IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

* *		
TODD SIMANSKI and JULIA SIMANSKI, as Parents and Next Friends of OLIVIA ANNE SIMANSKI, a minor	*	No. 03-103V Special Master Christian J. Moran
Petitioners,	*	
v.	*	Filed: May 13, 2010
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal of case; failure to meet Althen prongs; dismissing case after an order to show cause
Respondent.	*	
** *		

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA., for petitioners;
Traci R. Patton, United States Dep't of Justice, Washington, D.C., for respondent.

PUBLISHED DECISION DISMISSING CASE[*]

Todd Simanski and Julia Simanski allege that a vaccine received by their daughter, Olivia, caused her to develop Guillain-Barré syndrome. The Simanskis seek compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 et seq. (2006). The Simanskis have not presented evidence to fulfill their burden of proof and have declined the opportunity to present additional evidence. Thus, the undersigned has no choice but to issue a decision dismissing the Simanskis' case.

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[*] Because this published decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

I. Factual and Procedural History

The attached order to show cause (attached as Appendix A), filed November 20, 2009, details Olivia's medical history and the procedural history of this case. Thus, these histories are provided summarily.

When Olivia was two months old, she received a set of five vaccines. Four days later, Olivia had acute respiratory failure for which she was hospitalized. Olivia's treating doctors indicated that a respiratory syncytial virus (RSV) infected Olivia and caused the respiratory failure. Olivia continued to have problems, including difficulty breathing. Doctors diagnosed Olivia as having neuromuscular problems that contributed to or caused her respiratory problems. She was transferred to another hospital. The discharge record from this facility indicated that Olivia had a post infectious demyelinating neuropathy.

Olivia has continued to have health problems. She has been hospitalized, including a stay at Johns Hopkins University where a neurologist indicated that some findings suggested that Olivia suffered from a "GBS-like picture." Exhibit F at 2348 (note dated April 26, 2001). One record indicates that she is mentally challenged. Exhibit 15 at 2.

Olivia's case began with the filing of a petition in 2003. Gathering medical records about Olivia took several years. After the medical records were filed, the Simanskis searched for an expert who could support their claim that one or more of the vaccines caused Olivia's health problems.

The Simanskis filed a report from Dr. Yehuda Shoenfeld on March 19, 2009.[1] Exhibit 16. Dr. Shoenfeld's report was discussed with the parties in a status conference on April 13, 2009. Respondent argued that the Simanskis failed to meet their burden established in Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). An order was issued offering the Simanskis an opportunity to supplement Dr. Shoenfeld's report on five topics. Order, filed April 13, 2009. When issued, the April 13, 2009 order appeared to be uncontroversial because special masters frequently ask for and receive supplemental reports from experts. The Simanskis' case started to drift from the expected path when they filed a supplemental report from Dr. Shoenfeld that addressed only one of the five topics. Exhibit 18.

Another status conference was held to discuss the sufficiency of Dr. Shoenfeld's reports. Following this status conference, the Simanskis were ordered to file a second supplemental

[1] The Simanskis have also filed a report from Dr. Paul Maertens. Exhibit 11. This report generally does not advance the Simanskis' claim for compensation and the Simanskis' response to the show cause order does not focus on the report. Thus, the report from Dr. Maertens is not discussed in this decision. His report, however, has been considered because it is part of the record as a whole.

report because Dr. Shoenfeld's supplemental report had not addressed all the topics from the April 13, 2009 order. Order, filed June 26, 2009.

The Simanskis did not file an additional supplemental report from Dr. Shoenfeld. Instead, the Simanskis argued that they have already made a prima facie case and ordering an additional supplemental report was "not in accordance with law." Pet'r Resp., filed July 24, 2009, at 4, 5.

Another status conference was held to discuss the perceived deficiencies in Dr. Shoenfeld's two reports. The Simanksi were urged to obtain a supplemental report, rather than have a show cause order issued. At this status conference, the Simanskis were afforded additional time to consider their position. After reflection, the Simanskis stated that they did not wish to obtain a supplemental report from Dr. Shoenfeld.

Because the Simanskis did not comply with orders to present supplemental reports from Dr. Shoenfeld, the attached order to show cause was filed on November 20, 2009. The show cause order explained why the existing record indicated that the Simanskis had not met their burden of proof, offered the Simanskis an opportunity to obtain an additional report, and warned the Simanskis that a failure to comply with the order to provide a supplemental report would result in a dismissal of their case.

The Simanskis have declined to present another supplemental report from Dr. Shoenfeld. In the absence of another supplemental report, the parties have presented legal arguments about whether a dismissal is appropriate.[2] The most recently filed brief was a reply brief that the Simanskis filed on March 26, 2010. Thus, the case is ready for adjudication.

II. Analysis

The elements of petitioners' case are set forth in Althen, 418 F.3d at 1278. The basis of the show cause order was that the Simanskis have not met their burden of establishing the elements that are necessary for them to be entitled to compensation. See Show Cause Order at 9-20. The show cause order explained that Dr. Shoenfeld's reports did not present a medical theory causally connecting a vaccine that Olivia received with the onset of her Guillain-Barré syndrome. Show Cause Order at 9-15. The show cause order stated that Dr. Shoenfeld's reports did not establish that there was a medically appropriate time between Olivia's vaccinations and the onset of her Guillain-Barré syndrome. Id. at 15-18. Finally, the show cause order stated that Dr. Shoenfeld's reports did not establish a logical sequence of cause and effect showing that the

[2] The Simanskis have asked for a ruling on the record in their favor. Pet'r Resp., filed Jan. 21, 2010, at 10-11. This request is denied because, for the reasons explained above, the Simanskis have not advanced sufficient evidence to satisfy their burden. Furthermore, even if the Simanskis were found to have submitted persuasive evidence on each of the Althen elements, respondent would be entitled to an opportunity to challenge their evidence.

vaccination was the reason for Olivia's injury. Id. at 18-19. This failure to satisfy the Althen prongs means that the Simanskis cannot prevail.

The Simanskis' response to the show cause order is premised on an assertion that they have satisfied the Althen prongs. Pet'r Resp., filed Jan. 21, 2010, at 10-11. At best, the Simanskis can point to the conclusion of Dr. Shoenfeld's first report in which Dr. Shoenfeld states that "with great confidence and certainly [sic, probably should be "certainty"] I can say that the vaccines with all their immunological aspects were the cause of the GBS/CIDP leading to phrenic nerve paralysis and failure to extubate Olivia Simanski from artificial respiration." Exhibit 16 at 15. This statement is a conclusion. To fulfill the Simanskis' burden to present evidence, Dr. Shoenfeld's report needs to address the Althen factors. If the only evidence in the record about causation were Dr. Shoenfeld's statement, the Simanskis would not be entitled to compensation because the quoted sentence fails to address the Althen elements. See Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating an expert's "opinion is no better than the soundness of the reasons supporting it."); cf. Intellectual Science and Tech., Inc. v. Sony Electronics, Inc., 589 F.3d 1179, 1184 (Fed. Cir. 2009) (stating "An expert's unsupported conclusion on the ultimate issue of infringement will not alone create a genuine issue of material fact."); Sitrick v. Dreamworks, LLC, 516 F.3d 993, 1000 (Fed. Cir. 2008) (stating "Conclusory expert assertions cannot raise triable issues of material fact on summary judgment.").

The show cause order explained in detail the flaws in Dr. Shoenfeld's reports. The show cause order gave the Simanskis an opportunity to argue why Dr. Shoenfeld's reports satisfy the Althen factors. Yet, the Simanskis do not address, at all, the analysis contained in the show cause order. The Simanskis' brief fails to cite to any specific portion of Dr. Shoenfeld's reports. See Pet'r Resp., filed Jan. 21, 2010, at 10-11. An attorney's argument cannot replace evidence. Williams v. Social Sec. Admin, 586 F.3d 1365, 1368 (Fed. Cir. 2009) (stating "We decide cases on the record before us, not on the basis of facts stated by counsel."); Johnston v. IVAC Corp., 885 F.2d 1574, 1581 (Fed. Cir.1989) (attorney argument is no substitute for evidence).

From the (mistaken) premise that Dr. Shoenfeld's reports satisfy the Althen test, the Simanskis argue that the show cause order was issued in error. Pet'r Resp., filed Jan. 21, 2010, at 5-10. The crux of the Simanskis' argument is that the show cause order "created an ethical dilemma" in that the Simanskis have determined that "compliance with the [show cause] order was not in her best interest." Id. at 7 (emphasis in original).[3]

[3] The Simanskis have not explained why complying with the show cause order was not in Olivia's best interest. For example, the Simanskis have not identified a rule of professional conduct that would bar them from complying with an order. Even if the Simanskis believed that they satisfied the Althen test, the undersigned found differently. The Simanskis have not indicated how providing more information, which could change the undersigned's findings, would harm their case.

The Simanskis' attempt to separate their lack of compliance with the show cause order from their lack of evidence to satisfy the Althen test. For example, the Simanskis maintain that special masters lack the authority to dismiss a petition for their failure "to comply with [a] personal order for discovery without considering the remaining evidence contained in 'the record as a whole' as directed by the statute." Id. at 6. Yet, it was the "record as a whole" that led to the show cause order. If Dr. Shoenfeld's reports satisfied the Simanskis' evidentiary burden, then the show cause order would not have been issued.

