

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

[Redacted]V

Filed: July 31, 2007

Published

JANE DOE/03,	*	
	*	
Petitioner,	*	[Redacted]V
	*	Motion to Reassign;
v.	*	Vaccine Rule 5;
	*	Vaccine Rule 8
SECRETARY OF THE DEPARTMENT	*	
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Reissued August 14, 2007¹

ORDER²

On July 13, 2007, petitioner filed a motion to reassign this case to another special master, contending that statements made during a Vaccine Rule 5 status conference on July 10, 2007 rendered such reassignment “necessary for the efficient administration of justice” under Vaccine Rule 3(c). Respondent filed a brief opposing the motion on July 23, 2007.

Petitioner’s motion evinces a misapprehension of the statutory role of the special master and the specific purpose of a status conference held under Vaccine Rule 5.

¹ Pursuant to Vaccine Rule 18(b), petitioner has objected to her name being published and requested that it be redacted from the published opinion to protect her privacy. The Court has accordingly replaced her name in the caption, text of the opinion, and Special Master’s decision with the pseudonym “Jane Doe,” and has redacted the case number from the published opinion. With these alterations, and a few typographical adjustments, the opinion is reissued.

² Because I have designated this order to be published, petitioner has 14 days to request redaction of any material “that includes medical files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire order will be publicly available. 42 U.S.C. § 300aa12(d)(4)(B).

Treating this motion as one for recusal, I find that there is no reasonable basis for me to recuse myself in this matter. However, in view of the Chief Special Master's statutory authority pursuant to 42 U.S.C. § 300aa-12(d)³ to designate a special master to handle a case, I am referring petitioner's motion to the Chief Special Master for his decision on whether this case should be reassigned.

I. Background

On April 2, 2007, after numerous delays, petitioner filed the expert report of Dr. Jeffery Alper, who opined that petitioner suffers from systemic lupus erythematosus ["SLE"] caused by hepatitis B vaccinations she had received.⁴ Petitioner's Exhibit ["Pet. Ex."] 21. In his eleven page opinion, Dr. Alper referenced and summarized several medical articles. Among these, Dr. Alper mentioned a study by "D.A. Geier," describing it as a "case controlled epidemiologic study" of adverse events involving hepatitis B vaccines reported to the vaccine adverse event reporting system ["VAERS"]. Later on the same page of his report, Dr. Alper referenced "[a]nother study by the same author" on the risk of developing an autoimmune disease following hepatitis B vaccination.⁵ Pet. Ex. 21, p. 8. However, Dr. Alper only listed one article by D.A. Geier in his list of eleven references, an article entitled "A Review of Hepatitis B Vaccination." *Id.*, References (this page of Pet. Ex. 21 is not numbered). That article's lead author is Dr. Mark Geier; his son, David Geier, is the second author listed. Between the filing of the expert report on April 2, 2007 and the Rule 5 status conference on July 10, 2007, petitioner failed to file any of the cited medical articles as exhibits in this case.

Respondent filed a Vaccine Rule 4(c) report accompanied by the expert medical opinion of Dr. Bento Mascarenhas on June 6, 2007. Respondent likewise failed to file copies of the articles upon which Dr. Mascarenhas relied for his opinion that the hepatitis B vaccine did not cause petitioner's SLE.

The record being complete (other than the missing reference materials) and the parties having tentatively agreed on a hearing date of September 14, 2007, I set a

³ Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

⁴ Commonly known as "lupus," systemic lupus erythematosus is a chronic inflammatory disease. It is characterized by severe vasculitis, renal problems, and skin and nervous system lesions. Diagnosis is based on objective physical examination and laboratory tests for antinuclear antibody in the cerebrospinal fluid and a positive lupus erythematosus cell reaction, as well as on subjective findings. MOSBY'S MEDICAL DICTIONARY at 1813 (7th ed. 2006).

⁵ The Geier article listed on the references page of Dr. Alper's report does not include the data on relative risks associated with SLE that appear on page 8 of his report.

Vaccine Rule 5 status conference for July 10, 2007. Vaccine Rule 5 is entitled “Informal Review and Tentative Findings and Conclusions.” The rule requires a special master to conduct an informal conference “to review the materials submitted, evaluate the respective positions, and orally present tentative findings and conclusions.” It is intended to be a candid discussion of the merits of the parties’ evidence, arguments, and positions. Section VI of the Guidelines for Practice Under The National Vaccine Injury Compensation Program⁶ [“Guidelines”] provides additional information concerning the Rule 5 status conference. That section is set forth in its entirety below:

Under the Program, claim resolution will be more expeditious and less formal than under traditional litigation. To this end, Vaccine Rule 5 sets forth a procedure that should speed and simplify the decision-making process. Under the Rule, the special master, after reviewing the petition and respondent’s report, conducts an informal conference (either in person or by telephone) at which the special master (1) gives each party an opportunity to address the other’s position, (2) states a tentative view as to the merits of the case, and (3) establishes with the parties what issues remain to be addressed and the most efficient means for deciding those issues.

