

OFFICE OF SPECIAL MASTERS

Reissued July 28, 2005
No. 99-670V
Not for Publication

 JOHN DOE, *
 *
 Petitioner, *
 *
 v. *
 *
 SECRETARY OF THE DEPARTMENT OF *
 HEALTH AND HUMAN SERVICES, *
 *
 Respondent. *

Michael Roberts, Cincinnati, OH, joined by Clifford J. Shoemaker, Vienna, VA, for petitioner.
Catherine E. Reeves, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION ON REMAND¹

¹ This unpublished decision was initially issued on July 14, 2005, with the proviso that because it contains a reasoned explanation for the special master's action in this case, the special master intended to post this decision on remand on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. On July 28, 2005, petitioner's counsel orally moved the undersigned to redact the decision. The special master agreed and reissues this unpublished decision in redacted form.

Former Special Master E. LaVon French issued a decision in this case on October 5, 2004, followed by an Errata Decision, dated November 2, 2004, dismissing the case. On December 16, 2004, former Special Master French withdrew her entitlement decision of October 5, 2004 and issued a redacted decision, captioned John Doe, issued under the date of October 5, 2004. Doe v. Secretary of HHS, No. 99-670V, 2004 WL 3321302 (Fed. Cl. 2004).

Petitioner appealed the entitlement decision. On April 19, 2005, the Honorable Francis M. Allegra issued an Order responding to petitioner's claim that two articles ("A case-series of adverse events, positive re-challenge of symptoms, and events in identical twins following hepatitis B vaccination: analysis of the Vaccine Adverse Event Reporting System (VAERS) database and literature review," by M.R. Geier and D.A. Geier, 22 *Clinical and Experimental Rheumatology* 749-55 (2004); and "Autoimmune hazards of hepatitis B vaccine," by Marc Girard, 4 *Autoimmunity Reviews* 96-100 (2005)) constituted "newly-discovered evidence," justifying reopening this case for a re-examination of former Special Master French's entitlement decision. Judge Allegra remanded the case to the Office of Special Masters "in order to allow consideration as to whether the two articles cited above impact, and warrant modification of, any of the findings or conclusions previously reached by Special Master French. ... [T]he court emphasizes that the remand is limited to consideration of the cited articles...."

Judge Allegra followed his Order of April 19, 2005 with an Order dated June 2, 2005, after petitioner filed a motion for clarification of Judge Allegra's April 19th Order and respondent responded to petitioner's motion. Judge Allegra denied petitioner's motion for clarification, stating "An entire new trial of this matter is not warranted."

This case was transferred to the undersigned on June 7, 2005.

Former Special Master French's Findings and Conclusions

In order to determine whether the two articles impact, and warrant modification of, any of former Special Master French's findings or conclusions, the undersigned will summarize those findings and conclusions first before considering the Geiers' article and the Girard article.

In an exhaustive review of the many medical records, doctors' opinions, and theories in this case, former Special Master French held the following:

1. Petitioner received one hepatitis B vaccination, on either June 16 or 18, 1997. 2004 WL 3321302, at *6. At the time he received his vaccination, he had had a sore throat and mild fever that persisted for three weeks. Id.

2. Petitioner alleged that hepatitis B vaccine caused him anaphylaxis and anaphylactic shock. Id. at *1, *3, *8. Petitioner did not present any evidence to support this allegation, and former Special Master French rejected it. Id. at *8.

3. The parties agreed that petitioner has chronic fatigue syndrome (CFS). Id. at *4.

4. Petitioner claimed onset of rapid heartbeat, fever, aches, and pains within two or three hours of receiving hepatitis B vaccine. Id. at *7. His subsequent history was episodic. Id. at *9, *15. Sometimes, he felt fine. Id. Other times, he had difficulty with memory, aches, pain, and walking. Id. at *7-*9. His pre-vaccination history shows episodic pain, fatigue, dizziness, and disorientation. Id. at *5-*6.

5. Petitioner developed thyroid cancer for which he was treated by surgery. Id. at *20.

Former Special Master French held that petitioner did not prove that hepatitis B vaccine causes CFS. Id. at *25. Continuing her analysis of the evidence, former Special Master French

held that, assuming arguendo petitioner had proved that hepatitis B vaccine can cause CFS, he failed to prove that it caused his CFS. Id. at *32. She comments that several of the symptoms he suffered after vaccination were documented before vaccination. Id. at *26, *31. And these same symptoms are indicative of CFS. Id. at *26. She could not say that his condition would be any different absent hepatitis B vaccine. Id. Moreover, petitioner did not prove that hepatitis B vaccine was a more likely cause of his CFS than the virus he had at the time of vaccination (viruses can cause CFS). Id. at 27.