Three cases from appellate authorities in the Vaccine Program that were decided after the show cause order was filed on November 20, 2009, support the issuance of the show cause order. The first is Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315 (Fed. Cir. 2010), in which the Federal Circuit reconfirmed the requirement that a petitioner's expert's medical theory be reliable. The second case is Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126 (2010), in which a judge of the Court of Federal Claims expressed concerns about an opinion given by Dr. Shoenfeld. The third case is Shaw v. Sec'y of Health & Human Servs., 91 Fed. Cl. 715 (2010), which demonstrates the problems with the lack of pre-trial disclosure of an expert's opinion.

In Moberly, the Federal Circuit addressed whether the special master had erred in finding that Ms. Moberly had failed to establish that a diphtheria tetanus pertussis ("DPT") vaccination caused her daughter, Molly, to suffer a neurological injury. On appeal, Ms. Moberly argued that the special master erred by imposing too high an evidentiary standard. The Federal Circuit explained that the Moberlys "appear to mean not proof of causation by the traditional 'more likely than not' standard, but something closer to proof of a 'plausible' or 'possible' causal link between the vaccine and the injury, which is not the statutory standard." Moberly, 592 F.3d at 1322 (footnote omitted). Thus, the Federal Circuit held that the special master evaluated the petitioners' evidence using the correct standard. In addition, the Federal Circuit held that the special master had assessed the opinion of the petitioner's expert correctly. "[T]he special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Id. at 1324.

Moberly supports issuing the show cause order in three respects. First, as described in the attached show cause order, Dr. Shoenfeld's expert report expressed his opinion in terms of what a vaccine "may" do. Exhibit 16 at 12. A presentation of ideas about what "may" happen is foreclosed by the statement in Moberly that the evidence must be "more likely than not" for petitioners to prevail. Thus, much of Dr. Shoenfeld's opinion falls short of the appropriate legal standard. A second point, which is related to the first point, is that Dr. Shoenfeld posits many ideas (or possibilities) but does not explain what he believes happened to Olivia. This vagueness fails to comply with the requirement that petitioners "must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." Moberly, 592 F.3d at 1322 (emphasis added). Third, Dr. Shoenfeld's report does not provide the basis for many of his opinions. To take just one example from the order to show cause, Dr. Shoenfeld appears to suggest that Olivia's GBS began four days after vaccination when Olivia had "a cough, [upper

respiratory infection], mild respiratory distress, decreased feeding and some lethargy." Exhibit 16 at 2. The problem with this assertion is that GBS is a disease of the peripheral nervous system. Dr. Shoenfeld has not explained the basis for his opinion that GBS begins with respiratory problems, decreased feeding and lethargy. Dr. Shoenfeld may actually have a basis for his assertion and this basis may be reliable. But, the basis is not set forth in Dr. Shoenfeld's report and the Simanskis have not satisfied the show cause order by providing this information.

Problems with Dr. Shoenfeld's opinion are not unique to the Simanskis' case. The petitioner in Hennessey also retained Dr. Shoenfeld, who provided an opinion that vaccines triggered his type 1 diabetes. The special master found that Dr. Shoenfeld's opinion was not reliable for several reasons. Upon review of the special master's decision, a judge from the Court of Federal Claims stated "one of the special master's well-founded concerns with Dr. Shoenfeld's theory was its vagueness." Hennessey, 91 Fed. Cl. at 135. The court continued: "Not only was petitioner's medical theory vague, it also lacked support." Id. Both of the problems identified by the court in Hennessey, vagueness and a lack of support, are present in Dr. Shoenfeld's report in this case. Another report from Dr. Shoenfeld could cure these problems.

The third recently issued case demonstrates the consequence of not obtaining adequate disclosures of an expert's opinion before the hearing. In Shaw, Mr. Shaw proceeded to trial on one theory, lost on that theory, and filed a motion for reconsideration to present evidence that he could have presented during the hearing. Shaw, 91 Fed. Cl. at 717-18. The Court of Federal Claims ruled that the special master erred in denying the motion for reconsideration. Thus, the case was remanded for the special master to consider additional evidence. Id. at 720.

The result in Shaw – a remand to consider additional evidence – should be avoided, if possible. Repeated hearings increase the cost of litigation and consume judicial resources. One way special masters can avoid holding second hearings is to manage cases by requiring both petitioners and respondent to disclose evidence on which they rely before the hearing. See 42 U.S.C. § 300aa–12(d)(3)(B).

A special master "may require the submission of such information as may be reasonable and necessary." 42 U.S.C. § 300aa–12(d)(3)(B)(ii). Here, consistent with the authority given to special masters in section 12(d)(3)(B), the Simanskis have been ordered to disclose Dr. Shoenfeld's opinions and the basis for those opinions. The Simanskis have not complied with the order for more disclosure. If this disclosure had been made, then respondent could have addressed Dr. Shoenfeld's opinions, and, assuming that the parties disagreed, the case proceeded to a hearing. A hearing following the disclosure of all opinions and the basis for those opinions is far more likely to conclude in one session than a hearing in which the expert presents undisclosed opinions for the first time.

Shaw did not prompt the issuance of the show cause order. The same is also true for Moberly and Hennessey. The appellate courts decided all three cases after the show cause order

was issued. Nevertheless, these three recently decided cases are consistent with the rationale for the show cause order. In Hennessey and in the present case, Dr. Shoenfeld's opinion is vague and lacks support. In Moberly, the Federal Circuit reconfirmed that special masters may "require some indicia of reliability to support the assertion of the expert witness." 592 F.3d at 1324. The Simanskis could have met the burden described in Moberly by disclosing Dr. Shoenfeld's opinions. Finally, Shaw illustrates the potential consequences of not exercising the authority granted in section 12(d)(3)(B) – proceedings become lengthened unnecessarily.

In the final analysis, the issue is relatively straightforward. Special masters are authorized to require production of evidence. 42 U.S.C. § 300aa–12(d)(3)(B). The Simanskis were ordered to produce more information from the expert they retained, Dr. Shoenfeld. The Simanskis have refused. The Simanskis were warned that their case could not progress without more information from Dr. Shoenfeld and persisted in refusing to produce information. Given the Simanskis failure to present additional evidence, the reasonable response is to dismiss the case.

III. Conclusion

This case is dismissed for failing to comply with the show cause order, which required the Simanskis to produce sufficient evidence to meet the Althen prongs. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

IT IS SO ORDERED.

S/ Christian J. Moran
Christian J. Moran
Special Master

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

* *		
TODD SIMANSKI and JULIA SIMANSKI, as Parents and Next Friends of OLIVIA ANNE SIMANSKI, a minor	*	No. 03-103V Special Master Christian J. Moran
Petitioners,	*	Filed: November 20, 2009
v.	*	Order to show cause, petitioner's failure to comply with order requiring a supplemental expert report
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
** *		

ORDER TO SHOW CAUSE WHY CASE SHOULD NOT BE DISMISSED

Todd Simanski and Julia Simanski allege that a vaccine received by their daughter, Olivia, caused her to develop Guillain-Barré syndrome. The Simanskis seek compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 et seq. (2006).

Pursuant to 42 U.S.C. § 300aa–12(d)(B) and Vaccine Rule 21(b), Mr. and Mrs. Simanski are ordered to show cause why their case should not be dismissed for failure to comply with the April 13, 2009 order and the June 26, 2009 order, which required the Simanskis to obtain a supplemental expert report. This show cause order follows several unrecorded status conferences in which the undersigned discussed the reasons the Simanskis should obtain a supplemental expert report. Given that the Simanskis have refused to comply with the orders, the undersigned has no choice but to issue this show cause order. **A response from the Simanskis is due by December 22, 2009.** Respondent may file a response 14 days after the Simanskis file a response.

I. Medical History

On the question of whether a vaccine harmed Olivia, it appears that medical records created contemporaneously with the events that they describe are accurate. These medical records indicate that the following events occurred.

On November 2, 2000, Olivia was born. Her weight was relatively small for a full-term baby – 4 pounds and 12.9 ounces. Exhibit B at 100.[1]

Olivia's development appears to be normal for the first two months. See exhibit C at 196-99. When she was two months, she weighed 10 pounds and 2 ounces.

On January 24, 2001, Olivia was brought to her pediatrician for a two-month health maintenance visit. Olivia's mother reported that both Olivia and she were having some gastrointestinal problems, including diarrhea. Dr. Gavin recommended deferring vaccinations for a few days to avoid increasing Olivia's discomfort. Exhibit C at 193-94.

On January 26, 2001, Olivia returned for her immunizations. She received five vaccines – diphtheria, tetanus and acellular pertussis (DTaP), hemophilus influenzae type B (HiB), inactivated polio, pneumococcal conjugate and hepatitis B. Exhibit C at 141.[2]

On January 29, 2001, Olivia was lethargic, was mildly irritable, and ate a decreased amount. She also had difficulty breathing. Exhibit D at 1272, 1275-76.

