In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-160V
Filed: December 15, 2015
For Publication

ADAN GOMEZ and RAQUEL AYON, on behalf of the Estate of JOEL GOMEZ Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	Motion for discovery on a non-party vaccine manufacturer; discovery; Gardasil

Jeffrey T. Roberts, Newport Beach, CA, for petitioners.
Darryl R. Wishard, Washington, DC, for respondent.

MILLMAN, Special Master

ORDER DENYING PETITIONERS' MOTION FOR DISCOVERY ON A NON-PARTY VACCINE MANUFACTURER[1]

On February 20, 2015, petitioners filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10¬34 (2012) ("Vaccine Act"), on behalf of the estate of Joel Gomez alleging that the Gardasil vaccine caused their son, Joel Gomez, to develop myocarditis, which led to his death. On November 2, 2015, petitioners filed a motion requesting the Court's authority to issue a subpoena on the manufacturer of the Gardasil vaccine, Merck & Co., Inc. ("Merck"). Petitioners seek answers to interrogatories and the production of documents by Merck regarding the production, testing, and safety of Gardasil. Petitioner's motion does not meet the standard for discovery in the Vaccine Program. Therefore, petitioners' Motion for Discovery is **DENIED**.

[1] Vaccine Rule 18(b) states that 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 constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioners have 14 days to identify and move to redact such information prior to 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 redact such material from public access.

PROCEDURAL HISTORY

On February 20, 2015, petitioners filed a petition under the Vaccine Act, alleging that their son's receipt of the Gardasil vaccines on June 19, 2013 and August 19, 2013 caused him to develop myocarditis, which led to his death on August 20, 2013. See Pet. at ¶¶ 8-9, 11.

The initial status conference was held on April 16, 2015. During the status conference, petitioners' counsel raised the issue of requesting discovery on Merck. The undersigned discussed a ruling she had recently published in Phillips-Deloatch v. Sec'y of Health and Human Services, No. 09-171V, 2015 WL 1950107 (Fed. Cl. Spec. Mstr. Apr. 9, 2015), in which she denied petitioner's request for authority to subpoena Merck regarding the Gardasil vaccine.

On June 22, 2015, respondent filed her Rule 4(c) Report. Resp't's Rep. She agreed that petitioners' son had myocarditis, but disagreed with petitioners' view that the Gardasil vaccine caused the condition, noting the coroner stated Joel's myocarditis had been present for at least several days or even weeks. Id. at 8. Respondent argued that an autopsy of his liver and his elevated heart and respiration rates prior to his vaccination suggest that Joel Gomez likely had a "chronic, multi-symptom condition that may have contributed to or caused his death." Id. at 8-9.

On October 16, 2015, petitioners filed their expert report. Petitioners' expert, Dr. Sin Hang Lee, concluded that "the most plausible cause of death for [Joel Gomez] is cardiac failure brought about by a surge of myocardium-depressing cytokines . . . released from the macrophages activated by the HPV L1 gene DNA fragments present in the vaccine product" after petitioner's second dose of Gardasil. Pet'r's Rep. at 9.

On October 27, 2015, respondent filed a status report requesting that petitioners file Dr. Lee's CV and the medical literature he cited in his report. Respondent's counsel also requested the slides Dr. Lee examined when writing his report.

A telephonic status conference was held on October 28, 2015. The undersigned reviewed Dr. Lee's expert report with the parties, and noted that the report was well-written and thorough.

On October 30, 2015, petitioners filed a Motion for Discovery under the heading "Additional Documentation." The undersigned struck the filing on November 2, 2015 because it was filed under the incorrect docket heading. Petitioners refiled their motion under the correct heading, "Motion for Discovery," on November 2, 2015. In their motion, petitioners ask the Court for its authority to submit sixteen interrogatories to Merck about the production, testing, manufacture, and side effects of Gardasil, as well as possible adverse effects of Gardasil on the cardiac health of vaccinees. Petitioners also ask for authority to request Merck to produce documents regarding clinical studies of Gardasil, and documents showing that Gardasil can cause adverse effects on vaccinees' hearts.

Respondent filed her response to petitioner's motion on November 19, 2015. Petitioners

filed their reply to respondent's response on November 24, 2015, which the undersigned struck for being filed under the wrong heading. The petitioners refiled their reply on the same day. Respondent filed a sur-reply on November 30, 2015, noting that the U.S. Court of Federal Claims had published an Order on a similar issue on the same day she filed her reply November 24, 2015. See Sur-Reply at 1; Halverson v. Sec'y of HHS, No. 15-227V, 2015 WL 7445510 (Fed. Cl. Spec. Mstr. Oct. 29, 2015).

