

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

JOHN DOE 93, * No. xx-xxxV
 * Special Master Christian J. Moran
 Petitioner, *
 * Filed: October 8, 2010
v. * Reissued: October 20, 2010
 *
SECRETARY OF HEALTH * Entitlement, influenza (flu) vaccine,
AND HUMAN SERVICES, * transverse myelitis, reliable and
 * persuasive evidence, Daubert, case
 Respondent. * reports, animal models, differential
 * diagnosis, results in previous
 * litigation

Ronald C. Homer & Amy Fashano, Conway, Homer & Chin-Caplan, P.C., Boston, MA., for petitioner;
Glenn A. MacLeod, United States Dep't of Justice, Washington, D.C. for respondent.

PUBLISHED DECISION DENYING COMPENSATION*

Ms. Doe claims that the influenza (“flu”) vaccine, which she received in 2004, caused her to develop transverse myelitis, a condition in which the nerves in the spinal cord are damaged. Petition, filed June 28, 2007. Ms. Doe seeks compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. (2006).

At the causation hearing in this case, Ms. Doe’s expert opined that the flu vaccine can cause transverse myelitis. Respondent’s expert disagreed. The weight of the evidence, considered as a whole, does not support Ms. Doe’s position, as her expert’s theory was not persuasive. Thus, Ms. Doe is not entitled to compensation.

I. Factual Background

Ms. Doe was born in 1943. Exhibit 3 at 6. She was more or less healthy until 2004, when she received the flu vaccination at issue here. Before this vaccination, Ms. Doe had experienced numbness in her hands occasionally. Exhibit 1 at 21-24 (record dated June 11,

* Ms. Doe filed a motion pursuant to 42 U.S.C. § 300aa–12(d)(4) and Vaccine Rule 18(b), requesting that her name be redacted from the published version of the decision. That motion was granted and the decision is reissued with this change.

2003); exhibit 2 at 16-19 (record dated March 5, 2003); exhibit 3 at 7 and 12-20 (record dated April 28, 2004). Respondent argues that this numbness may constitute a manifestation of a neurological disorder that preceded the flu vaccination, and thus could not have been caused by it.

Also before vaccination, Ms. Doe had “urgency with incontinence.” She also began experiencing a new symptom of urinary retention and constipation. She was advised to see a urologist. Exhibit 6 at 10.

Ms. Doe received the flu vaccination on October 8, 2004. Exhibit 13 at 1. Ms. Doe experienced some soreness and redness after the vaccination. Exhibit 14 at 1-2. Soreness and redness are common reactions to a vaccination. They do not necessarily indicate that a more severe adverse reaction will follow. Tr. 75-76; tr. 150.

On December 8, 2004, two months after her flu vaccination, Ms. Doe was diagnosed with a urinary tract infection and given medications. Exhibit 18 at 1-2. She visited an emergency room four days later because she was retaining urine. She also reported a worsening pain in her abdomen for approximately two months. Health care providers drained approximately 1000 ml of urine (exhibit 5 at 1-14), signifying that her bladder was close to full. Tr. 109 (testimony of Dr. Tornatore).

The next day, Ms. Doe saw a urologist, Dr. Joseph Mobley. Dr. Mobley reported that before October, Ms. Doe “was having urgency with incontinence.” Now, Ms. Doe was having the opposite problem in which “she was unable to initiate [] her urinary stream.” Ms. Doe also reported weakness in her lower extremities and blurred vision. Dr. Mobley’s impression was “[a]cute urinary retention and voiding dysfunction of unknown etiology.” Exhibit 6 at 10.

Approximately two months later, Ms. Doe reported that she was having pain in her lower back. She also reported bladder incontinence. She was examined by an orthopedist, Dr. Dewayne Adams. Exhibit 7 at 9. Dr. Adams ordered an electromyography (“EMG”) / nerve conduction study, which was essentially normal. Id. at 19. The results of the EMG showed that Ms. Doe’s problem was not in her peripheral nervous system, meaning that the problem was in her central nervous system. Tr. 19 (testimony of Dr. Tornatore). Dr. Adams also ordered magnetic resonance imaging (“MRI”) of Ms. Doe’s lumbar spine. The MRI showed “1. mild diffuse lumbar spondylosis with mild spinal curvature to the left; 2. tiny central disc protrusion at L3-4 without canal or foraminal stenosis; 3. Enlargement and increased signal intensity within the distal cord and conus medullaris.” Exhibit 7 at 23-24.

The next day, Ms. Doe saw a neurosurgeon, Dr. John Campbell. He ordered additional MRIs for the thoracic and lumbar spines. Exhibit 7 at 31. These MRIs showed abnormal signal

intensity from T2 to the conus and cord enlargement from T5 to the conus.¹ Exhibit 10 at 6-7. On February 14, 2005, Ms. Doe was diagnosed with “[s]pinal cord mass and myelopathy, also cervicothoracic syrinx.”² Exhibit 9 at 44.

Ms. Doe was referred to Vanderbilt University Medical Center, where she saw another neurosurgeon, Dr. Oran Aaronson. Exhibit 9 at 121-22. She also saw Dr. Subramaniam Sriram, a neurologist in the Multiple Sclerosis Clinic. Dr. Sriram recorded a history that is reasonably consistent with the events described above. Dr. Sriram, who has testified for the respondent in other Vaccine Program cases, stated “At present, my feelings are this is probably questionable postinfectious, postvaccination etiology of an acute ascending myelopathy.” Exhibit 9 at 108. Dr. Sriram suggested other possible conditions, such as a paraneoplastic process or Devic’s disease, but later testing ruled out those possibilities. Tr. 37 (testimony of Dr. Tornatore); tr. 82; tr. 165-66 (testimony of Dr. Bielawski).

In 2005, Ms. Doe continued to experience problems with her extremities and also problems with urinating. Some of the medicines Ms. Doe took for these conditions caused her additional complications. By 2005, one neurologist, Dr. Karl Misulis, opined that Ms. Doe was “permanently and totally disabled.” Exhibit 8 at 8. Dr. Misulis also concluded that Ms. Doe had “[m]yelopathy/transverse myelitis.” Exhibit 8 at 14. By December 2007, when Ms. Doe signed an affidavit for this litigation, Ms. Doe had not improved significantly. She used a wheelchair to move around and was still having problems voiding due to her transverse myelitis. Exhibit 14 at 4-5.

There is no dispute that Ms. Doe suffers from transverse myelitis. See tr. 38-39; tr. 134-35. Transverse myelitis is inflammation of the spinal cord. Tr. 96 (testimony of Dr. Tornatore). The inflammation causes damage. Id.; see also exhibit 21, tab A (Douglas A. Kerr and Harold Ayetey, Immunopathogenesis of Acute Transverse Myelitis, 15(3) Curr Opin Neurol 339-47 (2002)).

The causes of transverse myelitis vary. The inflammation can be caused by an infectious agent directly or by an autoimmune process. Tr. 163 (testimony of Dr. Bielawski). The cause of the inflammation is not identified in approximately 5-15 percent of cases of transverse myelitis. Because the cause is not known, these cases are labeled “idiopathic transverse myelitis.” Tr. 131 (testimony of Dr. Bielawski); tr. 163 (same); tr. 166.

Some cases of transverse myelitis are believed to be “autoimmune” in origin. Tr. 39; tr. 128-29; tr. 163. “Autoimmunity” refers to a process by which the body’s immune system, which

¹ The conus medullaris is “the cone-shaped lower end of the spinal cord, at the level of the upper lumbar vertebrae.” Dorland’s Illustrated Medical Dictionary 415 (30th ed. 2003) (“Dorland’s”).

² A syrinx is “an abnormal cavity in the spinal cord.” Dorland’s at 1841.

usually protects against foreign substances (known as antigens), turns against itself and harms the body's own tissue. Tr. 41-42 (testimony of Dr. Tornatore); Tr. 128-29; tr. 163 (testimony of Dr. Bielawski). Scientists theorize that at least some autoimmune diseases are mediated through a process known as molecular mimicry. See tr. 167-68 (testimony of Dr. Bielawski). Molecular mimicry is the theory advanced by Ms. Doe in this litigation.

II. Procedural History

Ms. Doe filed her petition in June 2007. She filed a set of medical records and an amended petition in December 2007. The parties spent some time exploring the possibility of settlement, but these efforts did not succeed. After the parties decided to proceed with this litigation, respondent filed her report pursuant to Vaccine Rule 4(c) in August 2008. Respondent maintained that Ms. Doe was not entitled to compensation. Resp. Rep't at 2, filed August 29, 2008. Respondent also filed a report from Dr. Martin Bielawski, his curriculum vitae, and medical articles on which he relied. Exhibit A through E.

Ms. Doe, in turn, filed a report from Dr. Carlo Tornatore with associated literature appended and his curriculum vitae. Exhibit 21 and 22. Ms. Doe also filed a supplemental report from Dr. Tornatore. Exhibit 23.

The disclosure of the experts' opinions made this case ready for a hearing.³ The hearing was held in Washington, D.C., where Dr. Tornatore testified in person. Dr. Bielawski testified by telephone. After the hearing, the parties filed articles to which their experts had referred during the hearing but which had not been filed yet. The parties also submitted briefs. Following the briefs, the parties presented an oral argument, which was digitally recorded. The case is ready for adjudication.

