

OFFICE OF SPECIAL MASTERS

January 11, 2006
reissued redacted on January 24, 2006

SANDRA JACKSON, *
*
Petitioner, *
*
v. *
*
SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES, *
*
Respondent. *

No. 05-277V

ORDER¹

A telephonic status conference was held on January 10, 2006, during which petitioner’s counsel reiterated her intention to withdraw as counsel in this case. The undersigned stated petitioner’s counsel should file a Motion to Withdraw. Petitioner’s counsel stated that Sandra

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order 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. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Jackson, petitioner, intended to proceed pro se. The undersigned will hold a status conference to be set with Ms. Jackson and respondent's counsel.

Ms. Jackson should be aware that the only support² for her allegations comes from Dr. Burton A. Waisbren, Sr., about whom the undersigned has doubts about his credibility. Dr. Waisbren's opinion that Ms. Jackson has serum sickness, or multiple sclerosis, or a vaccine-induced demyelinating disease directly contradicts all the medical evidence in the records³ and respondent's expert report.⁴ There is nothing in Dr. Waisbren's opinion or notes to reflect that he actually read Ms. Jackson's medical records.

² Dr. Arlene Sagan, although she provided an expert opinion in this case, refused to give the basis for her opinion. Moreover, her medical records state, at Ex. 21, p. 1, on Jan. 5, 2004, that Ms. Jackson's symptoms are unlikely to be secondary to her hepatitis A vaccination due to the longevity of the symptoms (they did not resolve after three days).

³ Dr. Jesse Taber, a neurologist, stated on Feb. 24, 2004 that Ms. Jackson's neurological examination was normal and that [redacted] was probably playing a role in her symptoms. Ex. 5, p. 5. Dr. Taber stated there was no evidence for either post-vaccinal partial transverse myelitis or encephalomyelitis based upon the MRI scans. Ex. 5, p. 8. She had normal somatosensory evoked potentials of both her upper and lower extremities. Ex. 5, p. 15. Dr. Kevin L. Sullivan, ophthalmologist, noted no objective signs of optic neuritis on May 10, 2004. Ex. 11, p. 1. Dr. Martin D. Herman, surgeon, noted on June 15, 2004 no problems with Ms. Jackson's spine (even though Dr. Waisbren was opining that she had multiple sclerosis) and her brain MRI was normal. Ex. 12, p. 1. Dr. Herman thought her pain due to arthritis or muscle pain. Ex. 12, p. 3. Dr. [redacted] has treated Ms. Jackson for [redacted] since August 1994. Ex. 15, p. 1. Dr. Terrence C. Moisan noted on Jan. 27, 2005 that, although Ms. Jackson may have had a transient serum sickness reaction to hepatitis A vaccine, she did not have any residual immunologic or neurologic dysfunction. He found no objective evidence of any significant cardiovascular, respiratory, serologic, or neurologic abnormality. Ms. Jackson had no mechanical/structural or definable illness that would preclude her from resuming work. Ex. 19, p. 2. On Mar. 19, 2004, he noted that her cognitive function appeared normal. Her [redacted] may be heightening her complaints. Ex. 19, p. 4.

⁴ Dr. Alan I. Brenner, a rheumatologist, opined on behalf of respondent, in a report dated October 19, 2005, that hepatitis A vaccine was unlikely to be responsible for Ms. Jackson's chronic functional complaints. More likely, her underlying [redacted] condition and overlying ongoing [redacted] are responsible for her current condition. Ex. A.

For Ms. Jackson’s perusal, the undersigned attaches a workmen’s compensation decision, LORI MEYERS BAIN v. LIBERTY MUTUAL FIRE INSURANCE COMPANY, WCC No. 2002-0498, 2004 MTWCC 45 (Montana, Sept. 5, 2003), aff’d, 2005 MT 299N (Montana, Dec. 16, 2005) [copy attached], in which the claimant failed to prove that hepatitis B vaccinations caused her multiple illnesses. Dr. Waisbren testified on her behalf in that case and the judge found his testimony not credible. Below are excerpts from Judge Mike McCarter’s opinion:

¶74 Dr. Waisbren has impressive credentials. He has practiced medicine since 1944. (April 2, 2003 Tr. at 4.) He has taught at Marquette Medical School and the University of Minnesota Medical School. (Id. at 4.) He has taught immunology and established a clinic to treat immunological diseases, including multiple sclerosis. (Id. at 5.) He is board certified in internal medicine but not in immunology. (Waisbren Dep. at 22.)