The next day, Olivia had an acute respiratory failure. She was brought to Mercy Medical Center where she was intubated and placed on a ventilator. The doctors believed that Olivia was infected with respiratory syncytial virus (RSV) and diagnosed her with bronchiolitis. Exhibit D at 1275-76. (Dr. Shoenfeld asserted that Olivia developed a "progressive neuropathy" on this date. Exhibit 16 at 5.)

While at Mercy Medical Center, Olivia was the subject of numerous tests and examinations. An x-ray showed that Olivia had intermittent atelectasis and collapse. This means that Olivia's lung was collapsed. Dorland's Illustrated Medical Dictionary (30th Ed. 2002) at 171. A culture of Olivia's nares (nostrils) detected the presence of RSV. Exhibit D at 1420. Olivia's doctors indicated that they believed that she suffered from an RSV infection. Exhibit D at 1264, 1276-77. At admission, a CT scan of Olivia's brain was normal. Id. at 1476.

During her course at Mercy Medical Center, Olivia continued to have difficulties breathing. Doctors tried to extubate her twice, but each attempt was not successful. Eventually, Olivia extubated herself.

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[1] Usually, petitioners assign numbers to their exhibits. Office of Special Masters, Guidelines for Practice under the National Vaccine Injury Compensation Program (Rev. Ed. 2004) § II.B.6. However, the Simanskis' first attorney, who was new to the Vaccine Program, assigned letters.

[2] Dr. Shoenfeld's report omitted the hepatitis B vaccine. Exhibit 16 at 6.

The records from Olivia's initial hospitalization at Mercy Medical Center run into the hundreds of pages. Because the Simanskis claim that Olivia developed GBS due to the vaccination, the records discussing Olivia's neurologic condition are relatively more important.

Some progress notes from the first days of Olivia's hospitalization indicated that Olivia was neurologically "stable." E.g. exhibit D at 1367 (Feb. 5, 2001). A physical therapist's record indicated that, on February 7, 2001, Olivia had a full range of motion in her extremities and fluctuating muscle tone. Id. at 1523.

On February 7, 2001, Dr. Simplot noted that Olivia had not really had a neurologic status evaluation since her respiratory and cardiac arrest, "but she does move her extremities with stimuli." Id. at 1279. Dr. Simplot specializes in otolaryngology, which treats the ears, nose and throat. Id. at 1260.[3] (Dr. Simplot had been consulting on Olivia's case because of her trouble with breathing.)

A neurologist was consulted on February 8, 2001, because Olivia was arching her back and having staring spells. Dr. Narawong examined Olivia and concluded that she was moving her extremities well. Exhibit D at 1277. Two days later, Olivia was not having staring spells. Id. at 1359.

Dr. Narawong ordered additional tests. An EEG was essentially normal. Id. at 1515 (Feb. 9, 2001). An MRI of Olivia's brain showed some irregularities but was essentially normal. Id. at 1263, 1459 (Feb. 10, 2001).

Eventually, Olivia was transferred from Mercy Medical Center to the Mayo Clinic. At discharge, Olivia's doctors diagnosed her as having underlying neuromuscular problems, contributing or causing to her respiratory problems. Exhibit D at 1263, 1265.

Olivia was admitted to the Mayo Clinic on February 23, 2001. She was discharged on March 16, 2001. Exhibit E at 1958-59.

While in the Mayo Clinic, Olivia underwent an operation to determine whether her diaphragm was working correctly. Exhibit E at 1938.

Olivia also underwent electromyelograms ("EMG"). An EMG is conducted to record the extracelluar activity of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation. Dorland's at 598. One EMG showed that Olivia had a peripheral neuropathy, which could be seen in an inherited or metabolic disease. Exhibit E at 1953. Another EMG showed decreased response in Olivia's diaphragm. Id. at 1952.

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[3] Although Dr. Shoenfeld correctly noted Dr. Simplot's observation about the lack of neurologic examination, Dr. Shoenfeld did not mention that Dr. Simplot is not a neurologist. Exhibit 16 at 3.

On March 8, 2001, a handwritten progress note said that the author was "considering Guillain-Barré like syndrome [with] primarily axial [sic, possibly should be "axonal?] and phrenic [nerve] involvement." Exhibit E at 2152. When Olivia was discharged from the Mayo Clinic approximately one week later, the doctor indicated that she probably had a post infectious demyelinating neuropathy. Id. at 1975 .

After Olivia was discharged from the Mayo Clinic, her medical history is less relevant to determining whether any vaccine that she received in January 2001, caused her problem. Olivia's doctors generally seemed more concerned with treating (or curing) her problems and relatively less concerned about what caused her problem. Dr. Shoenfeld agrees, implicitly, with this distinction between records created after Olivia's discharge from the Mayo Clinic because he does not discuss Olivia's medical records from after her Mayo Clinic discharge in much detail. See exhibit 16 at 4-5.

In any event, the undersigned has reviewed Olivia's additional medical records. She was required to be hospitalized a second time at Mercy Medical Center on March 16, 2001 for chronic respiratory failure. Exhibit D at 1076. She returned a third time on April 12, 2001, for "chronic respiratory problems." Id. at 341.

She was also seen at Johns Hopkins University. A neurologist from that institution indicated that some findings suggested that Olivia suffered from a "GBS-like picture." Exhibit F at 2348 (note dated April 26, 2001).

In 2005, Olivia used a wheelchair and a ventilator. She was also mentally challenged. Exhibit 15 at 2.

II. Procedural History

Mr. and Mrs. Simanski filed their petition on January 17, 2003. At that time, Attorney Richard N. Winders represented the Simanskis. The Simanskis did not comply with the provision of the Vaccine Act that requires petitioners to file medical records with their petition. 42 U.S.C. § 300aa–11(c); accord Vaccine Rule 2(c).

Approximately one year after filing their petition, the Simanskis filed a set of medical records as exhibits A-G. At least some of the delay in filing the medical records was due to an error by the company responsible for copying the medical records. Joint Status Rep't, filed Oct. 27, 2003. On March 18, 2004, the chief special master, whose case this was, ordered the Simanskis to file an amended petition alleging the specific injury that Olivia suffered. Despite having received three enlargements of time to comply with orders to file an amended petition, the Simanskis have not done so.

On February 2, 2005, the chief special master issued an order to show cause due to the Simanskis' failure to produce films from X-rays. On March 2, 2005, the Simanskis reported that

X-rays had been obtained and forwarded to a doctor for review. On April 7, 2005, the Simanskis' attorney stated that he anticipated "receiving a report [from a reviewing doctor] in the near future."

On August 22, 2005, the Simanskis' attorneys reported that an expert had not been selected. Mr. Winders also reported that he was having difficulties with his health and was searching for another attorney to become counsel of record. In response, the Chief Special Master ordered another status report and stated that this case "has languished for some time." Order, filed August 25, 2005.

On March 23, 2006, the chief special master granted a motion requesting that Mr. Ronald C. Homer substitute as attorney of record for Mr. Winders. Mr. Homer has acted as counsel of record after that date. This same order also required the Simanskis to file a status report about their efforts to obtain a report from an expert.

The ensuing status report, which was the first status report filed by Mr. Homer in this case, reported that "a substantial amount of medical records were not collected." Thus, Mr. Homer's firm undertook the task of obtaining missing medical records.

This case was transferred to Special Master Edwards on August 7, 2007. Special Master Edwards held several status conferences to discuss the Simanskis' progress in obtaining an expert report. Eventually, the Simanskis filed a report from Dr. Paul Maertens on April 3, 2008. Exhibit 11. Dr. Maertens's report is one page in length. The Simanskis also submitted a collection of compact discs containing Olivia's medical records on April 2, 2008.

Dr. Maertens' report states that "Olivia's respiratory failure was due to RSV." He also stated that "The vaccine could have played a role as it was administered during the RSV incubation period. . . . The determination of whether the immunizations were a factor in the onset of GBS in a child who had an upregulated immune system from an infectious process is best made by an immunologist." Exhibit 11.

Special Master Edwards held a status conference. He "expressed his firm view that the opinion [of Dr. Maertens] failed to establish petitioners' *prima facie* actual causation claim." The Simanskis represented that they had consulted an immunologist, Dr. Bellanti, as recommended by Dr. Maertens. Special Master Edwards ordered the Simanskis to file an opinion from Dr. Bellanti or a status report proposing future proceedings. Order, filed April 29, 2008.

The Simanskis stated that they were discussing the case with Dr. Bellanti to determine whether he could participate. The Simanskis anticipated that if Dr. Bellanti could not, they would seek the assistance of another medical expert. Pet'r Status Rep't, filed May 30, 2008. Special Master Edwards ordered the Simanskis to file a report from an immunologist by August

1, 2008. Order, filed June 10, 2008. Approximately two months later, the case was reassigned to the undersigned.

On July 11, 2008, the Simanskis reported that Dr. Bellanti had agreed to review the case. The Simanskis proposed that Dr. Bellanti would file a report by November 3, 2008. On November 3, 2008, the Simanskis reported that Dr. Bellanti was not working on this case and that they were contacting an additional expert in immunology.

