in 15-24% of pediatric cases of GBS)). The Special Master concluded that "[a] fraction of GBS-afflicted people, perhaps one in five, requires ventilator assistance. But, all patients with SMARD are aided in their breathing. [O.A.S.]'s progression to permanent ventilator support weighs in favor of SMARD." Id. at *32. (emphasis in original).

[39] Dorland's Illustrated Medical Dictionary defines diaphragmatic eventration as "a congenital anomaly characterized by failure of muscular development of part or all of one (or occasionally both) hemi diaphragms, resulting in superior displacement of abdominal viscera and altered lung development." Dorland's Illustrated Medical Dictionary 655.

As a sixth data point in his discussion section, Special Master Moran evaluated the biopsy results of [O.A.S.]'s sural nerve, which showed normal myelination. Id. Special Master Moran observed that "[t]here is no question that the majority of biopsies from patients suffering either GBS or CIDP return abnormal results." Id. He also cited the testimony of Dr. Finkel, who "estimated that in cases of GBS, the biopsy is abnormal more than 90 per cent of the time," and noted that "Dr. Maertens agreed." Id. Dr. Maertens stated, however, that since the biopsy showed only "mild inflammation" and not any demyelination, the results did not go "in any specific direction." Id. The Special Master determined that "Dr. Maertens's opinion overlooks how frequently biopsies are abnormal in GBS/CIDP. It is also inconsistent with the literature that he provided." The Special Master also indicated that Dr. Finkel's statement that "[O.A.S.]'s normal biopsy was inconsistent with, but not impossible for, GBS/CIDP, is more persuasive." Id. Special Master Moran concluded, with regards to his sixth data point, that "[w]hile a normal biopsy is not dispositive of a diagnosis, [O.A.S.]'s normal biopsy would place her in the minority for GBS patients (ten percent)." Id. Therefore, the Special Master found that "[O.A.S.]'s normal biopsy supports a diagnosis of SMARD." Id.

As a seventh data point in his discussion section, Special Master Moran analyzed the results of [O.A.S.]'s CSF level testing. [O.A.S.]'s CSF level was tested on March 3, 2001, and the result was normal. Special Master Moran noted that "[i]n only approximately ten percent of GBS/CIDP cases is the protein level normal." Id. The Special Master also observed, relying on Dr. Finkel's testimony, that while "a patient does not have to have elevated protein levels for a diagnosis of GBS," "a normal protein level was 'certainly not consistent with general concepts about GBS' and that it would be 'unusual.'" Id. Dr. Maertens asserted, however, that a "normal [protein level] doesn't rule out GBS," and also testified that "he is quick to conduct a spinal tap in his patients because 'spinal fluid is all you need to make a diagnosis of GBS.'" Id. at *33. Dr. Maertens testified that the timing of the test is critical, and that the level of protein in the CSF depends "'on how active the demyelination is at the time of the lumbar puncture . . . if you do it too early, you might miss it, if you do it too late, you might miss it.'" Id.

Dr. Finkel disagreed, however, with Dr. Maertens' opinion, and explained that "the protein level 'can be normal in the first few days, and it does tend to go up in the first week to ten days . . . it will build up, but it doesn't just come back down to normal. So it's going to be elevated for several weeks.'" Id. Dr. Finkel maintained that "if [O.A.S.] suffered from a demyelinating disease (either GBS or CIDP) beginning 'a few weeks' before the lumbar puncture, as Dr. Maertens proffered, then she would still be undergoing demyelination on March 3, 2001 [the date of her CSF test]." Id. Special Master Moran, therefore, concluded:

> Although a normal CSF protein might occur in a patient with GBS/CIDP, a normal CSF protein is typical for a SMARD patient. Dr. Finkel stated that [O.A.S.]'s normal protein level was highly consistent with SMARD. Dr. Maertens, too, testified that a normal CSF protein level is consistent with

> SMARD. Therefore, [O.A.S.]'s normal CSF protein level tends to favor of [sic] a diagnosis of SMARD.

Id.

As an eighth data point in his discussion section, Special Master Moran considered [O.A.S.]'s creatinine levels. The Special Master cited to thirteen examples of [O.A.S.]'s creatinine level tests, which, with an exception of the results obtained at the Mayo Clinic, and one result obtained at the University of Iowa Hospitals, were consistently low. Id. The experts differed in their views as to whether [O.A.S.]'s creatinine levels results were consistent with SMARD. Dr. Maertens stated that "an abnormally low creatinine level is consistent with a diagnosis of SMARD," but, "in [O.A.S.]'s case her creatinine level did not support a diagnosis of SMARD or GBS/CIDP because her creatinine levels differed throughout her illness." Id. at *34. Instead, Dr. Maertens argued that "he would 'toss' the creatinine data point." Id. Dr. Finkel, on the other hand, maintained that [O.A.S.]'s creatinine test results were "consistent with a diagnosis of SMARD" even after the rise of creatinine level because "'children with SMARD can actually improve . . . they can increase their muscle strength.'" Id. Special Master Moran noted that "[n]either Dr. Finkel nor Dr. Maertens associated low levels of creatinine with GBS/CIDP," which was reflected in his chart as neutral for GBS/CIDP. Id. Special Master Moran concluded that "[O.A.S.]'s low creatinine level provides modest support for SMARD." Id.

The results of EMG tests and nerve conduction studies were Special Master Moran's ninth data point in his discussion section. The Special Master explained that "[t]he nerve conduction study can measure the latency, velocity, and amplitude of an electric signal. A low result for amplitude means that the axon, the part of the nerve that carries the electrical signal, is damaged. When the velocity is slow, the myelin is damaged." Id. The Special Master explained that in the background section of his decision, he had already summarized all of [O.A.S.]'s EMG test results, and provided the interpretations offered by both Dr. Maertens and Dr. Finkel. Therefore, he indicated that "[r]ather than repeat these summaries, this portion of the decision highlights the results of two tests – the first one, which was conducted on February 26, 2001, at the Mayo Clinic, and the fourth one, which was conducted on April 24, 2001,[40] at Johns Hopkins." Id. After analyzing the experts' evaluations of [O.A.S.]'s first EMG from the Mayo Clinic, the Special Master noted that "both Dr. Maertens and Dr. Finkel interpreted the first EMG as showing some axonal damage. But, there was some disagreement as to whether this EMG showed demyelination." Id. at *35. Specifically, "Dr. Finkel stated that he did not see any evidence of demyelination and Dr. Maertens said the results were 'not totally inconsistent with demyelination.'" Id. The EMG conducted at John Hopkins Hospital on April 26, 2001, showed, according to Dr. Maertens, some "'[d]emyelination,'" as well as indicated a clear decline of [O.A.S.]'s condition, so "that's more an axonal injury now." Id. at *36. Dr. Finkel also "concluded that the process

[40] As noted above, the correct date of the EMG study conducted at Johns Hopkins Hospital is April 26, 2001.

affecting [O.A.S.]'s nerves was axonal," but he determined that the test results showed "no segmental slowing," which is a hallmark for GBS/CIDP. Id. Therefore, "Dr. Finkel found this nerve conduction study as supporting SMARD, and not supporting GBS/CIDP." Id. After examining the evidence, the Special Master determined that the results of the EMG studies supported a "logical deduction" that [O.A.S.] did not have GBS/CIDP. See id.

As a tenth data point in his discussion section, Special Master Moran analyzed whether [O.A.S.]'s responses to the IVIG treatment were more consistent with SMARD or with GBS/CIDP. Special Master Moran noted the testimony of Dr. Maertens, who stated that [O.A.S.]'s improvement after the IVIG treatments strongly supports a diagnosis of GBS. Dr. Maertens explained that [O.A.S.] "responded to the first treatment, and she responded again a little bit to the second treatment, but definitely to the first treatment she responded to the point of coming off the vent. She really did improve remarkably. And you would not expect any response to treatment with SMARD, with IVIG." Respondent's expert, Dr. Finkel, also testified that after the IVIG treatments, [O.A.S.] showed "some marginal signs that hinted at some improvement." Id. at *37. Dr. Finkel argued, however, with respect to [O.A.S.]'s first IVIG treatment at the Mayo Clinic, after which her condition significantly improved, that "the improvement 'was largely due to the improvement in the RSV, not the underlying peripheral neuropathy.'" Id. Special Master Moran observed that after her second and third round of IVIG treatment, [O.A.S.] improved only slightly, if at all. Therefore, although admitting that "[t]his data point presents a closer call," the Special Master stated: "[i]f [O.A.S.] truly suffered from an immune-mediated neurological disease like GBS or CIDP, then she probably would have made a more significant improvement. Thus, on the whole, [O.A.S.]'s lack of response to IVIG tends to favor SMARD, but only slightly." Id.

As the eleventh data point in the discussion section of the Special Master's decision, although not included as a separate issue on his chart, Special Master Moran considered the diagnoses by [O.A.S.]'s treating doctors. At first, he noted that the "nomenclature" used by "some doctors" to "label [O.A.S.]'s condition," "limit[s] the value" of some of the treating physicians' opinions. Id. The Special Master noted that the phrase "'peripheral neuropathy,'" which some of the doctors used to describe [O.A.S.]'s condition, "without any modification – does not distinguish SMARD from GBS/CIDP. SMARD also affects the peripheral nerves." Id. The Special Master indicated that "the Simanskis appear to interpret this phrase as supporting their claim that [O.A.S.] suffered GBS/CIDP." Id. The Special Master also commented that "[i]n contrast, the phrase 'post-infectious demyelinating neuropathy' . . . points to GBS/CIDP because those conditions are demyelinating conditions and SMARD is not." Id. As a second issue, the Special Master mentioned the fact that "most pediatric neurologists were not aware of SMARD until 2003, when an article was published in Annals of Neurology," alerting most pediatric neurologists to the existence of the SMARD disease.[41] Id. at *38. He

[41] As noted above and as Dr. Finkel testified, an article on SMARD, authored by Dr. Grohmann, was published in the journal Annals of Neurology in 2003. See Grohmann, et al., Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54

emphasized that "[t]his lack of awareness needs to be taken into account when evaluating statements" from physicians diagnosing [O.A.S.] before 2003. Id. Special Master Moran noted that "[O.A.S.]'s treating physicians have consistently referenced SMARD as the proper diagnosis since 2003." Id. at *39. The Special Master stated that regarding a SMARD diagnosis for [O.A.S.], "[t]he Simanskis have done very little to refute these conclusions," including allowing genetic testing. Id. The Special Master also noted that, "in their reply brief, the Simanskis identified a single post-2003 medical record in which Dr. Gavin described [O.A.S.] as 'a four-year-old female with Peripheral Neuropathy of unknown etiology . . . . One medical consultant has suggested she may have Spinal Muscular Atrophy with Respiratory Distress but this diagnosis has yet to be confirmed.'" Id.

As his twelfth and final data point in the discussion section of his decision, although, as with the eleventh data point, not addressed as a separate consideration on the chart included in his decision, Special Master Moran compared two of the parties' experts: Petitioners' expert, Dr. Maertens, and Respondent's expert, Dr. Finkel. Noting that both experts are board-certified in pediatrics and neurology with a special competence in child neurology, Special Master Moran wrote that, "[u]nlike Dr. Maertens, Dr. Finkel also possesses separate board certification in electrodiagnostic medicine and a separate subspecialty certification in neuromuscular medicine," which "enable him to perform EMGs and nerve conduction studies." Id. at *40. Moreover, Special Master Moran also indicated that Dr. Finkel "also typically reviews the data of tests performed by other people and offers his interpretation of the study." Id. Special Master Moran further noted that Dr. Finkel "has written more than 60 articles published in peer-reviewed journals," almost all of which "discuss pediatric neuromuscular issues," and also has "served on the editorial board of the journal, Neuromuscular Disorders." Id. Dr. Finkel testified regarding SMARD that "the World Muscle Society, [] is where I first heard about it [SMARD], in about 2000-2001," while, in contrast, "Dr. Maertens testified that he first learned about SMARD in 2005 or 2006." Id. at *38. Special Master Moran further noted that "[i]n rejecting SMARD as a diagnosis, Dr. Maertens referred to the lack of a 'definitive test,' apparently meaning a genetic test." Id. at *40. Overall, the Special Master found Dr. Finkel "consistent and persuasive" while Dr. Maertens, according to the Special Master, "lack[ed] consistency and persuasiveness." Id. The Special Master did not address in any detail the other two experts, Petitioners' Dr. Shoenfeld and Respondent's Dr. McCusker, and gave Dr. Finkel's expert opinion more weight than Dr. Maertens' expert opinion.