The success of the “Rule 5 conference” depends upon the completeness of the petition and respondent’s report. For that reason, it is essential that each party develop fully its case **before** filing the petition or report, and set forth **fully and completely** the substance of its case therein. Information cannot be withheld or acquired later to be supplied at subsequent stages of the proceedings. The benefits from this early, full discussion of the case’s substance include:

- early notice of any deficiencies in the case in time to rectify such deficiencies;
- a third party’s view of the merits of the case, possibly fostering settlement;
- if settlement is not possible, an opportunity to narrow the issues through stipulation;
- if further proceedings are necessary, a discussion of the nature and timing of such proceedings; and

⁶ The current version of the Guidelines is dated November 2004 and may be found at www.uscfc.uscourts.gov.

- where appropriate, a final decision.

Please note, however, that any tentative conclusions noted by the special master at the Rule 5 conference are just that – **tentative**, as well as “off the record.” The special master’s comments will not have any official status and cannot be “relied upon” in any formal sense. Additional evidence, argument, or further consideration by the special master may change the special master’s view of the case. (underlining added).

During this telephonic Rule 5 status conference, I followed my usual practice of having my law clerk take notes while I discussed problem areas and strengths of each side’s case with the dual goals of encouraging the parties to consider settlement and of focusing evidentiary presentations for any subsequent hearing. I initially commented that neither counsel had filed the articles upon which the expert witnesses had relied and I requested, in view of the September 14, 2007 hearing date, that the parties do so at the earliest opportunity, because I carefully read each article filed prior to the hearing.

I then noted two problem areas in petitioner’s case: the destruction of some of the medical records for the time period around onset of petitioner’s symptoms, and Dr. Alper’s citation of articles principally authored by Dr. Mark Geier.⁷ I suggested that, in view of the criticisms leveled at Dr. Geier and his research, petitioner would be better served if her expert could opine favorably at the hearing without relying on the cited articles. I indicated that there was no need to file these articles because I had already read them. I did not prohibit petitioner from filing any article. To place my remarks in context, Dr. Alper’s report discussed several other articles and referenced ten other articles supporting his view of vaccine causation and I expressed no other opinion on Dr. Alper’s report.

I did not offer any opinion on whether petitioner can establish vaccine causation of her condition, only that I found that the articles authored by Dr. Geier unpersuasive and not scientifically sound, based on my prior reading of the articles and critiques of them. I am also aware that Dr. Geier is trained as a geneticist and obstetrician, not an immunologist, epidemiologist, or rheumatologist, and that my fellow special masters⁸

⁷ Petitioner’s Exhibit 21, the article listed on the references page of Dr. Alper’s report, has been severely criticized. Respondent’s Exhibits [“Res. Ex.”] H, I, and J, filed with respondent’s brief on the motion to reassign, are representative of the criticisms I have previously seen leveled at this article and its authors’ use of VAERS data to support their opinions regarding vaccine causation of various illnesses.

⁸ *Thompson v. Sec’y, HHS*, No. 99-436, 2003 WL 21439672 at *19 (Fed. Cl. Spec. Mstr. May 23, 2003)(special master found Dr. Geier unqualified to testify about infantile spasms and found his testimony filled with speculation); *Haim v. Sec’y, HHS*, No. 90-1031V, 1993 WL 346392 at *15 (Fed. Cl. Spec. Mstr. Aug. 27, 1993) (“Dr. Geier’s testimony is not reliable, or grounded in scientific methodology and procedure. His testimony is merely subjective belief and unsupported speculation.”); *Marascalco v. Sec’y,*

and several other judges⁹ have opined unfavorably on his qualifications and testimony as an expert.

I then turned to respondent's case, noting a more significant and systemic problem with respondent's expert report, in that Dr. Mascarenhas appeared to be applying a far higher standard for determining causation than is actually required by the Vaccine Act. I then quoted several sections of Dr. Mascarenhas' report in which he appeared to require scientific certainty rather than probability before he would accept that a vaccine caused petitioner's illness.