III. Standards for Adjudication

There are at least three distinct parts to evaluating whether a petitioner is entitled to compensation. One part is to articulate the elements of the petitioner's case. These elements are "what" petitioner must establish. A separate part of the analysis is the quantum of evidence that a petitioner must introduce, which is the burden of proof. A final aspect is the process of weighing or evaluating the evidence that is submitted. These three portions are discussed separately.

A. Elements of Petitioner's Case

To receive compensation under the Program, Ms. Doe must prove either: (1) that she suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding

³ At one point, Ms. Doe requested authorization to depose Dr. Sriram. Pet'r Mot., filed April 17, 2009. Later, Ms. Doe withdrew this request. Order, dated July 24, 2009. Respondent also did not pursue a deposition of Dr. Sriram. Resp. Status Rep't, dated August 3, 2009.

to the influenza vaccination, or (2) that she suffered an injury that was actually caused by the influenza vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, no injuries are associated with the influenza vaccine on the Vaccine Injury Table. Thus, Ms. Doe must prove causation in fact.

When a petitioner proceeds on a causation-in-fact theory, a petitioner must establish 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).

B. Burden of Proof

For the elements that petitioners are required to prove, their burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master’s decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty). In this regard, “close calls regarding causation are resolved in favor of injured claimants.” Althen, 418 F.3d at 1280.

C. How to Weigh Evidence

The preceding sections explain what a petitioner is required to establish and what level of proof satisfies the petitioner’s obligation. The remaining issue is how to evaluate evidence submitted to meet the standard of proof on those elements. Three authorities generally instruct special masters in how to evaluate evidence. They are Congress, the United States Court of Federal Claims, and the United States Court of Appeals for the Federal Circuit.

Congress is the first authority for instructions about how to weigh evidence. In enacting the National Vaccine Injury Compensation Act, specifically section 13, Congress provided some instructions about how special masters should analyze the evidence. Among other provisions, section 13 dictates that the special master should consider “the record as a whole.” Section 13 also provides that the special master shall consider “any diagnosis, conclusion, medical judgment or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition or death.” Nevertheless, “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court.”

The second authority is the United States Court of Federal Claims, in its capacity as rule maker. Congress authorized the Court of Federal Claims to promulgate rules of procedure for cases in the Vaccine Program. 42 U.S.C. § 300aa–12(d)(2). Collectively, the judges of the Court of Federal Claims have issued the Vaccine Rules. The Vaccine Rules, in turn, provide that the special master “must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.” Vaccine Rule 8(b)(1).

The third authority is the United States Court of Appeals for the Federal Circuit. Decisions by the Federal Circuit are binding precedent. 42 U.S.C. § 300aa–12(e). Within the Vaccine Program, the Federal Circuit expected that special masters would “consider[] the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis for the decision.” Hines v. Sec’y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

A particular topic on which the Federal Circuit has guided special masters is the process for evaluating the testimony of expert witnesses. In the Vaccine Program, an expert’s opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested;
- (2) whether the theory or technique has been subjected to peer review and publication;
- (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and,
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2, citing Daubert, 509 U.S. at 592-95.

After Terran, decisions from judges of the Court of Federal Claims have consistently cited to Daubert. E.g. Snyder v. Sec’y of Health & Human Servs., 88 Fed. Cl. 706, 742-45 (2009); Cedillo v. Sec’y of Health & Human Servs., 89 Fed. Cl. 158, 182 (2009), *aff’d*, No. 2010-5004, 2010 WL 3377325 (Fed. Cir. Aug 27, 2010); De Bazan v. Sec’y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) (“A special master assuredly should apply the factors

enumerated in Daubert in addressing the reliability of an expert witness's testimony regarding causation.”), rev'd on other grounds, 539 F.3d 1347 (Fed. Cir. 2008); Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006); Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 54 (2005).

The reliability of the expert's theory is not presumed. A “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” Moberly, 592 F.3d at 1324. Furthermore, the reliability of an expert's theory affects the persuasiveness of the evidence. Special masters may “inquir[e] into the reliability of testimony from expert witnesses. Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.” Id. at 1325. The finding that an expert's opinion passes a minimal standard of reliability does not require acceptance of that expert's theory because “disputes about the degree of relevance or accuracy (above this minimum threshold [of reliability]) may go to the testimony's weight.” i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010).

In evaluating expert testimony and scientific literature, special masters should analyze scientific literature “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard.” Andreu, 569 F.3d at 1379. “In other words, a finding of causation in the medical community may require a much higher level of certainty than that required by the Vaccine Act to establish a prima facie case. The special master must take these differences into account when reviewing the scientific evidence.” Broekelschen v. Sec'y of Health & Human Servs., 89 Fed. Cl. 336, 343 (2009), aff'd, No. 2009-5132, 2010 WL 3516444 (Fed. Cir. Sept. 10, 2010).

Generally, the Federal Circuit expects that a special master will present a reasonable basis for rejecting the opinion of an expert. Lampe, 219 F.3d 1361; Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

These standards will be used to determine whether Ms. Doe has established that she is entitled to compensation. For reasons explained in the following section, Ms. Doe has not met her burden of proof. Therefore, she is not entitled to compensation.

IV. Analysis

A. Althen Prong One

As noted earlier, Ms. Doe's burden is to establish, by a preponderance of the evidence, three elements. Althen, 418 F.3d at 1278. Among these three elements, the first element, “a medical theory causally connecting the vaccination and the injury,” is dispositive in this case.

1. Legal Standard

Regarding the medical theory, the parties appear to agree that not all theories satisfy a petitioner's burden. Oral Arg. at 2:12:30-2:13:01; 2:45:54-2:46:03. Beyond this initial point of agreement, the parties dispute what type of theory the petitioner must present.

The different views of the parties is reflected in the arguments that they present with regard to Althen prong 1. The parties' briefs modify the term "theory" using different adjectives. Ms. Doe advances the idea that "a petitioner satisfies the Althen prong 1 'medical theory' requirement by showing that it is biologically plausible that a vaccine caused the injury." Pet'r Reply at 12 (emphasis in original). In contrast, respondent does not agree that "biological plausibility" satisfies prong 1. "It is petitioner's burden here to show that the medical theory has objective scientific support to show that it actually occurs – that it establishes a probable, and not just possible or speculative, causal connection between vaccination and injury." Resp't Br. at 12. Respondent's argument continues: "to prevail in this case, petitioner was required to produce reliable scientific evidence demonstrating that a causal relationship likely does in fact exist between . . . the flu vaccine received by this petitioner and [transverse myelitis]." Id. (emphasis in original).

Between the two competing formulations, respondent's insistence that petitioner's theory be supported by "reliable scientific evidence" has much more support. One source of support is Vaccine Rule 8(b)(1), which directs special masters to "consider all relevant and reliable evidence." Although the term "reliable evidence" was not defined by the Court of Federal Claims when the Vaccine Rules were initially promulgated in 1989, see 16 Cl. Ct. XXL-LXI (1989); the reliability of an expert's opinion in the context of Federal Rule of Evidence 702 was subsequently discussed by the Supreme Court in Daubert, 509 U.S. 579, 589-590. The Federal Circuit approved the use of Daubert in the Vaccine Program, even though the Federal Rules of Evidence do not set the standards for the admission of evidence in these cases. 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).

In Daubert, the Supreme Court also stated that Federal Rule of Evidence 702 clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify. "'If scientific, technical or other specialized *knowledge will assist the trier of fact* to understand the evidence or to determine a fact in issue' an expert 'may testify thereto.'" (emphasis in original). Daubert, 594 U.S. at 508. The Court goes on to state that the subject of an expert's testimony must be "scientific knowledge," that is, the word "scientific" implied a grounding in the methods and procedure of science and the word "knowledge" implies more than subjective belief or unsupported speculation. To qualify as "scientific knowledge," the Court states that "an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation - i.e, 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." Id.

Other sources of support for respondent's argument that petitioner needs "reliable scientific evidence" are decisions from the Federal Circuit. "In the context of an off-table case,

where a petitioner is attempting to prove that a certain vaccine in fact actually caused a particular injury, . . . [petitioner’s proof] must be supported by a sound and reliable medical or scientific explanation.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). One of the cases cited by Knudsen for this proposition was Daubert. Before the Supreme Court decided Daubert, the Federal Circuit stated that “A reputable medical or scientific explanation must support this logical sequence of cause and effect.” Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Ms. Doe does not rely upon either Knudsen or Grant. Instead, Ms. Doe cites Althen, 418 F.3d at 1279, which states that “objective confirmation” of the medical theory is not needed. Pet’r Br. at 11; Pet’r Reply at 11-12. For additional support for her argument that “biological plausibility” is sufficient, Ms. Doe also cites Walther v. Sec’y of Health & Human Servs., 485 F.3d 1146, 1148 (Fed. Cir. 2007), and Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006). Pet’r Reply at 12 n.10.

To the extent that Althen’s statement is in tension with earlier Federal Circuit decisions, the Federal Circuit’s decision in Moberly resolves any tension. In Moberly, the petitioner-appellant, who was represented by the same law firm that represents Ms. Doe, advanced the argument that because petitioners are not required to establish their case with a scientific certainty, petitioners prevail when they establish that a condition was “‘likely caused’ by the . . . vaccine . . . something closer to proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury.” Moberly, 592 F.3d at 1322. The Federal Circuit rejected this argument. In off-Table cases, “the applicable level of proof is . . . the traditional tort standard of ‘preponderant evidence.’” Id. Thus, Moberly makes clear the opinion advanced by petitioners in support of their case must be reliable, although this reliability may be established in a variety of ways according to Althen, 418 F.3d at 1279.