After receiving several enlargements of time, on March 19, 2009, the Simanski stated that they were submitting a compact disc containing a report from Dr. Shoenfeld. Exhibit 16. This compact disc was received on April 1, 2009. In addition to Dr. Shoenfeld's report, the Simanskis submitted medical articles to which Dr. Shoenfeld had referred in his report. Exhibit 16 tabs 1 through 117.

The undersigned discussed Dr. Shoenfeld's report with the parties in a status conference on April 13, 2009. The undersigned offered the Simanskis an opportunity to address certain points in Dr. Shoenfeld's report. The Simanskis filed a status report on April 21, 2009, stating that they intended to file a supplemental report.

The Simanskis filed a supplemental report from Dr. Shoenfeld on June 3, 2009. Exhibit 18. However, Dr. Shoenfeld did not address four of the five questions posed by the undersigned special master in the April 13, 2009 order. Thus, the Simanskis were ordered to file a second supplemental report from Dr. Shoenfeld. Order, filed June 26, 2009.

The Simanskis stated that the special master's June 26, 2009 order sought a level of detail that "has never been encountered by a petitioner at this pre-hearing stage of the process." Pet'r Resp., filed July 24, 2009, at 3. The Simanskis continued and argued that Dr. Shoenfeld's reports established that "the vaccines Olivia received caused her GBS and sequelae." Id. at 4. Additionally, the Simanskis stated that the special master's order requiring "several supplemental expert reports prior to requiring a report from the respondent's expert . . . grossly elevates the petitioner's evidentiary burden and is not in accordance with law." Id. at 5. Thus, the Simanskis requested that the June 26, 2009 order be stayed and that respondent be ordered to file an expert report.

The Simanskis' position was discussed at a status conference on August 27, 2009. The undersigned special master urged the Simanskis to reconsider their position because if they maintained their position, an order to show cause would be issued. After additional deliberation by the attorneys representing the Simanskis, the Simanskis reported that they did not wish to obtain a supplemental report from Dr. Shoenfeld.

III. Discussion

A. Special Master's Authority to Order Supplemental Report

In regard to the availability of discovery, litigation in the Vaccine Program differs from typical civil litigation. The parties cannot engage in discovery "by right." Vaccine Rule 7(a); see also 42 U.S.C. § 300aa–12(d)(2)(E). Instead, special masters influence the information that is presented. The Vaccine Act grants the special masters authorities not commonly extended to judicial officials.

> In conducting a proceeding on a petition a special master —
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> (I) may require such evidence as may be reasonable and necessary,
>
> (ii) may require the submission of such information as may be reasonable and necessary,
>
> (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary.

42 U.S.C. § 300aa–12(d)(3)(B).

Appellate authorities have recognized the broad discretion extended to special masters to solicit information. See Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996) (stating "the permissible scope of the special master's inquiry is virtually unlimited. Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence."); Snyder v. Sec'y of Health & Human Servs., 86 Fed. Cl. 706, 713-15 & 737-38 (2009).

Pursuant to that authority, the undersigned has ordered the petitioners to obtain a supplemental expert report from Dr. Shoenfeld. Order, filed April 13, 2009; order, filed June 26, 2009.

Petitioners have chosen not to obtain a supplemental report that addresses the undersigned's orders. Petitioners have not argued that they "cannot" obtain a supplemental report. Instead, petitioners argue that they do not need to obtain a supplemental report. Under these circumstances, petitioners' failure to comply with the orders is "willful."

B. Consequences of Failure to Comply with an Order

The judges of the Court of Federal Claims have authorized special masters to dismiss a petition for failure to comply with orders. Vaccine Rule 21(b) provides: "The special master . . .

may dismiss a petition or any claim therein for failure of the petitioner to prosecute or comply with these rules or any order of the special master."[4]

Appellate authorities have affirmed a special master's decision to dismiss a petition for failure to prosecute and/or for failure to comply with orders. Way v. Sec'y of Health & Human Servs., No. 05-588V, 2007 WL 5161801, at *7 (Fed. Cl. Feb. 21, 2007); Sapharas v. Sec'y of Health & Human Servs., 35 Fed. Cl. 503 (1996); Tsekouras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 439 (1992), aff'd 991 F.2d 810 (Fed. Cir. 1993) (table).

"Failure to prosecute does not require that the party take affirmative steps to delay the case. A failure to comply with court orders, failure to respond to discovery, or other failure to act is sufficient to constitute a lack of prosecution." Opta Sys., L.L.C. v. Daewoo Electronics America, 483 F. Supp. 2d 400, 404 (D.N.J. 2007) (dismissing case).

C. Dismissal Appears to be the Appropriate Response for Failing to Comply with the Orders

When a party fails to comply with an order, dismissal is one possible sanction. Other, lesser sanctions are available. In determining whether dismissal is the appropriate sanction, a trial court should consider various factors. In an appeal from a patent case, the Federal Circuit reviewed precedent from the Sixth Circuit and stated that the appropriate factors to consider include: (1) prejudice to other party, (2) whether the non-compliant party was warned that failure to cooperate could lead to dismissal, and (3) whether less severe sanctions were considered. Wexell v. Komar Industries, Inc., 18 F.3d 916, 920 (Fed. Cir. 1994) (aff'g dismissal with prejudice and citing Regional Refuse Sys., Inc. v. Inland Reclamation Co., 842 F.2d 150, 154-55 (6th Cir. 1988)). In Wexell, the Federal Circuit also stated that "when the non-moving party has the ability to comply with the court's discovery order, the district court may properly dismiss the complaint with prejudice when the failure to comply results from wilfulness, bad faith, or fault of the non-moving party." Id.

The Federal Circuit also announced slightly different criteria when it followed a decision by the Ninth Circuit. In that case, the Federal Circuit instructed the trial court to consider the following factors: "(1) the public's interest in expeditious resolution of litigation; (2) the court's need to manage its docket; (3) the risk of prejudice to the defendants; (4) the public policy favoring disposition of cases on their merits; and (5) the availability of less drastic sanctions." Refac Intern., Inc. v. Hitachi, Ltd., 921 F.2d 1247, 1254 (Fed. Cir. 1990), citing United States for the Use and Benefit of Witec Guam, Inc. v. Kahaluu Constr. Co., Inc., 857 F.2d 600, 603 (9th Cir. 1988).

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[4] Vaccine Rule 21(b) is similar to Rule 41(b) of the Rules of the United States Court of Federal Claims. Rule 41(b), in pertinent part, provides: "If the plaintiff fails to prosecute or to comply with these rules or a court order, the court may dismiss on its own motion or the defendant may move to dismiss the action or any claim against it."

All of these factors will be analyzed. The section on whether a less severe sanction is appropriate, which is the first factor discussed below, contains the explanation for why Dr. Shoenfeld's existing reports are not adequate.

1. Less Severe Sanction

Dismissal appears to be the appropriate sanction because other possible sanctions would be tantamount to a dismissal. However, the parties' views are specifically requested on this point.

Dr. Shoenfeld's opinion is critical to the petitioners' case. Petitioners cannot prevail based upon their claims alone. Instead, petitioners are required to submit evidence that a vaccine listed in the Vaccine Injury Table caused Olivia an injury. This evidence may take the form of either "medical records" or "medical opinion." 42 U.S.C. § 300aa–13(a). Here, it appears that the medical records do not support the petitioners' claim for compensation in that petitioners have not identified any treating doctor who opined that Olivia's condition was caused by a vaccine. Therefore, the petitioners must rely upon Dr. Shoenfeld's "medical opinion."

To prove causation in fact, a petitioner must establish at least three elements. The 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 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Here, Dr. Shoenfeld's two reports fail to meet the petitioners' burden of producing persuasive evidence on these three prongs. Each prong is addressed separately.

a. A Medical Theory Causally Connecting the Vaccination and the Injury

Dr. Shoenfeld's two reports failed to identify the vaccination that caused Olivia's GBS. Dr. Shoenfeld's first report stated that on January 26, 2001, Olivia received four different vaccinations – DTaP, HiB, IPV, and pneumococcal conjugate. Olivia also received the hepatitis B vaccine.

Dr. Shoenfeld's report stated that various vaccines have been associated with GBS. At best, Dr. Shoenfeld stated that it is established that the influenza vaccine can cause GBS.[5] Exhibit 16 at 6. However, Olivia did not receive the influenza vaccine.[6] Thus, it does not advance the Simanskis' case for Dr. Shoenfeld to propose a theory that the influenza vaccine can cause GBS.

Dr. Shoenfeld's report also stated that "other vaccines [are] involved with GBS." Exhibit 16 at 6. There are two problems with this aspect of Dr. Shoenfeld's report. First, a statement that other vaccines "are involved with" differs from a statement that other vaccines "cause" GBS. If Dr. Shoenfeld holds the opinion that these other vaccines "cause" GBS, then Dr. Shoenfeld should state this opinion directly. Second, Dr. Shoenfeld listed several vaccines, such as smallpox, rabies, and mumps, measles and rubella, that Olivia did not receive in January 2001. Interjecting these vaccines does not advance, in any significant way, the Simanskis' case.