Special Master Moran summarized his findings as follows:

> [O.A.S.]'s course is very much consistent with SMARD. In contrast, as Dr. Finkel noted, [O.A.S.] would be an exception in almost every diagnostic

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Ann. Neurol. 719 (2003). As also noted above, the same lead author earlier had published a journal article on SMARD in 2001. See Grohmann, et al., Mutations in the Gene Encoding Immunoglobulin μ-binding Protein 2 Cause Spinal Muscular Atrophy with Respiratory Distress Type 1, 29 Nat. Genet. 75, 76 (2001).

> criteria for GBS. Tr. 1220. Dr. Maertens's opinion that [O.A.S.] suffered from GBS, which relapsed and turned into CIDP, largely ignores or minimizes the significance of most of [O.A.S.]'s symptoms. See Tr. 811-15 (Dr. Maertens repeatedly stating that various data points do not support either diagnosis). Under these circumstances, the preponderance of evidence supports the finding that [O.A.S.] suffers from SMARD.

Id. at *41 (footnote omitted). The Special Master continued: "A preponderance of the evidence establishes that [O.A.S.] suffers from spinal muscular atrophy with respiratory distress, not Guillain-Barré syndrome or chronic inflammatory demyelinating polyneuropathy. The Simanskis have offered no evidence to establish that [O.A.S.]'s vaccinations caused her to suffer SMARD. Therefore, the Simanskis are not entitled to compensation." Id. at *42.

After the Special Master issued his decision, the Petitioners filed a timely Motion for Review in this court on September 19, 2013. In their Motion for Review, Petitioners claim that the Special Master "ignored highly relevant evidence on each and every 'data point' he used to make this determination," and that "[t]he cumulative effect of failing to consider highly relevant evidence on each 'data point' resulted in a blatant error of law."[42] While the Petitioners agree that, "in certain cases, '[i]dentifying the injury is a prerequisite to the [Althen] analysis,'"[43] quoting Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 2010)), Petitioners reject the Special Master's "evaluation of the evidence with respect to each 'data point' [which] concluded that every single data point was 'consistent' with a diagnosis of SMARD."[44]

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[42] The court notes that Petitioners' Motion for Review is replete with bold, italicized or underlined phrases. In order to make this opinion more readable, the various forms of emphasis included by Petitioners in their Motion for Review have been removed and are not reflected as emphasis in each of Petitioners' quotes included in this opinion.

[43] As noted above, at oral argument on November 18, 2013, the Petitioners' counsel agreed with respect to the proceedings before the undersigned that "we're talking only about, for the purposes of this review, whether or not the SMARD conclusion by Special Master Moran is the correct one." Counsel also agreed at the hearing, and the Petitioners asserted in their Motion for Review, that "there was no need to explore in detail . . . whether the vaccines could have adversely affected [O.A.S.]'s SMARD via the Althen test."

[44] Petitioners also note that the Special Master arrived at this conclusion despite his initial statement that "'[s]ome signs and symptoms are consistent with SMARD and some are inconsistent, or not associated with SMARD.'" As is discussed below, although the Special Master appears to have made this statement, and although his chart, included above, indicates "Response to IVIG" as neutral for SMARD, the discussion section of the Special Master's decision does not indicate that any of the other of [O.A.S.]'s presentations for the numerous symptoms and tests are inconsistent with SMARD.

The Petitioners claim that "[t]he cumulative effect of failing to consider highly relevant evidence on each 'data point' . . . grossly elevated the petitioners' proof requirement and deprived them of the statutory preponderant requirement." Consequently, according to the Petitioners, "in dismissing [O.A.S.]'s claims, the special master abused his discretion and made arbitrary and capricious findings."

While the Petitioners contend that each and every determination made by the Special Master was arbitrary, capricious, and an abuse of discretion, Respondent more broadly addresses the Petitioners' allegations, stating generally that the Special Master's factual findings "were based on a full and amply reasoned consideration of the record evidence," and that Special Master Moran correctly determined that the majority of [O.A.S.]'s symptoms support a diagnosis of SMARD. According to the Respondent, based on Munn v. Secretary of the Department of Health and Human Services, 970 F.2d 863, 871 n.10 (Fed. Cir. 1992), the Vaccine Act imposes a highly deferential standard of review of a Special Master's factual findings, which can be set aside only when "arbitrary and capricious," and that the Special Master's decision was not arbitrary or capricious and should be sustained.

Respondent asserts that Special Master Moran correctly determined that the majority of [O.A.S.]'s signs, symptoms, and test results, included in his data points, support a diagnosis of SMARD. Respondent also argues that the Special Master "applied the correct evidentiary standard and stated a rational basis for his conclusion that 'the weight of the entire record indicates that [O.A.S.] suffers from SMARD.'" Respondent adds:

> While petitioners argue that the Special Master erred in making such a finding . . . . He described the diagnoses alleged by petitioners (GBS and CIDP) and respondent (SMARD), meticulously analyzed the relevant medical records and literature, and carefully evaluated the opinions of both petitioners' and respondent's medical experts.

Discussing Special Master Moran's finding that [O.A.S.]'s respiratory failure at twelve and a half weeks is consistent with the diagnosis of SMARD, Respondent notes that "[w]hile Dr. Maertens's testimony on this issue varied at differing times in his testimony, he conceded that onset of GBS in a two-month-old infant is 'extremely rare.'" Respondent also maintains, citing Gilmartin, et al., Guillain-Barré Syndrome with Hydrocephalus in Early Infancy, 34 Arch. Neurol. 567 (2007), that "literature provided by petitioners supports the Special Master's finding that [O.A.S.]'s age at onset argues against a diagnosis of GBS," because GBS "has not, to our knowledge, been reported in early infancy." According to the Respondent, the Special Master's other determinations also support the Special Master's finding of SMARD and are inconsistent with diagnosis of either GBS or CIDP, including [O.A.S.]'s need for permanent ventilator support, her EMGs and nerve conductions studies, her IUGR, her patterns of weakness and initial preservation of reflexes, as well as the results of her sural nerve biopsy and the CSF protein level testing. Moreover, Respondent points out

that medical records, as well as the statements from [O.A.S.]'s treating physicians, support the Special Master's conclusion that [O.A.S.] appears to suffer from SMARD. Finally, Respondent claims that "in analyzing the various symptoms and test results, the Special Master necessarily had to weigh the opinions offered by both pediatric neurologists, Drs. Finkel and Maertens," and that, based on their respective qualifications, and testimonies, Special Master Moran's decision to find Dr. Finkel's testimony more persuasive is "well-supported, without legal error, and is 'virtually unchallengeable on appeal,'" quoting Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1251 (Fed. Cir. 2011), reh'g en banc denied (Fed. Cir. 2012).

DISCUSSION

Although presented in an order different from the one the Special Master utilized, the Petitioners focus their objections on seven of the Special Master's determinations and dispute the Special Master's final conclusion. First, Petitioners contest the Special Master's tenth data point conclusion in the discussion section of his decision, that [O.A.S.]'s response to IVIG treatment was consistent with a diagnosis of SMARD, and that according to the Special Master:

> After [O.A.S.] received the first course of IVIG, she did not need assistance from a ventilator. However, it is less clear that she improved because of the IVIG . . . . Moreover, after the second and third doses of IVIG, [O.A.S.] improved only slightly, if at all. If [O.A.S.] truly suffered from an immune-mediated neurological disease like GBS or CIDP, then she probably would have made a more significant improvement. Thus, on the whole, [O.A.S.]'s lack of response to IVIG tends to favor SMARD.

Petitioners claim that the Special Master ignored relevant evidence when he concluded [O.A.S.]'s response to IVIG treatment was consistent with a diagnosis of SMARD. Petitioners note that the "medical literature does indicate that, 'Responsiveness to immune modulating therapy is an important feature of CIDP and intravenous immunoglobulin (IVIG) is effective.'" Therefore, according to Petitioners, it is significant that [O.A.S.]'s health improved "dramatically" after the IVIG treatment, and, four days after the completion of treatment with IVIG, "[O.A.S.] was weaned off positive pressure to room air." Petitioners also point out that soon thereafter, on March 28, 2001, [O.A.S.] was discharged from the hospital in improved condition: "She remained extubated, her reflexes returned, and movement of her arms and legs were noted. By the time of discharge, she had been weaned off tube feedings and was bottle fed." Therefore, Petitioners argue that the IVIG treatment was "an effective treatment for [O.A.S.]'s GBS/CIDP."

Petitioners dispute Dr. Finkel's expert report, stating that [O.A.S.] showed no apparent therapeutic benefit from IVIG, and contrast the report with Dr. Finkel's testimony, during which, according to Petitioners, "he conceded that [O.A.S.] showed some marginal improvement after both courses of IVIG." Petitioners further argue that "SMARD does not have a relapsing remitting course and, IVIG is not effective in

treatment of SMARDs." Further, Petitioners contend that the Special Master ignored the testimony offered by the Petitioners' expert, Dr. Maertens, who testified that, based on his experience, the effectiveness of IVIG wears off 2-3 weeks after treatment. Petitioners note that after [O.A.S.]'s March 28, 2001 discharge from Mercy Medical Center, in an improved condition after an IVIG treatment, "she required the reinstitution of oxygen at low levels at about 20 days after her last treatment with IVIG." They allege, therefore, that "[O.A.S.]'s deterioration about 20 days after her last treatment with IVIG is entirely consistent with the time frame Dr. Maertens' noted deterioration in his patients who receive IVIG." Thus, Petitioners assert, "[O.A.S.]'s improvement after her IVIG treatments clearly supports a diagnosis of GBS/CIDP, and is highly inconsistent with a SMARD diagnosis."

Additionally, Petitioners claim that [O.A.S.]'s response to the second course of IVIG therapy, which showed less improvement in her health than the previous one, easily can be explained by the testimony of Dr. Maertens, who stated that, since [O.A.S.]'s EMG exam showed axonal damage, "he would not expect as much improvement because it takes time and persistence with injury at that level." Dr. Maertens also added that "[a]xonal injuries are more irreversible," and, although the potential for recovery exists, "you never get back to normal. At some point you cannot recover at all." Petitioners note that "[O.A.S.]'s treating physician at Iowa understood this,"[45] and stated, on May 7, 2001, although before the 2003 apparently more widely recognition of SMARD in the medical community, "Acute motor predominantly axonal neuropathy - not unlike axonal GBS. Pt has been w 4 courses of IVIG + 1 of steroids. Pt now more recently shows some improvement in legs w reapp. of reflexes. Would expect gradual incomplete[[46]] recovery slowly."

Second, Petitioners disagree with Special Master Moran's determination that [O.A.S.]'s EMG studies were consistent with a diagnosis of SMARD, the Special Master's ninth data point in his discussion section. Petitioners note that although "[O.A.S.] underwent five (5) EMG studies," the Special Master concentrated on [O.A.S.]'s April 26, 2001 EMG study, and "ignored the several studies that supported a diagnosis of GBS." Petitioners argue that all five of [O.A.S.]'s EMG studies, conducted on March 7, 2001,[47] April 17, 2001, April 26, 2001, May 8, 2001 and September 17, 2003, support a diagnosis of a peripheral neuropathy, which they allege is symptomatic

[45] The court notes that the May 7, 2001 note was not issued by Dr. Mathews, who prepared the May 8, 2001 report about history of [O.A.S.]'s disease.

[46] The court notes that Petitioners appear to quote the last sentence incorrectly, indicating that the University of Iowa Hospitals note stated: "Would expect gradual incomplete recovery slowly." In the original, there is a question mark after the word "incomplete."

[47] The court notes that there was no EMG performed on that day. The date listed in [O.A.S.]'s medical records for an EMG at the Mayo Clinic is March 6, 2001. Also, as noted above, [O.A.S.] underwent six, not five, EMG studies.

for GBS/CIDP. Petitioners conclude that "[f]or the special master to have made a determination that [O.A.S.]'s EMG studies do not support a GBS/CIDP diagnosis is another blatant abuse of discretion."

Third, Petitioners challenge Special Master Moran's statement regarding his fifth data point in the discussion section of his decision that:

> "The probabilities make [O.A.S.]'s unfortunate need for ventilator support more consistent with SMARD, not GBS. The need for ventilator assistance, however, is not unheard of in GBS cases. A fraction of GBS-afflicted people, perhaps one in five, requires ventilator assistance. But, all patients with SMARD are aided in their breathing. [O.A.S.]'s progression to permanent ventilator support weighs in favor of SMARD."

(emphasis in original).

Petitioners contend that while Special Master Moran and Dr. Finkel agree that progression to permanent ventilation support within one month of the onset of respiratory failure is "highly consistent" with SMARD, "[O.A.S.] did not progress to permanent ventilation support after her respiratory failure." They claim that during his testimony, Dr. Finkel "agreed that [O.A.S.] was extubated for approximately one month after her arrival in respiratory failure." Moreover, Petitioners claim that "[f]ollowing [O.A.S.]'s improvement, she was readmitted to the hospital on April 13, 2001 in respiratory distress. This relapsing and remitting course, however, is inconsistent with a diagnosis of SMARD, but is characteristic for relapsing GBS and CIDP."

