

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

MARY SCHOEBERLEIN,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 14-697V

Special Master Christian J. Moran

Filed: January 11, 2018

entitlement, bench ruling, flu
vaccine, Wegener's granulomatosis.

Mark T. Sadaka, Mark T. Sadaka, LLC, for petitioner;

Darryl R. Wishard, United States Dep't of Justice, Washington, DC, for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION¹

Ms. Schoeberlein claims that an influenza vaccination, given to her on September 13, 2012, significantly aggravated her pre-existing (but undiagnosed) condition formerly known as Wegener's granulomatosis, now known as granulomatosis with polyangiitis ("GPA"). After Ms. Schoeberlein filed her medical records, the undersigned directed that the expert reports would constitute the experts' direct testimony at any hearing. The parties filed a series of reports from Dr. Eric Gershwin (petitioner's expert) and Dr. Thomas Forsthuber (respondent's expert).

A hearing was held on January 10, 2018. After the parties submitted all their evidence, the undersigned issued a bench decision, finding that Ms. Schoeberlein had failed to establish that she was entitled to compensation. See Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 704 n. 18 (2008) (noting "[e]ven a special master's ruling on entitlement may be delivered from the bench, with no written opinion").

The undersigned is issuing this document for two reasons. First, this document will become available to the public pursuant to 42 U.S.C. § 300aa—12(d)(4).

Second, this document provides an abbreviated recitation for the basis of decision. See Hebern v. United States, 54 Fed. Cl. 548 (2002) (example of a judge from the United States

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Court of Federal Claims formalizing a bench ruling denying a motion for review). As explained in the bench ruling, the undersigned considered all the evidence, including the medical records, expert reports, medical articles, and oral testimony. The undersigned's consideration of this evidence began when the evidence was received, as outlined in the recitation of the case's procedural history. See also Vaccine Rule 5 (providing for a framework in which special masters evaluate the evidence, and even make tentative findings and conclusions, prior to issuing a decision).

Ms. Schoeberlein bore a burden to establish her case on a more-likely-than-not basis. 42 U.S.C. § 300aa-13(a); Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). The elements of a significant aggravation case are set out in Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135 (2009). See W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013).

As explained in more detail in the bench ruling, Ms. Schoeberlein failed to meet her burden of proof for several overlapping reasons. These include the following:

First, Ms. Schoeberlein relied upon an expert, Dr. Gershwin, who has relatively little experience in treating patients with GPA. While Dr. Gershwin's relatively small amount of direct experience with GPA actually exceeds the negligible experience of Dr. Forsthuber, Ms. Schoeberlein bears the burden of presenting a persuasive case. See Dean v. Sec'y of Health & Human Servs., No. 13-808V, 2017 WL 2926605 at *18 n.12 (Fed. Cl. Spec. Mstr. June 9, 2017) (noting that the opinions of an expert need not be accepted merely because they are more credentialed on the topic than the opposing expert).² Dr. Gershwin's relative unfamiliarity with GPA appeared to affect his opinion as he changed / revised / clarified his written reports during his oral testimony. Overall, Dr. Gershwin's presentation and demeanor reduced his credibility.

Second, Ms. Schoeberlein did not establish the persuasiveness of Dr. Gershwin's theory that the flu vaccination would prompt the production of antibodies contributing to a worsening of Ms. Schoeberlein's GPA (known as bystander activation). Dr. Gershwin's pre-trial reports did not explain the bystander activation theory in either an understandable or persuasive way. The literature filed by the petitioner did not illuminate this topic. In contrast, Dr. Forsthuber established, much more persuasively, that bystander activation is the flimsiest of the widely proposed hypotheses offered to try to explain how autoimmune diseases originate. Dr. Forsthuber also supported his opinion with studies that showed that the flu vaccination tends to elicit antibodies to flu antigens only. These studies undermined Dr. Gershwin's opinion.

Third, the problems with the bystander activation theory make crediting Dr. Gershwin's opinion regarding the timing difficult. See Langland v. Sec'y of Health & Human Servs., 109 Fed. Cl. 421, 443 (2013) ("With no reputable theory as to how the vaccination could cause the injury, [examining the temporal relationship] is not possible."). Despite opportunities in pre-hearing reports and in questioning at the hearing, Dr. Gershwin did not present a clear opinion about how long the production of antibodies via the bystander activation theory would take and, accordingly, how long it may take for symptoms to begin developing. His inability to do so was

² Both parties would have benefited from retaining doctors who routinely treat patients with vasculitis or kidney disease.

consistent with the theory's lack of scientific rigor.³ This lack of clarity was a problem because Ms. Schoeberlein started having nausea, which can be a symptom of renal disease, the day of the vaccination. Exhibit 6 at 6. Whether or not this nausea was consistent with petitioner's bystander activation hypothesis—or refutes petitioner's hypothesis by showing that she began showing symptoms of renal disease too early for the vaccine to be the cause—is undeterminable due to the weakness of petitioner's medical theory. As noted in Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008), special masters may consider whether the symptoms arose before the time predicted under petitioner's medical theory.

Finally, and perhaps most importantly, a preponderance of the evidence established that Ms. Schoeberlein's course appeared to track the predicted course for untreated GPA. Dr. Gershwin and Dr. Forsthuber agreed that by July 2012, Ms. Schoeberlein was manifesting symptoms of GPA—her nosebleeds. While her treating doctors did not recognize that she was suffering from GPA until January 2013, by the time her kidneys were failing, this was consistent with testimony and articles from both parties indicating that GPA often goes undiagnosed. Dr. Forsthuber established—and Dr. Gershwin agreed—that before doctors learned how to treat GPA, patients often died of kidney failure within six months of onset. Thus, the progression of Ms. Schoeberlein's GPA was not quicker than expected and was not more severe than expected. In fact, Dr. Forsthuber stated that Ms. Schoeberlein's disease progression has been better than average.

In summary, for the reasons noted above and further elucidated in the bench ruling, the undersigned finds that the petitioner has not met her burden of proof under the Vaccine Act. The evidence does not support, by a preponderance of the evidence, that Ms. Schoeberlein's vaccinations significantly aggravated her GPA.

The undersigned further directs the Clerk's Office to enter judgment based upon the decision in this case if a motion for review is not filed. When the time for filing a motion for review (see Vaccine Rule 23) begins to run is for an appellate tribunal to decide.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

³ As the United States Supreme Court noted in Daubert v. Merrell Dow Pharmaceuticals, Inc., falsifiability of a hypothesis is a central characteristic of scientific knowledge. 509 U.S. 579, 593 (1993).