Dr. Shoenfeld's report next discussed the pertussis vaccine. There are several gaps with regard to the pertussis vaccine. First, Olivia did not receive the whole cell version of pertussis vaccine. Many (but not all) of the articles cited by Dr. Shoenfeld discuss the whole cell version of the pertussis vaccine. Dr. Shoenfeld may believe that the acellular pertussis vaccine can cause the same problems as the whole cell pertussis vaccine. If Dr. Shoenfeld holds this belief, then he should clearly state his opinion and provide the basis for his opinion. Some articles seem to be discussing the disease pertussis. E.g. Dubus, Vogel, Huang, Samore, Haslov. If so, the articles seem to hold less significance because Olivia was given a vaccine containing (presumably) inactivated pertussis toxin.

Another problem with Dr. Shoenfeld's report regarding pertussis vaccine is that he states that "pertussis vaccine can aggravate other infections." If Dr. Shoenfeld believes, to a level of medical probability, that the acellular pertussis vaccine aggravated Olivia's RSV, then Dr. Shoenfeld should propose that theory explicitly. Dr. Shoenfeld's report is ambiguous in that on page 6, Dr. Shoenfeld appears to be advancing the idea that an unspecified vaccine caused Olivia's GBS. In contrast, on page 11, Dr. Shoenfeld appears to be advancing the idea that the acellular pertussis vaccine aggravated an infection with RSV. Dr. Shoenfeld's conclusion does not dispel the confusion. Dr. Shoenfeld's concluding section stated that "It is also conceivable that the early vaccination aggravated the effects of the RSV (if indeed it existed) and especially the pertussis vaccine effect." Exhibit 16 at 15. Saying that aggravation is "conceivable" falls short of a statement that it is more probable than not that a vaccination aggravated the RSV. If Dr. Shoenfeld believes, to a level of more probable than not, that an administration of acellular pertussis plus an infection with RSV resulted in GBS for Olivia, then he should make his opinion and reasoning on this point clear.

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[5] Whether Dr. Shoenfeld is correct is not relevant in this case.

[6] A vaccine against hemophilus influenzae type b (Hib) is not the same as a vaccine against an influenza virus.

Dr. Shoenfeld also discussed the mechanism by which vaccines may induce autoimmunnity. There are, again, multiple problems with this portion of Dr. Shoenfeld's report.

First, Dr. Shoenfeld failed to express the idea that he believes that autoimmunity explains what happened to Olivia. Dr. Shoenfeld's discussion about autoimmunity may be scientifically correct, but autoimmunity has relevance in this case only if this principle helps establish that a vaccine caused an injury to Olivia. Dr. Shoenfeld's report does not connect autoimmunity to Olivia. Thus, without a clarifying statement from Dr. Shoenfeld, his discussion about autoimmunity appears to lack relevance. See Bitler v. A.O. Smith Corp., 391 F.3d 1114, 1121 (10th Cir. 2004) (stating "Evidence appropriate for one purpose, therefore, may not be relevant for a different purpose, and it is the trial court's task to make this fitness determination.").

A second and related point is that Dr. Shoenfeld did not express ideas with sufficient clarity to constitute a preponderance of the evidence. His report stated:

> [V]accines which are designed to imitate infections may induce autoimmunity via similar mechanisms . . . . However, vaccines are constructed from several excipients besides the infectious antigen including adjuvant, diluents, preservatives, stabilizers and remnants from the manufacturing process (i.e. egg, yeast). These ingredients may independently stimulate autoimmunity via mechanisms described in other settings (Fig. 1). It is currently believed that avoiding such triggers may allow an individual to remain asymptomatic for many years

Exhibit 16 at 12 (reference deleted) (emphasis added).

Dr. Shoenfeld asserted three ideas about autoimmunity that "may" happen. Expressing that something is "possible" or something "may" happen does not assist the Simanskis in meeting their burden of proof.

Cases within the Vaccine Program have long recognized that expressions that the vaccine "may have caused" a problem do not constitute probative evidence that it was more likely than not that a vaccine did cause a problem. Van Epps v. Sec'y of Health & Human Servs., 26 Cl. Ct. 650, 654 (1992); Doe v. Sec'y of Health & Human Servs, 19 Cl. Ct. 439, 450 (1990) ("an assertion that something is 'highly possible' does not rise to the level necessary to establish causation by a preponderance of the evidence"); Duncan v. Sec'y of Health & Human Servs., No. 90-3809V, 1997 WL 75429, at *4 (Fed. Cl. Spec. Mstr. Feb. 6, 1997) ("The court notes further that [petitioner's expert] is unwilling to state his opinion to a reasonable degree of 'medical probability' but as 'a possibility' only, a standard that cannot support a finding of a preponderance of evidence."); Lacour v. Sec'y of Health & Human Servs., No. 90-316V, 1991 WL 66579, at * 5 (Cl. Ct. Spec. Mstr. Apr. 15, 1991) ("Expert medical testimony which merely

expresses the possibility – not the probability – of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred.").

Finding that opinions expressed as "possibilities" do not constitute persuasive evidence is consistent with Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1378 (Fed. Cir. 2009). In Andreu, the child, Enrique, received the DTaP vaccination and within one day had movements that were consistent with a seizure. Some evidence indicates that DTaP can cause febrile seizures, that is, seizures associated with a fever. Thus, if Enrique had a fever immediately after receiving the DTaP vaccine, then more evidence would support his claim that the DTaP caused his seizure disorder. A medical record showed that when Enrique was hospitalized eleven days after his vaccination his temperature was 99.4 degrees. Id. at 1378. The Federal Circuit stated that "it is quite possible that [the child] had a low-grade fever in the period immediately after his vaccination." The Federal Circuit drew this conclusion from the documented evidence that Enrique's temperature in the hospital was 99.4 degrees. In any event, the Federal Circuit did not find, as a fact, that Enrique had a low-grade fever because this fact was extraneous to its analysis. The Federal Circuit explained, in the next paragraph, that even if there were no fever, the special master erred in denying compensation. Id. Thus, the Federal Circuit's discussion of a "possible" fever is dicta in that the discussion could have been eliminated without changing the outcome of the case. National American Ins. Co. v. United States, 498 F.3d 1301, 1306 (Fed. Cir. 2007).

A case decided by the Federal Circuit after Andreu illustrates the need for an expert to state opinions with sufficient confidence that the opinions are probative. A veteran, Timothy Fagan, sought benefits for developing bilateral hearing loss while in the military. The VA's examiner wrote a report stating "it is not possible to determine if [Mr. Fagan's hearing problem] is related to military service." Fagan v. Shinseki, 573 F.3d 1282, 1284 (Fed. Cir. 2009). The Court of Appeals for Veterans' Claims affirmed a denial of compensation, reasoning that the examiner's statement "may be characterized as non-evidence." Id. at 1285, citing 2008 WL 2130166, at *3.

The Federal Circuit also affirmed, although the Federal Circuit took care to express that it was troubled to refer to the examiner's statement as "non-evidence." Id. at 1289 n.4. The Federal Circuit stated that "[t]he examiner's statement, which recites the inability to come to an opinion, provides neither positive nor negative support for service connection. . . . Therefore, it is not pertinent evidence, one way or the other, regarding service connection." Id. at 1289.

Cases from outside the Vaccine Program have also indicated that experts' opinions about "possibilities" do not meet a plaintiff's burden to present a preponderance of evidence. United States v. Frazier, 387 F.3d 1244, 1263-65 (11th Cir. 2004) (en banc) (affirming exclusion of a portion of the opinion of an expert who a criminal defendant intended to call as a witness); Fedorczyk v. Caribbean Cruise Lins, Ltd., 82 F.3d 69, 75 (3d Cir. 1996) (following New Jersey law and stating that "The possibility of the existence of an event does not tend to prove its probability."); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1320 (11th Cir. 1999) (following

Georgia law and affirming exclusion of expert's opinion); Bowers v. Norfolk Southern Corp., 537 F. Supp. 2d 1343, 1367-70 (2007) (granting motion to exclude expert). For a decision discussing several decisions by Court of Appeals for various circuits that were issued before Daubert, see Schulz v. Celotex Corp., 942 F.2d 204, 208-9 (3d Cir. 1991); see also Mays v. Ciba-Geigy Corp., 661 P.2d 348, 360 (Kan. 1983).[7]

Taken together these authorities require that Dr. Shoenfeld articulate his opinion that "it is more probable than not" that something happened (or did not happen). Dr. Shoenfeld's report stated that a vaccine "may induce" autoimmunity. Exhibit 16 at 12. This statement, as currently expressed, does not discharge the Simanskis' obligation to present a preponderance of evidence.

Dr. Shoenfeld may believe, to a reasonable degree of probability, that a vaccine (including a component of the vaccine) caused Olivia to develop autoimmunity. That is, Dr. Shoenfeld may believe not only that a vaccine "may induce autoimmunity" (to quote Dr. Shoenfeld's report), but also that a vaccine received by Olivia did induce autoimmunity in Olivia. If Dr. Shoenfeld holds this opinion, then the Simanskis should file a supplemental report from Dr. Shoenfeld, which would inform both respondent and the undersigned.