Fourth, Petitioners contest Special Master Moran's determination on his second data point in his discussion section, that [O.A.S.]'s "presentation with respiratory failure" is consistent with SMARD. Petitioners dispute his finding that [O.A.S.]'s "'health preceding her respiratory arrest and her respiratory arrest are generally consistent with SMARD,'" and that "'the presentation with respiratory failure is more common in SMARD, than in GBS/CIDP.'" Petitioners argue:

> The medical literature filed in [O.A.S.]'s case indicates that every child who was diagnosed with SMARD with a known gene mutation had the onset of symptoms prior to the presentation of respiratory arrest. In other words, there was a history of abnormality noted by either the parents or the pediatricians prior to the respiratory arrest. This is unlike [O.A.S.]'s history, one that is clearly documented in the records of her multiple hospitalizations. Every hospitalization notes that [O.A.S.] was doing well, gaining weight, and without developmental issues prior to her respiratory arrest.

Petitioners highlight that "even the special master stated, 'Before the January 26, 2001 vaccinations, [O.A.S.] was basically healthy.'"

Petitioners also cite the Grohmann article in the record, Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719 (2003), stating that:

> prior to the onset of respiratory failure at a median age of 3.5 months, 100% of patients had a weak cry (median age 1 month) and respiratory distress (median age 3 months), 50% of patients had inspiratory stridor (median age 0.5 months), while 58% of patients exhibited poor feeding prior to the respiratory failure.

Petitioners assert that "[O.A.S.] experienced none of these symptoms prior to her respiratory arrest." Petitioners conclude that the Special Master failed to consider the evidence that "all patients with genetically confirmed SMARD were symptomatic prior to presenting with respiratory failure at a median age of 3.5 months," while "[O.A.S.] was completely asymptomatic prior to presenting with respiratory arrest."

Fifth, Petitioners contest the Special Master's determination that "[O.A.S.]'s treating physicians have consistently referenced SMARD as the proper diagnosis since 2003," his eleventh data point in the discussion section, is also arbitrary, capricious and an abuse of discretion. Petitioners cite to ten examples of [O.A.S.]'s doctors' diagnoses of peripheral neuropathy, which Petitioners assume is the same as a diagnosis of GBS, eight diagnoses in 2001, a diagnosis to that effect in 2003 and one in 2004, as follows:

> -Results of a February 26, 2001 EMG indicated, "The findings are those of a length-dependent sensorimotor peripheral neuropathy, such as could be seen in inherited or metabolic neuropathies. There is no evidence of a diffuse disorder of anterior horn cells or a myopathy."
>
> -On March 7, 2001, Dr. Kotagal stated, "The prolonged distal latency in the [left] peroneal is suggestive of a demyelinating process, an acute or subacute inflammatory demyelinating neuropathy."
>
> -On March 8, 2001, a progress noted indicated, "Given the [increased] phrenic nerve latency[,] considering Guillain Barre syndrome [with] primarily axial and phrenic nerve involvement."
>
> -A March 8, 2001 record also stated, "[Question of] AIDP variant."
>
> her discharge diagnosis was "probable post-infectious demyelinating neuropathy."
>
> -On April 26, 2001, [O.A.S.] had a motor nerve conduction and needle electromyography. The results indicated, "This study demonstrates the presence of widespread neuropathic weakness. The pattern is consistent with either a motor neuropathy or a sensorimotor axonal neuropathy."
>
> -[O.A.S.]'s May 3, 2001 admission note to the University of Iowa Hospitals stated, "6 month old [with] likely progressive sensorimotor neuropathy."

> -On May 7, 2001, a neurological consult indicated that [O.A.S.] suffered an "acute motor predominant axonal neuropathy – not unlike axonal GBS."
>
> -The results of an EMG/Nerve Conduction study from May 8, 2001 indicated, "These findings favor the diagnosis of peripheral neuropathy over motor neuron disease."
>
> -On May 10, 2001, Dr. Katherine Mathews, a neurologist, stated, "[O.A.S.]'s exam and findings are most suggestive of a peripheral neuropathy . . . . Her clinical picture is not compatible with spinal muscular atrophy (and DNA testing has been negative)."[48]
>
> -On September 17, 2003, [O.A.S.] underwent an EMG study, which indicated, "INTERPRETATION: There is neurophysiologic evidence for a severe, diffuse sensorimotor peripheral neuropathy characterized primarily by axonal loss."

Petitioners also state that even "after the 2003 benchmark that the special mater [sic] uses as support of a SMARD diagnosis, [O.A.S.]'s treating physician stated, [O.A.S.] showed "Peripheral Neuropathy of unknown etiology . . . . One medical consultant has suggested she may have Spinal Muscular Atrophy with Respiratory Distress but this diagnosis has yet to be confirmed." Petitioners also assert that the Special Master did not indicate that a SMARD diagnosis was never confirmed, which also was noted by Dr. Finkel in his February 20, 2013 testimony.

Sixth, Petitioners also argue that "the Special Master's determination that clinical findings alone can accurately diagnose SMARD is arbitrary, capricious, and an abuse of discretion." Petitioners assert, "[t]he respondent's literature shows the poor predictive value of using the clinical findings alone to predict whether a child has the genetic mutation that confirms the diagnosis of SMARD." Petitioners cite to the Grohmann article, Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719 (2003), which "explores 65 patients with the SMARD phenotype (clinical signs and symptoms) who actually were tested for the genetic mutation. Of these 65, more than half, thirty-six (36), were negative for the genetic mutation associated with SMARD (IGHMBP2)." Finally, Petitioners argue that [O.A.S.] "did not have the clinical signs and symptoms prior to her respiratory failure that were noted in patients who were eventually diagnosed with SMARD," but even if she did, "the medical literature supports the poor predictive value of clinical findings alone to confirm the diagnosis of SMARD."

Seventh, Petitioners claim that Special Master Moran's failure to consider relevant evidence on other "data points," including [O.A.S.]'s IUGR, the Special Master's first data point in the discussion section, the normal sural nerve biopsy, the Special Master's sixth data point in the discussion section, her CSF protein level, the Special

[48] As explained above, no genetic testing of [O.A.S.] has been conducted and the Petitioner parents have declined to conduct such testing.

Master's seventh data point in the discussion section and her creatinine level, the Special Master's eighth data point in the discussion section, were arbitrary, capricious, and an abuse of discretion. Regarding [O.A.S.]'s IUGR, Petitioners claim that Special Master Moran concluded that [O.A.S.]'s IUGR "supports a diagnosis of SMARD," but that he failed to consider Dr. Finkel's concession that while IUGR places an infant at higher risk for developing problems, "'[i]t doesn't imply that they will have problems, of course.'" Moreover, Petitioners claim Special Master Moran failed to mention Dr. Finkel's testimony in which he indicated that "his review of [O.A.S.]'s early pediatric records did not reveal that [O.A.S.] suffered any ill consequences from her IUGR."

Regarding the normal sural biopsy, Petitioners state that Special Master Moran "ignored undisputed evidence that a sampling error could result in obtaining a 'normal' tissue during biopsy." They also allege that the Special Master ignored expert testimony that [O.A.S.]'s sural nerve biopsy was supportive of an inflammatory neuropathy. Finally, Petitioners claim that the Special Master ignored the Grohmann article, Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719 (2003), which indicated that "sural nerve biopsy was positive in 10 of 15 patients with the confirmed genetic mutation in SMARD, and showed axonal degeneration." Petitioners claim that [O.A.S.]'s nerve biopsy did not show axonal degeneration, but that the Special Master failed to acknowledge this in his decision.

Turning to [O.A.S.]'s "normal" CSF protein level, Petitioners note that Special Master Moran cited both experts, Dr. Finkel and Dr. Maertens, who each indicated that [O.A.S.]'s normal protein level was either highly consistent with SMARD (Dr. Finkel) or consistent with SMARD (Dr. Maertens). Petitioners, however, claim that the Special Master ignored "highly relevant" evidence from both [O.A.S.]'s medical records and from the medical literature in the record, which explain that the reason for a normal CSF protein level "may be that CSF was sampled relatively late in the illness as CSF protein alteration is maximal in the first 2 weeks of illness." Moreover, Petitioners claim that several of the articles in the record demonstrate that normal protein levels are present in certain GBS cases. The first article Petitioners cite, Eckert, et al., A Case of Influenza Vaccination Induced Guillain Barré Syndrome with Normal Cerebrospinal Fluid Protein and Improvement on Treatment with Corticosteroids, 37 Scand. J. Infect. Dis. 621 (2005), indicates that approximately 10% of GBS patients show "no characteristic protein elevation in the CSF." Another article cited by the Petitioners, Deceunick RMB, et al., Epidemiology of Guillain-Barré Syndrome in the Province of Quebec, 35 Can. J. Neurol. Sci. 472 (2008), references a study in which lumbar punctures were performed in thirty two of thirty three patients, and the elevated protein was only found in twenty patients. Finally, the third article referenced in Petitioners' Motion for Review, Gai-Fen, et al., A Case-Control Study on Children with Guillain-Barre Syndrome in North China, 16 Biomed. Environ. Sci. 105 (2003), discusses a case-control study on children with GBS in Northern China, in which thirty five of fifty one patients "'had elevated protein level - about 1/3 had normal levels.'" Regarding [O.A.S.]'s creatinine levels, Petitioners claim that the Special Master "made no mention of the concession by Respondent's expert, Dr. Finkel that 'no other physician considered her creatinine level to be indicative or supportive of a diagnosis of SMARD.'"

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

In order to recover under the Vaccine Act, Petitioners must prove that the vaccine caused the purported injury. See W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355-56 (Fed. Cir. 2013) ("The Vaccine Act created the National Vaccine Injury Compensation Program, which allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had significantly aggravated' a vaccine-related 'illness, disability, injury, or condition.'" (quoting 42 U.S.C. § 300aa–11(c)(1)(C))); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1350 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 2011) ("A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine."); see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013); Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011). Regarding the standard of review, articulated in Markovich v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1366 (Fed. Cir.) (The United States Court of Appeals for the Federal Circuit stated that "we 'perform[ ] the same task as the Court of Federal Claims and determine[ ] anew whether the special master's findings were arbitrary or capricious.'" (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))) (brackets in original), reh'g and reh'g en banc denied (Fed. Cir. 2013); W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355,

1363 (Fed. Cir. 2012); Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under the same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh'g and reh'g en banc denied (Fed. Cir. 2008); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1277; Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 817 (2013). The arbitrary and capricious standard is "well understood to be the most deferential possible." Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 870.

Therefore, this court may set aside a Special Master's decision only if the court determines that the "findings of fact or conclusion of law of the special master . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 42 U.S.C. § 300aa-12(e)(2)(B); see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1350 ("We uphold the special master's findings of fact unless they are arbitrary or capricious.") (internal citations omitted); Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1321; Markovich v. Sec'y of Health & Human Servs., 477 F.3d at 1356-57; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360. The United States Court of Appeals for the Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard . . . ; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 871 n.10; see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Griglock v. Sec'y of Health & Human Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249 (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1345) (explaining that the reviewing court does "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder"); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 47.

"With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference – no change may be made absent first a determination that the special master was 'arbitrary and capricious.'"

Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B). Generally, "if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Human Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Dep't of Health & Human Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a "rational connection between the facts found and the choice made."'" (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

> As noted by the United States Court of Appeals for the Federal Circuit:
>
> "Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute."

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366 (quoting Hodges v. Sec'y of Dept. of Health & Human Servs., 9 F.3d at 961) (modification in original); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363; Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012). The United States Court of Appeals for the Federal Circuit has further explained that the reviewing courts "'do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" See Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363) (modification in original); see also Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010). "'Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.'" Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Dept. of Health & Human Servs., 970 F.2d at

870 n.10); see also Paluck v. Sec'y of Health & Human Servs., 113 Fed. Cl. 210, 224 (2013) ("A special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are 'supported by substantial evidence.'" (quoting Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir.), cert. denied, 131 S. Ct. 573 (2010))). Additionally, as instructed by the United States Court of Appeals for the Federal Circuit, "[u]nder the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses. Indeed, we have held that a Special Master's 'credibility determinations are virtually unreviewable.'" Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1347 (quoting Hanlon v. Sec'y of Health & Human Servs., 191 F.3d 1344, 1349 (Fed. Cir. 2010) (quotation omitted)).

Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 728 (2009); see also Paluck ex rel. Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 467 (2012) ("[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Human Servs., 601 F.3d at 1355], he cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2011))).

Regarding the causation analysis, as indicated by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health and Human Services:

> The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356; Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 50; Paluck v. Sec'y of Health & Human Servs., 113 Fed. Cl. at 212; Fesanco v. Sec'y of Health & Human Servs., 99 Fed. Cl. 28, 31 (2011). The United States Supreme Court has explained that:

> Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation. A claimant may also recover for unlisted side effects, and for

> listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.

Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073-74 (2011) (footnotes omitted); Kennedy v. Sec'y of Health & Human Servs., 99 Fed. Cl. 535, 539 (2011), aff'd, 485 F. App'x. 435 (Fed. Cir. 2012).

Petitioners state that, as a result of the vaccinations [O.A.S.] received on January 26, 2001, "[O.A.S.] suffered both from GBS and CIDP. In this regard, as the special master is well aware, GBS and CIDP are the acute and chronic forms of the same injury." GBS and CIDP are not listed as injuries on the Vaccine Table. See 42 U.S.C. § 300aa-14. Under the off-Table theory of recovery, a Petitioner is entitled to compensation if he or she can demonstrate, by a preponderance of the evidence, see 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table, but which was caused by a vaccine that is listed on the Vaccine Injury Table. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322)); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d at 1525.

Since [O.A.S.]'s conditions do not meet the requirements of a presumptively on-Table, vaccine-related condition, to prove entitlement for an off-Table injury, Petitioners must

> prove causation-in-fact. Grant [v. Sec'y of Health & Human Servs.], 956 F.2d [1144,] 1147-48 [(Fed. Cir. 1992)]. [The United States Court of Appeals for the Federal Circuit has] held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm."

de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 ("To prove causation, a petitioner must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352–53)). A "'substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant

cause of her injury, just that it was a substantial factor." Id. (citing Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)). A judge of this court has explained the relationship between "but-for" causation and "substantial factor" causation in our court's decision in Deribeaux ex rel. Deribeaux v. Secretary of Health and Human Services:

> The de Bazan court defined but-for causation as requiring that "the harm be attributable to the vaccine to some nonnegligible degree," and noted that, although substantial is somewhere beyond the low threshold of but-for causation, it does not mean that a certain factor must be found to have definitively caused the injury. Id. [de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351] Accordingly, a factor deemed to be *substantial* is one that falls somewhere between causing the injury to a non-negligible degree and being the "sole or predominant cause." Id.
>
> This definition of substantial—somewhere between non-negligible and predominant—is applicable to respondent's burden to prove a sole substantial factor unrelated to the vaccine. Accordingly, a respondent's burden is to prove that a certain factor is the only *substantial* factor—one somewhere between non-negligible and predominant—that caused the injury.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 105 Fed. Cl. 583, 595 (2012), aff'd, 717 F.3d 1363 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2013) (emphasis in original).

The Petitioners must prove their case by a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation.'" Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of Dep't of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("In this off-table case, the petitioner must show that it is 'more probable than not' that the vaccine caused the injury." (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80)). Decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard" and by the vaccine system created by Congress, in which "close calls regarding causation are resolved in favor of injured claimants" without the need for medical certainty. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280; see also Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322, 1332 n.4 (Fed. Cir. 2011), cert. denied, 132 S. Ct. 1908 (2012); Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009) ("In Althen, however, we expressly rejected the Stevens test, concluding that requiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence . . . and negates the system created by Congress' through the Vaccine Act.") (modification in original); La Londe v. Sec'y of Health & Human Servs.,

110 Fed. Cl. 184, 198 (2013) ("Causation-in-fact can be established with circumstantial evidence, i.e., medical records or medical opinion."). The Althen court further noted that "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 of how vaccines affect the human body." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280 (citing Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356. When proving eligibility for compensation for an off-Table injury under the Vaccine Act, however, Petitioner may not rely on her testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See 42 U.S.C. § 300aa-13(a)(1).

The Federal Circuit in Althen defined a three-prong test which a Petitioner must meet to establish causation in an off-Table injury case:

> To meet the preponderance standard, [Petitioner] must "show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y of Health & Humans Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]" Grant, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface [v. Sec'y of the Dep't of Health & Human Servs.], 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [Petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by 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.

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (brackets in original); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367; Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322; Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757, 766 (2013); Contreras v. Sec'y of Health & Human Servs., 107 Fed. Cl. 280, 291 (2012).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, the Althen court analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. Id. at 1278-80; see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. at 358. In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Althen court turned to the analysis undertaken in Knudsen by Knudsen v. Secretary of the Department of Health and Human Services, 35 F.3d at 549. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80. In Knudsen by Knudsen v. Secretary of the Department of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d at 549. Further,

> [t]he Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [Petitioner's] injury or that the [Petitioner's] injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury. See 42 U.S.C. § 300aa-13(a)(1), (b)(1).

Id. (brackets added). The Federal Circuit recently indicated in this very case on appeal form the Special Master's earlier dismissal of the case:

> Although a finding of causation "must be supported by a sound and reliable medical or scientific explanation," causation "can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms." Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d 543, 548–49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be.

Simanski v. Sec'y of Health & Human Servs., 671 F.3d at 1384 (omission in original).

The second prong of the Althen test requires the Petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367; Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355. In order to prevail, the Petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). In Capizzano v. Secretary of Health and Human Services, 440 F.3d at 1326, the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa-11(c)(1)–13(a)(1)).

The third prong of the Althen test requires the Petitioner to demonstrate, by a preponderance of evidence, "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Secretary of Health and Human Services, when it noted that, "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358; see also de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1352 ("Thus, the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." (citing Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358)). Requiring evidence of strong temporal linkage is consistent with the third requirement articulated in Althen because "[e]vidence 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." Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358 (citing Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326). The Pafford court further explained:

> If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination,

> because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

Id.

According to the court in Capizzano v. Secretary of Health and Human Services, evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong."). If a Petitioner satisfies the Althen burden and meets all three prongs of the test, the Petitioner prevails, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d at 547 (brackets in original; citation omitted).

When the nature of a Petitioner's injury is in dispute, however, the Special Master must first identify the injury before conducting an Althen causation analysis. See Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353. In Lombardi, the petitioner's experts offered different theories as to her injury. One of Petitioner's experts asserted that Petitioner suffered from transverse myelitis, the other testified that she suffered from either chronic fatigue syndrome or systemic lupus erythematosus. The government's experts disputed those diagnoses, and proposed five other possible diagnoses. See id. at 1352. The United States Court of Appeals for the Federal Circuit stated that:

> In the face of such extreme disagreement among well-qualified medical experts, each of whom had evaluated the petitioner, it was appropriate for the special master to first determine what injury, if any, was supported by the evidence presented in the record before applying the Althen test to determine causation.

Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352–53 (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346). The Lombardi court continued: "In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." Id. at 1353. "If a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by 'reputable medical or scientific explanation,' by which a vaccine can cause the kind of injury that the petitioner claims to have suffered." Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1365 (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278); see also Locane v. Sec'y of Health & Human Servs., 685 F.3d at 1381 ("Given the Special Master's finding that the illness was present before the vaccine was administered, logically, the vaccine could not have

caused the illness. The Althen inquiry is inapplicable.") (footnote omitted); Vinconti v. Sec'y of Health & Human Servs., 103 Fed. Cl. 600, 612 (2012); Carrino v. Sec'y of Health & Human Servs., No. 08-0266V, 2013 WL 3328903, at *11 (Fed. Cl. Spec. Mstr. June 6, 2013); cf. Contreras v. Sec'y of Health & Human Servs., 107 Fed. Cl. at 293 (Stating that "in an atypical case, where 'the question of causation turns on which injury [the Petitioner] suffered,' the special master is permitted to choose between two competing diagnoses of dissimilar diseases as a first step in the causation analysis." The United States Court of Federal Claims noted that this is an "exception" to "the general rule, first stated in Knudsen [by Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d at 549], that special masters should not diagnose alleged vaccine injuries."). In the above-captioned case, during the November 18, 2013 oral argument held in in this court, the Petitioners' counsel agreed that, "there was no need to explore in detail . . . whether the vaccines could have adversely affected [O.A.S.]'s SMARD via the Althen test." Instead, Petitioners' counsel agreed that "we're talking only about, for the purposes of this review, whether or not the SMARD conclusion by Special Master Moran is the correct one."

A Petitioner's burden of proof regarding the sustained injury is a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1); see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353 (noting that the Vaccine statute "places the burden on the petitioner to make a showing of at least one defined and recognized injury"); Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1350. If a Petitioner can show by a preponderance that he or she, in fact, suffered the injury claimed, he or she can continue to the question of causation, unless the government can demonstrate, also by preponderance of the evidence, an "alternative evidence on injury." See Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1350. The record in the current case includes differing evidence, as presented by the respective experts and [O.A.S.]'s medical history, with regards to the nature of [O.A.S.]'s illness. The parties presented alternative diagnoses as to the Petitioners' disease based on the record, and their respective experts also disagreed as to the many of [O.A.S.]'s symptoms and the disease she presented. See Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352–53. Therefore, the Special Master had to first determine what diagnosis applied to [O.A.S.]'s illness, before conducting a causation analysis under the Althen test. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278.

As discussed below, the Special Master rejected Petitioners' allegation in their Petition that [O.A.S.] suffered from GBS/CIDP, and concluded that each of the twelve data points he considered in the discussion section of his decision supported a diagnosis of SMARD.[49] In addition, on the Special Master's chart, summarizing the ten data points he included in his decision, the Special Master indicated that six data points are "inconsistent" with GBS/CIDP and "consistent" with SMARD," namely, [O.A.S.]'s age at onset of her disease, her reflex and her weakness pattern, the permanent ventilator support, the sural nerve biopsy showing no demyelination, her normal CSF protein

[49] The Special Master's conclusion on each data point in his discussion section ranged from "consistent," "slightly favors," "tends to favor," to "modest support for SMARD."

levels and the EMG and nerve conduction studies. [O.A.S.]'s response to the IVIG treatment was considered "inconsistent" with GBS/CIDP and "neutral" for SMARD. The Special Master stated that [O.A.S.]'s age of onset was "extremely rare" for GBS/CIDP, and that sural nerve biopsy showing no demyelination, and the EMG and nerve conduction studies showing axonal damage, not demyelination, were "strongly" inconsistent with GBS/CIDP. Regarding two other data points reflected on his summary chart included in his decision, review of [O.A.S.]'s IUGR record and her creatinine levels, the Special Master used the term "neutral" for GBS/CIDP. Only one data point included on his summary chart, although not considered in the body of his decision as a separate data point,[50] [O.A.S.]'s health before her respiratory arrest, was considered by the Special Master as potentially consistent with GBS/CIDP.

In his decision, the Special Master described the etiology of the GBS and CIDP. He noted that the Asbury criteria, as described in Asbury, et al., Assessment of Current Diagnostic Criteria for Guillain-Barré Syndrome, 27 Ann Neurol 21 (1990), "establish the symptoms frequently used to diagnose GBS," and indicated that they include "elevated protein in the spinal fluid, response to IVIG treatment," and "'reduced or absent reflexes."[51] The Special Master did not discuss other diagnostic criteria for GBS.[52]

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[50] As discussed above, the court notes a discrepancy between the Special Master's discussion section of his decision and the data point summary chart he included in his decision. See, generally, Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *41. The Special Master did not discuss [O.A.S.]'s health before her respiratory arrest as one of his discussion data points, although he included it in the summary chart. He also indicated acute respiratory failure was a presenting sign as a second discussion data point, but that also was not reflected on his chart. The opinions of the treating physicians, his eleventh discussion data point, and the comparison of the experts, his twelfth discussion data point, also were not reflected in the summary chart.

[51] The Special Master noted how the Respondent's expert, Dr. Finkel, had testified that the "'reflexes are typically lost early in GBS/CIDP. That's a hallmark. That's one of the two main criteria of GBS.'" Id. at *6. The Special Master further quoted the testimony of the Petitioners' expert, Dr. Maertens, who stated, "'[i]n most cases, the reflex[es] are decreased or lost.'" Id.