A petitioner’s presentation of a reliable opinion containing “a medical theory causally connecting the vaccination and the injury” does not satisfy the petitioner’s burden to present “preponderant evidence.” Althen, 418 F.3d 1278. By statute, the petitioner’s burden is to present a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1); Moberly, 592 F.3d at 1321-22. ; see also Grant, 956 F.2d at 1148 (stating “[t]he [Vaccine] Act relaxes proof of causation for injuries satisfying the Table . . . but does not relax proof of causation in fact for non-Table injuries.”).

The difference between reliable evidence and preponderant (or persuasive) evidence is implicit in cases discussing a district court’s role as a gate-keeper preventing unreliable evidence from reaching a jury. See Micro Chemical, Inc. v. Lextron, Inc., 317 F.3d 1387, 1392-93 (Fed. Cir. 2003) (holding that district court properly admitted expert’s opinion and holding that, “in a classic example of competing experts,” substantial evidence supported the jury’s choice of which expert to believe); Biotec Biologische Natuerverpackungen GmbH & Co. v. Biocorp, Inc., 249 F.3d 1341, 1349-50 (Fed. Cir. 2001) (stating “the court’s obligation was to assure that evidence was reliable and relevant” and stating that when the evidence was in conflict, the “jury’s evaluation of the evidence could include determinations of the reliability of the data.”).

Examples from other circuit courts of appeals include Duke v. Wal-Mart Stores, Inc., 603 F.3d 571, 602 (9th Cir. 2010) (noting that because the district court properly found the expert's report, which supported the plaintiffs' motion for class certification, admissible, the jury will decide whether the expert's opinion was persuasive); Blake v. Pellegrino, 329 F.3d 43, 48 (1st Cir. 2003) (holding that the trial judge erred in excluding evidence from the jury's consideration when the trial judge found that the evidence was not persuasive); Western Industries, Inc. v. Newcor Canada Ltd., 739 F.2d 1198, 1202 (7th Cir. 1984) (role of the trial judge was to balance weight of the evidence in ruling on objections, not to weigh the persuasiveness of the evidence which was a question for the jury). These cases indicate that reliability differs from persuasiveness because, in traditional tort cases, the evaluations are performed by different entities – judges evaluate the reliability of an expert's opinion and the jury evaluates the persuasiveness.

This division of duties is not present in the Vaccine Program because special masters decide the case without a jury. In practice, the special master's role means that Daubert motions to exclude an expert's opinion are rarely filed because, among other reasons, the concern about allowing an unreliable opinion to reach the finder of fact is not present. See Snyder, 88 Fed. Cl. at 744-45; Veryzer v. Sec'y of Health & Human Servs., No. 06-522V, 2010 WL 2507791, at *21 (Fed. Cl. Spec. Mstr. June 15, 2010). Rather than resolve separately the questions of whether the expert's opinion is reliable and whether the expert's opinion is persuasive, these two tasks are undertaken simultaneously. See Garcia v. Sec'y of Health & Human Servs., No. 05-720V, 2010 WL 2507793, at *5 (Fed. Cl. Spec. Mstr. May 19, 2010). For example, in Terran, the opinion of the petitioner's expert was admitted and then the special master evaluated that opinion with reference to the four factors listed in Daubert. Terran v. Sec'y of Health & Human Servs., No.95-451V, 1998 WL 55290, at *11 (Fed. Cl. Spec. Mstr. Jan. 23, 1998). The Federal Circuit approved this procedure. Terran, 195 F.3d at 1316.

Terran, therefore, supports the notion that a Daubert analysis, which, strictly speaking, district courts use to determine the reliability of an expert's opinion, may be used to evaluate the persuasiveness of an expert's opinion. See Davis v. Sec'y of Health & Human Servs., No. 07-451V, 2010 WL 2928968, at *9 (July 12, 2010) (stating “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, at least in bench proceedings conducted by special masters in vaccine cases” and citing Terran, 195 F.3d at 1316, and Moberly, 592 F.3d at 1324); Snyder, 88 Fed. Cl. at 744 (stating, “the special master considered all of the relevant evidence submitted by both parties, using the Daubert factors only to determine the reliability of that evidence and, hence, the weight it should be assigned.”). The overlapping criteria was also recognized by the Federal Circuit in a patent case: “disputes about the degree of relevance or accuracy (above this minimum threshold [of reliability]) may go to the testimony's weight.” i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010).

Collectively, these precedents demonstrate that the petitioner's burden is to present an opinion that is both reliable and persuasive. The way that Ms. Doe has attempted to meet this

burden of proof is by presenting various pieces of evidence to support Dr. Tornatore's opinion. The analysis of this evidence is taken up in the following section.

2. Evidence Regarding Can the Flu Vaccine Cause Transverse Myelitis

Ms. Doe has presented both testimonial and documentary evidence to support her argument that the flu vaccine can cause transverse myelitis. "In support of her theory, she has provided an expert opinion, case reports, scientific literature, the statements of treating physicians, and her own affidavit." Pet'r Br. at 10. Respondent, in turn, presented other evidence to weaken Ms. Doe's case. See Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (stating "[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.")

For purposes of analysis, the evidence is organized into different categories, roughly corresponding to the type of evidence identified in Ms. Doe's brief. This categorization is somewhat artificial because the true test is whether "the record as a whole" supports a finding of entitlement. 42 U.S.C. § 300aa-13(a). Nevertheless, breaking the evidence into parts simplifies the analysis of those individual parts. This approach appears to be consistent with the Federal Circuit's comment that "[a]n expert 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).

As explained below, Ms. Doe has not established the persuasiveness of Dr. Tornatore's theory that flu vaccine can cause transverse myelitis. To be sure, as discussed below, some of the evidence supports Ms. Doe's claim for compensation. One obvious example is the testimony from Dr. Tornatore. Tr. 53-54. Ms. Doe's introduction of supporting evidence does not compel a finding that she has fulfilled her burden of proof because other evidence makes Ms. Doe's evidence less persuasive. Cf. Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (indicating that the presence of some evidence contradicting the special master's finding that petitioner failed to meet her burden of proof does not mean that the special master's finding was arbitrary or capricious). Ultimately, the evidence considered as a whole does not support a finding that Ms. Doe has presented a persuasive medical theory causally connecting the flu vaccine to transverse myelitis.

a. Opinion of Petitioner's Expert, Dr. Tornatore

Ms. Doe relies upon the opinion of Dr. Tornatore. Dr. Tornatore has been a neurologist for more than 20 years. Dr. Tornatore teaches neurology to medical students at Georgetown University, is the director of the neurology residency program there, and is the director of the multiple sclerosis center at Georgetown. Among the honors bestowed on Dr. Tornatore during his professional career is a membership in the American Neurological Association, which is offered after a selection process. Tr. 8-12. In his career, Dr. Tornatore has treated between 200-300 patients who suffered from transverse myelitis, which is the condition afflicting Ms. Doe.

Tr. 94. Dr. Tornatore's experience and qualifications mean that his opinions warrant careful consideration.

Dr. Tornatore stated that the flu vaccination "was the most probable cause and substantially resulted in the transverse myelitis." He based his opinion on (1) the medical records for Ms. Doe, (2) the ruling out of other causes, and (3) the literature showing that a vaccine can cause transverse myelitis, including case reports of flu vaccine preceding transverse myelitis. Tr. 53-54. Dr. Tornatore offered the theory of molecular mimicry to explain how the flu vaccine can cause transverse myelitis. Tr. 39-46; tr. 64-65.

Molecular mimicry is a theory to explain the etiology of autoimmune diseases, including transverse myelitis. Molecular mimicry rests upon the idea that the molecular structure of some antigens resembles (or mimics) the molecular structure of portions of the body. When the body encounters an antigen with similarity to host tissue, the response of the immune system eventually leads to damage to the host. Tr. 42.

Dr. Tornatore stated that the flu vaccine can stimulate the process that leads, through molecular mimicry, to transverse myelitis. Tr. 65-68. For this statement, Dr. Tornatore relied upon various articles that are discussed below.

Whether the flu vaccine can cause transverse myelitis is a critical issue for which Ms. Doe must present a preponderant amount of evidence. On this issue, the two experts disagreed. Compare tr. 53-54 (testimony of Dr. Tornatore) with tr. 123-24 (testimony of Dr. Bielawski).⁴ When the expert's opinions conflict, one way to resolve which opinion is more persuasive is to review the information on which the experts base their opinions. See Moberly, 592 F.3d 1324; Perreira, 33 F.3d 1375.

b. Medical Literature

When the parties present medical articles, special masters may evaluate the expert's opinion with reference to the article. Moberly, 592 F.3d at 1325-26; Andreu, 569 F.3d 1379; Terran, 195 F.3d 1316. In doing so, special masters should analyze scientific literature "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Andreu, 569 F.3d at 1379.

⁴ Dr. Bielawski's recognition that it was a possibility that the flu vaccine can cause transverse myelitis does not materially advance Ms. Doe's case. See Hogan v. Shinseki, 544 F.3d 1294, 1298 (Fed. Cir. 2009) (concluding that an ambiguous statement from a treating doctor "was insufficient to establish service connection"); Van Epps v. Sec'y of Health & Human Servs., 26 Cl. Ct. 650, 653-54 (1992); King v. Sec'y of Health & Human Servs., No. 03-584, 2010 WL 892296, *69-72 (Fed. Cl. Spec. Mstr. March 12, 2010) (expert's opinion did not materially advance the case because while there was a mathematical possibility of an association between the vaccine and injury, there was no evidence in the record to support the claim).