The third problem about Dr. Shoenfeld's discussion of autoimmunity relates to Dr. Shoenfeld's failure to identify which vaccine caused Olivia's GBS. It seems that Dr. Shoenfeld implicates the acellular pertussis vaccine because he discusses pertussis (the disease, the whole cell vaccine, and the acellular vaccine) more than any other vaccine. However, petitioners in the Vaccine Program generally do not allege that the pertussis vaccine causes an autoimmune response. Instead, more commonly, petitioners have offered the theory that the pertussis vaccine causes a toxic response, that is, the pertussis vaccine directly damages the body (usually portions of the central nervous system). These petitioners have not postulated that the harmful effects of the pertussis vaccine are mediated through the immune system. (Whether Dr. Shoenfeld proposes a direct toxic effect or an indirect immune-mediated effect influences the timing portion, as discussed below.)

The fact that petitioners in other cases have rarely offered the theory that the acellular pertussis vaccine causes an autoimmune response does not prevent Dr. Shoenfeld from presenting this theory. However, what is required at this stage of the proceeding is that the Simanskis disclose Dr. Shoenfeld's theory. If Dr. Shoenfeld's theory is that the acellular pertussis vaccine caused Olivia to have an autoimmune response, then Dr. Shoenfeld should state that theory and provide the reasons why he believes the theory is reliable.

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[7] Several cases cited in the text caution against requiring "magic" words. E.g. Bowers, 537 F.Supp.2d at 1369. An expert, such as Dr. Shoenfeld, may express his opinion using various phrases, such as "it is more likely than not" or "it is probable that" or "to a reasonable degree of probability" or "to a reasonable degree of medical probability." But, these phrases differ from an expression that something "may" have happened.

In connection with Dr. Shoenfeld's discussion of autoimmunity, Dr. Shoenfeld presented the theory of molecular mimicry. Dr. Shoenfeld stated that "an infectious antigen incorporated in vaccines (i.e. recombinant, live or attenuated virus etc.) may resemble host antigen and trigger autoimmunity." Exhibit 16 at 13 (emphasis added). The same set of problems recurs.

Dr. Shoenfeld did not state that he believes that it is more likely than not that molecular mimicry is a theory connecting a vaccine to Olivia's GBS. If Dr. Shoenfeld holds this opinion, then he should express it.

The greater problem is that Dr. Shoenfeld does not provide a basis for finding that molecular mimicry is a reliable theory in Olivia's case. Olivia received five vaccines. From this fact, certain questions arise. Does a portion of one of these vaccines resemble a portion of the body? If so, which vaccine? And, which portion of the body? It would appear that respondent's should be informed about the basic information underlying Dr. Shoenfeld's assertion of molecular mimicry.

Dr. Shoenfeld's simple assertion of molecular mimicry does not constitute a reliable "medical theory causally connecting [Olivia's] vaccination and [her] injury." Althen, 418 F.3d at 1278. In some cases, petitioners have demonstrated the reliability of molecular mimicry by presenting evidence that there is homology (that is, a similar sequence in molecular structure) between a component in a vaccine that the petitioner received and an injured part of the body.[8] If

[8] A showing that homology exists strikes a balance between presenting a theory without any reliability and presenting a theory that is proven to a medical certainty. Petitioners bear the burden of presenting a medical theory that is "reliable." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993); Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (affirming special master's use of Daubert in vaccine program cases). The term "reliable" suggests that some evidence must be presented to demonstrate that the expert's theory passes the test established by the Supreme Court in Daubert and, subsequently, endorsed by use in the Vaccine Program by Terran. There may be many ways to demonstrate the reliability of molecular mimicry as a theory in this case and Althen instructs special masters not to require any particular type of evidence to show reliability. Introducing evidence that homology exists is a method that other petitioners have used to meet their burden of presenting a reliable medical theory.

On the other hand, petitioners are not required to establish their medical theory to a level of scientific certainty. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Requiring some indication of reliability, such as homology, is not the same as requiring proof to a level of scientific certainty. For example, even if homology were shown to exist, the theory of molecular mimicry posits that the body's antibodies attack the host. Proving this aspect of molecular mimicry is difficult and has probably been persuasively established for only one condition – an infection with the streptococcal bacteria causes rheumatic fever. But, petitioners are not required to establish molecular mimicry with as much evidence used to support the connection between streptococcal bacteria and rheumatic fever.

petitioners in other cases could present evidence showing that molecular mimicry is a valid theory in their cases, then it is reasonable to expect that Dr. Shoenfeld could make a similar showing. How Dr. Shoenfeld establishes the reliability of molecular mimicry as a theory is for Dr. Shoenfeld and the Simanskis to decide. But, the present record lacks any indication that molecular mimicry is a reliable theory causally connecting any of Olivia's vaccines to her GBS.

The last substantive portion of Dr. Shoenfeld's initial report presented information about adjuvants. This information does not help the Simanskis meet their burden of proof. The same deficiencies appear again.

First, Dr. Shoenfeld failed to identify an adjuvant that he believes, to a level of more probable than not, that affected Olivia. For example, Dr. Shoenfeld asserted that the adjuvant known as alum "improved antigen presentation and T cell activation" in mice. Assuming that studies involving mice are transferrable to humans, does Dr. Shoenfeld believe that the "improved antigen presentation and T cell activation" caused Olivia to develop GBS? If this is Dr. Shoenfeld's theory, he should make his theory explicit.

Second, Dr. Shoenfeld raised a point that seems irrelevant to Olivia's case. He discussed a study involving the pertussis vaccine and the anthrax vaccine. But, Olivia did not receive the anthrax vaccine. So, without more information from Dr. Shoenfeld, this study appears not to advance the Simanskis' case that a vaccine that Olivia did receive caused her GBS.

In sum, Dr. Shoenfeld's report failed to present any statement that could be considered, on the existing record, to be a medical theory causally connecting a vaccine that Olivia received to an injury that Olivia suffered. If the Simanskis cannot meet their burden of proof on this issue, then they cannot prevail and their case will be dismissed.

b. A Showing of a Proximate Temporal Relationship Between Vaccination and Injury

Although Althen lists the temporal relationship prong third, in this case, the analysis is clearer if it is discussed second. The temporal relationship prong can be divided into two different parts. The first part is the time that medical science accepts as an appropriate basis to infer that the vaccination caused the disease. The second part is whether the petitioner (Olivia) showed manifestations of the disease within this temporal window. On both aspects, more information from Dr. Shoenfeld is needed before the Simanskis meet their burden of proof.

In Dr. Shoenfeld's initial report, he suggested that the appropriate interval between vaccination and the onset of problems is 5-21 days after vaccination. Exhibit 16 at 7, 14-15. He asserted that Olivia was a healthy child who "received a battery of vaccine . . . and four days later, developed a progressive neuropathy." Exhibit 16 at 5. Obviously, four days is outside of a 5-21 day window. Dr. Shoenfeld stated that "It is conceivable that in such a young infant the

severe stimulation of the immature immune system may lead to a hyper reactive response." Exhibit 16 at 15.

The undersigned provided an opportunity for the Simanskis to obtain a supplemental report from Dr. Shoenfeld. The order, among other items, noted the problem with timing. Order, filed April 13, 2009.

Dr. Shoenfeld presented a supplemental report, which addressed the timing but not the other items in the April 13, 2009 report. Dr. Shoenfeld presented three "explanations for why Olivia responded earlier by one day." First, he stated that Olivia had an immature immune system. Second, the transfer of antibodies from mother to child during pregnancy "may also enhance and accelerate the eventual reaction by increasing the titers of autoantibodies in the infant which could lower the threshold for inflammation to autoantigens and potentially pathogenesis." Third, Dr. Shoenfeld stated that Olivia's mother "may have had prior sensitization to bacteria . . . [which] could lead to enhanced autoimmunity." Exhibit 18 (all emphases added). The uncertainty inherent in Dr. Shoenfeld's opinions, as they are expressed in his written reports, does not constitute persuasive evidence that Olivia could have reacted as quickly as Dr. Shoenfeld asserted that she did react.

There are more problems with Dr. Shoenfeld's opinion, as presented in his two reports, regarding the time that medical science expects for an adverse reaction to appear. Dr. Shoenfeld initially suggested that the shortest amount of time medical science expected was five days and cited one article in support of this proposition. Exhibit 16, tab 70. But, the two subjects of that article seem much different from Olivia. Both were relatively older adults (one 62 years old and the other was 70 years old). Olivia was only three months old when she was vaccinated. Both of the adults reported in the article received the influenza vaccine. Olivia did not. Finally, the two adults did not develop GBS. Instead, they developed acute disseminated encephalomyelitis and transverse myelitis with acute motor axonal neuropathy. Thus, the only article that Dr. Shoenfeld offered to support his assertion that a neurologic problems can appear in as few as five days after vaccination appears to have questionable usefulness in this case.

Dr. Shoenfeld, then, attempted to modify the starting point, which was five days, to allow for an earlier onset in Olivia's case. However, the "explanations," as contained in the existing record, do not rise to a level of more likely than not. Dr. Shoenfeld mentioned that Olivia had an immature immune system, and that the immune system of babies differs from the immune system of adults. This assertion seems reasonable. But, Dr. Shoenfeld does not explain how this difference affects Olivia's case.

