In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-171V
Filed: April 9, 2015
To be Published

ZENORIA PHILLIPS-DELOATCH, as Personal Representative of the Estate of MOSHELLA F. ROBERTS,	*	
Petitioner,	*	Renewed motion for subpoena on vaccine manufacturer; discovery; human papillomavirus (HPV) vaccine (Gardasil); sudden death
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

John F. Caldwell, Sarasota, FL, for petitioner;
Debra A. Filteau Begley, Washington, DC, for respondent.

ORDER DENYING PETITIONER'S RENEWED MOTION FOR SUBPOENA[1]

Petitioner has requested the Court's authority to issue a subpoena on the manufacturer of Gardasil vaccine, Merck & Co., Inc. ("Merck"). Petitioner seeks (1) records of any reports of sudden death temporally related to Gardasil vaccination and (2) any papers, reports, or memoranda discussing a possible biological mechanism by which Gardasil could cause or trigger sudden death.

This is petitioner's third request for this subpoena. On April 27, 2010, Special Master Christian J. Moran issued a ruling quashing a subpoena served on Merck. Phillips-Deloatch v. Sec'y of HHS, No. 09-171V, 2010 WL 5558349 (Fed. Cl. Spec. Mstr. Apr. 27, 2010) (Published Ruling Quashing Subpoena, Apr. 27, 2010, ECF No. 33) (reissued with a correction on July 28, 2010). Special Master Moran denied petitioner's renewed motion for a subpoena on September

[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 categories listed above, the special master shall redact such material from public access.

20, 2011. Published Ruling on Renewed Mot. for Subpoena, Sept. 20, 2011, ECF No. 55.

Petitioner has again renewed her request to subpoena Merck. The undersigned agrees with Special Master Moran's prior rulings on this issue and finds that petitioner has presented no additional evidence to merit granting her renewed motion for subpoena.

PROCEDURAL HISTORY

On March 19, 2009, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10–34 (2006), alleging that human papillomavirus vaccine ("Gardasil" or "HPV vaccine") administered April 1, 2008 to decedent Moshella F. Roberts caused her death on April 5, 2008.

The case was assigned to Special Master Moran. On May 26, 2009, petitioner filed a motion to subpoena Merck, the vaccine manufacturer, for records of any reports of sudden death temporally related to Gardasil vaccination and any papers, reports, or memoranda discussing a possible biological mechanism by which Gardasil could cause or trigger sudden death. Mot. for Subpoena, May 26, 2009, ECF No. 9. Respondent did not object, and Special Master Moran granted the motion for subpoena. Order, June 30, 2009, ECF No. 14.

After the subpoena was served, Merck filed a motion to quash the subpoena. Mot. to Vacate Order & Quash Subpoena, Aug. 19, 2009, ECF No. 18. The parties and Merck briefed the issue, and an oral argument was held. On April 27, 2010, Special Master Moran granted Merck's motion to quash the subpoena, leaving open the possibility for petitioner to renew her request for discovery if she developed "additional information to explain why discovery is necessary." 2010 WL 5558349, at *6 (Published Ruling Quashing Subpoena, ECF No. 33).

Petitioner renewed her motion for subpoena on November 8, 2010. Renewed Mot. for Subpoena, Nov. 8, 2010, ECF No. 40. Respondent did not object. Resp't's Resp., Nov. 24, 2010, ECF No. 41. Special Master Moran ordered petitioner to serve a copy of her motion and respondent's response on Merck. The parties and Merck again briefed the issues, and on September 20, 2011, Special Master Moran denied petitioner's renewed motion for a subpoena on Merck. Published Ruling on Renewed Mot. for Subpoena, ECF No. 55.

On October 31, 2011, petitioner filed a petition for a writ of mandamus directing the special master to issue a subpoena on Merck. The Court of Federal Claims denied the petition for writ of mandamus, stating that should petitioner lose, she may argue the propriety of the special master's discovery determinations on review of the decision. Phillips-Deloatch, 104 Fed. Cl. 223, 226 (Fed. Cl. 2012) (Published Opinion (Redacted), Apr. 20, 2012, ECF No. 73).

On March 13, 2013, the case was reassigned to Special Master Nora B. Dorsey.

On July 21, 2014, respondent moved to dismiss. Respondent argues that petitioner's claim necessarily fails because her expert has conceded he cannot opine to a reasonable degree

of medical probability that Ms. Roberts' death was caused by Gardasil vaccine. Mot. to Dismiss 1, July 21, 2014, ECF No. 110.