¶75 Dr. Waisbren presently operates the Waisbren Clinic, a clinic that he describes as engaged in “investigative internal medicine.” (Waisbren Dep. Ex. 12.) He maintains a website on which he criticizes the hepatitis B vaccine. He contends that the vaccine is unsafe for universal use and should be limited to high-risk individuals. He believes that the vaccine may cause multiple sclerosis and other demyelinating diseases. (Waisbren Dep. Ex. 6.)

¶76 The claimant and Dr. Martin discovered Dr. Waisbren by searching the internet. (Martin Tr. Test. at 44; Waisbren Dep. at 14.)

¶77 Dr. Waisbren testified that the claimant’s first vaccination in January 1996 caused the following conditions: lichen planus, arthritis, chronic fatigue, ataxia (unsteadiness in standing), iritis (inflammation of the eye), demyelinating disease, and fibromyalgia, all of which he attributed to an autoimmune reaction to the vaccine. (Waisbren Dep. at 15-17, 87; April 2, 2003 Tr. at 53.) According to Dr. Waisbren, the second, March 1996, vaccination just “made whatever happened worse.” (Id. at 20.) In video conference testimony before the Court, he testified:

17 My diagnosis was that she had developed a
18 chronic autoimmune disease due to the hepatitis B
19 vaccination as has been reported throughout the medical
20 literature.

(April 2, 2003 Tr. at 21.)

¶78 I have carefully and seriously considered Dr. Waisbren’s opinions. However, I find them unpersuasive.

¶79 Initially, I note that it is abundantly clear that Dr. Waisbren is a **crusader** against the use of the hepatitis B vaccine except for high-risk individuals. He testified before Congress in 1999 against the hepatitis B vaccination policies of the Centers for Disease Control (CDC) and Food and Drug Administration (FDA). In his introductory remarks, he said, “I am here because I feel an injustice is being done to the children of this country. Included among these children are my sixteen grandchildren.” (Waisbren Dep. Ex. 5.) He helped plan the 20/20 Exposé which was aired in January 1999 and which triggered the claimant to bring forth her claim. (Waisbren Dep. at 14.) [Emphasis added.]

¶80 He has also written and self-published (13) a book advocating strict limitations on the use of the vaccine and arguing that it is responsible for a host of adverse reactions. The book is entitled The Hepatitis B Vaccination Program in the United States – Lessons for the Future. It is found in its entirety at Exhibit 7. Citations hereafter to the book are the page number of the book (“Waisbren Book”) rather than the page number of the exhibit.

¶81 In his book, Dr. Waisbren advocates appealing to the courts for injunctive relief limiting hepatitis B vaccination, writing:

I think the best hope to cure the most egregious injustice in the hepatitis B vaccine situation, the push for universal hepatitis B vaccination, is the obtaining of injunctive relief. I feel that if federal and/or state judges were presented the weakness in the arguments for universal hepatitis B vaccination that they would grant injunctions to stop this program. . . . It would seem apparent to me that a fair-minded judge would issue an injunction to halt this program until the need for and the ethics of this vaccination could be established.

(Waisbren Book at 69.)

¶82 In his book, Dr. Waisbren identifies the following autoimmune conditions as ones which can be caused by the hepatitis B vaccine:

- ? Multiple sclerosis.
- ? Meningoencephalitis.
- ? Chronic fatigue syndrome.
- ? Guillain-Barre syndrome. (14)

He further writes in the introduction, “This book will share my concerns regarding how proponents of vaccines have developed an intricate system by which the dangers of vaccinations have been withheld from the public in order to promulgate ambitious programs of vaccinations.” (Id.)

¶83 Dr. Waisbren’s bias is also reflected in his failure to adequately review the claimant’s medical history and records. He saw the claimant on two occasions, the first time on February 7, 2000, and the second on October 29, 2002, when the present litigation had “heated up.” (Waisbren Dep. at 27.)