The difference may make the Simanskis' claim less persuasive. In a different case, the undersigned heard the testimony of a leading neonatal immunologist. This doctor testified that children less than six months old are less likely to develop an autoimmune reaction because the children's immune system is not sufficiently strong enough to attack the host. See Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000) (quoting Hodges v.

Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) for the proposition that special masters may use their accumulated expertise in evaluating cases); Ultimo v. Sec'y of Health & Human Servs., 28 Fed. Cl. 148, 152-53 (1993). If Dr. Shoenfeld's theory that a vaccine caused Olivia's GBS through molecular mimicry, then Olivia's immature immune system would seem to discredit this theory.

In addition to age, Dr. Shoenfeld offers two other "explanations" for why the temporal window should accept reactions at four days. However, these other explanations are not complete. Elaboration on these points would place respondent on notice about the extent of Dr. Shoenfeld's opinions, would allow the undersigned to prepare for a hearing, and may simplify any hearing by narrowing the issues in dispute.

For example, Dr. Shoenfeld stated that congenital autoimmunity has been known to occur in various conditions. However, Dr. Shoenfeld did not list GBS as a disease caused by congenital autoimmunity. If GBS is not caused by congenital autoimmunity, then those other diseases appear not to be relevant. Dr. Shoenfeld should explain why these other diseases are comparable to Olivia's GBS.

The third potential "explanation" for increasing the temporal window appears to lack any factual basis. Dr. Shoenfeld stated that Olivia's mother "may have had prior sensitization to bacteria." But, Dr. Shoenfeld has cited no evidence to support this assertion. If Dr. Shoenfeld is aware that Olivia's mother was sensitized to bacteria, then Dr. Shoenfeld should identify the record (by exhibit and page number) to allow the respondent and the undersigned to consider this material.

The flaws in Dr. Shoenfeld's reports about timing probably flow from the lack of a clearly articulated theory. If Dr. Shoenfeld's theory is based upon a toxic response to the vaccine (which may happen with pertussis vaccine), then the onset is likely to be soon. For example, the Vaccine Injury Table establishes that an encephalopathy is presumed to be caused by pertussis vaccine when the encephalopathy appears 0-72 hours after the vaccination. 42 C.F.R. § 100.3 (paragraph II). In contrast, if Dr. Shoenfeld's theory is based upon an autoimmune response, then the onset is likely to happen after a lapse of time. For example, the Vaccine Injury Table establishes a presumption for measles vaccine and thrombocytopenia purpura when the onset is 7-30 days. Id. (paragraph V). The delay reflects that the body must first develop an immune response before the body develops an autoimmune response. See De Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008) (holding that special master correctly found that the alleged reaction occurred too soon after the vaccination for causation to be attributed to the vaccination). If Dr. Shoenfeld clarified his opinion with regarding to the theory, his opinion with regard to the time that medical science expects for a vaccine reaction would also become more clear.

As mentioned previously, an opinion about the time medical science expects is only one portion of the third prong from Althen. The other component is that the Simanskis must establish that Olivia's problem began during the time expected.

Dr. Shoenfeld's reports fail to satisfy the Simanskis burden on this point. Dr. Shoenfeld has not identified what behavior that occurred four days after vaccination was a sign or symptom of GBS. Dr. Shoenfeld stated that Olivia developed "a cough, [upper respiratory infection], mild respiratory distress, decreased feeding and some lethargy." Exhibit 16 at 2, citing exhibit D at 1275-76. Dr. Shoenfeld does not state that these symptoms are a manifestation of GBS. They appear not to be manifestations of GBS because GBS is a disease involving the peripheral nervous system. Dr. Shoenfeld may hold the opinion that these problems are manifestations of GBS. If so, Dr. Shoenfeld should make his opinion clear and provide the basis for his opinion.

When presenting his opinion Dr. Shoenfeld should consider, as he noted in his report, that a neurologist examined Olivia on February 8, 2001 (13 days after vaccination and 9 days after the date on which Dr. Shoenfeld stated that Olivia began to develop a "progressive neuropathy"). This physical examination showed that Olivia's moved her extremities well and that her muscle tone was normal with 2+ deep tendon reflexes. Exhibit D at 1277-78. This examination appears to be inconsistent with someone suffering from a dysfunction in her peripheral nervous system. If Olivia was not showing signs of GBS on February 8, 2001, then Dr. Shoenfeld should explain when she first did manifest signs of GBS.

As the record stands, the Simanskis have failed to meet their burden of proof with regard to the third Althen prong.

c. A Logical Sequence of Cause and Effect Showing That the Vaccination Was the Reason for the Injury

The remaining prong from Althen is the second prong. Given the problems with Dr. Shoenfeld's reports on the theoretical connection (the first prong) and the temporal connection (the third prong), it is not surprising that Dr. Shoenfeld failed to articulate a logical sequence of cause and effect showing that the vaccination was the reason for Olivia's injury.

Dr. Shoenfeld's initial report presented Olivia's "case history." Exhibit 16 at 2-5. There do not appear to be any significant flaws in this recitation. The problem, as noted on pages 10-15 above, is that Dr. Shoenfeld's report did not talk about Olivia again until its conclusion, which starts on page 14.

Dr. Shoenfeld also omitted any significant discussion of RSV. Dr. Shoenfeld stated that "[t]he only cultures of RSV which were positive [were] from the nares. All other cultures were negative for RSV." Exhibit 16 at 3 (emphasis deleted). At the end of his report, Dr. Shoenfeld stated "[i]is not conceivable that the [RSV] infection (if existed) can be responsible for the polyneuropathy by and large and for the phrenic nerve paralysis in particular." Exhibit 16 at 15.

It appears that Dr. Shoenfeld suspects that Olivia was not infected with RSV, but if this is his opinion Dr. Shoenfeld has not expressed it in his report.

d. Additional Comments Regarding *Althen* Factors

In the Simanskis' July 24, 2009 response, the Simanskis argued that Dr. Shoenfeld's two reports meant that they had "made a *prima facie* case that her vaccines caused her GBS." Pet'r Resp. at 4. This statement is conclusory. The Simanskis brief did not analyze each of the Althen elements.

The Simanskis' July 24, 2009 response made, at best, two points in support of an argument that they had met their burden of proof by submitting reports from Dr. Shoenfeld. First, they noted that Dr. Shoenfeld cited 117 scientific articles. This is correct. But, as discussed at length above, the relevance of many of these articles is not apparent. For example, 16 articles discuss the flu vaccine, but Olivia did not receive the flu vaccine. Dr. Shoenfeld's report is more like a general discourse about various topics instead of presenting a theory for explaining how a vaccine that Olivia received caused her GBS. The filing of a hundred articles alone does not establish the reliability of an expert's opinion. See Allison v. McGhan Medical Corp., 184 F.3d 1300, 1309-22 (11th Cir. 1999) (aff'g district court's rejection of plaintiff's experts despite their impeccable qualifications and submitting hundreds of articles).

The Simanskis also quoted Dr. Shoenfeld's conclusion in which he stated that "with great confidence and certainly [sic, probably should be "certainty"] I can say that the vaccines with all their immunological aspects were the cause of the GBS/CIDP leading to phrenic nerve paralysis and failure to extubate Olivia Simanski from artificial respiration." This statement does not eliminate the need for the Simanskis to obtain a supplemental report from Dr. Shoenfeld. Dr. Shoenfeld's reports do not contain an assertion of any reliable theory to explain why a vaccine that Olivia received caused her to develop GBS. They do not contain an assertion of any theory to explain why a vaccine that Olivia received aggravated her underlying RSV and caused her to develop GBS. Dr. Shoenfeld's reports do not discuss the temporal relationship prong comprehensively. Dr. Shoenfeld's "opinion is no better than the soundness of the reasons supporting it." Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (aff'g decision of special master that petitioner's case lacked a reasonable basis despite an expert's opinion). Dr. Shoenfeld's reports – despite the language used in the conclusion – do not set forth the reasons for his opinion. At best, Dr. Shoenfeld's reports set forth some ideas, which may be or may not be, the reason for Dr. Shoenfeld's opinion. Without an explicit presentation of Dr. Shoenfeld's opinions that fit Olivia's case, there appears to be "too great an analytic gap" to support Dr. Shoenfeld's conclusion. See General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997); see also Snyder, 86 Fed. Cl. at 742-43 (citing Joiner in a Vaccine Program case). The Simanskis can cure these deficiencies by obtaining a supplemental report from Dr. Shoenfeld.

e. Summary Regarding Less Severe Sanctions

Dr. Shoenfeld submitted two reports. The combined effect of these reports does not establish the Simanskis' burden of proof with respect to any of the Althen elements. The failure is most notable for the first prong, a reliable medical theory.

A sanction less than a dismissal, such as barring Dr. Shoenfeld from testifying at a hearing about "a medical theory causally connecting the vaccination and the injury" would make little sense. Without introducing evidence from Dr. Shoenfeld on this element, the Simanskis could not prevail. Therefore, the appropriate sanction appears to be a dismissal. However, if the Simanskis believe that a different sanction is appropriate, the Simanskis may propose one in their response to this order.

2. Prejudice to Other Party

A failure to submit a supplemental report from Dr. Shoenfeld prejudices respondent. Dr. Shoenfeld's report contains many ideas expressed as possibilities. Other than his conclusion, Dr. Shoenfeld expressed relatively few opinions as "more probable than not."