Counsel for both sides commented on my evaluation of the case, with petitioner's counsel responding affirmatively to my comments and respondent's counsel indicating that she was aware that her expert had difficulty separating medical certainty from legal causation. After inquiring whether the parties saw any likelihood of settling this case and receiving indications that they did not, we discussed the hearing location and logistics of witness testimony.¹⁰

HHS, No. 90-1571V, 1993 WL 277095 at *5 (Fed. Cl. Spec. Mstr. July 9, 1993) (where the special master described Dr. Geier's testimony as intellectually dishonest); *Aldridge v. Sec'y, HHS*, No. 90-2475V, 1992 WL 153770 at *9 (Cl. Ct. Spec. Mstr. June 11, 1992) (special master found Dr. Geier's reliance on statement from two outdated medical textbooks which was not included in the current edition to be disingenuous. "Were Dr. Geier an attorney, he would fall below the ethical standards for representation."); *Ormechea v. Sec'y, HHS*, No. 90-1683V, 1992 WL 151816 at *7 (Cl. Ct. Spec. Mstr. June 10, 1992) ("Because Dr. Geier has made a profession of testifying in matters to which his professional background [obstetrics and genetics] is unrelated, his testimony is of limited value to the court."); *Daly v. Sec'y, HHS*, No. 90-590V, 1991 WL 154573 at *7 (Cl. Ct. Spec. Mstr. July 26, 1991) ("[T]his court is inclined not to allow Dr. Geier to testify before it on issues of Table injuries. Dr. Geier clearly lacks the expertise to evaluate the symptomatology of the Table injuries and render an opinion thereon.").

⁹ *Piscopo v. Sec'y, HHS*, 66 Fed. Cl. 49 (2005) (special master did not abuse his discretion in determining that Dr. Geier did not have the education, training or experience to proffer a reliable opinion on the cause of petitioner's autoimmune disorder); *Graham v. Wyeth Laboratories*, 906 F.2d 1399, 1418 (10th Cir. 1990) (Dr. Geier's calculation error was of sufficient magnitude so as to warrant a new trial); *Doe v. Ortho-Clinical Diagnostics*, 440 F. Supp. 2d 465, 474 (M.D.N.C. 2006) (excluding Dr. Geier's testimony as based on "hypothesis and speculation."); *Redroot v. B.F. Ascher & Company*, 2007 U.S. Dist. LEXIS 40002 (N.D. Ca 2007) (excluding Dr. Geier as an expert, finding his testimony "not reliable.") *Pease v. American Cyanamid Co.*, 795 F. Supp. 755, 760-61 (D. Md 1992) (in granting summary judgment, trial judge noted inconsistencies in Dr. Geier's opinion); *Jones v. Lederle Laboratories, American Cyanamid Co.*, 785 F. Supp. 1123, 1126 (E.D. NY 1992) ("the court was unimpressed with the qualifications, veracity, and bona fides" of Dr. Geier); and *Militrano v. Lederle Laboratories, American Cyanamid Co.*, SCt NY, 3 Misc. 3d, 523, 537-38 (2003) (characterizing Dr. Geier's affidavit as "conclusory and scattershot" and "undermined by many of the materials submitted in support of it").

¹⁰ The information concerning what transpired during this status conference is taken from my recollections and from my law clerk's transcribed notes. My law clerk was present during the entire telephone status conference. This particular status conference was not recorded, following the usual practice in Vaccine Act proceedings.

II. Discussion

The legislative history of the Vaccine Act has been set forth at length in numerous opinions of special masters, judges of the Court of Federal Claims, and in opinions of the Federal Circuit. I will not repeat that history here, except to note that, by design, special masters are not merely passive recipients of information.¹¹

The Act requires that the Vaccine rules must “provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.” Section 300aa-12(d)(2)(E) (emphasis added). As Judge Wolski of the Court of Federal Claims has noted: “instead of being passive recipients of information, such as jurors, special masters are given an active role in determining the facts relevant to Vaccine Act petitions. One reason that proceedings are more expeditious in the hands of special masters is that special masters have the expertise and experience to know the type of information that is most probative of a claim.” *Doe v. Sec’y, HHS*, 76 Fed. C. 328, 338-39 (2007).

Special masters are required to consider all “relevant medical and scientific evidence contained in the record,” but are not required to give any particular “diagnosis, conclusion, judgment, test result, report, or summary” any weight. Section 300aa-13(b)(1)(emphasis added). “Nothing in the [Vaccine Act] requires the special master to concur with medical expert opinions as to the interpretation of scientific studies.” *Munn v. Sec’y, HHS*, 21 Cl. Ct. 345, 350 (1990). As noted in *Van Epps v. Sec’y, HHS*, 26 Cl. Ct. 650, 654 (1992), even an uncontroverted expert opinion is not binding on a special master. See also, *Thibaudeau v. Sec’y, HHS*, 24 Cl. Ct. 400, 403 (1991) (trier of fact not required to accept even an uncontradicted expert opinion). Special masters have wide discretion in how they conduct proceedings in vaccine injury cases. *Guillory v. U.S.*, 59 Fed. Cl. 121, 126 (2003).