The Geiers' Article

The first article to which Judge Allegra's remand order refers is the Geiers' article.

The Geiers' article describes four categories of cases of illness following hepatitis B vaccination. Category I deals with arthritis, rheumatoid arthritis, systemic lupus erythematosus, optic neuritis, Guillain-Barre syndrome, glomerulonephritis, pancytopenia/thrombocytopenia, and myelitis in the scientific literature. Category I does not deal with CFS and is therefore irrelevant to this case.

Category II deals with arthritis, rheumatoid arthritis, myelitis, optic neuritis, multiple sclerosis, Guillain-Barre syndrome, glomerulonephritis, pancytopenia, and thrombocytopenia in the VAERS (Vaccine Adverse Event Reporting System) database. Category II does not deal with CFS and is therefore irrelevant to this case.

Category III does deal with chronic fatigue, among other conditions, but only in the context of positive re-challenge adverse events reported to VAERS. Petitioner in this case had only one hepatitis B vaccine. In order to have a positive re-challenge, he would have had to have at least two vaccinations (so that the second or third vaccination was a positive re-challenge to

his immune system). Since there is no positive re-challenge in this case, category III is irrelevant to this case.

Category IV deals with fatigue-myalgias-eye pain as well as other fatigue, myalgia, and pain conditions, among other conditions in the scientific literature, but not specifically with CFS. Moreover, it is in the context of positive re-challenge or significant exacerbations of reactions after recombinant hepatitis B vaccine. Since petitioner had just one hepatitis B vaccination, he did not have either a positive re-challenge or a significant exacerbation of a reaction to a prior hepatitis B vaccination. Therefore, category IV is irrelevant to this case.

The undersigned concludes that the Geiers' article does not impact upon or warrant modification of former Special Master French's findings and conclusions in this case.

The Girard Article

The second article to which Judge Allegra's remand order refers is the Girard article.

Dr. Girard discusses, inter alia, the relationship of hepatitis B vaccine and CFS by noting "an early alert on the risk of chronic fatigue syndrome [citing a Canadian report] which was later refuted [citing another Canadian report]...." Article at 98. Dr. Girard refers to himself as "the single Author" and states that he considers the refutation of the early alert to be on weak evidence (without specifying why) and says "the single Author's experience collected at least a dozen of cases of post-vaccination fatigue syndrome, in which HBV was by far the most likely cause." Id.

Dr. Girard does not cite any article to support his assertion that hepatitis B vaccine caused more than "at least" one dozen cases of CFS. Moreover, Dr. Girard does not give a basis for his

conclusion that hepatitis B was “by far” the most likely cause of more than one dozen cases of CFS. The reader is just supposed to accept Dr. Girard’s conclusion without any support.

The Girard article hardly manifests scientific rigor with its bald assertions absent data.

Dr. Girard admits that much in his concluding sentence:

More research is necessary and there is a need that the scientific community exerts pressure on health authorities to obtain that all existing data become available for peer-reviewed debate. [Dr. Girard’s native language is French and some of his phraseology is strained.]

Article at 100.

Dr. Girard’s speculative conclusion about hepatitis B vaccine and CFS is more a plea for research in the area of vaccine adverse events rather than a temperate, scientific discussion of what data show. Apparently, the reason there is so little data in his article is that it has not yet been discovered by medical research or produced by health authorities.

Dr. Girard’s professional occupation may explain the bias he shows in his article. He describes himself “As a medical expert witness specialised in drug monitoring and pharmaco-epidemiology (and unfortunately *not* in immunology or auto-immunity)....” Article at 97 (emphasis included by the author). Since he functions as an expert witness in medical cases, and is not trained in immunology or autoimmunity, the undersigned finds Dr. Girard’s opinion as expressed in his article to be suspect.

The undersigned concludes that the Girard article, being speculative, unscientific, and biased, does not impact upon or warrant modification of former Special Master French’s findings and conclusions in this case.

CONCLUSION

The undersigned holds that neither of the two articles petitioner has presented as newly-discovered evidence has an impact upon or warrants modification of former Special Master French's findings and conclusions in this case because either the article is irrelevant (the Geiers' article) or the article is speculative, unscientific, and biased (the Girard article).

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master