The Simanskis argue that respondent should obtain an expert report. However, respondent should not be required to respond until Dr. Shoenfeld clarifies which opinions he holds to a reasonable degree of probability.

If the Vaccine Program followed the Federal Rules of Civil Procedure (or their counterpart, the Rules of Procedure for the Court of Federal Claims), then ordering a supplemental disclosure might be less necessary. In traditional litigation, respondent would have the right to depose Dr. Shoenfeld before the hearing. Respondent could ask questions to establish what opinions Dr. Shoenfeld holds to a reasonable degree of medical probability and to discover the basis for those opinions. However, in the Vaccine Program, respondent does not possess this right. 42 U.S.C. § 300aa–(d)(2)(E); Vaccine Rule 7(a).

Thus, the failure to provide a detailed disclosure of Dr. Shoenfeld's opinion is prejudicial to respondent. The cure for the vagueness and uncertainty of Dr. Shoenfeld's opinion is to obtain a supplemental written report that clarifies the nature and scope of his opinion.

3. Warning Before Dismissal

This order warns the petitioners that their failure to comply with the earlier orders to obtain a supplemental report from Dr. Shoenfeld may result in dismissal.

4. Public Interest in Expeditious Resolution of Litigation

In following law established by the Ninth Circuit, the Federal Circuit has instructed trial courts to consider the "public's interest in expeditious resolution of the litigation." Refac, 921 F.2d at 1254.

This litigation has not been "expeditious." The Simanskis did not file what appears to be a complete set of medical records until April 2, 2008 (docket entry 65). More than five years elapsed from the filing of the petition to the filing of a complete set of medical records. This delay is notable because a complete set of medical records should have been filed when the petition was filed. 42 U.S.C. § 300aa–11(c); Vaccine Rule 2(c).[9]

The process of obtaining a report from an immunologist began no later than April 29, 2008, when petitioners reported that they had consulted Dr. Bellanti. Dr. Shoenfeld's first report was filed nearly one year later, on March 19, 2009. (Some of this delay is attributable to Dr. Bellanti's decision not to continue working in this case.)

The history leading to the Simanskis' filing of a report from Dr. Shoenfeld is provided for context. It shows that the Simanskis are responsible for the delay in adjudicating this case. But, regardless of how the case arrived at this point, the relevant question is how can the case be resolved most expeditiously?

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.

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.

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[9] The Simanskis current counsel of record, Mr. Homer, was not counsel of record until March 2006, when the case had already been pending for slightly more than three years.

5. The Public Policy Favoring Disposition of Cases on Their Merits

This factor favors allowing the petitioners to continue their case. Of course, this factor cannot be dispositive. If this factor were dispositive, then no case could ever would ever be dismissed.

6. The Court's Need to Manage its Docket

The remaining factor identified by the Federal Circuit in Refac is the "the court's need to manage its docket." Refac, 921 F.2d at 1254. In interpreting Ninth Circuit law, the Federal Circuit has stated "although we will not second guess the district court's need to manage its docket, the district court in this case did not invest the time or endure the disruption that [occurred in another case]." Bowling v. Hasbro, Inc., 403 F.3d 1373, 1378 (Fed. Cir. 2005) (finding that the district court abused its discretion in dismissing a case with prejudice when the district court did not consider a lesser sanction (dismissal without prejudice) and did not warn the offending party that a dismissal with prejudice was possible).

"A district court has the inherent power to 'control the disposition of the causes on its docket with economy of time and effort for itself, for counsel and for litigants.' Landis v. North Am. Co., 299 U.S. 248, 254, 57 S.Ct. 163, 166, 81 L.Ed. 153 (1936). Incident to this power is the court's ability to dismiss a lawsuit." L.E.A. Dynatech, Inc. v. Allina, 49 F.3d 1527, 1530 (Fed. Cir. 1995).

Here, an efficient management of the undersigned's docket is best served by obtaining a supplemental report from Dr. Shoenfeld. As discussed in section III.C.1 above, Dr. Shoenfeld's two reports raise many questions. The easiest and most economical way to obtain answers to these questions is for the Simanskis to obtain a supplemental report from Dr. Shoenfeld.

The Simanskis' proposed alternative – to require respondent to obtain an expert report – is unfair to respondent. Pursuant to L.E.A. Dynatech, the undersigned may manage his docket with an eye toward being efficient not only for the judicial officers but also for the "litigants." Respondent is not obligated to incur the cost of obtaining an expert report until Dr. Shoenfeld states his opinions and the bases for those opinions with more clarity.

For these reasons, this factor favors a dismissal if the Simanskis fail to present an expert report from Dr. Shoenfeld in response to this show cause order.

D. Additional Comments

This show cause order began by reciting the authorities authorizing special masters to manage cases. The Vaccine Act states that a special master "may require the submission of such information as may be reasonable and necessary." 42 U.S.C. § 300aa–12(d)(3)(B)(ii). Moreover, the judges of the Court of Federal Claims by enacting the Vaccine Rules authorize

special masters to "evaluate the parties' respective positions" relatively early in the case. See Vaccine Rule 5.

The Simanskis argued that undersigned's questions about Dr. Shoenfeld's opinion "inappropriately provide the respondent, and the respondent's expert, with a road map as to how to attack the opinions of Dr. Shoenfeld." Pet'r Resp. at 4.

But, the previous orders have given the Simanskis and this order presently gives the Simanskis an opportunity to cure any gaps in Dr. Shoenfeld's opinion. (In giving the Simanskis these additional chances to improve their case, the Simanskis have been given more process than is required. See Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 55 (2005) (stating that the "principles of fundamental fairness did not dictate that this petitioner be given a second chance to find an expert after his first expert was rejected.")). If the Simanskis present a supplemental response from Dr. Shoenfeld that addresses the concerns in this show cause order, their case will be improved and the case will continue. See Adams v. Principi, 256 F.3d 1318, 1322 (Fed. Cir. 2001) (affirming decision of Court of Appeals for Veterans' Claims to remand case to Board of Veterans Appeals to seek additional information from a doctor who opined that the veteran's condition "may have preexisted his admission to the service"); Hanlon v. Sec'y of Health & Human Servs., 191 F.3d 1344, 1350 (Fed. Cir. 1999) (holding that special master did not abuse her discretion in requesting testimony of a doctor who testified first for petitioners and then reached a new opinion).

The Simanskis also stated that "the level of detail sought by the special master . . . has never been encountered by a petitioner at this pre-hearing stage." Pet'r Resp. at 3. By distinguishing the pre-hearing stage from the hearing stage, the Simanskis are suggesting that more details will be forthcoming at a hearing. However, special masters are obligated to "afford[] each party a full and fair opportunity to present its case." Vaccine Rule 3(b)(2). For respondent to have a "fair opportunity" to respond to Dr. Shoenfeld's opinions, respondent should be placed on notice about Dr. Shoenfeld's opinions and the basis for those opinions. Fairness is advanced by a system in which Dr. Shoenfeld explains, in his pre-hearing report, the basis for his ultimate conclusions. If Dr. Shoenfeld sets forth, to a level of more probable than not, the reasons for his opinions and if respondent disagrees with a position advanced by Dr. Shoenfeld, then a hearing can be held. But, until Dr. Shoenfeld provides more information, there is no reason to hold a hearing. See 42 U.S.C. § 300aa-12(d)(3)(B)(v) (special masters "may conduct such hearings as may be reasonable and necessary"); Vaccine Rule 8(d) (special masters "may decide a case on the basis of written submissions without conducting an evidentiary hearing"); Hovery v. Sec'y of Health & Human Servs., 38 Fed. Cl. 397, 400-01 (1997) (affirming special master's decision denying petitioners' request for an evidentiary hearing).

Ultimately, Congress authorized special masters to require the evidence that they think is necessary to adjudicate the case. 42 U.S.C. § 300aa–12(d)(3)(B); Whitecotton, 81 F.3d at 1108. Here, the undersigned has twice ordered the Simanskis to submit information. Yet, they have

refused. Thus, they are ordered to show cause why their case should not be dismissed for failing to comply with the April 13, 2009 order and the June 26, 2009 order.

IV. Summary

Beginning before she reached three months old, Olivia's significant medical history is lengthy. It is also unfortunate.

Beginning in 2003, the procedural history of this case is also lengthy. But, the Simanskis have not established that their decisions not to obtain a supplemental report from Dr. Shoenfeld were justified.

Therefore, the Simanskis are ORDERED to show cause why their case should not be dismissed for failure to comply with the April 13, 2009 order and the June 26, 2009 order, requiring the Simanskis to obtain a supplemental expert report from Dr. Shoenfeld. The Simanskis shall file a response to this show cause order by **December 22, 2009**.[10] Respondent may present a response to the Simanskis' brief within **14 days**. Although respondent may comment on any topic, an issue of particular interest is whether a sanction less severe than dismissal would be an appropriate alternative.

IT IS SO ORDERED.

S/ Christian J. Moran
Christian J. Moran
Special Master

[10] If the Simanskis need additional time to file a response due to the end of the year holidays, they may file a motion for additional time pursuant to Vaccine Rule 19.