[52] In a recent decision, Carrino v. Secretary of Health and Human Services, 2013 WL 3328903, a Special Master noted that a "diagnostic guidance" offered by Francine Vriesendorp, Clinical Features and Diagnosis of Guillain–Barré Syndrome in Adults, "was available and relevant in October 2006." Id. at *14 n.29. Moreover, Dr. Maertens attached to his December 28, 2012 supplemental expert report an article listing the current diagnostic criteria for CIDP. See European Federation of Neurological Societies/Peripheral Nerve Society Guideline on Management of Chronic Inflammatory Demyelinating Polyradiculoneuropathy. Report of a Joint Task Force of the European Federation of Neurological Societies and the Peripheral Nerve Society, 10 J. Peripher Nerv Syst 220 (2005). Special Master Moran also cites the same article when discussing whether a sural nerve biopsy had any role in the diagnosis of GBS, CIDP or SMARD. See Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568,

The court notes that the Special Master's decision quoted the definition of GBS from Dorland's Illustrated Medical Dictionary at 1832: "GBS begins with 'paresthesias of the feet,'" but the Special Master did not discuss how [O.A.S.] presented on the issue. The Special Master, however, quoted Dr. Maertens, who testified that it is "'extremely difficult to make a diagnosis of GBS in a very young infant . . . because the child doesn't walk, doesn't sit up, and it's a lot easier to miss. It's going to be the hardest thing to diagnose.'" Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *6. A recent decision by a Special Master which considered the diagnostic criteria for GBS, Carrino v. Secretary of Health and Human Services, 2013 WL 3328903, described the presentation of GBS as also including "Lost or significantly diminished deep tendon reflexes;" "Progressive weakness;" "Paresthesia;" "Symmetric symptom presentation;" "Elevated protein levels in the cerebrospinal fluid;" and "EMG abnormalities." Id. at *14-17. In his decision, Special Master Moran discussed [O.A.S.]'s reflex patterns, [O.A.S.]'s tests indicating low protein level in the cerebrospinal fluid, and her EMG test results, finding that [O.A.S.]'s condition was inconsistent with GBS. The Special Master, however, did not discuss whether [O.A.S.] had paresthesia, whether there was a noted progression of [O.A.S.]'s weakness, and whether there was a symmetric presentation of her symptoms. The Special Master mentioned, in passing, that [O.A.S.]'s subsequent EMG tests, conducted after her initial EMG on February 26, 2001, indicated progress in her neuropathy, but he did not consider the progression in [O.A.S.]'s condition as one of the hallmarks for GBS. Finally, the Special Master did not include in his decision any discussion with respect to a symmetric presentation of [O.A.S.]'s symptoms.

SMARD is a rare and somewhat recently identified disease. As discussed above, Dr. Finkel and Special Master Moran indicated that neurologists became aware of SMARD in 2003, after the publication of an article in the Annals of Neurology. See Grohmann, et al., Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719 (2003). Moreover, there are no cases identified in the opinions issued by this court or in any of the decisions by the Office of the Special Masters, which specifically consider a SMARD diagnosis.[53] It appears that when

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at *16. The clinical diagnostic criteria for typical CIDP included as an exhibit by the Petitioners were described as similar to those for GBS: "Chronically progressive, stepwise, or recurrent symmetric proximal and distal weakness and sensory dysfunction of all extremities, developing over at least 2 months; cranial nerves may be affected; and [a]bsent or reduced tendon reflexes in all extremities."

[53] The court notes that in a published order to show cause issued by another Special Master in Sharkey v. Secretary of Health and Human Services, No. 99-669V, 2007 WL 5185477 (Fed. Cl. Spec. Mstr. Aug. 23, 2007), the Special Master mentioned that the Sharkey child had undergone genetic testing for spinal muscular atrophy (SMA), which made a diagnosis of SMA less likely. Id. at *5. (noting that since the "test found Ryan that has at least one intact SMN gene," he "could be among the 2% of children with SMA that do not have deletions of both SMN genes"). The child in Sharkey also had suffered a respiratory failure, but the Special Master did not indicate in the order to show cause a possible diagnosis of spinal muscular atrophy with respiratory distress

Special Master Moran concluded that [O.A.S.] suffers from SMARD, he relied heavily on the testimony and expert reports provided by Dr. Finkel. In his September 28, 2012 expert report, Dr. Finkel had provided a chart, which summarized his interpretation of the data points, which the Special Master ultimately included in the discussion section of his decision. Dr. Finkel's "[d]ata items" included: "Intrauterine Growth Retardation (IUGR)"; "[r]espiratory failure – acute onset, as the presenting symptom, with early right hemi-diaphragm eventration"; "[r]espiratory failure presenting at age 2 months, 3 weeks"; "[p]rogression to permanent ventilation support within one month of onset of respiratory failure"; "[w]eakness in limbs, trunk, neck muscles – onset within days to few weeks of respiratory failure (RF)"; "[w]eakness: distribution of lower>upper limbs, distal>proximal, symmetric"; "[n]erve conduction and EMG findings – length-dependent axonal sensorimotor polyneuropathy, without focal or segmental changes. (May have slowing of conduction initially that raises the consideration of GBS or CIDP)"; "[s]ural nerve biopsy"; "[c]erebrospinal fluid (CSF) profile"; "[l]ow serum creatinine (0.1) upon admission 1/20/00, suggestive of chronic muscle wasting (non-specific as to etiology)"; "[s]low decline in motor function over years, following the initial acute deterioration"; "[e]xcessive sweating (diaphoresis)"; "[n]o apparent therapeutic benefit from IVIg or prednisolone Rx." In his chart, Dr. Finkel interpreted [O.A.S.]'s medical records as either highly consistent (HC), consistent (C), inconsistent (I), highly inconsistent (HI), or neutral (N) with the three diseases at issue: SMARD, GBS and CIDP.

In Dr. Finkel's chart, the following data items were ranked "HC," i.e., highly consistent with SMARD: IUGR; respiratory failure – acute onset, as the presenting symptom; progression to permanent ventilator support within one month of onset of respiratory failure; weakness in limbs, trunk, neck muscles; weakness: distribution of lower>upper limbs, distal>proximal, symmetric; nerve conduction and EMG findings – length-dependent axonal sensorimotor polyneuropathy, without focal or segmental changes; cerebrospinal fluid (CSF) profile; slow decline in motor function over years; and excessive sweating. In Dr. Finkel's chart, the following data items were ranked "C," i.e., consistent with SMARD, "[s]ural nerve biopsy" and "[l]ow serum creatinine (0.1) upon admission 1/20/00, suggestive of chronic muscle wasting (non-specific as to etiology)." Additionally, in Dr. Finkel's chart, the following data item was ranked "N," i.e., neither support or inconsistent with SMARD, "[n]o apparent therapeutic benefit from IVIg or prednisolone Rx." The first four data items, and nerve conduction and EMG findings were found by Dr. Finkel "particularly predictive of SMARD1, where genetic confirmation of a mutation in the IGHMBP2 gene is likely to occur – with an estimate of over 90%." As is further discussed below, the Special Master's reliance on Dr. Finkel's expert report and testimony, and the principles identified in the medical community as diagnostic criteria for GBS and SMARD, was not arbitrary or capricious, nor was the Special Master's conclusion that [O.A.S.]'s injury is most consistent with a diagnosis of SMARD.

(SMARD). Ultimately, the Special Master's decision in the Sharkey case did not discuss the possibility of a SMA diagnosis, but instead concluded that the Petitioner in the case suffered from GBS. See Sharkey v. Sec'y of Health & Human Servs., No. 99-669V, 2010 WL 5507915 (Fed. Cl. Spec. Mstr. Dec. 10, 2010).

As noted above, Petitioners assert that the Special Master "ignored highly relevant evidence on each and every 'data point.'" Petitioners, however, do not specifically identify or object to three of Special Master Moran's data points: his third data point in the discussion section, regarding the onset of [O.A.S.]'s respiratory failure at twelve weeks; his fourth data point in his discussion section, regarding [O.A.S.]'s weakness patterns and reflexes, and twelfth data point in the Special Master's discussion section, the comparison of experts, which is not directly mentioned by Petitioners, although Petitioners' objections to the Special Master's conclusions indicate their objection to this data point. Petitioners object to the Special Master's determination that the results of the IVIG treatments, EMG studies, [O.A.S.]'s progression to permanent ventilator support, and [O.A.S.]'s presentation with respiratory failure were consistent with the diagnosis of SMARD. Petitioners further disagree with the Special Master's conclusion that the diagnoses offered by [O.A.S.]'s treating doctors support a diagnosis of SMARD. Moreover, Petitioners argue that "clinical findings alone" cannot accurately diagnose SMARD. Finally, Petitioners claim that the Special Master's failure to consider relevant evidence with regards to other "data points" he considered, including the IUGR, normal sural biopsy test results, normal CSF and creatinine levels was arbitrary, capricious, and an abuse of discretion.

Because the Special Master's ten point chart included in his decision does not fully reflect his twelve point discussion sections in the decision, and because his chart does not include a comparison of the expert opinions offered by Dr. Maertens and Dr. Finkel, the court has developed a summary chart, to facilitate understanding of the complex issues presented by [O.A.S.]'s case, which is included below:

Data Point	Petitioners' Expert, Dr. Maertens' Pebble Rating	Dr. Maertens' Conclusions	Respondent's Expert, Dr. Finkel's Pebble Rating	Dr. Finkel's Conclusions	Special Master's Data Points Chart Summary	Special Master's Conclusion (GBS, CIDP or SMARD) in his Decision
Intrauterine Growth Retardation (IUGR)	No scale/pebble estimate; "toss" (on neither side of the scale)	In his expert report noted that neither supportive nor inconsistent with SMARD; at the hearing first stated that "consistent with" but not a prerequisite for SMARD; later stated IUGR not useful data in distinguishing GBS/CIDP or SMARD	Medium size pebble for SMARD (size three)	Highly supportive feature for SMARD	Neutral for GBS/CIDP; consistent with SMARD	"supports a diagnosis of SMARD"
Health Before Respiratory Arrest [not a separate data point in discussion section but mentioned in the "Acute Respiratory Failure" discussion and in the chart summary]	No scale/pebble estimate	Not consistent with SMARD	No scale/pebble estimate	Consistent with SMARD [[O.A.S.]'s weak cry earliest symptom of SMARD]	Consistent with GBS/CIDP; consistent with SMARD	Special Master stated it was "difficult" to evaluate "the strength or weakness of [O.A.S.]'s cry" but concludes "health preceding her respiratory arrest . . . consistent with SMARD"
Acute Respiratory Failure as a Presenting Sign	No scale/pebble estimate; "toss" (on neither side of the scale)	In his expert report noted that consistent with SMARD; but also can be a "complication" to GBS and CIDP	"strong pebble" for SMARD (size four)	Consistent with SMARD	[Not included in the summary chart]	"slightly favors the SMARD diagnosis"
Onset of Respiratory Failure at 12 Weeks	No scale/pebble estimate	In his supplemental expert report, stated "GBS occurs at all ages" but at the hearing testified "extremely rare" to have GBS at 2 mo.; also, that onset at 2 mo. could occur with SMARD	Size five for SMARD	Consistent with SMARD, inconsistent with GBS or CIDP	Inconsistent with GBS/CIDP; consistent with SMARD	"tends to favor SMARD"
Weakness Pattern and Reflexes	No scale/pebble estimate	Data point favors neither SMARD nor GBS/CIDP	No scale/pebble estimate	Preservation of reflexes makes diagnosis of GBS/CIDP less likely	Inconsistent with GBS/CIDP; consistent with SMARD	Consistent with SMARD

Progression to Permanent Ventilator Support	No scale/pebble estimate	Probably goes more towards SMARD; but also occurs with GBS and persist in CIDP	No scale/pebble estimate	Typical for SMARD; inconsistent with GBS and highly inconsistent with CIDP	Inconsistent with GBS/CIDP; consistent with SMARD	More consistent with SMARD
Sural Nerve Biopsy	No scale/pebble estimate	The results did not go in any specific direction	No scale/pebble estimate	Normal biopsy inconsistent with, but not impossible for GBS/CIDP	Inconsistent with GBS/CIDP; consistent with SMARD	More consistent with SMARD, only 10% of GBS patients have normal biopsy
Cerebrospinal Fluid (CSF) Protein	No scale/pebble estimate	Consistent with SMARD	No scale/pebble estimate	Highly consistent with SMARD	Inconsistent with GBS/CIDP; consistent with SMARD	"tends to favor of [sic] a diagnosis of SMARD" because only 10% of GBS patients have normal CSF protein level
Creatinine Levels	No scale/pebble estimate; would "toss" this data point because different results through her illness	Consistent with SMARD but because different results throughout [O.A.S.]'s illness, the results did not support either SMARD or GBS/CIDP	No scale/pebble estimate	Consistent with SMARD	Neutral with GBS/CIDP; consistent with SMARD	"modest support for SMARD"
EMG Tests and Nerve Conduction Studies	No scale/pebble estimate	Could be consistent with GBS	No scale/pebble estimate	Supportive of SMARD because tests do not show segmental slowing, typical for GBS/CIDP	Inconsistent with GBS/CIDP; consistent with SMARD	Supports diagnosis of SMARD
Response to IVIG Treatment	No scale/pebble estimate	Improvement after IVIG strongly supports diagnosis of GBS	No scale/pebble estimate	Questionable to what degree improvement due to IVIG; later only marginal improvement if at all	Inconsistent with GBS/CIDP; neutral for SMARD	"tends to favor SMARD, but only slightly"
Views of Treating Doctors	No scale/pebble estimate	No conclusion	No scale/pebble estimate	Noted that medical community became aware of SMARD in 2003	[Not included in the summary chart]	Supports diagnosis of SMARD

The court notes that the Special Master's twelfth data point in his discussion section is a comparison of Dr. Finkel's and Dr. Maertens' expert opinions. The chart does not include this item, which is discussed below.