In this case, Ms. Doe presented various types of medical articles. These can be grouped into certain categories, depending upon what was studied. For example, some articles reported observations about humans. Another article described experiments with biological compounds in test tubes. Other articles discussed studies on animals. Because the analysis of these types of articles differs, this decision separates them into different categories.

(1) Medical Textbooks and Case Reports

In concluding that the flu vaccine can cause transverse myelitis, Dr. Tornatore relied upon discussions of transverse myelitis that appear in medical textbooks and case reports in peer-reviewed journals. Tr. 48-49; tr. 54. Of the articles that Dr. Tornatore cited in his report, Ms. Doe solicited relatively short testimony from Dr. Tornatore about three articles and two textbooks. Tr. 48-49. These are the same articles that Ms. Doe cites in her brief. See Pet'r Br. at 14; Pet'r Reply at 13. The two textbooks are exhibit 21, tab O (Michael P. Pender and Pamela A. McCombe, Autoimmune neurological disease (1995)) and exhibit 21, tab P (Clinical Neuroimmunology, Jack Antel et al., eds. (2d ed. 2005)). The Pender textbook states: "A wide variety of vaccines have been reported to trigger . . . acute transverse myelitis, including influenza . . .". Exhibit 21, tab O at 156 (citations omitted). The Antel textbook appears to be less relevant and Ms. Doe submitted only one page from the textbook, making the context difficult to understand. See exhibit 21, tab P at 50; see also tr. 50 (testimony of Dr. Tornatore indicating that the Antel textbook associates the "hepatitis B vaccination specifically" with transverse myelitis).

In addition to these two textbooks, Ms. Doe and Dr. Tornatore cited three articles. These are exhibit 21, tab A (Kerr, Immunopathogenesis), exhibit 21, tab I (Naoko Nakamura et al., Neurologic Complications Associated with Influenza Vaccination: Two Adult Cases, 42(2) Internal Medicine 191 (2003)), and exhibit 21, tab R (A. J. Larner and S.F. Farmer, Myelopathy Following Influenza Vaccination in Inflammatory CNS Disorder Treated With Chronic Immunosuppression, 7(6) Eur J Neurol 731-33 (2000)). Among these three reports, Dr. Tornatore referred most frequently to the article by Dr. Kerr.

Dr. Kerr's views about whether the flu vaccination can cause transverse myelitis are unclear. At one point, the article suggests that Dr. Kerr finds that a causal relationship has been established:

Several reports of ATM [acute transverse myelitis] following vaccination have recently been published. Indeed, it is widely reported in neurology texts that ATM is a post-vaccination event. One publication reports a case of post 'flu vaccine myelitis in which a 42-year-old man with a history of bilateral optic neuritis developed ATM 2 days after an influenza vaccination [20].

Exhibit 21, tab A (Kerr) at 340. Reference 20 in Dr. Kerr's article is the Larner case report, which is contained in Ms. Doe's record as exhibit 21, tab R.

Here, Dr. Kerr's article continues and seems to question a causal connection. It states:

The suggestion from such studies is that a vaccination may induce an autoimmune process resulting in ATM [acute transverse myelitis]. However, it should be noted that extensive data continue to show overwhelmingly that vaccinations are safe and are not associated with an increased incidence of neurological complications [22-29]. Therefore, such case reports must be viewed with caution, as it is entirely possible that two events occurred in close proximity by chance alone.

Id. at 341.

The point that a temporal proximity does not indicate causation is also made in another case report cited by Dr. Tornatore. For example, Dr. Larner reported a case in which a 42 year old man developed neurological problems that were controlled with medication. Two years later, he received a flu vaccination. Two days after the vaccination, he developed additional neurological problems. Exhibit 21, tab R (Larner) at 731-32. Echoing the ambiguous views of Dr. Kerr, Dr. Larner stated:

Although the current case may possibly represent a chance relapse of an inflammatory CNS disorder unrelated to influenza vaccination, a number of factors suggest that neurological deterioration was causally related to vaccination: the temporal relationship between the two events; the anatomical concordance of cord lesion and injection site; and the absence of prior cord symptoms or signs.

Id. at 732-33.

The Nakamura article is the last of the group of articles discussed by Dr. Tornatore and cited by Ms. Doe. Dr. Nakamura reported two cases of a flu vaccination preceding neurological complications. Dr. Nakamura stated that "both myelitis and GBS-type polyneuropathy might occur after vaccination." Exhibit 21, tab I (Nakamura), at 194.

Collectively, these articles and textbooks do not present a persuasive case that flu vaccine can cause transverse myelitis. Dr. Kerr and Dr. Nakamura recognize that a causal connection between flu vaccination and transverse myelitis is possible. But, these authors refrain from concluding that causation has been established.

Extending the findings of a written article beyond what the authors stated is not always persuasive. This point is demonstrated by the Supreme Court's decision in General Electric Co. v. Joiner, 522 U.S. 136 (1997). Mr. Joiner claimed that polychlorinated biphenyls (PCBs) caused him to suffer lung cancer and relied upon the opinion of experts. Id. at 139-40. The experts'

opinions, according to Mr. Joiner, were reliable because the experts relied upon animal studies and four epidemiological studies. The district court and later the Supreme Court rejected Mr. Joiner's argument. In one of the epidemiological studies, because the authors "were unwilling to say that PCB exposure had caused cancer among the workers they examined, their study did not support the experts' conclusion that Joiner's exposure to PCB's caused his cancer." Id. at 145. Ultimately, the Supreme Court found that the district court did not abuse its discretion in excluding the experts' opinions. Id. at 147.

Courts have adopted the Supreme Court's reasoning in Joiner when considering whether a cited article supports an expert's opinion. See Moore v. Ashland Chemical, Inc., 151 F.3d 269, 278 (5th Cir. 1998) (en banc) (affirming trial court's exclusion of expert testimony because, among other reasons, the authors of a study relied upon by the expert "made it clear that their conclusions were speculative because of the limitations of the study"); Huss v. Gayden, 571 F.3d 442, 459 (5th Cir. 2009) (DeMoss, J.) (stating that "It is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proven," citing, among other cases, Joiner, and remanding for a new trial);⁵ Amorgianos v. Nat'l RR Passenger Corp., 137 F. Supp. 2d 147, 187 (E.D.N.Y. 2001) (stating "Given that Means et al. declined to attribute the [peripheral nervous system] effects they observed to xylene simply because it was the most prevalent solvent in the lacquer, it is highly questionable how Dr. Rutchkic can reliably conclude from their work that xylene can cause [polyneuropathy]" and excluding expert's testimony), aff'd in relevant part, 303 F.3d 256, 270 (2d Cir. 2002) (finding that district court did not abuse its discretion in excluding expert's opinion). In Joiner, Moore, and Amorgianos, the expert's opinion was not admitted into evidence because the opinion was not reliable. The exclusion of the expert's opinion prevented the fact-finder from considering it and also led to a judgment against the plaintiffs in those cases.

Here, the reasoning in Joiner is being adopted for a slightly different purpose, which is as a means to evaluate the weight to be given to Dr. Tornatore's opinion. If a disconnect between a report's findings as presented by the authors and the report's significance as discussed by an expert in litigation supports the exclusion of the expert's opinion entirely, then the same disconnect would support assigning the expert's opinion less weight. Consequently, in accord with Joiner, Dr. Tornatore's citation to the articles by Dr. Kerr and Dr. Nakamura is not persuasive.

Compared to the ambiguity expressed by Dr. Kerr and Dr. Nakamura, a slightly more assertive statement of causation is found in the Lerner article. But, Dr. Lerner's statement is tempered by the notation that the case he presented "may possibly represent a chance relapse . . . unrelated to the influenza vaccination." Exhibit 21, tab R, at 732. Furthermore, to the extent that Dr. Lerner has concluded that the flu vaccination caused his patient's problem, this conclusion is at odds with the reasoning expressed by several courts of appeals examining whether case reports

⁵ The portion of Huss quoted in the text was a statement of only one judge. The two other judges on the panel did not join this portion of the opinion.

support an expert's opinion regarding causation. Legal precedents recognize that case reports have little reliability in establishing causation. See, e.g., McClain v. Metabolife Intern., Inc., 401 F.3d 1233, 1253 (11th Cir. 2005); Meister v. Medical Engineering Corp., 267 F.3d 1123, 1129 (D.C. Cir. 2001); Glastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986, 989-90 (8th Cir. 2001); see also Mary Sue Henefin et al., "Reference Guide on Medical Testimony," in Reference Manual on Scientific Evidence 439, 475 (2d ed. 2000) (stating "[c]ausal attribution based on case studies must be regarded with caution," largely because they lack controls and thus do not provide the level of information or detail found in epidemiologic studies). Dr. Tornatore essentially agrees with this reasoning. He stated that "causality is always difficult just based on the case report." Tr. 115. Therefore, the Larner article provides relatively weak support for the proposition that the flu vaccine causes transverse myelitis.