¶84 In his initial report of February 7, 2000, Dr. Waisbren wrote that his opinion causally relating the claimant’s medical conditions to her hepatitis B vaccinations were “based on a careful review of her [claimant’s] medical records.” (Ex. 1 at 274.) In fact, Dr. Waisbren had not reviewed any of the claimant’s medical records. (Waisbren Dep. at 25.) The history he took from the claimant, which is set out in one and a half pages of his handwriting, was sorely incomplete when compared to the claimant’s medical records. Dr. Waisbren also testified that he “did not get any idea of multiple medical problems prior to” her vaccinations. (Id.) The claimant’s medical records are inconsistent with Dr. Waisbren’s impression.

¶85 On the claimant’s first visit, and without reviewing her medical records, Dr. Waisbren offered to testify on her behalf, writing, “As a public service, I will be glad to testify to the above [opinions] without charge to her attorney or the patient for the testimony as an expert who has also examined the patient.” (Waisbren Dep. at 22.) Dr. Waisbren has testified on behalf of plaintiffs in between five and ten cases involving hepatitis B vaccinations. (Waisbren Dep. at 6.) Despite his professed altruism in not charging the claimant for his testimony, the Court notes that he charged Liberty \$4,000 for a two hour and twenty-five minute deposition. (Waisbren Dep. at 4-5, 90.) With his extensive litigation experience, I doubt he was unaware that his deposition would be taken by Liberty.

¶86 When Dr. Waisbren saw the claimant a second time on October 29, 2002, he still had not reviewed any medical records except those of Dr. Martin, to whom he said he had talked and whom he characterized as “empathetic.” (Waisbren Dep. at 31.)

¶87 Other facts and testimony also lead me to reject Dr. Waisbren’s opinions.

¶87a Initially, Dr. Waisbren’s causation opinion is based upon his finding that the claimant suffered an “anaphylactoid type of reaction to the vaccine which is consistent with the type of reaction noted in the vaccine recovery act table” (Waisbren Dep. at 20 and Dep. Ex. 2; April 2, 2003 Tr. at 18.) His characterization of her reaction as “anaphylactoid type” is in turn based on the claimant’s report of immediate symptoms, including a feeling of electrical shock, loss of balance, vomiting, inability to visually focus, nausea, and flu-like symptoms. An anaphylactoid reaction is similar to an anaphylactic reaction. They differ principally in whether there is IGE antibody present. The antibody is present in anaphylactic reactions but not in anaphylactoid reactions. (Montanaro Dep. at 9.) The reaction in either case is characterized by “hives, shortness of breath, swelling of the lips and tongue” (Id. at 9-10.) Anaphylactic reactions may also involve closing of the throat, wheezing, and low blood pressure. (Id. at 10-11.) In extreme cases death may ensue. (Id. at 10.)

¶87b Dr. Anthony Montanaro, whose credentials and testimony I discuss more fully later on, reviewed the symptoms which the claimant reported as occurring in conjunction with her vaccinations, including her report of both an “electric shock and a feeling of impending doom.” (Id. at 23.) He found her report consistent with classic symptoms of anxiety and hyperventilation, and inconsistent with an anaphylactic reaction. (Id. at 24, 27-31.) His opinion concerning the nature of the claimant’s reaction to the vaccinations is supported by the facts and is persuasive.

¶87d Claimant admitted to a fear of needles. (L. Bain Trial Test. at 224.) In 1993, Dr. Bradley Root, a psychiatrist treating claimant for myofascial upper back pain, noted claimant’s resistance to trigger point injections, commenting that claimant “still expresses the desire to avoid injections if at all possible.” (February 18, 1993 medical record.) Four months later he noted, “She states that it [myofascial pain] is getting to the point that it is so uncomfortable that even though patient is very much afraid of needles and injections that she might be willing to try some therapeutic injections.” (June 7, 1993 Medical Record.) On June 10, 1993, Dr. Root further noted that claimant was going ahead with trigger point injections even though “she is deathly afraid of needles [sic]” but that she had brought her husband, whom she later divorced, along “for support and to drive her.” (June 10, 1993 Medical Report.) I find it significant that two and a half years later, in getting the hepatitis B vaccinations, she brought her current husband along for support and to drive her.

¶87e When offered the hepatitis B vaccinations by Shopko, the claimant procrastinated and had to be repeatedly reminded of their availability. Her hesitation indicated a reluctance to undergo the shots and is consistent with her fear of needles.