As noted above, the Petitioners, in their Motion for Review, made seven objections to determinations made by the Special Master, although not in the order presented by the Special Master.

a. IVIG Treatment

Petitioners object to the Special Master's determination regarding IVIG, the Special Master's tenth data point in the discussion section, as arbitrary and capricious:

> After [O.A.S.] received the first course of IVIG, she did not need assistance from a ventilator. However, it is less clear that she improved because of the IVIG . . . . Moreover, after the second and third doses of IVIG, [O.A.S.] improved only slightly, if at all. If [O.A.S.] truly suffered from an immune-mediated neurological disease like GBS or CIDP, then she probably would have made a more significant improvement. Thus, on the whole, [O.A.S.]'s lack of response to IVIG tends to favor SMARD . . . .

Petitioners claim that [O.A.S.]'s health improved "dramatically" after the IVIG treatment, and, that four days after the completion of treatment with IVIG, "[O.A.S.] was weaned off positive pressure to room air." Petitioners note that "medical literature does indicate that, 'Responsiveness to immune modulating therapy is an important feature of CIDP and intravenous immunoglobulin (IVIG) is effective.'" Accordingly, Petitioners claim that the IVIG treatment was "an effective treatment for [O.A.S.]'s GBS/CIDP." Petitioners further state that "SMARD does not have a relapsing remitting course, and, IVIG is not effective in treatment of SMARDs. Thus, [O.A.S.]'s improvement after her IVIG treatments clearly supports a diagnosis of GBS/CIDP, and is highly inconsistent with a SMARD diagnosis."

Additionally, Petitioners contend that the Special Master ignored the testimony of Dr. Maertens, who testified that, based on his experience, the effectiveness of IVIG wears off 2-3 weeks after a treatment. Petitioners note that after [O.A.S.]'s March 28, 2001 discharge from Mercy Medical Center, "she required the reinstitution of oxygen at low levels at about 20 days after her last treatment with IVIG." Petitioners allege, therefore, that "[O.A.S.]'s deterioration about 20 days after her last treatment with IVIG is entirely consistent with the time frame Dr. Maertens' noted deterioration in his patients who receive IVIG." Furthermore, Petitioners claim that [O.A.S.]'s response to the second course of IVIG therapy, which showed less improvement in her overall health than the previous one, also can be explained by the testimony of Dr. Maertens, who stated that since [O.A.S.]'s EMG exam showed axonal damage, "he would not expect as much improvement because it takes time and persistence with injury at that level." Dr. Maertens also added that "[a]xonal injuries are more irreversible," and, although the potential for recovery exists, "you never get back to normal. At some point you cannot recover at all." Petitioners note that "[O.A.S.]'s treating physician at Iowa understood this," and stated, on May 7, 2001: "Acute motor predominantly axonal neuropathy - not unlike axonal GBS. Pt has been w 4 courses of IVIG + 1 of steroids.

Pt now more recently shows some improvement in legs w reapp. of reflexes. Would expect gradual incomplete [?] recovery slowly."[54]

In fact, all four testifying experts agreed that [O.A.S.] responded positively to her first IVIG treatment at the Mayo Clinic in May 2001, although the Special Master only minimally addressed the testimony of two experts, Dr. Shoenfeld, for the Petitioners, and Dr. McCusker, for the Respondent, in this regard.[55] The experts' opinions differed as to whether the improvement in [O.A.S.]'s health was due exclusively to the IVIG treatment. Respondent's expert, Dr. Finkel, noted that [O.A.S.]'s apparent response to IVIG

> needs to be considered . . . within the context of her clinical situation, which was with RSV, and we know that we expect the RSV to improve, so it's not at all surprising that the respiratory aspect improved transiently, but the underlying condition with her neuropathy did not improve; in fact progressed such that she presented again on April 13[, 2001] with respiratory distress, respiratory failure yet again, this time without the provocation of an underlying illness like the RSV.

Dr. Finkel believed that [O.A.S.]'s improvement, resulting in her temporary extubation, was more likely the result of the resolution of her RSV infection. At the February 2013 hearing before the Special Master, Dr. McCusker, one of Respondent's experts, whose testimony was not mentioned in Special Master Moran's decision, stated that "[w]hether or not that was a response to the IVIG or the evolution of her infections process I don't think that you can say." Dr. McCusker also testified that, at the time, in addition to the treatment with IVIG, [O.A.S.] also was being treated with steroids and other medications for RSV, and the cumulative effect of the treatments helped [O.A.S.] improve to the point of being extubated. Special Master Moran cited to the note prepared by [O.A.S.]'s treating pediatrician, Dr. Gavin, who described [O.A.S.]'s treatment received at the Mayo Clinic as follows: "They went ahead and gave her a 4-day course of IVIG, but it is questionable as to what degree she responded clinically." Special Master Moran also referred to statements by Petitioners' expert, Dr. Maertens, including his discussion of the Asbury criteria, including response to IVIG treatment, and Dr. Maertens' explanation that "you would not expect any response to treatment with SMARD, with IVIG," as well as Dr. Maertens' conclusion that most GBS cases resolve and that most children respond positively to IVIG treatment.[56] Simanski v. Sec'y of

[54] As noted above, Petitioners incorrectly quoted the last sentence in their Motion for Review, without a question mark after the word "incomplete."

[55] In addition, [O.A.S.]'s treating physician at the Mayo Clinic, Dr. Kuntz, noted in [O.A.S.]'s discharge note: "Improved head control. Would expect continued gradual improvement in strength. Will sign off."

[56] An article attached by Dr. Maertens to his expert report noted that 76% of CIDP patients improved after an IVIG treatment. See Van Doorn, et al., Treatment of Immune Neuropathies, 15 Curr Opin Neurol. 623, 627 (2002). The testimony of Petitioners'

Health & Human Servs., 2013 WL 7017568, at *37. The Special Master, however, did not mention Dr. Maertens' testimony concerning the temporary effects of the IVIG treatment, namely that the effects usually wear off 2-3 weeks after treatment, as well as the testimony of Dr. McCusker.

Nevertheless, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. at 728; see also Paluck ex rel. Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Human Servs., 601 F.3d at 1355], he cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. at 668)). With respect to [O.A.S.]'s IVIG treatment, Special Master Moran weighed the evidence to arrive at his conclusion that the results of [O.A.S.]'s IVIG treatment slightly support the diagnosis of SMARD. After reviewing the available evidence in the record, the court finds that the Special Master did not abuse his discretion when he concluded that [O.A.S.]'s response to the IVIG treatment "presents a closer call," and, while inconsistent with a diagnosis of GBS or CIDP, only "slightly" confirms a diagnosis of SMARD. See Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *37.

b. Electromyography (EMG) Studies

Petitioners allege that "[O.A.S.] underwent five (5) EMG [electromyographies] studies" but that the "special master ignored the several studies that supported a diagnosis of GBS, and focused solely on [O.A.S.]'s April 26, 2001" EMG study. Petitioners present as examples [O.A.S.]'s EMG studies, which were conducted on "March 7, 2001,"[57] "April 17, 2001," "April 26, 2001," "May 8, 2001" and "September 17, 2003," as support for a diagnosis of a peripheral neuropathy, symptomatic for GBS/CIDP. Petitioners conclude that "[f]or the special master to have made a determination that [O.A.S.]'s EMG studies do not support a GBS/CIDP diagnosis is another blatant abuse of discretion."

In the Special Master's decision, preceding the discussion of [O.A.S.]'s EMGs, his ninth data point, was a detailed explanation regarding the purpose of the EMG studies and the way they are conducted. See Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *13-14. Special Master Moran indicated that EMGs are "often conducted in association with another test formally known as an electroneurography. Electroneurographies are more commonly known as nerve

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expert, Dr. Shoenfeld, however, indicated that GBS patients who recover are "lucky." Dr. Shoenfeld also stated, "we have progressive cases which do not recover, and despite IVIG and despite plasmapheresis they progress."

[57] Petitioners incorrectly state that the first EMG was conducted on "March 7, 2001," although the correct date is "February 26, 2001."

conduction studies. One purpose of a nerve conduction study is to locate an injury to the peripheral nerve." Id. In the fact section of his decision describing [O.A.S.]'s medical history, Special Master Moran discussed all six of [O.A.S.]'s EMGs and nerve conduction studies, as well as Dr. Finkel's and Dr. Maertens' interpretations of those studies, relying, in some instances, on the medical literature. See, generally, id. at *14-23. Special Master Moran also compared Dr. Finkel's qualifications and Dr. Maertens' qualifications with respect to conducting and interpreting EMGs, noting that:

> There was a notable disparity in the experience of the two experts in regards to conducting and interpreting EMGs. Dr. Maertens does not usually interpret his own EMGs. He relies on the interpretation of the person who conducted the test. Dr. Finkel received specialized training to perform and to interpret EMGs. He became board-certified in the relevant discipline, electrodiagnostic medicine, in 1999, and a primary part of his clinical practice is to conduct and to interpret pediatric EMGs. Additionally, Dr. Finkel teaches medical school residents how to perform and to interpret pediatric EMGs.

Id. at *14 (internal citations omitted).

In his analysis section, Special Master Moran explained that "[r]ather than repeat these summaries [of the EMGs studies], this portion of the decision highlights the results of two tests – the first one, which was conducted on February 26, 2001, at the Mayo Clinic," and the fourth one at Johns Hopkins Hospital on April 26, 2001. Id. at *34. He noted that the first test is important because Dr. Maertens pointed out that [O.A.S.]'s condition started as a demyelinating process and then resulted in damage to her axons. See id. Dr. Maertens testified that a diagnosis of [O.A.S.]'s condition is in part based on that nerve conduction study, which shows a demyelinating process. Dr. Maertens also stated: "Well, it's true that you could see that in many disorder [sic], and metabolic disorder [sic] could do it and inherited disorder [sic] could do it too, but it's basically a demyelinating process." Special Master Moran noted that although both Dr. Maertens and Dr. Finkel agreed that the first EMG showed some axonal damage, the experts disagreed as to whether the EMG showed demyelination. See id. at *34-35. Moreover, although Dr. Finkel testified that the EMG did not show evidence of demyelination, Dr. Maertens interpreted the February 26, 2001 EMG results as showing "a demyelinating process," but, according to the Special Master, Dr. Maertens "did not elaborate on what specific portions showed demyelination." Id. Special Master Moran further remarked that when pressed on cross-examination to "show evidence of demyelination on this EMG," Dr. Maertens did not correctly interpret the test results, and "erred" when discussing what part of the test indicates demyelination. Id. at *34. In contrast, Special Master Moran noted that Dr. Finkel testified that [O.A.S.] "started with an axonal neuropathy, and it progressed and continued as an axonal neuropathy."

[O.A.S.]'s first EMG and nerve conduction study, conducted at the Mayo Clinic on February 26, 2001, included the following interpretation of the results by Dr. Rubin, an EMG consultant, "length-dependent sensorimotor peripheral neuropathy, such as could

be seen in inherited or metabolic neuropathies. There is no evidence of a diffuse disorder of anterior horn cells or a myopathy." The other EMG performed on [O.A.S.], discussed by Special Master Moran in the analysis section of his decision, was conducted on April 26, 2001 at Johns Hopkins Hospital by Dr. Crawford, which "[b]oth Dr. Maertens and Dr. Finkel complimented" as thorough. Id. at *36. Dr. Crawford interpreted this study as indicating that [O.A.S.] has "either a motor neuronopathy or a sensorimotor axonal neuropathy."[58] The April 26, 2001 EMG study was deemed important by Dr. Finkel because, as Dr. Finkel indicated, it was "the first example where anybody has stimulated the nerve at three sites," "into three segments, by making marks at [O.A.S.]'s wrists, distal elbow, proximal elbow, and axilla." Id. at *21. Dr. Finkel, reading the conduction velocity number for those three sections, concluded that there is "no segmental slowing," which is, "what you would expect to see in GBS or CIDP," but, "it's not there." Id. In his testimony, Dr. Finkel suggested that it is possible that at the time Dr. Crawford performed [O.A.S.]'s EMG study in April 2001, Dr. Crawford was not aware of SMARD: "I don't know. I can't answer for him. But it hadn't hit the neurology literature yet. And he doesn't usually go to the World Muscle Society, which is where I first heard about it [SMARD], in about 2000-2001." Noting that with SMARD, "there is clearly a problem at the motor neuron level pathologically, at least in some cases," and "yet there is also pathology in the peripheral nerve," Dr. Finkel admitted, that "the pathology here is still very vexing to me," and, "[t]his is not your standard." Special Master Moran also noted, however, that Dr. Maertens, when asked to comment on Dr. Finkel's interpretation that there was no segmental slowing, testified, "so to me it's not segmental, but it's neither distal, and it's very diffuse. It's definitely not a distal, axonal damage," perhaps conceding "that this EMG did not show segmental slowing in [O.A.S.]," a hallmark of GBS or CIDP. Id. at *36.