The Pender textbook is the reference that most strongly supports Ms. Doe's claim. The Pender textbook states: "A wide variety of vaccines have been reported to trigger . . . acute transverse myelitis, including influenza." Exhibit 21, tab O at 156 (citations omitted). Read in isolation, this statement might support a finding that prong 1 of Althen is established, but the statement in the textbook appears to be based upon case reports, which are weak evidence of causation. Consequently, when considered in the context of the other evidence, the Pender textbook does not make up for other deficiencies in Ms. Doe's case.

(2) In Vitro Study

The previous articles report what has been observed with human beings. A different type of article is a report about an experiment in which biological samples are manipulated in a laboratory. This type of study is known as an "in vitro" study. Tr. 103; Dorland's at 948; Snyder v. Sec'y of Health & Human Servs., No. 01-162V, 2009 WL 332044, at *29 n.79 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), motion for review denied, 88 Fed. Cl. 706 (2009). One such article is exhibit 26 (Kai W. Wucherpfennig and Jack L. Strominger, Molecular Mimicry in T Cell-Mediated Autoimmunity: Viral Peptides Activate Human T Cell Clones Specific for Myelin Basic Protein 80 Cell 695 (1995)).⁶

In this article, Dr. Wucherpfennig tested a fundamental aspect of molecular mimicry. Dr. Wucherpfennig searched a database containing sequences of proteins to identify various viral and bacterial peptides that appeared to share molecular structure with myelin basic protein. Peptides are "any member of a class of compounds of low molecular weight that yield two or more amino acids on hydrolysis." Dorland's at 1396. After the database identified candidates, Dr. Wucherpfennig tested these peptides to see if they stimulated the production of T-cells. Exhibit 26 (Wucherpfennig) at 695-96. The results showed that some peptide sequences stimulated a large amount of T-cells. The source of these peptides included herpes simplex virus, Epstein-Barr virus, adenovirus type 12. Another peptide sequence that led to a large response was a

⁶ Ms. Doe filed exhibit 26 after the hearing because Dr. Tornatore referred to this article during his testimony. Tr. 67, tr. 102 (referring to the Cell paper).

particular portion of the influenza A virus. However, three other portions of the influenza virus did not produce a large amount of T-cells. Id. at 698-701.

Dr. Tornatore asserted that the Wucherpfennig study supported the theory of molecular mimicry because the T-cells, which should have reacted only to myelin basic protein, actually reacted to other antigens, including a peptide sequence from the influenza virus. Tr. 67-68. This conclusion is reasonable.

Extending the Wucherpfennig study to support Dr. Tornatore's opinion in Ms. Doe's case is more difficult because of the differences between what Dr. Wucherpfennig studied and what happened to Ms. Doe. Ms. Doe received the influenza vaccine. Dr. Wucherpfennig tested the influenza A virus. The difference between the influenza vaccine and the influenza virus could be significant. Different portions of the influenza A virus caused different reactions. Dr. Wucherpfennig commented "The observation that certain viral strains are capable of stimulating MBP-specific T cells while other strains are not may be important in defining the epidemiology of the disease." Exhibit 26 (Wucherpfennig) at 700-01. Ms. Doe has not presented any evidence that the flu vaccine has been tested under conditions like the Wucherpfennig study.

More importantly, there is no evidence that the portions of the influenza virus that mimicked MBP are the same portions of the virus used in the influenza vaccine. Dr. Tornatore indicated that he could "determine if there is a specific similarity between the flu vaccine that Ms. Doe received and myelin basic protein." Tr. 227-28.⁷ If Dr. Tornatore had performed such a test and if the test confirmed Dr. Tornatore's theory that the molecular structure of the flu vaccine resembles the molecular structure of parts of myelin, then Dr. Tornatore's overall theory that the flu vaccine can cause transverse myelitis would be more likely.

The lack of testing as to whether the flu vaccine has similarity with myelin basic protein does not compel an automatic rejection of Dr. Tornatore's theory, and in this case, Dr. Tornatore's theory has not been rejected solely because he has not tested it. Nevertheless, the lack of testing is another factor against finding that Dr. Tornatore's opinion is persuasive. See Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 606 (2009) (discussing the lack of testing for petitioner's theory), aff'd, 592 F.3d at 1324 (Fed. Cir. 2010). "[W]hether a theory or technique can be (and has been) tested" is one factor that may be considered in evaluating the expert's opinion. Daubert, 509 U.S. at 593.

(3) Animal Models

According to Dr. Tornatore, if a similarity in molecular composition were established, then the next step would be to conduct experiments on animals. A purpose of this animal study would be to test whether the substance causes demyelination. Tr. 68. With reference to this portion of Dr. Tornatore's testimony, Ms. Doe argues that her case is supported by animal models. Pet'r Br. at 15-16, citing tr. 68-69; Pet'r Reply at 14, citing the same. Respondent

⁷ No evidence indicates that this testing would be performed on human subjects.

contends that the animal models do not support Dr. Tornatore's theory. Resp't Br. at 18, citing tr. 69.

Given that both parties cite the same transcript pages and yet draw opposite conclusions from the evidence, Dr. Tornatore's testimony bears close examination. He testified that in experimental allergic encephalitis ("EAE"), animals are given a vaccine that is known to have a molecular composition that is similar to the molecular structure of portions the central nervous system and these animals develop acute encephalomyelitis. Tr. 66. Experiments on animals involving the flu vaccine leading to an inflammatory myelopathy have not been done according to Dr. Tornatore.⁸ Tr. 69.

Ms. Doe takes the example that experimental allergic encephalitis shows molecular mimicry under some circumstances and argues that this animal model supports the idea that molecular mimicry exists. Pet'r Br. at 15-16. This evidence slightly advances Ms. Doe's case. Even without Dr. Tornatore's discussion of animal models with EAE, a preponderance of evidence showed that the medical community accepts molecular mimicry as a way that some autoimmune diseases begin. Tr. 168 (Dr. Bielawski's testimony that molecular mimicry "is applicable in some cases."); tr. 206-07 (Dr. Bielawski's testimony that molecular mimicry explains how streptococcal bacteria can cause Sydenham's chorea). Thus, Dr. Tornatore's testimony about EAE is not really necessary to show, on a preponderance of the evidence standard, that molecular mimicry exists in the abstract. See Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 137 (2010) (quoting testimony from a government's expert stating that "after '22 years of intensive research on molecular mimicry from many laboratories . . . we have got very little evidence for it.'").

Dr. Tornatore's testimony about EAE would add something additional if it were more specific, such as a showing that EAE is a basis for concluding that the flu vaccine can cause transverse myelitis in humans. There are two hurdles that Ms. Doe and Dr. Tornatore must clear before his opinion becomes persuasive. First, the substance that is given is different. Animals are given a protein that is known to have "a lot of homology to myelin or central nervous systems protein." In contrast, "[W]ith the vaccine there is the chance that protein may have homology there." Tr. 66 (Dr. Tornatore). As discussed in connection with the Wucherpfennig article, the vaccine is not known to have homology and Dr. Tornatore is only able to state that "there is a chance."

The second problem with extrapolating from an animal study is that animals are not the same as humans. According to Dr. Tornatore, the immune systems of animals "are different." Tr. 69. Whether the difference between animals and humans prevents the use of animal models

⁸ Dr. Bielawski testified that he was not aware of any animal models showing that flu vaccine causes transverse myelitis. Tr. 124, tr. 149, tr. 217.

to show how a substance can cause a condition has been discussed by several appellate courts, although not by the Federal Circuit.⁹

In opinions by the Court of Federal Claims that have discussed animal studies presented to special masters, the results have been mixed. In some cases, the Court of Federal Claims has suggested that animal models support a finding of causation. See, e.g., Kelley v. Sec’y of Health & Human Servs., 68 Fed. Cl. 84, 99 (2005). In other cases, the Court of Federal Claims has not accepted animal models as proof of causation. Hennessey, 91 Fed. Cl. at 137; Adams v. Sec’y of Health & Human Servs., 76 Fed. Cl. 23, 40 n.27 (2007) (stating “Dr. Wiznitzer’s critique of the ‘kindling theory’ was well-taken, because this theory was based on a ‘mouse model [and] there is still major controversy as to whether it’s truly applicable to the human.’”).

A survey of decisions by other circuit courts of appeal shows that these courts have debated the usefulness of animal studies. See Allison v. McGhan Medical Corp., 184 F.3d 1300, 1314 (11th Cir. 1999) (stating “Daubert decisions in other courts warn against leaping from an accepted scientific premise to an unsupported one” and citing cases); In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 779-81 (3d Cir. 1994) (discussing cases and stating “The case law on the admissibility of animal studies in various contexts is mixed.”).

Ms. Doe has not presented any evidence to show that the EAE animal models are transferrable to her case. Certainly, Dr. Tornatore holds the opinion that these animal models support his opinion that the flu vaccine can cause transverse myelitis. Tr. 66. But, Dr. Tornatore’s saying so appears to be opinion evidence that a trial court may discount in evaluating the expert’s opinion. Joiner, 522 U.S. at 144-45; Moberly, 592 F.3d at 1325 (stating “Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.”); Snyder, 88 Fed. Cl. at 744-45 (citing Joiner).

Consequently, the record with regard to animal studies is too superficial to be useful to Ms. Doe. The animal studies were not submitted into the record and Dr. Tornatore did not explain why the animal studies were transferable to humans.