Vaccine Rule 8 requires the consideration of “relevant and reliable evidence.” In

¹¹ The Guidelines also address the role of the special master. Section V provides in part:

The special master’s role is somewhat different from that of an adjudicator in traditional litigation. The special master will be more actively involved in the early stages of proceedings than is usually the case with a judge in a traditional civil proceeding, e.g., identifying and assisting a party in obtaining information, making tentative findings where appropriate (see Section VI, *infra*), asking the parties to clarify their positions, and working actively with the parties to develop a streamlined method for resolving each particular case. Further, in recognition of Congress’s intent that the special masters be more “inquisitorial” than in typical litigation, the special master will question witnesses where appropriate, ask for more documents when such a need is determined, and keep the parties informed at all stages concerning what further proof is necessary to prove their cases.

other courts, the determination that scientific evidence is relevant and reliable is performed by the judge in a gatekeeping role. If the proponent of scientific or technical evidence cannot establish its reliability, the evidence is excluded before trial.¹² *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U. S. 579, 589 (1993). *Daubert* has been applied to Vaccine Act cases by *Terran ex rel. Terran v. Secretary of Health and Human Services*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Within the Vaccine Program, that gatekeeping function may be performed by considering the evidence and determining its reliability as a threshold matter—excluding it before trial—or by hearing the evidence and deciding not to rely upon it in rendering an opinion.

Research purporting to show vaccine causation of various conditions which is based solely or primarily on VAERS data may not meet the reliability standards articulated in *Daubert* because the VAERS database is based on a passive surveillance system with inherent biases. See Respondent's Exhibit ["Res. Ex."] H (one of many articles critical of research based primarily on VAERS data because of the flaws inherent in the data collection process). See also, *Ryman v. Sec'y, HHS*, 65 Fed. C. 35 (2005) (special master not required to accord substantial weight to VAERS reports)

My comments regarding the Geier articles were not a prejudgment of the ultimate causation question or of the evidence presented by petitioner up to this point, and in context, could not reasonably be interpreted as such. Just as jurors are not expected to leave their common sense and knowledge of the ways of the world at the courthouse door, special masters are not required to disregard obvious problems in evidentiary reliability. When a conclusion is drawn from an artificially narrow sample population, that conclusion is inherently suspect as applied to any group other than that sample population. In the case of VAERS data, conclusions drawn only from the sample population of those who report vaccine reactions (which include both mandatory and highly discretionary reports) cannot be reliably applied to other populations. I also note that those reporting "vaccine reactions" are not required to be health care providers.

In hearing other vaccine act cases, I have encountered medical witnesses who were unaware of scientific criticism leveled at articles or studies upon which they based their opinions. The nature of the criticism and the degree to which the expert relied on the challenged data are factors affecting the weight I have given to that expert's ultimate opinion on causation. In attempting to assist this petitioner in presenting the strongest possible case for vaccine causation of her illness, I urged her counsel to caution her expert against relying on the Geier articles he cited. If efforts to implement Vaccine Rule 5's guidance are routinely answered by motions to reassign cases based

¹² I note that in federal court systems where the rules of evidence apply, medical or scientific journal articles would be considered hearsay and not considered as evidence at all, unless they qualified as "learned treatises" under Federal Rule of Evidence 803 (18) or some other evidentiary exception to the hearsay rule.

on “prejudgment” of the issues, special masters may cease having candid discussions at such conferences and let the chips fall where they may when an expert’s opinion is challenged at the causation hearing on the basis that it relied upon discredited or unreliable evidence.

In the instant case, I did not exclude petitioner’s expert’s opinion; in fact, I sought to make it stronger by recommending that petitioner remove a potential basis for questioning it. I did not rule that what has now been filed as Pet. Ex. 21 is inadmissible as unreliable evidence, although I might well do so if such a motion were to be made. I merely indicated my familiarity with the cited article and my conclusion that research of this nature based on VAERS data has significant reliability problems. If Dr. Alper chooses to base his testimony on the Geiers’ research, in whole or in part, I will consider and evaluate that testimony based on all the evidence before me, including Res. Ex. H, I, and J.

Finding no reasonable basis for petitioner’s request for case reassignment, I decline to recuse myself. However, this case is referred to the Chief Special Master for his decision on case reassignment.

IT IS SO ORDERED.

s/ Denise K. Vowell
Denise K. Vowell
Special Master _____