As noted above, when the "medical evidence [is] not definitive" the special master may rely heavily on expert medical testimony. See Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1347. As instructed by the United States Court of Appeals for the Federal Circuit, "[u]nder the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses. Indeed, we have held that a Special Master's 'credibility determinations are virtually unreviewable.'" Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1347 (quoting Hanlon v. Sec'y of Health & Human Servs., 191 F.3d at 1349).

[O.A.S.]'s condition was diagnosed differently by her treating physicians over a number of years, and the etiology of her condition was disputed by her doctors and the testifying experts. Special Master Moran gave more weight to the testimony of Dr. Finkel, based on Dr. Finkel's specialized training to perform EMG studies, his extensive experience with conducting and interpreting EMG studies, and his experience in his clinical practice, in which Dr. Finkel routinely conducted and interpreted pediatric EMGs, as opposed to Dr. Maertens, who himself did not interpret EMG studies. The Special Master also favorably considered the opinions of [O.A.S.]'s treating doctors, who concluded [O.A.S.] suffered from SMARD, after SMARD was identified in the medical

[58] Petitioners claim that "all five (5) of [O.A.S.]'s EMG studies" support this diagnosis.

community. Special Master Moran's finding, and heavy reliance on Dr. Finkel's testimony as more persuasive than that of Dr. Maertens, regarding the EMGs and nerve conduction studies, to indicate that the tests on [O.A.S.] did not support a finding of GBS or CIDP, together with the evidence in the record, was supportive of a finding of SMARD, and was not arbitrary or capricious.

c. Progression to Permanent Ventilator Support

Petitioners dispute Special Master Moran's finding on his fifth data point in his discussion section, that [O.A.S.]'s progression to permanent ventilator support is consistent with SMARD, because they argue "[O.A.S.] did not progress to permanent ventilation support after her respiratory failure." They claim that Dr. Finkel, during his testimony, "agreed that [O.A.S.] was extubated for approximately one month after her arrival in respiratory failure." Moreover, Petitioners claim that "[f]ollowing [O.A.S.]'s improvement, she was readmitted to the hospital on April 13, 2001 in respiratory distress. This relapsing and remitting course, however, is inconsistent with a diagnosis of SMARD, but is characteristic for relapsing GBS and CIDP." Special Master Moran noted that Dr. Finkel indicated that all "SMARD patients require ventilator support," and that "Dr. Maertens agreed that [O.A.S.]'s progression to permanent ventilator support 'would probably go more towards SMARD.'" Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *31. Special Master Moran also noted that, in contrast, only "[a] fraction of GBS-afflicted people, perhaps one in five, requires ventilator assistance." Id. at *32. Although Petitioners argue that the "relapsing and remitting course" of [O.A.S.]'s condition is "inconsistent with a diagnosis of SMARD," the record before the court does not support such a conclusion. Specifically an article in the record, Eckart, et al., The Natural Course of Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 129 Pediatrics e148, e150 (2012), describing a study of eleven patients with infantile SMARD, indicates that only five out of eleven patients progressed to permanent ventilation immediately after respiratory distress. Two other patients progressed after two weeks, while another two progressed to permanent ventilator support a month after respiratory distress, as was the case with [O.A.S.]. Moreover, the remaining two patients progressed to permanent ventilator support a month and a half following their respiratory distress. Therefore, according to the evidence in the record, including the medical literature, it appears that the progression to permanent ventilator support does not necessarily have to occur immediately after the patient's respiratory failure. While Special Master Moran did not cite to the Eckart article in his decision, based on the record before the court, including the expert reports and the expert's testimony, as well as the literature introduced into the record, the Special Master's conclusion that progression to permanent ventilator support is more consistent with the diagnosis of SMARD was not arbitrary or capricious.

d. Presentation with Respiratory Failure

As noted above in the chart prepared by this court, [O.A.S.]'s health before her respiratory failure, included in the Special Master's chart, was not a separate data point in the Special Master's discussion section, but was included in the analysis on his

second data point, presentation with respiratory failure, in the discussion section. Petitioners contest the Special Master's finding that "'[O.A.S.]'s health preceding her respiratory arrest and her respiratory arrest are generally consistent with SMARD,'" and his determination that "'[t]he more persuasive evidence suggests that the presentation with respiratory failure is more common in SMARD, than in GBS/CIDP.'" The Petitioners argue that "[w]hile 'presentation' with respiratory failure may be common in SMARD, the special master fails to note that there is a difference between onset of symptoms and presentation with symptoms. The onset of symptoms is when the symptoms began, where 'presenting symptoms' are the symptoms exhibited at the time emergency care was sought." Petitioners claim that Special Master Moran failed to consider the evidence that "all patients with genetically confirmed SMARD were symptomatic prior to presenting with respiratory failure at a median age of 3.5 months," while "[O.A.S.] was completely asymptomatic prior to presenting with respiratory arrest." Petitioners state that [O.A.S.] had no "history of abnormality noted by either the parents or the pediatrician prior to the respiratory arrest." Petitioners rely on the Grohmann 2003 article, Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719, 720 (2003) (which indicates that for those diagnosed with SMARD, "100% of patients had a weak cry (median age 1 month) and respiratory distress (median age 3 months), 50% of patients had inspiratory stridor (median age 0.5 months), while 58% of patients exhibited poor feeding prior to the respiratory failure."). Petitioners' citation to the Grohmann 2003 article, however, appears somewhat misleading. Petitioners fail to point out that the article also mentions other typical features of SMARD which [O.A.S.] did present, for example, IUGR, which was "observed in almost all SMARD1 infants."

Moreover, while [O.A.S.] may have appeared healthy prior to respiratory failure, the parties' experts differed in their opinions as to whether [O.A.S.] had a "normal cry," as indicated by Dr. Maertens after seeing [O.A.S.]'s December 28, 2000 video, which was made part of the record, whereas Dr. Finkel indicated that [O.A.S.]'s cry was "feeble" and "not a robust cry," after seeing the same video. Dr. Finkel stated that "when I looked at the [December 28, 2000] video, it was my interpretation that her cry was weak. And I do understand the points that you're [Petitioners' attorney] making that the parents felt that she had a vigorous cry and a good suck, but I would note that she did not demonstrate a vigorous cry on the video." Dr. Finkel added that "a feeble cry can be the earliest symptom, the earliest feature, of SMARD, and it can precede the onset of respiratory failure." In addition, there is a note prepared by a nurse at Mercy Medical Center, stating that on January 31, 2001, [O.A.S.] had a weak cry. Therefore, contrary to Petitioners' assertions that "[O.A.S.] was completely asymptomatic prior to presenting with respiratory arrest," based on the record, it appears that [O.A.S.] may have presented with certain symptoms typical for SMARD before her respiratory arrest on January 30, 2001.

Additionally, on the issue of respiratory arrest, the court notes that Respondent's expert, Dr. McCusker, a pediatric immunologist, stated in her expert report in the record, although not cited or discussed by Special Master Moran in his decision, that [O.A.S.]'s "presentation with sudden onset respiratory failure associated with RSV infection and

subsequent dependency on mechanical ventilation is also consistent with this diagnosis in my limited (3 patients) clinical experience with this disease [SMARD]." The Special Master, therefore, had a basis that was not arbitrary or capricious for concluding that [O.A.S.]'s "health preceding her respiratory arrest and her respiratory arrest are generally consistent with SMARD." Based on the record, including the medical literature, the expert reports and the testimonies of the experts, early-onset respiratory distress is a common feature in the diagnosis of SMARD. Therefore, Special Master Moran's conclusion that this data point favors a diagnosis of SMARD was not arbitrary or capricious.

e. Treating Physician Determinations

In Capizzano v. Secretary of Health & Human Services., 440 F.3d 1317, the Federal Circuit instructed that probative value should be assigned to the opinions of the treating physicians because they "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.'" Id. at 1326 (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280) (brackets in original); see also Campbell v. Sec'y of Health & Human Servs., 90 Fed. Cl. 369, 387 (2009) (holding that statements made by treating physicians should be afforded more than some consideration); Cortez v. Sec'y of Health & Human Servs., No. 09-176V, 2012 WL 4829301 (Fed. Cl. Spec. Mstr. Aug. 31, 2012). Petitioners disagree with Special Master Moran's statement that "[O.A.S.]'s treating physicians have consistently referenced SMARD as the proper diagnosis since 2003." They claim that "the record is replete with statements from [O.A.S.]'s treating physicians and test results that indicate she suffered from GBS." Petitioners provide ten examples of [O.A.S.]'s doctors' diagnoses of peripheral neuropathy. Among those ten examples, however, there is only one post-2003 example, dated October 25, 2004, which was in the form of a letter to an insurance company from [O.A.S.]'s pediatrician, Dr. Gavin, stating that [O.A.S.] is "a four-year-old female with Peripheral Neuropathy of unknown etiology . . . . One medical consultant has suggested she may have Spinal Muscular Atrophy with Respiratory Distress but this diagnosis has yet to be confirmed." The court notes that this example is not consistent with Petitioners claims that [O.A.S.] "suffered from GBS."

In his decision, Special Master Moran listed multiple examples of post-2003 diagnoses of SMARD by treating physicians, including Dr. Gavin's November 11, 2003 letter to an insurance company stating that [O.A.S.] has "a current working diagnosis of . . . SMARD;" a note on admission to Mercy Hospital in February 2004, stating "[k]nown neuromuscular disorder – SMA-RD type;" a January 11, 2007 letter from Dr. Kabbani, a pediatric neurologist at Blank Children's Hospital in Des Moines, Iowa, noting that [O.A.S.] is "a 6-year-old girl with a clinical diagnosis of sensorimotor axonal neuropathy that also can be called spinomuscular atrophy with respiratory distress;" and an October 8, 2008 letter from Dr. Flores, a pediatric pulmonologist at the Blank Children's Hospital, that [O.A.S.] "has Spinal Muscular Atrophy with Respiratory Distress." The record also includes, although not mentioned by the Special Master in his decision, an August 11,

2011 note written by Dr. Judy Walker of Blank Children's Hospital, which described [O.A.S.] as a 10 year old girl with a history of spinal muscular atrophy.[59]

f. Predictive Value of Clinical Findings Regarding SMARD

Petitioners point to the Grohmann article, Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719, 720 (2003), to indicate that there is a "poor predictive value of using the clinical findings alone to predict whether a child has the genetic mutation that confirms the diagnosis of SMARD."[60] Petitioners also rely on the Guenther article, Guenther, et al., Clinical and Mutational Profile in Spinal Muscular Atrophy With Respiratory Distress (SMARD): Defining Novel Phenotypes Through Hierarchical Cluster Analysis, 28 Human Mutation 808 (2007) for the same proposition.[61] Petitioners emphasize that [O.A.S.] "did not have the clinical signs and symptoms prior to her respiratory failure that were noted in patients who were eventually diagnosed with SMARD," but even if she did, "the medical literature supports the poor predictive value of clinical findings alone to confirm the diagnosis of SMARD." Although not addressed by Respondent, the court notes that based on the record, however, the Petitioners have not demonstrated with a preponderance of evidence that [O.A.S.] suffers from GBS or CIDP.

Petitioners also argue that Special Master Moran omitted the fact that a SMARD diagnosis for [O.A.S.] was never confirmed. Because the parents would not agree to genetic testing, although urged to do so, Special Master Moran was not out of line when he stated that "[t]he Simanskis have done very little to refute these conclusions." Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *39. Based on his review of the record, the Special Master concluded that a diagnosis of SMARD was supportable, in part because a number of [O.A.S.]'s treating physicians concluded that [O.A.S.] suffered from SMARD or presented symptoms close to SMARD, after 2003,

[59] As indicated above, a diagnosis of spinal muscular atrophy (SMA) is distinct from a diagnosis of spinal muscular atrophy with respiratory distress (SMARD).

[60] As indicated above, the Grohmann article "explores 65 patients with the SMARD phenotype (clinical signs and symptoms) who were tested for the genetic mutation. Of these 65, more than half, thirty-six (36), were negative for the genetic mutation associated with SMARD (IGHMBP2)." Grohmann, et al., Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719 (2003).

[61] Petitioners state that the Guenther article "examines a larger population study which involved 141 patients with the SMARD phenotype." Petitioners note that "[o]f these 141 patients, only 47, or approximately 33% qualified for further study." Therefore, according to the Petitioners, "[t]he larger study demonstrates an even greater likelihood that making a SMARD diagnosis without confirmatory genetic findings would lead to an erroneous diagnosis of SMARD in approximately 67% of the population who have the clinical phenotype for SMARD."

when, according to Dr. Finkel and Special Master Moran, SMARD became more widely known in the medical community. The Special Master's conclusion should not be considered arbitrary or capricious.