In sum, the scientific literature (textbooks, case reports, the Wucherpfennig article, and animal models) fall short of making Dr. Tornatore’s opinion persuasive. For Ms. Doe to meet her burden of proof, she presents arguments regarding differential diagnosis, the views of respondent’s expert, and results in other litigation. These points are taken up in the following sections.

⁹ Golub v. Sec’y of Health & Human Servs., 243 F.3d 561 (Fed. Cir. 2000) (table), mentions the special master’s discounting of animal studies in passing. Golub, 2000 WL 1471643, at *4. Golub, however, is not precedential because it was issued pursuant to Fed. Cir. Rule 47.6, which prohibited the citation of unpublished decisions. Ryman v. Sec’y of Health & Human Servs., 65 Fed. Cl. 35, 40 n.9 (2005).

c. Differential Diagnosis

Ms. Doe asserts that Dr. Sriram, who was her treating neurologist, and Dr. Tornatore used a “differential diagnosis” as a tool to form their opinions. Pet’r Br. at 17; Pet’r Reply at 18 n.20. Ms. Doe argues that “a differential diagnosis of the treating physician sufficiently meets the reliability standard set forth in Daubert . . . and may be used as indirect evidence of causation.” Pet’r Br. at 11, citing Kelley v. Sec’y of Health & Human Servs., 68 Fed. Cl. 84, 90 n.7 (2005). There are three problems with this argument. The first problem pertains to Dr. Sriram’s differential diagnosis. The second problem relates to Dr. Tornatore’s differential diagnosis. The last problem is about differential diagnosis in general.

First, Dr. Sriram did not conclude – via the process of differential diagnosis or by any other means – that the flu vaccine caused Ms. Doe’s neurological problem. Dr. Sriram’s diagnosis on April 6, 2005 included “questionable post-infectious, post vaccination etiology of acute ascending myelopathy.” Exhibit 9 at 108. After additional testing, Dr. Sriram stated that Ms. Doe had an “inflammatory myelopathy” of “unknown etiology.” Exhibit 9 at 55 (report dated Oct. 24, 2005). Thus, Ms. Doe’s argument stretches beyond what the facts support.¹⁰ If Dr. Sriram actually had stated that the flu vaccine caused Ms. Doe’s myelopathy, then his statement regarding causation would be very important to consider. See Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). But, here, Ms. Doe has not identified any record in which Dr. Sriram or any other treating doctor directly stated that the flu vaccine caused Ms. Doe’s problem.

Second, despite Dr. Sriram’s conclusion that Ms. Doe’s condition was of “unknown etiology,” Ms. Doe argues that the differential diagnosis supports her case because of Dr. Tornatore’s opinion. Dr. Tornatore notes that Dr. Sriram’s April 6, 2005 letter essentially left two possible causes: “post-infectious” or “post vaccination.” Because Dr. Tornatore eliminates “post-infectious,” Dr. Tornatore says that the remaining cause must be vaccination. Tr. 34-38; tr. 73 (noting no other causes for transverse myelitis were identified).

Dr. Bielawski stated that infectious causes should not be dismissed too quickly. In his initial report, Dr. Bielawski stated that “[t]he search for infectious etiologies for myelitis with potentially myelopathic organisms was not complete. There was no evaluation for mycoplasma pneumoniae.” Exhibit A at 4. Dr. Tornatore agreed that the immune system’s response to an infection with mycoplasma pneumoniae can lead to autoimmune transverse myelitis. Tr. 234-35; accord, exhibit 21, tab A (Kerr) at 340. Thus, a preponderance of evidence indicates that mycoplasma pneumoniae can cause transverse myelitis. The question, then, becomes is there evidence that Ms. Doe suffered such an infection?

Here, there is relatively little coherent evidence about any contribution of a mycoplasma pneumoniae infection. Both experts indicated that Ms. Doe did not display symptoms typically reported with this infection. Tr. 233 (Dr. Tornatore); tr. 170 (Dr. Bielawski); see also tr. 45-46

¹⁰Dr. Sriram’s report is also discussed in section IV B below.

(Dr. Tornatore). Yet, both experts also agreed that a mycoplasma pneumoniae infection does not always cause respiratory problems. Tr. 133-34 (Dr. Bielawski); tr. 169-72 (same); tr. 233 (Dr. Tornatore); see also exhibit C, tab 2 (Randeep Guleria et al., Mycoplasma pneumonia and central nervous system complications: A review, 146 J Lab Clin Med 55 (2005)) at 2. On this record, it is difficult to determine whether it is more likely than not that Ms. Doe suffered such a mycoplasma pneumoniae infection.

A finding that mycoplasma pneumoniae remained a potential cause for Ms. Doe's condition would be detrimental to her case. See Doe 11, 601 F.3d at 1358 (stating that "Because [petitioner's expert] supported his theory of causation by discounting SIDS as a possible cause, [petitioner's] prima facie case depended in part on whether the special master credited [the expert's] opinion on SIDS."); Knudsen, 35 F.3d at 550 (stating, in an on-Table case, that "This conflicting record evidence does not in our view either compel a finding of viral alternative causation nor preclude one. If the evidence is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded" and remanding the case).¹¹

Resolving how the meager amount of evidence preponderates is not necessary because the evidence about Ms. Doe's possible mycoplasma pneumoniae infection affects only the persuasiveness of Dr. Tornatore's use of differential diagnosis. Even if Dr. Tornatore's opinion were accepted entirely, the approach of differential diagnosis, in general, does not constitute persuasive evidence that the flu vaccine can cause transverse myelitis.

This is the third and most important point regarding differential diagnosis. Differential diagnosis cannot be used to show that the flu vaccine can cause transverse myelitis. This point is made in Westburry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999), which is the case relied upon by Kelley in its discussion of differential diagnosis. (Kelley is the case cited by Ms. Doe in support of her argument that a physician's use of differential diagnosis can support a finding of causation.)

Westburry is a case in which an exposure to a substance allegedly caused a personal injury. Mr. Westburry claimed that his contact with airborne talc caused him to develop sinus problems and offered the opinion of his treating doctor to support his claim of causation. The primary issue on appeal was whether the district court had erred in admitting this opinion. Id. at 260. The defendant argued that the treating doctor's use of differential diagnosis was faulty because the doctor had failed to "rule in" talc as a cause of the sinus problems. The Fourth Circuit rejected this argument because "there was no dispute that exposure to high concentrations of airborne talc could cause irritation to mucous membranes." Id. at 264. Thus, Westburry stands for the proposition that a differential diagnosis is an appropriate (or a reliable) method for

¹¹ The statement in Knudsen about what happens if the evidence were equally balanced came in a case in which the petitioners successfully established a Table claim. In Knudsen, the burden shifted to the government to establish an alternative factor caused the child's illness. Id. at 547.

identifying the likely cause of a condition only from a list of causes that have been shown capable of causing the condition.

Other courts have ruled that a finding of “can cause” is a prerequisite for including a particular substance in the differential diagnosis. Tamraz v. Lincoln Elec. Co., No. 08-4015, 2010 WL 3489002, at *8 (6th Cir. Sept. 8, 2010); Hendrix ex rel. G.P. v. Evenflo Co., Inc., 609 F.3d 1183, 1197-98 (11th Cir. 2010) (affirming district court’s exclusion of expert’s opinion because the doctor “fail[ed] to show how, by ‘scientifically valid methodology’ traumatic brain injury could ever be a possible cause of autism in anyone.”) (citation omitted); Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (affirming trial court’s exclusion of an expert’s opinion on the ground that the opinion was not reliable according to the Daubert standard); see also Neiberger v. Fed Ex Ground Package System, Inc., 566 F.3d 1184, 1190-91 (10th Cir. 2009) (affirming district court’s ruling that a reliable basis existed for expert’s opinion on general causation because expert’s use of the differential diagnosis methodology considered the possible recognized causes and eliminated those contradicted by the evidence before him); Best v. Lowe’s Home Centers, Inc., 563 F.3d 171, 179-180 (6th Cir. 2009) (where expert’s opinion was found to be reliable using a differential diagnosis methodology because expert compiled list of possible causes of injury and ruled out alternative causes).

Thus, Ms. Doe’s reliance on the technique of differential diagnosis does not constitute persuasive evidence that the flu vaccine can cause transverse myelitis. As the various cases cited above have noted, the approach of differential diagnosis requires some showing that a putative agent can cause the suspected condition. Evidence in this case has not established this predicate.

d. View of Respondent’s Expert

Ms. Doe also relies upon portions of the opinion of respondent’s expert, Dr. Bielawski. See Pet’r Br. at 14; Pet’r Reply at 13-14. Dr. Bielawski agreed that transverse myelitis is an autoimmune disease and that molecular mimicry may explain how some autoimmune diseases, including transverse myelitis, originate. Tr. 168. Dr. Bielawski also acknowledged that transverse myelitis has been reported to follow after vaccinations. Tr. 188. Dr. Bielawski and Ms. Doe part company on the topic of the flu vaccination.

Dr. Bielawski stated that information does not support the idea that flu vaccine can cause transverse myelitis. Tr. 123-24. To support this statement, Dr. Bielawski relied upon various articles, which are also discussed below. Dr. Bielawski acknowledged that it was “possible” that the flu vaccine could cause transverse myelitis, but Dr. Bielawski was clear that his opinion is that it is not probable that the flu vaccine causes transverse myelitis. Tr. 128-29; see also tr. 157-59.