On August 19, 2014, petitioner filed a renewed motion for a subpoena.[2] Petitioner presents many of the same arguments as presented in her earlier discovery motions. See Resp. to Mot. to Quash, Aug. 31, 2009, ECF No. 19; Renewed Mot. for Subpoena, Nov. 8, 2010, ECF No. 40; Reply, May 19, 2011, ECF No. 54. She adds Dr. Miller's May 23, 2014 statement that absent information regarding other sudden deaths after Gardasil vaccination or a possible biological mechanism by which Gardasil could trigger sudden death, the cause of death is not knowable. Renewed Mot. for Subpoena 1, Aug. 19, 2014, ECF No. 113. Petitioner argues that the reasonableness of the burden on Merck to provide this information is not at issue since Merck did not previously raise the argument that production would be burdensome. Id. at 3.

Also on August 19, 2014, petitioner responded to respondent's motion to dismiss. She argues that dismissal is premature absent petitioner's ability to subpoena the vaccine manufacturer. Resp. to Mot. to Dismiss 1, Aug. 19, 2014, ECF No. 114.

On November 13, 2014, respondent filed a response to petitioner's renewed motion for subpoena. Resp't's Resp. to Renewed Mot. for Subpoena & Reply to Resp. to Mot. to Dismiss, Nov. 13, 2014, ECF No. 121. On January 8, 2015, the case was reassigned to the undersigned. Also on January 8, 2015, petitioner filed her reply in support of her motion for subpoena. Reply, Jan. 8, 2015, ECF No. 126. The matter is now fully briefed and ripe for a ruling.

FACTS

Ms. Roberts received HPV vaccine on April 1, 2008, at age 20. Med. recs. Ex. 8, at 1. She had no major health issues prior to her vaccination. Ms. Roberts did not present to her treating physician with any symptoms or complaints prior to her vaccination, and she did not report any symptoms or complaints after her vaccination. See med. recs. Ex. 6. Four days after receiving the vaccination, she was found dead in a home where she worked as a home health care aide for a paralyzed person. Med. recs. Ex. 1, at 2–3; Ex. 13, at 2. The only abnormality in Ms. Roberts' autopsy was focal nodular hyperplasia in the liver, which the medical examiner noted could not account for her death. Med. recs. Ex. 2, at 5. The toxicology from her autopsy was negative. Id. at 9–10. The cause of death listed on Ms. Roberts' autopsy was "undetermined" and remains unknown. Id. at 5.

EXPERT REPORTS

On May 23, 2014, petitioner filed an expert report from pathologist Dr. Douglas C. Miller, who concludes that his review of Ms. Roberts' tissue slides and autopsy is mostly negative. Ex. 20, at 1. Dr. Miller recut histological slides from the original tissue blocks and reviewed them, as well as the original set of slides from 17 different sections. Id. Dr. Miller

[2] During a status conference on August 12, 2014, Special Master Dorsey determined that petitioner need not serve her renewed subpoena motion on Merck.

discussed possible causes for sudden death in a young adult and ruled them out in Ms. Roberts' case. Id. at 2. Her heart was normal, and her brain did not have any evidence of a chronic, undiagnosed seizure disorder or meningitis, encephalitis, or vasculitis. Id. Her limited pulmonary edema did not cause her death but was an effect of the dying process. Id. Dr. Miller did find a striking abnormality in one slide of a kidney, with chronic inflammation commonly associated with pyelonephritis. Id. After conferring with the Medical Examiner's office, Dr. Miller received additional brain and kidney sections. Id. The brain sections were as unremarkable as the original brain sections, except that in a slide of the cerebellum, there were two blood vessels with minimal perivascular lymphocytic infiltrates, representing a focal encephalitis. Id. This could represent a minimal viral infection or a minimal autoimmune reaction triggered by vaccination, but the evidence was too limited for Dr. Miller to conclude that either hypothesis was correct. Id. The inflammation was also too limited to be a cause of death. Id. The additional kidney sections were unremarkable except for some congestion in the medulla. Id.