¶87f No sort of anaphylactic reaction was noted by the trained nurse who administered the vaccinations. Indeed, she recalled the claimant suffered anxiety. Moreover, according to the claimant, another nurse present when she received the second injection told her she was hyperventilating, a symptom consistent with an anxiety reaction.

¶87g Many of the symptoms that Dr. Waisbren thought had arisen immediately after the injections did not in fact arise until several weeks later.

¶88 I therefore find, as fact, that the claimant merely suffered anxiety attacks when vaccinated on January 30 and March 11, 1996, and did not suffer an anaphylactoid reaction. Thus, the initial factual predicate for Dr. Waisbren’s causation opinion is lacking.

¶89 Dr. Waisbren also dismissed the possibility that the claimant’s hepatitis C is contributing to her condition, stating that her liver biopsy was “negative” and that her liver function tests were “normal.” (Waisbren Dep. at 29-30.) Neither statement is accurate and reflects Dr. Waisbren’s failure to review the claimant’s medical records.

¶90 Dr. Waisbren was unable to cite empirical studies supporting his hypothesis that the hepatitis B vaccine causes autoimmune reactions, including demyelinating reactions. He relied instead on an accumulation of anecdotal case reports and his extrapolation of medical research concerning multiple-antigenic-mediated-autoimmunity (MAMA). (Waisbren Dep. at 29.)

¶91 Dr. Waisbren insisted in his deposition and at trial that individual reports of adverse reactions to the hepatitis B vaccine are not anecdotal. In his deposition, he testified,

“[T]hese are not anecdotal for the reason that anecdotal by definition refers to one story. And as we pointed out here, there have been over a hundred case studies written by literally hundreds of scientists in about 50 journals around the world whose editors agreed. And so that body of information is not anecdotal because it’s much more than one story. . . .”

(Waisbren Dep. at 34.) In his book he wrote that his discoveries concerning autoimmune reactions to the hepatitis B vaccine are based on his “bedside observations” and the observations of “other bedside clinicians.” (Waisbren Book at 7.)

¶92 I find Dr. Waisbren’s logic is flawed. An “anecdote is a short account of an event or story.” Multiple anecdotes are nothing more than “multiple anecdotes;” they do not scientifically validate the theories for which they are proffered. A hundred reports of persons having heart attacks at baseball games does not support a theory that baseball games cause heart attacks. Pure chance indicates that some persons attending baseball games will have heart attacks. If the incidence of heart attacks among baseball fans is no greater than the incidence of heart disease among the population in general, the fact that some individuals suffer heart attacks at baseball games does not establish that their heart attacks are caused by their attendance at the games. Similarly, pure chance indicates that some persons receiving hepatitis B vaccine will suffer from medical conditions prevalent in the general population. The critical question, therefore, is whether there is scientific evidence of a causal relationship between any given condition and the vaccine, or whether there is good statistical or epidemiological (15) evidence showing that more than pure chance.

¶93 This is what the Institute of Medicine (16) had to say about the value of case reports:

Case reports are useful for describing the domain of concerns, but the data are usually uncorroborated clinical descriptions that are insufficient to permit meaningful comment or to contribute to a causality argument. Case reports can, however, lead to hypothesis generation and the committee values their potential utility in this regard. . . .

(Ex. 11 at 28.) In other words, case reports are a good starting point for investigation of a possible relationship between the hepatitis B vaccine and various reported conditions, but they

are not proof of a relationship between the vaccine and the reported conditions. Indeed, Dr. Waisbren admitted this very point in his own self-published book, in which he said:

Case reports have been used for centuries as teaching tools to alert physicians as to what they might see in the future. This idea was advanced in the thirteenth century AD by a physician in Bologna, Italy, Dr. Taddeo Alderotti. He called collections of case reports, “Consilia”. It is in this frame of reference that the following case reports are being presented. (17) These reports do not prove causation but when they are considered with numerous similar case reports in the literature they may stimulate physicians to give pause when a patient presents with an adverse event that followed a hepatitis B vaccination.

(Waisbren Book at 29, bolding and underlining added for emphasis.) Thus, his own prior statements concerning the value of case studies undermines his reliance on those studies as supporting his opinions in this case.

...

