IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

ZENORIA PHILLIPS DELOATCH, As Personal Representative of the estate of MOSHELLA F. ROBERTS,	*	No. 09-171V Special Master Christian J. Moran
Petitioner,	*	Filed: April 27, 2010 Reissued: July 28, 2010
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	human papillomarivus (HPV) vaccine (Gardasil), death, discovery, motion to quash subpoena issued to manufacturer
Respondent.	*	

Altom M. Maglio, Maglio, Christopher Toale & Pitts, Sarasota, FL, for petitioner;
Debra A. Filteau Begley, United States Dep't of Justice, Washington, D.C. for respondent;
Dino S. Sangiamo, Venable, LLP, Baltimore, MD, for Merck & Co., Inc.

PUBLISHED RULING QUASHING SUBPOENA*

Zenoria Phillips Deloatch, acting as the representative of the estate of Moshella F. Roberts, claims that the human papillomavirus (HPV) vaccine caused Ms. Roberts's death and seeks compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. (2006). Ms. Phillips Deloatch requests information from Merck & Co., Inc., which manufactures and markets the HPV vaccine as Gardasil. Merck objects to providing the

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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 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).

requested information. For the reasons explained below, Ms. Deloatch has not met the heightened standard for discovery in the Vaccine Program. Thus, Merck's motion to quash the subpoena is GRANTED.

I. Facts and Procedural History

The facts about Ms. Roberts that are relevant to this issue are relatively few. For this reason and because cases in the Vaccine Program are sealed, see 42 U.S.C. § 300aa–12(d)(4); the facts are presented summarily.

Ms. Roberts was born in 1987. At age 20, she received a dose of the HPV vaccination. Exhibit 8 at 1. Four days after receiving the vaccination, Ms. Roberts was found deceased at a home where she cared for a paralyzed person. Exhibit 1 at 2-3. An autopsy was performed. The medical examiner stated that the cause of Ms. Roberts's death was "undetermined." Exhibit 4 at 5.

Ms. Phillips Deloatch filed a petition seeking compensation and, with the petition, she filed information about Ms. Roberts's medical history. Ms. Phillips Deloatch also requested, pursuant to Vaccine Rule 7, authorization to serve a subpoena duces tecum on Merck to request information about Gardasil. Pet'r Mot. for Subpoena, filed May 26, 2009.[1] Respondent did not object to the serving of the subpoena. Resp't Status Rep't, filed June 26, 2009. An order authorized Ms. Phillips Deloatch to serve the subpoena. Order, filed June 30, 2009. Ms. Phillips Deloatch served the subpoena on Merck.[2]

Merck responded by filing a motion to quash the subpoena arguing that Ms. Phillips Deloatch has not satisfied the standard for discovery. This action led to more briefing and an oral argument.[3] This motion is ready for adjudication.

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[1] Specifically, Ms. Phillips Deloatch requested the following information:

> 1. Any reports of sudden death temporally related to Gardasil vaccination (please redact any patient identifying information).
> 2. Any papers, reports, or memoranda discussing a possible biological mechanism by which the Gardasil vaccine could cause or trigger sudden death.

[2] Initially, Ms. Phillips Deloatch did not use Form 7A contained within the Appendix of Forms for the Rules of the Court of Federal Claims. Merck noted this inconsistency. Ms. Phillips Deloatch eventually served a subpoena using Form 7A.

[3] This oral argument was recorded using the court's Electronic Digital Recording (EDR) system. Citations to the oral argument refer to the time on the EDR system.

II. Discovery in the Vaccine Program

This dispute arises in the Vaccine Program in which the rules for discovery differ from the rules about discovery in litigation conducted pursuant to the Federal Rules of Civil Procedure. A stark contrast is that in the Vaccine Program the parties do not have a right to conduct discovery. Congress directed the Court of Federal Claims to adopt rules that "provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims." 42 U.S.C. § 300aa-12(d)(2)(E).

Rather than the usual system of discovery in which the parties seek the information that they believe is helpful, special masters manage discovery. 42 U.S.C. § 300aa–12(d)(3)(B); Vaccine Rule 7. Special masters oversee discovery because they are authorized to "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)(iii). The statutory standard - "reasonable and necessary" - has been interpreted to mean that discovery is appropriate when

> 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.