The opinion of respondent’s expert can be a valuable piece of evidence. For example, in Andreu, the Federal Circuit found that the evidence supported a finding of causation in part because respondent’s expert “did little to cast doubt on [petitioner’s expert’s] theory of causation. To the contrary, he ‘did not dispute the biologic plausibility of [petitioner’s expert’s] medical

theory’ and acknowledged that the pertussis toxin can cause neurotoxicity and neurological symptoms.” Andreu, 569 F.3d 1377-78.

Ms. Doe’s case is not the same as Andreu. Dr. Bielawski testified that he “do[es] not believe that flu vaccine causes transverse myelitis.” Tr. 124; accord tr. 157. Therefore, Dr. Bielawski’s opinion, on the precise question, does not assist Ms. Doe in establishing, by a preponderance of the evidence, that the flu vaccine can cause transverse myelitis.

Ms. Doe relies upon other opinions expressed by Dr. Bielawski. Ms. Doe’s brief states that Dr. Bielawski “agreed that vaccines can cause” transverse myelitis. Pet’r Br. at 14, citing tr. 188-89. This testimony does not get Ms. Doe very far. Dr. Bielawski’s concession that some vaccines have been reported to cause transverse myelitis offers only slight support for the proposition that Ms. Doe is required to establish by a preponderance of evidence in this case: that the flu vaccine can cause transverse myelitis. On this specific point, as discussed above, Dr. Bielawski’s opinion was negative.

Ms. Doe also states that Dr. Bielawski recognized that the wild flu virus can cause transverse myelitis. Pet’r Br. at 15, citing tr. 159. From this point, Ms. Doe reasons that “as the special master is aware, the Institute of Medicine acknowledges that if the wild virus can cause an injury, the viral vaccine can cause the same injury.” Id., citing Stratton et al., Adverse Events Associated with Childhood Vaccines other than Pertussis and Rubella, 271(20) Journal of American Medical Ass’n, 1602-05 (1994). Ms. Doe’s argument overlooks an important qualification in the IOM’s report. The IOM article, which Ms. Doe was ordered to file after she cited it for the first time in her post-hearing brief, states “if a patient receives a live viral vaccine, experiences a pathological condition known to be associated with the natural virus, and [there is additional scientific evidence], causality between the vaccine and the pathological condition is established for this patient.” Exhibit 27 (Stratton) at 1603. The IOM’s reasoning is based upon a presupposition that the patient received a “live viral vaccine.” The flu vaccine, however, is not a “live viral vaccine.” The viral component in the flu vaccine is “inactivated,” meaning that the virus does not replicate inside a person. This distinction between vaccines containing a live virus and vaccines containing an inactivated virus makes Ms. Doe’s extension of the IOM article unpersuasive.

e. Results in Previous Litigation

Ms. Doe argues that results in previous litigation support her argument that the flu vaccine can cause transverse myelitis. Ms. Doe identifies two different types of cases – cases in which respondent agreed to resolve the case to avoid the costs and risks of continued litigation and one case in which a special master found that the flu vaccine caused the petitioner’s transverse myelitis. Pet’r Br. at 13-14. Ms. Doe’s arguments are not persuasive, although the analysis of her arguments is slightly different.

Ms. Doe identifies two cases in which respondent has agreed to compensate petitioners who alleged that a flu vaccine caused transverse myelitis: Harris v. Sec’y of Health & Human

Servs., No. 07-449V (Fed. Cl. Spec. Mstr. Nov. 12, 2008), and Lee v. Sec’y of Health & Human Servs., No. 07-457V (Fed. Cl. Spec. Mstr. Oct. 8, 2008). The decisions adopting the parties’ stipulation explain that respondent “denies that [the petitioner’s] transverse myelitis was caused-in-fact by his . . . influenza vaccination.”

Ms. Doe contends that more should be read into the respondent’s decision to resolve cases like Harris and Lee. Ms. Doe maintains that “it is noteworthy that the respondent never enters such stipulations unless it is biologically plausible that the vaccine can cause the alleged injury.” Pet’r Br. at 14.

The problem with Ms. Doe’s argument is that it, if accepted, would probably reduce the number of settlements. If respondent’s agreement to compensate one petitioner could be viewed as evidence in all other cases involving the same vaccine and same injury, respondent almost certainly would refrain from settling cases. The public policy of encouraging settlements is reflected in Rule 408 of the Federal Rules of Evidence and has been discussed by the Federal Circuit. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 265 F.3d 1294, 1308 (Fed. Cir. 2001) (affirming district court’s refusal to permit discovery into settlement negotiations in favor of a policy to protect settlement negotiations from being admitted as evidence, thus serving to encourage settlements); see also KMS Fusion, Inc. v. United States, 29 Fed. Cl. 593, 598-599 (1997) (upholding defendant’s argument that its settlement of many of the outstanding issues prior to trial should not be used as evidence that its position was not substantially justified. The court stated that such a result would have a chilling effect on settlement negotiations.)

The policy of encouraging settlements remains effective in the Vaccine Program even though the Federal Rules of Evidence are not the standard by which evidence is admitted into the Vaccine Program. See Hart v. Sec’y of Health & Human Servs., No. 01-357V, 2004 WL 3049766, at *3 n. 6 (Fed. Cl. Spec. Mstr. Dec. 17, 2004); cf Whalen v. United States, 93 Fed. Cl. 579, 589 (2010) (explaining that offensive nonmutual collateral estoppel cannot be used against the United States and citing cases from the Supreme Court). Consequently, the settlements in Harris and in Lee do not constitute evidence favoring Ms. Doe’s claim.¹²

Ms. Doe’s citation to a special master’s finding that flu vaccine can cause transverse myelitis stands on firmer ground. One special master found that petitioner’s receipt of the flu vaccination was a “but for” cause of the petitioner’s transverse myelitis. Schmidt v. Sec’y of Health & Human Servs., No. 07-20V, 2009 WL 5196169, at *11-14 (Fed. Cl. Spec. Mstr. Dec.

¹² Ms. Doe argues that the inconsistency between, on the one hand, Harris and Lee, and, on the other hand, her case is “unfair” to her. Pet’r Br. at 14. Ostensibly, respondent has treated Ms. Doe differently. Respondent has not explained why it agrees to resolve some cases but not other cases. See Resp’t Br. at 13. Ultimately, respondent does not need to provide an explanation in this forum because decisions about how to litigate a case, including decisions whether to settle a case, are made by members of the Executive Branch. See 28 U.S.C. § 517; 28 C.F.R., part 0, subpt. Y, app.

17, 2009). Unlike resolutions based upon settlements, public policy does not require ignoring the decision in Schmidt.

While a decision by one special master may be considered, an earlier decision is not binding precedent for another special master. Hanlon v. Sec’y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998), aff’d, 191 F.3d 1344 (Fed. Cir. 1999). After careful consideration, the undersigned does not find Schmidt to be persuasive. First, some evidence is different. For example, in Schmidt, the treating doctor testified on behalf of the petitioner. Id. at *13. Ms. Doe did not introduce statements from treating doctors supporting her claim. The differences in evidence may explain why different outcomes occur in cases with ostensibly similar allegations. See Lampe, 219 F.3d at 1368 (noting that many cases in the Vaccine Program “turn[] on [their] facts.”).

Second, some of the overlapping evidence appears to have been given different weight. For example, Schmidt interpreted Dr. Kerr’s article as supporting a finding that vaccines can cause transverse myelitis. Id. at *11. In contrast, for the reasons discussed above, the undersigned finds more significant Dr. Kerr’s statement that a series of case reports “must be viewed with caution, as it is entirely possible that two events occurred in close proximity by chance alone.” Exhibit 21, tab A (Kerr) at 341. See Whitcotton v. Sec’y of Health & Human Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996) (stating “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.”).

f. Epidemiology

Epidemiology is “the science concerned with the study of the factors determining and influencing the frequency and distribution of disease, injury, and other health-related events and their causes ... to prevent and control their development and spread.” Dorland’s at 626. When epidemiological studies are presented, “a special master may consider [them] in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.” Andreu, 569 F.3d at 1379.

The parties have different views about the epidemiology. Dr. Tornatore did not rely upon epidemiology. Tr. 55-63. He is aware that there are epidemiological studies that do not show an increased incidence of neurological problems after the flu vaccine. Tr. 59. The lack of epidemiological studies supporting Dr. Tornatore’s theory is not fatal to Ms. Doe’s claim because a petitioner may prevail without introducing epidemiological studies. Althen, 418 F.3d at 1279-1280.

Respondent filed three epidemiological studies that investigated whether the flu vaccine affects demyelinating diseases. Exhibit C, tab 6 (A.E.Miller et al., A multicenter, randomized, double-blind, placebo-controlled trial of influenza immunization in multiple sclerosis, 48 Neurology 312 (1997)); exhibit C, tab 7 (Christian Confavreux et al., Vaccinations and the Risk of Relapse in Multiple Sclerosis, 344 No. 5, N Engl J. Med 319 (2001)); exhibit C, tab 8 (Frank

DeStefano et al., Vaccinations and Risk of Central Nervous System Demyelinating Diseases in Adults, 60 Arch Neurol 504 (2008)). These studies failed to detect any increased incidence of a demyelinating disease after the flu vaccine. Id.; see also tr. 58-59. From these studies, Dr. Bielawski and respondent concluded that they are “evidence that the influenza vaccine is not a causative agent for transverse myelitis.” See Resp’t Br. at 21, quoting tr. 128 (testimony of Dr. Bielawski).