¶104 In finding a causal relationship between the hepatitis B vaccine and autoimmune diseases, Dr. Waisbren cited a possible explanation based on molecular mimicry (MAMA). (Waisbren Book at 47 and ¶ 91.) Dr. Hollinger disagreed with Dr. Waisbren’s MAMA model. (Id. at 33.) He noted that the studies of MAMA were inapposite since they were based on mimicry by whole proteins present in vaccines, whereas the recombinant vaccine received by claimant did not have whole proteins, rather it is based on surface antigens. (Id. at 32-33.)

...

¶112 In considering the causation of the claimant’s medical conditions, I also note that the claimant’s hepatitis C provides an explanation for most of her conditions other than the demyelinating disease. As found earlier, symptomatic hepatitis C causes chronic fatigue, myalgias, and arthralgias. Dr. Waisbren never adequately explained why he disregarded the hepatitis C as the cause for those conditions.

¶113 The claimant’s attorney made a point about the failure of Drs. Montanaro and Hollinger to examine the claimant. I am unpersuaded that actual examination of the claimant makes any difference. The question is one of causation which does not depend upon examination. The claimant’s medical conditions are well documented and that documentation was available to all of the physicians who testified in this case. Indeed, Dr. Waisbren examined the claimant on only two occasions, the latest when this litigation was “heating up” and obviously in anticipation of the litigation. Importantly, he paid little if any attention to the claimant’s medical records. Drs. Montanaro and Hollinger, on the other hand, reviewed the records before reaching their opinions.

...

¶135 The merits of the causation issue rest on my evaluation of the medical testimony in this case and the facts on which that testimony was based. In assessing the medical opinions I take into consideration, among other things, (1) whether the opining physician reviewed the claimant’s medical records before reaching his or her conclusions; (2) in cases where actual examination of a claimant is important, whether the physician physically examined the claimant;

(3) the professed or obvious biases of the physician; (4) the specific areas of expertise of the physician; (5) peer reviewed articles authored by the physician, particularly in the subject area in which opinions are rendered; (6) the physician's standing among peers in the specialized medical area involved in the opinions; (7) the physician's specific analysis in the case; (8) the physician's consideration and evaluation of other explanations for the claimant's condition; (9) the accuracy of the facts upon which the physician's opinions are based; and (10) medical and scientific literature brought to the Court's attention which tends to support or contradict the physician's conclusions. Ultimately the claimant proved to the Court's satisfaction that she suffered anxiety reactions to the two vaccinations. Those reactions, however, were transitory. Her claim for benefits rests on her contention that the vaccinations caused a demyelinating disease, chronic fatigue, myalgias, arthralgias, mental confusion and memory loss. I am unpersuaded. I found the testimony of Dr. Waisbren -- the only physician providing opinions supporting the claim -- **unconvincing**, while finding the testimony of Drs. Montanaro and Hollinger persuasive. [Emphasis added.]

...

¶138 The claimant suffered an anxiety reaction when vaccinated for hepatitis B in January 1996, however, the reaction was transient and caused her no permanent harm, medical expense, or disability. She has failed to demonstrate a causal relationship between her disabling conditions and her vaccinations and is not entitled to benefits. Moreover, her claim is time-barred. Her petition is therefore dismissed with prejudice.

A further criticism of Dr. Waisbren came from one of the testifying physicians:

Dr. Hollinger, who reviewed Dr. Waisbren's bibliography, noted that most of Dr. Waisbren's published articles were related to infectious diseases. "Almost all of them were either on gram negative sepsis, which is bacterial; gram negative shock, septic shock, bacterial infections, fungal infections, and there were some burn things because he was in a burn unit for a while." (Hollinger Test. at 67.) He noted that although Dr. Waisbren has authored a book and four journal pieces regarding the hepatitis B vaccine, none were peer reviewed. (Id.) He pointed out that Dr. Waisbren's published pieces regarding the hepatitis B vaccine were letters to the editor, not peer reviewed articles. (Id.)

[Footnote 19 to the opinion.]

Ms. Jackson is reminded that, even if she had an initial reaction to the hepatitis A vaccination, her symptoms had to have persisted beyond six months in order for her to receive compensation. 42 U.S.C. § 300aa-11(c)(1)(D)(I).

Ms. Jackson will be receiving a telephone call soon from the undersigned's law clerk, Nabila Isa-Odidi, (202) 357-6356, to set a telephonic status conference with the undersigned and with respondent's counsel.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master