In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder of a Similar Neurodevelopmental Disorder, Master Autism File, 2004 WL 1660351, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004).[4]

Thus, the standard for ordering discovery is high. Consistent with this elevated showing, special masters have refrained from ordering discovery in a variety of contexts. See In Re: Omnibus Autism Proceeding, Master Autism File, 2007 WL 1983780 (Fed. Cl. Spec. Mstr. May 25, 2007) (three special masters declined to order production of information from Vaccine Safety Data project held by an insurance company); Werderitsh v. Sec'y of Health & Human Servs., No. 99–319V, 2005 WL 3320041 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (special master denied petitioner's request for access to information from Vaccine Adverse Event Reporting System), compensation granted, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. March 30, 2006); Schneider v. Sec'y of Health & Human Servs., No. 99–0160V, 2005 WL 318697, at *5 (Fed. Cl. Spec. Mstr. Feb. 1, 2005) (special master denied request for access to information about manufacturing and testing hepatitis B vaccine from manufacturer), aff'd 64 Fed. Cl. 742, 745-46 (2005).

[4] This case describes discovery in the Vaccine Program thoroughly.

Among these cases, Schneider resembles the present case most closely because in both cases petitioner sought information from a vaccine manufacturer. As noted above, the special master denied discovery. On appeal, the Court of Federal Claims affirmed this denial. 64 Fed. Cl. at 745-46. Not permitting discovery against companies that manufacture vaccines is consistent with expressions of Congressional intent. See H.R. Rept. No. 99-908, at 6-7 (1986) reprinted in 1986 U.S.C.C.A.N. 6345-47; see also In re Claims, 2004 WL 1660351, at *5-6 (discussing discovery sought from vaccine manufacturers).

The foregoing paragraphs provide the background for evaluating Ms. Phillips Deloatch's discovery request. To recapitulate, discovery is appropriate when the special master determines that the requested information is necessary for a "fair and well-informed ruling."[5] Although Ms. Phillips Deloatch, the respondent, and Merck agree that this standard is the appropriate standard, Ms. Phillips Deloatch and Merck disagree about whether the requested material should be produced pursuant to this standard.[6] The arguments of Ms. Phillips Deloatch and Merck are taken up in the following section.

III. Analysis

The substantive issue is whether Ms. Phillips Deloatch has established that the requested information is necessary for a "fair and well-informed ruling" as to whether Gardasil caused Ms. Roberts's death. Before that issue can be resolved, one preliminary question needs to be addressed. This question is whether Merck has standing to present the argument that the requested information is not necessary for a "fair and well-informed ruling." If the procedural rules prevent Merck from arguing this point, then the substantive question need not be reached. However, for the reasons explained in section A below, Merck has the capacity to raise the substantive argument. Additionally, as explained in section B below, Merck's substantive argument is sound – Ms. Phillips Deloatch has failed to explain persuasively why the requested information is necessary for a fair and well-informed ruling. Thus, Merck's motion to quash the subpoena is granted.

A. Standing

The initial issue to be resolved is whether Merck has standing to contend that the information requested by Ms. Phillips Deloatch is not "reasonable and necessary" for determining whether Ms. Phillips Deloatch is entitled to compensation. For the reasons that follow, Ms. Phillips Deloatch's challenge to M's standing is not persuasive.

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[5] Merck has not challenged the reasonableness of the request by arguing, for example, that the request places an undue burden on it.

[6] The respondent has largely remained neutral in the dispute between Ms. Phillips Deloatch and Merck. Resp't Resp., filed Aug. 31, 2009; Oral Arg. at 2:26:55-2:28:00.

Ms. Phillips Deloatch argues that Merck may not present this argument because only the parties to the action (here, the respondent and herself) may argue whether a subpoena should issue. Ms. Phillips Deloatch's argument seems based upon the assumption that the undersigned has already found that the requested information is reasonable and necessary for a fair and well-informed ruling in authorizing the subpoena on June 30, 2009. Thus, according to Ms. Phillips Deloatch, Merck may raise only those objections that relate to Merck, itself, such as "overbreadth or trade secrets." Pet'r Br., filed Aug. 31, 2009, at 8; Oral Arg. at 2:06:10 - 2:10:43.

Ms. Phillips Deloatch makes too much of this procedural sequence. On June 30, 2009, Ms. Phillips Deloatch's motion for authorization to issue a subpoena was not opposed. Ms. Phillips Deloatch's motion did not assert that the requested information was "reasonable and necessary." Pet'r Mot. for Subpoena, filed May 26, 2009. The views of Merck had not been obtained.[7] Thus, Ms. Phillips Deloatch to overestimates the significance of the June 30, 2009 order.

In any event, a nonparty recipient of a subpoena in traditional civil litigation possesses the right to challenge the subpoena. See Rule 45(c)(3) of the Rules of the Court of Federal Claims.[8] Trial courts have entertained challenges to subpoenas issued to third parties on the basis that the requested information is not relevant. E.g. JZ Buckingham Investments LLC v. United States, 78 Fed. Cl. 15, 19 (2007); Gonzales v. Google, Inc., 234 F.R.D. 674, 679 (N.D. Cal. 2006); Compaq Computer Corp. v. Packard Bell Electronics, Inc., 163 F.R.D. 329, 335-36 (N.D. Cal. 1995). It would be anomalous if vaccine manufacturers had fewer rights to oppose discovery in the Vaccine Program than they would enjoy in traditional litigation particularly because discovery is not a right and the Vaccine Program was designed, in part, to shield vaccine manufacturers from discovery.

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[7] The procedure could have followed an alternative path. Ms. Phillips Deloatch could have requested information from Merck informally, that is, without a subpoena. If Merck did not produce the information requested, then Ms. Phillips Deloatch could have filed a motion for authorization to serve a subpoena and notified Merck of the filing of this motion. Under this procedure, Merck would have had an opportunity to oppose the issuance of the subpoena.

Ms. Phillips Deloatch's case is different because the subpoena has already been authorized and served. Merck, therefore, has filed a motion to quash the subpoena. Substantively, there appears to be no difference between the legal standards for determining whether a subpoena should be issued and the legal standards for determining whether a subpoena should be quashed.

[8] Considering cases decided pursuant to Rule 45 of the Federal Rules of Civil Procedure is appropriate because Vaccine Rule 7 references Rule 45 of the Rules of the Court of Federal Claims, which is analogous to Rule 45 of the Federal Rules of Civil Procedure.

For these reasons, Ms. Phillips Deloatch's argument that Merck's substantive argument should not be addressed on the merits is unpersuasive. Thus, the following section addresses whether the requested discovery meets the standards for ordering discovey.

B. Merits

As explained in In re Claims, 2004 WL 1660351, at *9, the issue is whether the special master "could not make a fair and well-informed ruling on [the contested] issues without the requested material." The contested issue in this case is whether Gardasil caused Ms. Roberts's death. Ms. Phillips Deloatch establishes causation, in turn, by introducing a preponderance of the evidence showing "(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 and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Thus, the requested information is necessary only to the extent that it affects the ability of Ms. Phillips Deloatch to establish one of the elements of Althen.

To support her request for information from Merck, Ms. Phillips Deloatch filed an affidavit from Barbara Harty-Golder, who is a board-certified pathologist and a licensed attorney. Dr. Harty-Golder asserts that "As the Gardasil human papillomavirus vaccine is a recently released novel vaccine, there is a dearth of published information in the medical literature on likely adverse effects of the vaccine and the mechanisms by which such effects would likely occur." Pet'r Mem., exhibit 4 ¶ 13. According to Dr. Harty-Golder, given this absence of published information about Gardasil, information from Merck would allow a "full examination" of whether Gardasil caused Ms. Roberts's death. Id. ¶ 15.

Neither Ms. Phillips Deloatch's brief nor Dr. Harty-Golder's affidavit present persuasive reasons to order discovery from Merck primarily because they fail to explain how the requested information would help Ms. Phillips Deloatch meet her burden of proof with regard to any prong of Althen. Secondarily, neither Ms. Phillips Deloatch nor Dr. Harty-Golder address other information that is already available.

Among the three prongs of Althen, the requested information seems to fit best with the first prong – a medical theory causally connecting Gardasil to a person's death. Despite the prospect for linking documents possessed by Merck with the elements that Ms. Phillips Deloatch is required to prove, Ms. Phillips Deloatch has failed to present a persuasive showing that an expert cannot present a medical theory without the information from Merck. Dr. Harty-Golder's affidavit, which states that in the absence of information from Merck a pathologist "cannot conduct a full and complete review," is conclusory. Dr. Harty-Golder does not explain why the information sought from Merck will help an expert develop a medical theory. For example, an expert could advance the theory that the molecular structure of Gardasil resembles or mimics a component of human tissue. Presumably, the expert could learn about the molecular structure of Gardasil by testing Gardasil. In this example, it appears that an expert could develop a theory

without information from Merck. Therefore, Ms. Phillips Deloatch has not established that the information is necessary for a fair and well-informed ruling.

The second deficiency in the arguments advanced by Ms. Phillips Deloath is that she does not explain why available information about Gardasil is not adequate. Before special masters may find that requested discovery is necessary, they should evaluate what other information is available. See In re Claims, 2004 WL 1660351, at *8, citing Golub v. Sec'y of Health & Human Servs., 44 Fed. Cl. 604, 609 (1999) (affirming special master's denial of discovery), rev'd on other grounds, 243 F.3d 561 (Fed. Cir. 2000).

Here, one source of information that is available to any expert retained by Ms. Phillips Deloatch is the "package insert" for Gardasil.[9] The package insert summarizes information about Gardasil, such as the manufacturing process (Gardasil is derived from products grown in yeast cells), the composition of Gardasil (among other chemicals, Gardasil contains aluminum and sodium chloride), and the mechanism of action (generating humoral immune responses). Exhibit 18 at 1. The FDA regulates the package insert. See 21 C.F.R § 201 et seq.

Because the package insert informs the medical community about Gardasil, this resource would appear to be a natural starting point for anyone interested in learning about Gardasil. However, Dr. Harty-Golder does not discuss the package insert at all. See Pet'r Mem., exhibit 4. This omission undermines Dr. Harty-Golder's assertion that a pathologist can conduct a "full and complete review" only with information from Merck.[10]

Ms. Phillips Deloatch and Dr. Harty-Golder press the broad argument that more information is better than the alternative. For example, Ms. Phillips Deloatch contends that the requested information "would be of use to the medical review." Pet'r Br. at 16. Dr. Harty-Golder contends that the requested information allows for a more "full" examination than less information. Pet'r Mem., exhibit 4 ¶ 15. On one level, this argument makes sense: more

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[9] The package insert is exhibit 18 in this case.

[10] Although Dr. Hardy-Golder omits discussion of the package insert, Dr. Hardy-Golder discusses two other publically available sources of information about Gardasil. The first is an article written by researchers from the FDA and the Centers for Disease Control and Prevention, who investigated the safety of Gardasil and published an article in the Journal of the American Medical Association. Barbara A. Slade et al., Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine, 302(7) JAMA.750-7 (2009). The second publically available source of information is the set of reports filed with the Vaccine Adverse Event Reporting System (VAERS). Ms. Phillips Deloatch has obtained VAERS information through a request pursuant to the Freedom of Information Act. Even if Dr. Hardy-Golder were correct that the JAMA article and the VAERS information do not assist a pathologist in determining whether Gardasil caused Ms. Roberts's death, this point does not address the package insert.

information is almost certainly more helpful than less information. But, this argument lacks merit for two reasons. First, the standard for discovery in the Vaccine Program is not usefulness; it is "reasonable and necessary." 42 U.S.C. § 300aa–12(d)(3)(B)(iii). Second, the argument is so general that if it were accepted, then discovery could be obtained from manufacturers routinely. Any petitioner seeking compensation for an off-Table injury could argue that information from a manufacturer would allow for a more complete review. Accepting such a practice would contradict Congress's instruction that discovery in the Vaccine Program would be limited. See 42 U.S.C. § 300aa-12(d)(2)(E).

Ms. Phillips-Deloatch and Dr. Harty-Golder attempt to distinguish the present case from other cases by pointing out that Gardasil is a new vaccine. The newness of Gardasil means that, according to Dr. Harty Golder, there is a "dearth" of information about Gardasil. Pet'r Mem., exhibit 4 ¶ 14; accord Pet'r Br. at 17 n.9.

The newness of the vaccine does not modify the standard for approving discovery. Congress anticipated that vaccines would be added to the Vaccine Program. See 42 U.S.C. § 300aa–14(c) (authorizing Secretary of Health and Human Services to add vaccines). Yet, Congress did not create special rules for new vaccines. The sole statutory standard is that the requested information be "reasonable and necessary." 42 U.S.C. § 300aa–12(d)(3)(B)(iii). As discussed above, Ms. Phillips Deloatch has failed to demonstrate how the information that she has requested would assist Dr. Harty-Golder (or any expert retained by Ms. Phillips Deloatch) in developing a medical theory explaining how Gardasil can cause someone's death.

To summarize, in creating the Vaccine Program, Congress changed the standard for discovery and imposed a much higher standard. In re Claims, 2004 WL 1660351, at *7-8. Pursuant to this standard, a party seeking discovery must demonstrate that the special master cannot make a fair and well-informed decision without the information. Here, Ms. Phillips Deloatch has not satisfied this threshold. Ms. Phillips Deloatch has not explained why an expert cannot present a medical theory causally connecting Gardasil to a recipient's death without the requested information. Thus, Merck's motion to quash the subpoena is granted.

Denying Ms. Phillips Deloatch access to Merck's information may cause two consequences. First, any experts retained by Ms. Phillips Deloatch may require a relatively lengthy amount of time to develop a theory to explain how Gardasil can cause a person's death. As long as Ms. Phillips Deloatch demonstrates that her experts are making some progress in developing a theory, Ms. Phillips Deloatch will have a reasonable amount of time to obtain an expert report.

The second potential consequence may flow from the previous point. Ms. Phillips Deloatch may decide that, despite this ruling, she wants the requested information. Ms. Phillips Deloatch may seek the information by an alternate route. Ms. Phillips Deloatch may leave the Vaccine Program to pursue an action against Merck in state or federal court. See 42 U.S.C. § 300aa–21. If so, Ms. Phillips Deloatch may present a similar discovery request to Merck that

would be evaluated by the rules of that forum. Under this scenario, Merck's successful motion to quash the subpoena in this action may result in it being named as a defendant in a lawsuit over Gardasil. Merck is aware of this possibility. Oral Arg. 3:32:52 - 3:39:14. Although the possibility of a lawsuit against Merck is inconsistent with one purpose of the Vaccine Program, Congress expressly left open the possibilities for some lawsuits against vaccine manufacturers. 42 U.S.C. § 300aa–21.[11] The possibility that Merck may be required to produce some or all of the requested information in litigation governed by different discovery rules does not affect the outcome of this case in which the discovery rules impose a more stringent standard.

IV. Conclusion

For the reasons explained above, the record does not contain a persuasive reason for requiring production of information from Merck. Thus, Merck's motion to quash the subpoena is GRANTED. If Ms. Phillips Deloatch develops additional information to explain why discovery is necessary, she may renew her request for discovery. See In re Claims, 2004 WL 1660351, at *16 (declining to impose a deadline for requesting discovery from manufacturers). The Clerk's Office is instructed to provide a copy of this decision to Merck.

A status conference for the parties (not Merck) will be held on **Friday, May 7, 2010 at 3:00 P.M.**.

IT IS SO ORDERED.

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

[11] The United States Supreme Court recently granted certiorari in a case in which a plaintiff, having proceeded through the Vaccine Program, sued a vaccine manufacturer. Bruesewitz v. Wyeth, 561F.3d 233 (3d Cir. 2009) (affirming grant of summary judgment to manufacturer), cert. granted, 78 U.S.L.W. 3521 (U.S. Mar. 8, 2010) (No. 09-152).