To the extent the epidemiological studies have any evidentiary significance, they are in line with the general conclusion that Ms. Doe has failed to present preponderant evidence that the flu vaccine can cause transverse myelitis. These studies have not detected an increased incidence of transverse myelitis among people who received the influenza vaccine. These studies suggest, but do not prove, that the occurrence of transverse myelitis after receiving the influenza vaccine was a coincidence. This suggestion, in turn, is further supported by the relative rarity of case reports noting that flu vaccine preceded the onset of transverse myelitis. If flu vaccine were causing transverse myelitis in very rare cases, then there probably would be more reports associating flu vaccine and transverse myelitis in the literature. This expectation was not met because the record contains fewer than ten such cases. So, on the whole, the epidemiology does not favor finding causation in this case.

It is important to emphasize that these epidemiological studies have relatively little value in determining whether Ms. Doe has established, by a preponderance of the evidence, that the flu vaccine can cause transverse myelitis. Respondent appears to have filed the epidemiological studies as one way “to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case-in-chief.” Bazan, 539 F.3d at 1353. Ms. Doe’s evidence on the first element of Althen has been discussed in the proceedings sections. As explained in those sections, the proof that Ms. Doe has offered has not been persuasive. Because Ms. Doe’s own evidence fails, respondent’s rebutting evidence is superfluous. The same result would have been reached even if the epidemiological evidence had not been filed or were not considered.

g. Summary

The preceding sections have divided Ms. Doe’s evidence into various categories. The categorization brings to the front the recurring failing in Ms. Doe’s attempt to establish, by a preponderance of the evidence, that the flu vaccine can cause transverse myelitis.

Ms. Doe relies upon Dr. Tornatore’s opinion and Dr. Tornatore’s opinion rests upon certain medical articles, case reports, and animal models. Collectively, these sources supply a basis for Dr. Tornatore to infer that the flu vaccine can cause transverse myelitis. In other words, because Dr. Tornatore must infer a causal relationship, these sources are “circumstantial evidence” that are offered as support for Ms. Doe’s claim.

Circumstantial evidence is a permissible form of evidence. Capizzano, 440 F.3d 1325-26. Yet, there is a difference between allowing petitioners to submit circumstantial evidence and requiring special masters to find the circumstantial evidence persuasive. An expert’s opinion is

not always persuasive because a “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” Moberly, 592 F.3d at 1324. In cases in which the underlying material does not support the conclusion drawn by the expert, the expert’s opinion may be rejected as unreliable. “[T]rained experts commonly extrapolate from existing data, but nothing . . . requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion.” General Electric, 522 U.S. at 146.

In addition to evidence (the exhibits and testimony in this case), Ms. Doe presents arguments regarding settlements in other cases and Schmidt. These arguments, too, have been considered but do not meaningfully advance petitioner’s case for the reasons explained above.

At the end, the simple question is: has Ms. Doe established, on a more likely than not standard, that flu vaccine can cause transverse myelitis. The answer is no. A preponderance of evidence in this case does not support a finding that the flu vaccine can cause transverse myelitis.

B. Althen Prong Two

The second prong of Althen is “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. This phrasing is sometimes simplified to asking did the vaccine cause the injury. See Pafford, 451 F.3d 1359-60 (affirming of special master’s “can cause” and “did cause” test as consistent with the Althen test). In determining whether petitioners have introduced preponderant evidence on this element, special masters have been instructed to consider the views of treating physicians. Capizzano, 440 F.3d 1326.

Ms. Doe argues that she supplied such evidence. Ms. Doe cites to her affidavit in which she avers that her treating neurologist, Dr. Sriram, told her to file a claim in the Vaccine Program. Pet’r Br. at 18, citing exhibit 20 at 1. Ms. Doe’s second-hand assertion is not strong evidence about Dr. Sriram’s views.

Dr. Sriram’s opinions are expressed in the reports that he created while he was treating Ms. Doe. Dr. Sriram stated that Ms. Doe’s transverse myelitis was of “unknown etiology.” Exhibit 9 at 55. As a medical record created to promote Ms. Doe’s treatment, this statement by Dr. Sriram is presumed to set forth Dr. Sriram’s view accurately. Cucuras v. Sec’y of Health & Human Servs., 993 F.2d 1515, 1528 (Fed. Cir. 1993). Ms. Doe’s affidavit, which was created two and a half years after Dr. Sriram treated her, does not rebut the presumed accuracy of Dr. Sriram’s report. Ms. Doe may have misheard, misunderstood, or innocently erred in remembering her conversation with Dr. Sriram. Between the two pieces of evidence that are relevant to Dr. Sriram’s views, Dr. Sriram’s statement and Ms. Doe’s affidavit, the stronger

evidence about Dr. Sriram's views is his own statement. Therefore, Dr. Sriram's statement that Ms. Doe's transverse myelitis was of "unknown etiology" will be credited.¹³

Dr. Sriram's statement that he could not determine the etiology of Ms. Doe's transverse myelitis is consistent with the statements of other doctors who treated Ms. Doe. See, e.g., exhibit 6 at 10 (Dr. Mobley). Other than her own affidavit relaying the statement of Dr. Sriram, Ms. Doe has not identified any treating doctor who opined that the flu vaccine caused her transverse myelitis. See Pet'r Br. at 17-18.

In addition to the argument about Dr. Sriram, Ms. Doe presents the opinion of Dr. Tornatore who employed the following logic: Ms. Doe received a vaccine that can cause transverse myelitis, she suffered transverse myelitis, the onset of symptoms of transverse myelitis occurred within a medically appropriate time, and no other cause of her transverse myelitis has been identified. From these propositions, Ms. Doe argues "it is logical to conclude that the vaccine is the reason for her [transverse myelitis] and it is illogical to conclude otherwise." Pet'r Br. at 18.

The Federal Circuit has already rejected this reasoning. In Moberly, the petitioners, who were represented by the same law firm that represents Ms. Doe, made essentially the same argument. The Federal Circuit summarized the facts about the child, Molly Moberly: "Molly was healthy before she received her second DPT vaccination; she suffered seizures within 36 hours of receiving the vaccine; DPT vaccine is capable of causing seizures and permanent brain damage; and no alternative cause of her condition has been identified." The Federal Circuit stated that "the problem with that evidence is that it amounts at most to a showing of temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the ultimate neurological injury." This proof, according to the Federal Circuit, was not sufficient. Thus, the Federal Circuit found that the special master's decision to deny compensation was not arbitrary or capricious. Moberly, 592 F.3d at 1323.

The reasoning in Moberly supports a finding that Ms. Doe has failed to establish the "logical sequence of cause and effect" required by Althen. Setting aside the point regarding Dr. Sriram, Ms. Doe's evidence seems to be no better than the insufficient evidence in Moberly. The same result is followed here. Ms. Doe has not demonstrated, by a preponderance of evidence, the second prong from Althen.

¹³ Respondent points out that Ms. Doe initially sought to subpoena Dr. Sriram to a deposition and then declined to pursue this request. Resp't Br. at 24, citing Pet'r Mot., filed April 17, 2009. From this sequence of events, respondent argues that an adverse inference can be drawn from Ms. Doe's failure to obtain testimony from Dr. Sriram. Id. Ms. Doe replied that because Dr. Sriram has been retained by the respondent in other cases in the Vaccine Program, "it is clear that Dr. Sriram believed that he was ethically bound to advise [Ms. Doe] to file a claim, but, having served as an expert for the respondent, was uncomfortable testifying on behalf of petitioner." Pet'r Reply at 22. Although Dr. Sriram's discomfort is far from "clear," no adverse inference has been drawn from the lack of testimony from Dr. Sriram.

C. Althen Prong Three

Although Ms. Doe has failed to establish the first and second prongs of Althen, the remaining prong will also be discussed. To be entitled to compensation, Ms. Doe must establish “a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278. She has done so.

Ms. Doe received the flu vaccine on October 8, 2004. Exhibit 13 at 1. On December 12, 2004, Ms. Doe visited an emergency room because she was retaining urine. She also reported that she had been having a worsening pain in her abdomen for approximately two months.

Both experts stated that if it were assumed that the flu vaccine can cause transverse myelitis, then the timing of events in Ms. Doe’s case was consistent with a finding that the flu vaccination caused her transverse myelitis. Dr. Tornatore stated that the autoimmune process may take as long as 10 weeks. Tr. 48. Dr. Bielawski agreed that the timing in Ms. Doe’s case was appropriate. Tr. 163. Therefore, Ms. Doe has established the “proximate temporal relationship.”

A finding of a proximate temporal relationship does not, by itself, establish that Ms. Doe is entitled to compensation. The Federal Circuit has consistently stated that timing, by itself, does not demonstrate causation-in-fact. Moberly, 592 F.3d at 1323 (quoting Althen, 418 F.2d at 1278); Grant, 956 F.2d at 1148. In addition to an appropriate temporal relationship, successful petitioners also establish “(1) a medical theory causally connecting the vaccination and the injury; [and] (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. For the reasons explained above, Ms. Doe’s case was lacking on these other two elements.

V. Conclusion

Ms. Doe has not established, by preponderant evidence, the elements required by Althen. Therefore, she is not entitled to compensation. The Clerk’s Office is instructed to enter judgment in accord with this decision if a motion for review is not filed.

IT IS SO ORDERED.

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