The matter is now ripe for adjudication.

FACTS

Joel Gomez received his first dose of the Gardasil vaccine on June 19, 2013. He received his second dose of the vaccine on August 19, 2013. He had no major health issues prior to his vaccinations, although he had previously visited his pediatrician after experiencing pain in his chest after running and had elevated pulse and respiratory rate during several visits to his doctors, despite the fact that he trained extensively for high school football. See med. recs. Ex. 3, at 11; id. at 8; id. at 6; id. at 2. He had also visited the doctor due to a low white blood cell count. Id. at 6. On August 20, 2013, the day after his second Gardasil vaccine, Joel Gomez was found unresponsive in bed. Med. recs. Ex. 5. He was taken to the San Gabriel Valley Medical Center Emergency Room in full cardiac arrest. Med. recs. Ex. 13. After performing an autopsy, Dr. Ribe noted that Joel had myocarditis. Med. recs. Ex. 10. The cause of death was listed as unknown. Id. at 6.

EXPERT REPORTS

On June 22, 2015, respondent filed her Rule 4(c) Report, which concludes that Joel's myocarditis was not related to his receipt of the Gardasil vaccine. See resp't's rep. at 8. Respondent's view, without having the pathology slides examined by an expert pathologist, is that Joel may "have had disease processes within his lungs and liver." Id. She bases this belief on the coroner's findings that Joel had extremely heavy lungs, which she states are unlikely to have become so heavy shortly after his Gardasil vaccination, and the fact that Joel had "portal inflammation and fibrosis with piecemeal necrosis of the liver." Id. Respondent also notes that Joel's heart and respiration rates were high, which is abnormal for a healthy adolescent undertaking heavy football training. Id.

Petitioners filed their expert report on October 16, 2015. Their expert, Dr. Sin Hang Lee, states that Joel most likely had a healing myocardial infarct, not viral myocarditis, because Joel did not have flu-like symptoms in the weeks before his death. Med. recs. Ex. 15, at 4. Additionally, slides of the left ventricle of the heart indicate that the myocardial infarct was a few weeks old and in the process of healing. Id. Because Joel was able to participate in football practice without complaining of shortness of breath or chest pain, Dr. Lee believes the myocardial infarct was not the primary cause of Joel's death. Id. at 4-5. Instead, Dr. Lee states, Joel's death was caused by cardiac failure produced by a "surge of myocardium-depressing cytokines . . . released from the macrophages activated by the HPV L1 gene DNA fragments

present in the vaccine product after the injection of the second dose of Gardasil." Id. at 9. The first dose of the Gardasil vaccine caused cytokines to surge through his body, leading Joel to develop a myocardial infarction, which was in the process of healing at the time of his death. Id. The second Gardasil vaccination caused a new surge of cytokines which led to an episode of hypotension, resulting in Joel's death from "left heart failure due to insufficient blood perfusion to the heart muscle and brain." Id.

DISCUSSION

1. Discovery Standard

Discovery is not a matter of right in the Vaccine Program. A special master's authority to direct discovery is outlined in the Vaccine Act, which provides:

> (B) In conducting a proceeding on a petition a special master—
>
> (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,
> (iv) shall afford all interested persons an opportunity to submit relevant written information—
> . . . and
> (v) may conduct such hearings as may be reasonable and necessary.
>
> There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

42 U.S.C. § 300aa-12(d)(3)(B). Thus, the plain language of the statute indicates that the special master may require discovery of evidence that is "reasonable and necessary" to the proceedings in a case. "Reasonable and necessary" has been interpreted to mean that

> the special master should require production if the master concludes that, given the overall context of the factual issues to be decided by the master, he or she could not make a *fair and well-informed* ruling on those factual issues without the requested material. Requiring the requested testimony or document production must also be "reasonable" under all the circumstances, which means that the special master must consider the *burden* on the party who would be required to testify or produce documents. That is, the importance of the requested material for purposes of the special master's ruling must be balanced against the burden on the producing party.

In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2004 WL 1660351, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004)

(emphasis in original) (hereinafter "Omnibus Autism Proceeding"); see also Werderitsh v. Sec'y of HHS, No. 99-319V, 2005 WL 3320041, at *4–*5 (Fed. Cl. Spec. Mstr. Nov. 10, 2005).

Special masters have generally refrained from granting extensive discovery. See Omnibus Autism Proceeding, 2004 WL 1660351 (Special Master Hastings denied a motion seeking discovery from Merck); *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2007 WL 1983780 (Fed. Cl. Spec. Mstr. May 25, 2007) (three special masters denied a motion for discovery of vaccine safety information held by the Vaccine Safety DataLink Project); Werderitsh, 2005 WL 3320041 (Special Master Sweeney denied petitioner's request for access to information from the Vaccine Adverse Event Reporting System); Schneider v. Sec'y of HHS, No. 99-0160V, 2005 WL 318697 (Fed. Cl. Spec. Mstr. Feb. 1, 2005), aff'd, 64 Fed. Cl. 742, 746 (Fed. Cl. 2005) (Special Master Edwards denied discovery of the vaccine manufacturer's information about the manufacturing and testing of hepatitis B vaccine).

Petitioners' Motion for Discovery requests the authority to require Merck to answer interrogatories and produce documents in possession of the vaccine manufacturer. As discussed in the Omnibus Autism Proceeding, vaccine manufacturers are not exempt from discovery in the Vaccine Program: "[T]he statutory language plainly does not exempt *anyone* from being potentially required to provide testimony or documents, stating that a special master may 'require the testimony of *any person* and the production of *any* documents.'" Omnibus Autism Proceeding, 2004 WL 1660351, at *6 (quoting 42 U.S.C. § 300aa-12(d)(3)(B)(iii)). Moreover, Congress included "trade secret[s] or commercial or financial information" as a category of information to be excluded from disclosure in Vaccine Program decisions, which suggests Congress may have anticipated a vaccine manufacturer would submit information in a vaccine claim. See id. (discussing § 300aa-12(d)(4)(B)). These statutory provisions thus support that a special master has the authority to require a vaccine manufacturer to provide information.

In summary, the relevant inquiry is whether the information requested by petitioners is "reasonable and necessary" for the undersigned to make a "fair and well-informed decision" on whether Gardasil vaccine caused Joel Gomez's death.

2. Analysis

To carry their burden of proof, petitioners must show by preponderant evidence: "(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 HHS 418 F.3d 1274, 1278 (Fed. Cir. 2005). As the Federal Circuit stated in Grant v. Secretary of Health & Human Services, 956 F.2d 1144, 1149 (Fed. Cir. 1992), without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation."

Petitioners ask the Court for authority to subpoena Merck because they believe Dr. Lee's expert opinion "could be further assisted" by information from the vaccine manufacturer.

Pet'r's Mot. at 1. However, petitioners' claims are already supported by an expert report that is, as the undersigned noted during the October 28, 2015 status conference, extremely thorough and well-written. Therefore, any information petitioners may obtain from Merck is not necessary for petitioners to go forward with their claim.

Petitioners state in their reply to respondent's response to their Motion for Discovery that Dr. Lee "has already provided a persuasive medical theory as to Gardasil causing the death of Joel Gomez," and that they have met their evidentiary burden, but they say that does not mean they "should discontinue seeking stronger evidence" to assist the special master. Pet'rs' Reply, at 2. As another Special Master stated recently in Halverson, petitioners' burden is "a preponderance of the evidence standard, not scientific certainty." Halverson v. Sec'y of HHS, No. 15-227V, 2015 WL 7445510, at *5 (Fed. Cl. Spec. Mstr. Oct. 29, 2015). Petitioners are not required to produce epidemiological evidence to prevail. Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Petitioners appear to want this information simply to bolster their case against respondent. It is not reasonable for petitioners to request information from Merck solely to provide stronger evidence for a case they are already able to make without that information. Therefore, the information requested by petitioners is not reasonable or necessary for the undersigned to make a "fair and well-informed decision" on whether Gardasil vaccine caused Joel Gomez's death. The undersigned has studied petitioners' motion and finds it does not adequately make a reasonable showing of why burdening Merck with a discovery request is reasonable and necessary.

CONCLUSION

The record does not contain a persuasive reason to require production of information and documents from Merck & Co., Inc. Petitioners' Motion for Discovery is **DENIED**.

IT IS SO ORDERED.

Dated: December 15, 2015

/s/ Laura D. Millman
Laura D. Millman
Special Master