Dr. Miller made a further request of the Medical Examiner's office for additional lung tissue, which resulted in a complete set of 17 recut slides duplicating the original slides, but no additional pieces of lung tissue. Id. Dr. Miller believes that Ms. Roberts' previously undiagnosed kidney infection did not cause her death. Id. at 3. As the Medical Examiner stated and Dr. Miller reiterates, there is no demonstrable cause of death. Id. There is no evidence of an inflammatory autoimmune process in Ms. Roberts. Id. There is no evidence of an anaphylactoid response, although Dr. Miller notes her pulmonary edema might support such a cause of death. Id. But, Dr. Miller rejects anaphylaxis as a cause of Ms. Roberts' death because anaphylaxis occurs minutes after vaccination, not four days after vaccination with no apparent intervening illness, as was the case with Ms. Roberts. Id. Dr. Miller notes that other causes of death in Gardasil cases involved thrombotic occlusions or emboli in vessels in vital organs, but Ms. Roberts did not have any emboli or thrombi. Id. From his review of the medical literature, he notes different types of fatalities following Gardasil vaccination that "encompass a mixture of pathological events which are not obviously related." Id. Dr. Miller concludes:

> [A]bsent further data or information regarding other reports of sudden death temporally related to Gardasil vaccination, or information, perhaps in the possession of the manufacturer or the government regulatory bodies involved with this vaccine, regarding a possible biological mechanism by which the Gardasil vaccine could trigger sudden death, I am forced to conclude that the cause of death in this case is not knowable to a reasonable medical probability.

Id.

On November 13, 2014, respondent filed an expert pathologic report from Dr. Mark T. Curtis. Dr. Curtis confirms that the cause of Ms. Roberts' death is undetermined. Ex. C, at 3. He agrees with petitioner's expert Dr. Miller that Ms. Roberts' death should be considered as a sudden death in a young adult. Id. at 4. He also agrees with Dr. Miller that Ms. Roberts' heart showed no abnormalities that would explain her sudden death, and her brain showed no

meningitis, encephalitis, or vasculitis. Id.

DISCUSSION

1. Applicable Legal Standards

a. 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). The

parties do not dispute that this is the appropriate standard. Renewed Mot. for Subpoena 2–3, ECF No. 113; Resp't's Resp. 4, ECF No. 121.

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). When special masters have granted extensive discovery motions, the motions have been uncontested; for example, Special Master Moran originally granted petitioner's first motion for subpoena in this case. See also O'Neill v. Sec'y of HHS, No. 08-243V, Order, Dec. 3, 2008, ECF No. 14 (The undersigned granted petitioner's uncontested motion to subpoena information regarding Menactra vaccine and demyelinating neurological disorders from the Menactra vaccine manufacturer, Sanofi Pasteur, Inc. It is unclear whether the documents were produced, as they were not filed in the case.).

Petitioner's renewed motion for subpoena requests discovery of 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 petitioner is "reasonable and necessary" for the undersigned to make a "fair and well-informed decision" on whether Gardasil vaccine caused Ms. Roberts' death.

b. Law of the Case

Special Master Moran previously ruled on petitioner's two requests for an identical subpoena. Under the law of the case doctrine, "[a] court will not generally revisit an issue once decided in the litigation." Mendenhall v. Barber-Greene Co., 26 F.3d 1573, 1582 (Fed. Cir. 1994). However, this doctrine "merely expresses the practice of courts generally to refuse to reopen what has been decided, not a limit to their power." Id. (quoting Messinger v. Anderson,

225 U.S. 436, 444 (1912)). Prior to a final judgment, a court has discretion to revisit and modify any interlocutory orders. McGowan v. Sec'y of HHS, 31 Fed. Cl. 734, 737 (Fed. Cl. 1994). Nevertheless, a court will typically revisit an already decided issue only in exceptional circumstances, such as "discovery of new and material evidence," "an intervening change of legal authority," or upon a showing that "the prior decision is clearly incorrect and its preservation would work a manifest injustice." Toro Co. v. White Consolidated Industries, Inc., 383 F.3d 1326, 1336 (Fed. Cir. 2004) (quoting Intergraph Corp. v. Intel Corp., 253 F.3d 695, 698 (Fed. Cir. 2001)).

2. Analysis

The undersigned has reviewed Special Master Moran's previous rulings and the arguments contained in the briefings on those motions, as well as the briefings on the current renewed motion. Though the undersigned will not repeat the entirety of Special Master Moran's previous rulings, she is persuaded that the previous requests for discovery were properly quashed and denied. Petitioner has not presented any additional evidence to justify a different ruling. Indeed, her second renewed motion for subpoena is largely identical to the 2010 memorandum in support of her first renewed motion for subpoena, albeit with the addition of Dr. Miller's statements. This addition is not material.

In order for this discovery motion to be granted, the information requested by petitioner must be "reasonable and necessary" for the undersigned to make a "fair and well-informed decision" on whether Gardasil vaccine caused Ms. Roberts' death. To carry her burden of proof, petitioner 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."

Petitioner has provided no new arguments to support her second renewed motion. The only new evidence presented in her second renewed motion for subpoena is a report from Dr. Miller stating the same argument petitioner has been raising throughout this process: that studies discussing a possible biological mechanism by which Gardasil could trigger sudden death could possibly provide a clue to solve Ms. Roberts' cause of death.

Contrary to petitioner's assertion, there does not seem to be a dearth of information available about the Gardasil vaccine. Respondent cites 29 articles discussing the safety of Gardasil, including two articles discussing surveillance studies conducted by Merck. Resp't's Resp. 5 n.18, 7 nn.26–28, Nov. 13, 2014, ECF No. 121. Petitioner counters that these articles do not help to support her case. However, several of these articles do address sudden death after Gardasil vaccine and conclude that the deaths were not related to Gardasil vaccine. Pet'r's Reply 7, 9, 13, Jan. 8, 2015, ECF No. 126.

As Special Master Moran stated in his previous order denying petitioner's renewed motion for subpoena:

> In essence, [petitioner] claims that because she could not locate articles on a possible biological mechanism, Merck might be able to assist in providing this information. She asks that she be permitted to use discovery in search of this information that Merck *might possess* that would help her expert. But, as stated previously, the possibility that Merck might have information that would be helpful is not adequate.

Published Ruling on Renewed Mot. for Subpoena 7, Sept. 20, 2011, ECF No. 55 (emphasis added). In fact, petitioner has not even shown that evidence Merck might possess would actually be helpful to petitioner's case, but rather that it *might* be helpful to petitioner's expert in developing a theory of vaccine causation. The mere possibility of a clue does not satisfy the "reasonable and necessary" standard. Petitioner presents hypothetical upon hypothetical as an argument for discovery, essentially requesting a fishing expedition for information that may or may not help prove her case.

The Federal Circuit has placed great emphasis on the opinions of treating doctors in evaluating a petitioner's medical condition and its cause. Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006). See also Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1347 (Fed. Cir. 2010); Andreu v. Sec'y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009). The medical doctors whom Ms. Roberts saw before her death did not note anything in her records that would connote she had an illness, such as epilepsy or heart disease, that could lead to her sudden death. In addition, the two medical examiners who performed her autopsy opined that the cause of her death is indeterminate.

Dr. Miller cannot provide evidence of a "persuasive medical theory" connecting Gardasil vaccine with Ms. Roberts' death because the cause of her death is undetermined. Althen, 418 F.3d at 1278. Even if the undersigned were to grant a subpoena for Merck's records and those records showed individuals dying of heart disease, lung disease, epilepsy, and the panoply of causes that Dr. Miller listed in his expert report, Dr. Miller already analyzed Ms. Roberts' tissues for these diseases and found no disease that could have caused her death. Ms. Roberts did not die of a known disease process after receiving Gardasil. Even after a thorough review of Ms. Roberts' tissues, Dr. Miller's own slides from her tissues, and more tissues provided from the medical examiners, Dr. Miller still does not know the cause of Ms. Roberts' death. The Medical Examiners do not know the cause of Ms. Roberts' death. Respondent's expert Dr. Curtis does not know the cause of Ms. Roberts' death. All four pathologists who have reviewed Ms. Roberts' tissues have opined the cause of death is undetermined. There is no reason to believe that Merck could provide evidence that would elucidate the cause of Ms. Roberts' death. Even if it provided evidence that Gardasil can cause death and the biological mechanism for causing death, it is unlikely it would prove Gardasil caused Ms. Roberts' death since multiple doctors have reviewed her tissues and found nothing abnormal. Petitioner has not presented persuasive evidence to show that the discovery requested is reasonable and necessary for the special master

make a fair and well-informed decision.

CONCLUSION

The record does not contain a persuasive reason to require production of information from Merck & Co., Inc. Petitioner's renewed motion for subpoena is **DENIED**.

Given that the arguments presented in petitioner's response to the motion to dismiss are now moot, petitioner will need to file a supplemental response to respondent's motion to dismiss. The undersigned gives petitioner until **Friday, May 8, 2015**, to do so. After petitioner files her response to respondent's motion to dismiss, the undersigned will set a telephonic status conference in this case.

IT IS SO ORDERED.

Dated: April 9, 2015

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