Consequently, even if the clinical findings alone cannot achieve a completely accurate diagnosis of SMARD, based on the totality of the record before him, Special Master Moran's determination, relying on the medical records, expert reports and literature to conclude [O.A.S.] did not demonstrate presentation for GBS or CIDP, but rather presented closer to a SMARD diagnosis, was not arbitrary or capricious.

g. Failure to Consider Relevant Evidence Regarding [O.A.S.]'s IUGR, Normal Sural Nerve Biopsy, Normal CSF Protein Level and Creatinine Level

Finally, as a catch-all, Petitioners take issue with a number of findings by the Special Master regarding other data points in the discussion section of the Special Master's decision. Petitioners' contend that Special Master Moran failed to consider two admissions made by Respondent's expert, Dr. Finkel, in his testimony with regards to IUGR. The court notes [O.A.S.]'s IUGR was the first data point in the discussion section of the Special Master's decision. First, Petitioners argue that Dr. Finkel conceded that while IUGR places an infant at higher risk for developing problems, "[i]t doesn't imply that they will have problems, of course." Second, Petitioners note that Dr. Finkel indicated that "his review of [O.A.S.]'s early pediatric records did not reveal that [O.A.S.] suffered any ill consequences from her IUGR." According to Petitioners, the Special Master's failure to mention those two admissions by Dr. Finkel makes Special Master Moran's finding that "[O.A.S.]'s IUGR supports a diagnosis of SMARD" arbitrary, capricious and an abuse of discretion. Special Master Moran, however, relied on medical literature, including the Grohmann article, Infantile Spinal Muscular Atrophy with Respiratory Distress Type 1 (SMARD1), 54 Ann. Neurol. 719, 721 (2003), as well as the Guenther article, Clinical and Mutational Profile in Spinal Muscular Atrophy With Respiratory Distress (SMARD): Defining Novel Phenotypes Through Hierarchical Cluster Analysis, 28 Human Mutation 808 (2007), to arrive at his conclusion that that IUGR can be considered as one of the earliest symptoms of SMARD. Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *26. Regarding IUGR, his first data point in his discussion section, Special Master Moran, however, referred to the testimony of Dr. Maertens,' who indicated that although IUGR was "consistent with" SMARD, it was "not a prerequisite for SMARD." Id. With respect to the second issue raised by the Petitioners, the Special Master's failure to mention in his decision Dr. Finkel's statement that [O.A.S.]'s early pediatric records do not indicate any consequences from [O.A.S.]'s IUGR, Special Master Moran's August 20, 2013 decision stated that "[b]efore the January 26, 2001 vaccinations, [O.A.S.] was basically healthy." Id.

Petitioners further contest Special Master Moran's conclusion on his sixth data point in his discussion section, regarding the sural nerve biopsy, and assert that the Special Master failed to consider testimony offered by Dr. Maertens on a possible

sampling error that resulted in [O.A.S.]'s sural nerve biopsy showing "normal" tissue. Special Master Moran, however, cited Dr. Finkel's testimony explaining that, "because [O.A.S.] had weakness in her lower extremities, her sural nerve must have been affected." Id. at *32. Therefore, the Special Master appears to have correctly concluded that a possible sampling error, claimed by Petitioners, seemed unlikely.

Petitioners further claim that Special Master Moran ignored evidence from medical records and medical literature, which explain that the reason for [O.A.S.]'s normal cerebrospinal fluid[62] protein level "may be that [[O.A.S.]'s] CSF was sampled relatively late in the illness as CSF protein alteration is maximal in the first 2 weeks of illness." Petitioners also claim that several medical articles demonstrate that normal protein levels are present in certain GBS cases. One of the articles in the record Petitioners cite, Eckert, et al., A Case of Influenza Vaccination Induced Guillain Barré Syndrome with Normal Cerebrospinal Fluid Protein and Improvement on Treatment with Corticosteroids, 37 Scand. J. Infect. Dis. 621, 623 (2005), however, notes that only approximately 10% of GBS patients show "no characteristic protein elevation in the CSF," presumably indicating that 90% of GBS patients show an elevated protein level, which is consistent with the Special Master's determination that SMARD was a more likely diagnosis. Petitioners also reference a study, Deceunick RMB, et al., Epidemiology of Guillain-Barré Syndrome in the Province of Quebec, 35 Can. J. Neurol. Sci. 472, 474 (2008), in which lumbar punctures were performed on thirty-two of thirty-three patients, and an elevated protein level was only found in twenty patients. Finally, Petitioners cite a case-control study on children with GBS in North China, Gai-Fen, et al., A Case-Control Study on Children with Guillain-Barre Syndrome in North China, 16 Biomed. Environ. Sci. 105 (2003), in which thirty-five of fifty-one patients had elevated protein levels, while about one third had normal levels. The three articles, however, appear to refer to rare, atypical cases of GBS, exceptions to the general rule that the vast majority of GBS patients have elevated CSF levels. While it may be true that a sampling error, or a particularly atypical course of GBS/CIDP could result in patient's normal CSF level, the literature examples Petitioners cite support Special Master Moran's finding that a normal CSF protein level appears inconsistent with diagnosis of a GBS or CIDP. Moreover, [O.A.S.]'s treating physicians also seemed to agree that [O.A.S.]'s normal CSF level was inconsistent with a diagnosis of GBS/CIDP. For example, Dr. Mathews at the University of Iowa Hospitals, in her May 8, 2001 report about [O.A.S.]'s medical history, noted that: "She was treated for possible Guillain-Barré syndrome, however, her CSF protein was normal." Thus, Special Master Moran was not arbitrary and capricious when he concluded that [O.A.S.]'s normal CSF level was consistent with the diagnosis of SMARD.

Petitioners also claim that Special Master Moran "omits from his analysis the concessions and errors made by the Respondent's expert, Dr. Finkel," who, during the hearing, tried to reconcile different patterns of [O.A.S.]'s creatinine values, and suggested that the slightly higher level of [O.A.S.]'s creatinine level at the Mayo Clinic

[62] As discussed above, both experts, Dr. Finkel and Dr. Maertens testified that normal CSF levels are typical for patients with SMARD.

may be a result of her "improving" and her "increased muscle bulk," although the creatinine level was measured on the day of [O.A.S.]'s admission to the Mayo Clinic, so that there could be no "clinical improvement noted yet." Special Master Moran, however, discussed the testimony in which Dr. Finkel noted "something peculiar about the Mayo Clinic lab," and "what I don't have is an answer why Mayo Clinic's labs seem to be higher than other hospitals." Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *33. In his decision, Special Master Moran provided thirteen examples of [O.A.S.]'s creatinine levels, which, with an exception the test obtained at the Mayo Clinic, and one test obtained at University of Iowa Hospitals, were consistently low. Id. Dr. Finkel and Dr. Maertens testified that low creatinine levels are consistent with a diagnosis of SMARD, a conclusion with which the Special Master agreed.

Although [O.A.S.]'s symptoms, at times, over the course of multiple years, appeared not entirely typical for a diagnosis of SMARD, the Special Master acknowledged in his decision, based on the record before him, that a preponderance of evidence, nevertheless, indicates that [O.A.S.] did not suffer from GBS or CIDP and that her symptoms and illness were more consistent with SMARD. Given these conclusions, which this court has found not to be arbitrary or capricious, the Special Master was not required to conduct an Althen test analysis regarding causation. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. This court agrees that the Petitioners have not met their burden to prove that the Special Master was arbitrary and capricious in finding that [O.A.S.] does not suffer from GBS or CIDP, as alleged in their Petition.

In his decision, the Special Master infrequently referred to the parties' two other experts, Dr. Shoenfeld, an immunologist, retained by the Petitioners, and Dr. McCusker, a pediatric immunologist, retained by the Respondent, who also submitted expert reports for the record, and who subsequently testified at the hearing held by the Special Master in February 2013. Special Master Moran mentioned, in a footnote, that "[t]he testimony of Dr. Shoenfeld and Dr. McCusker has been considered" but, since "they have much less expertise in diagnosing neurological problems in infants . . . the recitation of facts cites to the testimony of the treating neurologists." Simanski v. Sec'y of Health & Human Servs., 2013 WL 7017568, at *9 n.15. The Special Master mostly dismissed the evidence provided in their testimony and expert reports, concluding that, "[t]he debate between Dr. Shoenfeld and Dr. McCusker is largely academic because the evidence overwhelmingly favors a finding that [O.A.S.] suffers from SMARD." Id. at *1. While describing the structure of the nervous system, in the background section of his decision dedicated to the etiology and symptoms of GBS and CIDP, the Special Master briefly mentions the disagreement between Dr. Shoenfeld and Dr. McCusker regarding the possibility of autoimmune diseases in infants, as follows: "Whether the immune system of newborns is sufficiently strong to damage myelin was a disputed point between the two immunologists, Dr. Shoenfeld and Dr. McCusker." Id. at *5. Special Master Moran noted Dr. McCusker's view that "a newborn's immune system is not robust enough to cause autoimmunity is in accord with the general incidence of autoimmune diseases, including GBS," and relied on Dr. Maertens' testimony, who testified that reports of GBS in infants less than three months old were very rare. See id. The court notes that Dr. McCusker also stated in her expert report:

> In the case of [O.A.S.] Simanski, her age and the stage of development of her immune system significantly reduces the likelihood of development of autoimmune GBS . . . . The vaccine implicated in the only case of infantile GBS at age 3 months was oral live attenuated polio vaccine and [O.A.S.] received IPV [polio vaccine]. In addition I am not aware of evidence in humans, in the extant literature, of causal associations between the other vaccine components she received and GBS in infants under 6 months of age.

Moreover, Dr. McCusker concluded in her expert report: "I find no evidence in the extant literature supporting a role for the vaccines she received 4 days prior in her deterioration and subsequent clinical evolution."[63]

Petitioners plead their case by calling the court's attention to specific, isolated medical findings or assertions which allegedly support their position. The battle of medical experts and reports, however, only further highlights why deference to the Special Master's analysis is warranted. As the United States Court of Appeals for the Federal Circuit has held, in reviewing Vaccine Act decisions, "'[t]he statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process.'" Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366 (quoting Hodges v. Sec'y of Dept. of Health & Human Servs., 9 F.3d at 961). Petitioners' attempts to identify potential, but not necessarily even likely or probable, alternative explanations for a given set of facts will not lead the reviewing court to find the Special Master's reasoned conclusion arbitrary and capricious. Instead, the court must defer to the Special Master's reasonable balancing of the facts in such cases, as this court is not empowered to "'examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.'" Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Dept. of Health & Human Servs., 970 F.2d at 870 n.10); see also Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1347. If "'the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" See Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363) (modifications in original). In the above-captioned case, the record is replete with expert testimony, articles, and statements from [O.A.S.]'s treating physicians indicating that [O.A.S.] more likely than not suffered from SMARD, and not GBS or CIDP. Far from being merely "not wholly implausible," the reasonable conclusion from the record, drawn through a detailed step-by-step review of likely indicators of the above diseases, is that [O.A.S.] suffers from SMARD. See id. Generally, "if the special master 'has considered the relevant evidence of record, drawn

[63] Dr. Shoenfeld disagreed with Dr. McCusker and testified that an autoimmune disorder can present very quickly after a vaccination, even as soon as three to five days thereafter.

plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d at 1528). Petitioners have not been able to overcome the high burden of showing reversible error in this instance.

This court finds that Special Master Moran fully examined the relevant evidence in the record ultimately presented in the above-captioned case. The Special Master's conclusion on each data point, as reflected in his decision, and his analysis of [O.A.S.]'s symptoms appears supported by [O.A.S.]'s medical records, the medical literature, and the expert reports and testimony. As noted above, the chart included in the Special Master's decision, reflecting the various data points that the Special Master used in his decision, and the Special Master's discussion on the twelve data points differ slightly. The court observes, however, that despite those differences, the Special Master's decision does include, albeit in various places throughout his decision, a thorough analysis of pertinent diagnostic symptoms of [O.A.S.]'s condition.

CONCLUSION

The court recognizes that [O.A.S.]'s condition is serious and expresses sympathy for both her condition and for the lengthy litigation process which has occurred in this case. Upon review of the extensive and extended record before this court, including the transcripts, medical records, exhibits, conflicting expert reports and testimony, the court concludes that the Petitioners have failed to prove that the Special Master's decision was arbitrary, capricious, or unsupported by substantial evidence. The record does not support a finding of either GBS or CIDP for [O.A.S.]'s diagnosis, as urged by the Petitioners. Accordingly, the Special Master's decision that Petitioners are not entitled to compensation under the Vaccine Act is **AFFIRMED**.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge