

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-488V

Filed: April 17, 2023

* * * * *	*	
RUTH VIZCARRA,	*	
	*	UNPUBLISHED
Petitioner,	*	
	*	
v.	*	Motion to Limit Expert Testimony
	*	
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* * * * *	*	

Andrew Downing, Esq., Downing, Allison & Jorgenson, Phoenix, AZ, for petitioner.
Alec Saxe, Esq., United States Department of Justice, Washington, DC, for respondent.

ORDER GRANTING IN PART MOTION TO LIMIT TESTIMONY¹

Roth, Special Master:

On April 22, 2020, Ruth Vizcarra (“Ms. Vizcarra” or “petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² (the “Vaccine Act” or “Program”). Petitioner alleged that she developed sudden sensorineural hearing loss (“SSNHL”) after receiving an influenza (“flu”) vaccination on September 21, 2019. *See* Petition (“Pet.”), ECF No. 1.

¹ Although this Order has been formally designated “unpublished,” it will nevertheless be posted on the Court of Federal Claims’s website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Order will be available to anyone with access to the internet.** However, the parties may object to the Order’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Order will be available to the public. *Id.*

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

On March 20, 2023, respondent filed an expert report authored by Herman F. Staats, Ph.D. Respondent Exhibit (“Resp. Ex.”) C, ECF No. 52. According to his CV, Dr. Staats is a tenured Professor of Pathology and Professor of Medicine and Immunology at Duke University Medical Center (“DUMC”). Resp. Ex. D, ECF No. 52. He holds a Ph.D. in Basic Medical Sciences (Microbiology and Immunology). *Id.*

On March 21, 2023, petitioner filed a Motion to Limit the Testimony of Dr. Staats. Motion, ECF No. 54. She argued that Dr. Staats is “neither legally nor ethically permitted to address specific causation in the Vaccine Program”. *Id.* at 1. Petitioner’s Motion seeks to limit Dr. Staats’ testimony relating to specific causation—*Althen* prong II—because he is not a medical doctor and lacks the credentials to opine on a medical diagnosis or possible causes. *Id.* at 1-2. Petitioner argued that “[c]ourts have insisted time and again that an expert may not give opinion testimony regarding specific causation if the expert has not engaged in the process of differential diagnosis.” *Id.* at 3, citing *In re Paoli R.R. Yard PCB Lit.*, 2000 WL 1279922, at *5 (E.D. Pa. Sept. 6, 2000) (emphasis added). Because Dr. Staats is not a medical doctor, he cannot render a differential diagnosis or an opinion as to possible causes, and therefore, his testimony should be limited to general causation only. Motion at 3.

On March 31, 2023, respondent filed a Response to petitioner’s Motion. Response, ECF No. 55. In his Response, respondent detailed Dr. Staats’ qualifications and accomplishments, including his position as Vice Chair of Research in the Pathology Department at DUMC and his participation in a research laboratory funded by the National Institute of Health that focuses on the development and use of novel vaccine adjuvants. *Id.* at 1. Respondent pointed out that petitioner failed to cite any Vaccine Program cases to support her request and relied only on an unreported decision from the Eastern District of Pennsylvania and a decision from the Supreme Court of Appeals for West Virginia. *Id.* at 2.

Respondent further argued that special masters are not bound by the rules of evidence but rely on the *Daubert* factors to assign weight to an expert’s testimony. Response at 3. “The typical practice in Vaccine Act cases is for the special masters to employ the factors in *Daubert*, to weigh an expert’s opinion, not exclude it.” *Id.*, citing *See Oliver v. Sec’y of Health & Human Servs.*, 900 F.3d 1357, 1362 (Fed. Cir. 2018) (holding that “the Chief Special Master did not misapply *Daubert* in weighing the parties’ experts’ testimony and supporting evidence . . .”); *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (affirming a “[s]pecial [m]aster’s analysis . . . using *Daubert*[] . . . as a tool or framework for conducting the inquiry into the reliability of the evidence,” where the special master’s “application of the *Daubert* factors [was] reasonable”); *see also Garcia v. Sec’y of Health & Human Servs.*, No. 05-0720V, 2010 WL 2507793, at *17, n.7 (Fed. Cl. May 19, 2010) (“where an expert’s methodology is at least generally aligned with accepted scientific method, his conclusions are weighed on probative merit; they are not excluded, even if the factfinder may consider his testimony to be less persuasive than that of the other party’s expert.”).

Respondent disagreed with petitioner that specific causation necessarily involves rendering a differential diagnosis. Response at 4-5. Other federal courts have noted that differential diagnosis is only one method used to establish specific causation. *Id.* at 5, citing *Parenti v. Cnty. of Monterey*, No. 14-CV-05481-BLF, 2017 WL 1709349, at *3 (N.D. Cal. May 3, 2017); *Bell v. Gonzales*, No.

CIV.A. 03-163 (JDB), 2005 WL 3555490, at *17 (D.D.C. Dec. 23, 2005); *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 474-76 (1st Cir. 2016).

Further, respondent argued that non-medical doctors have been permitted to engage in a differential diagnosis process. For example, the U.S. Court of Appeals for the Third Circuit held that the lower court abused its discretion in excluding the testimony of the plaintiff's non-physician experts because they lacked medical degrees and were not trained in differential diagnosis. Response at 6, citing *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 855-56 (3d Cir. 1990).

Moreover, respondent pointed out that Dr. Staats deferred to both petitioner's expert and respondent's other expert on the issue of petitioner's diagnosis. Response at 8; *see also* Resp. Ex. C at 2. Dr. Staats also did not opine on what caused petitioner's SSNHL, but rather, stated that the cause is not clear. Response at 8-9; *see also* Resp. Ex. C at 12. Respondent argued that Dr. Staats' opinion was that petitioner's theory "is not supported by the published literature" and "petitioner's proposed mechanism of vaccine-induced damage that resulted in sudden hearing loss is not supported by the scientific literature." Response at 9; *see also* Resp. Ex. C at 12. Dr. Staats is qualified to rely on his interpretation of the medical literature to support his opinion that petitioner's theory lacks immunological support. Response at 9.

Finally, in a footnote, respondent requested that petitioner be denied any attorneys' fees or costs for the drafting and filing of the present Motion. Response at 10 n.1.

Petitioner submitted a Reply on April 7, 2023. Reply, ECF No. 56. Petitioner distinguished the cases relied on by respondent, stating that nothing in the cases related to a Ph.D. attempting to testify as a medical doctor on specific causation. *Id.* at 1, 2, citing *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1052-53 (9th Cir. 2003); *Southern States Co-op., Inc. v. Melick Aquafeeds, Inc.*, 476 Fed. Appx. 185, 186 (11th Cir. 2012). "Dr. Staats is not the correct professional to discuss specific causation"; rather, the "correct professional" is a medical doctor with expertise in the area at issue. Reply at 2.

According to petitioner, only a medical doctor may render an opinion on specific causation in humans. Reply at 2. Petitioner agreed that the *Daubert* factors are used in the Vaccine Program to assess the weight given to expert testimony. *Id.* at 3. Because Dr. Staats cannot "evaluate, diagnose, treat, or opine of the specific cause of any medical condition", his opinion is "unreliable and entitled to no weight in this case on specific causation." *Id.*

Petitioner has no issue with Dr. Staats' opinions as long as they do not include specific causation. Reply at 3. However, in his expert report Dr. Staats wrote, "[I]n this section, I will discuss why the specific scientific articles Dr. Hicks cites to support his proposed theory of vaccine-induced damage do not support the proposed mechanism of damage in this specific case." *Id.*, citing Resp. Ex. C at 7. According to petitioner, this is an opinion on *Althen* prong II—specific causation. Reply at 3-4. Further, Dr. Staats included a section heading entitled "Logical Sequence of Cause and Effect" and analyzed the timing in petitioner's case to refute specific causation. *Id.* at 4. Finally, Dr. Staats stated that it is his opinion that petitioner's hearing loss was unrelated to the flu vaccine. *Id.*, citing Resp. Ex. C at 12-13.

Petitioner requested that respondent's "assertion of withholding attorney's fees be ignored", as it is a threat by respondent to "attempt to get Petitioner's attorneys to stop advocating for their clients." Reply at 4.

After consideration of both parties' arguments, petitioner's Motion to Limit the Testimony of Dr. Staats is **GRANTED in part**.

I. Discussion

Special masters use the framework established in *Althen v. Sec'y of Health & Human Servs.* to determine causation in off-Table vaccine cases. 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners show by preponderant evidence that a vaccination petitioner received caused his or her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioner's Motion only concerns Dr. Staats' testimony on prong II—a logical sequence of cause and effect. Petitioner may satisfy prong II with medical opinion alone, but the special master may require "some indicia of reliability to support the assertion of the expert witness." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (citing *Terran*, 195 F.3d at 1316).

In other federal courts, judges either admit or exclude evidence based on guidance from the Federal Rules of Evidence ("FRE"). The FRE play an important role in our judicial system ensuring that the evidence admitted is sufficiently reliable and relevant to empower a jury to reach a just outcome.

In contrast, vaccine cases are not tried before a jury. Rather, the special master is the sole finder of fact. Thus, the need for strict rules of evidence is obfuscated, as the special masters are extremely familiar with the law and are in a better position to determine what evidence is reliable when compared to a layperson. It is well-established in the Vaccine Program that special masters are tasked with the responsibility of assessing the reliability of testimony, including testimony from expert witnesses. *Moberly*, 592 F.3d at 1325. Special masters employ the *Daubert* factors to evaluate expert testimony. In distinguishing this Court from other federal courts, the Chief Special Master noted that

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial [courts] (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted") . . . In this

matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Lozano v. Sec’y of Health & Human Servs., No. 15–369V, 2017 WL 3811124, at *10 (Fed. Cl. Spec. Mstr. Aug. 4, 2017). In weighing expert testimony, special masters may consider factors such as an expert’s experience, training, research credentials, and specialization—or lack thereof. See *Copenhaver v. Sec’y of Health & Human Servs.*, 129 Fed. Cl. 176, 183 (2016) (citations omitted).

Several experts who participate in Vaccine Program cases for both petitioners and respondent are not medical doctors but hold Ph.D.’s in a relevant field. Their testimony has been helpful in resolving claims both in favor of and against petitioners. See e.g., *Hazlehurst v. Sec’y of Health & Human Servs.*, No. 03–654V, 2009 WL 332306, at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (finding that three of petitioner’s experts and four of respondent’s experts—all of whom held Ph.D.’s and not M.D.’s—were qualified and credible witnesses, though some were more persuasive). Dr. Staats holds a Ph.D. in Immunology and is a tenured Professor of Pathology and Professor of Immunology and Medicine at a highly regarded medical school. Resp. Ex. D. He has completed post-doctoral research in immunology, specifically studying Mucosal HIV vaccines. *Id.* He has published over eighty peer reviewed articles, often working alongside medical doctors. *Id.* I find, and petitioner concedes, that Dr. Staats is well qualified in his field. Motion at 2.

However, all experts, including Dr. Staats, are cautioned to limit their testimony to their areas of expertise and defer where appropriate. For example, respondent utilized Robert Fujinami, Ph.D., who has a somewhat similar background to Dr. Staats, in *Bielak v. Sec’y of Health & Human Servs.*³ No. 18-761V, 2023 WL 35509, at *18 (Fed. Cl. Spec. Mstr. Jan. 3, 2023). The Chief Special Master approvingly noted in his decision that Dr. Fujinami deferred to respondent’s other expert “as to any matters pertaining to [petitioner’s] diagnosis, medical course, or the manner in which GBS is believed to occur biologically” and “instead focused on the science behind [p]etitioner’s theory” in his own testimony. *Id.*

Rendering a diagnosis is reserved for those with the appropriate training, education, and credentials: medical doctors. Petitioner and respondent are both correct that differential diagnosis is a well-accepted method to determine causation. The Third Circuit addressed the reliability of differential diagnosis as a method for assessing causation, holding:

We have recognized that differential diagnosis is a technique that involves assessing causation with respect to a particular individual, *In Re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 758 (3d Cir.1994). Differential diagnosis is defined for physicians as “the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings.” *STEDMAN’S MEDICAL DICTIONARY* 428 (25th Ed.1990). The elements of a differential diagnosis may

³ Both Dr. Staats and Dr. Fujinami are Professors of Pathology and Immunology at different medical schools, and they both have studied microbiology. See Resp. Ex. D; *Bielak*, No. 18-761V, 2023 WL 35509, at *18.

consist of the performance of physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests. A doctor does not have to employ all of these techniques in order for the doctor's diagnosis to be reliable. *See Paoli*, 35 F.3d at 759. A differential diagnosis may be reliable with less than all the types of information set out above. *See id.* Indeed as we held in *Paoli* to the extent that the district court concluded otherwise [i.e. that a differential diagnosis made on less than all types of information cannot be reliable] we hold that it abused its discretion.... As noted by this court in *Paoli*, evaluation of the patient's medical records is a reliable method of concluding that a patient is ill even in the absence of a physical exam. *Kannankeril v. Terminix*, 126 F.3d 802, 807–08 (3d Cir.1997).

Dr. Staats is a Ph.D.—not a practicing clinician. He is not trained to treat patients, diagnose patients, or prescribe medication. Rather, Dr. Staats, as a Ph.D., has expertise in the science of immunology and pathology, which is relevant to cases in the Vaccine Program. Dr. Staats as a Ph.D. rather than an M.D. is only one of many factors considered in weighing his expert opinions in this matter. However, he must focus on the science behind petitioner's theory and defer to other experts credentialed to opine on diagnosis, medical course and/or the manner in which sudden sensorineural hearing loss or SSNHL is believed to occur biologically.

Therefore, petitioner's Motion to Limit Dr. Staats' testimony is granted only to the extent that Dr. Staats should focus his opinions on the science behind petitioner's theory. Following review of all the evidence and as the trier of fact, the weight of each expert's opinion, including that of Dr. Staats, will be determined, as will all the evidence filed in this matter.

As to respondent's footnote concerning the payment of fees associated with the filing of this Motion, the pending Motion for Fees does not include charges for this Motion. *See* ECF No. 57. Thus, I will not address the arguments on this point. However, it is the responsibility of all counsel in any case to advocate for their client without the fear of retribution for doing so.

Accordingly, petitioner's Motion to Limit Testimony is hereby **GRANTED in part** as set forth above.

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master