

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 07-360V

June 8, 2009

To be Published

JANE DOE, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Neil J. Fialkow, Pasadena, CA, for petitioner.
Chrysovalantis P. Kefalas, Washington, DC, for respondent.

Entitlement: hepatitis B vaccine;
two to three weeks later, ADEM
or MS; respondent moves for a
ruling on the record

MILLMAN, Special Master

RULING ON ENTITLEMENT¹

Petitioner filed a petition dated June 6, 2007, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on

¹ 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 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. Since petitioner in this case filed a petition under the name "Jane Doe" (which is not her real name), this case is already redacted and further motion from petitioner is unnecessary.

November 16, 2004 caused her either acute disseminated encephalomyelitis (ADEM) or multiple sclerosis (MS).

In January 2006, before this case was filed, 65 cases were transferred to the undersigned constituting the Omnibus hepatitis B vaccine-demyelinating injury cases, dealing with transverse myelitis (TM), Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), and MS.

The undersigned issued four Omnibus paradigm decisions in favor of petitioners.² In these decisions, the undersigned held that the medically appropriate time frame between hepatitis B vaccine and the onset of GBS, CIDP, TM, or MS is between three and 30 days, based on the testimony of petitioners' expert Dr. Vera Byers and respondent's expert Dr. Roland Martin. Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525, at *12, *15 (Fed. Cl. Feb. 24, 2006).

In the instant action, petitioner's onset of MS or ADEM fits well within the parameters established in the Omnibus proceeding, as well as within two months post-vaccination for which respondent in another case stated respondent would not expend resources to defend. Pecorella v. Secretary of HHS, No. 04-1781, 2008 WL 4447607, at *1 (Fed. Cl. Spec. Mstr. 2008) (petitioner prevailed where TM occurred 60 days post-hepatitis B vaccination).

² Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (hepatitis B vaccine caused TM; onset was 12 or 13 days after first vaccination with recovery; onset of TM was one week after second vaccination); Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (hepatitis B vaccine caused GBS and CIDP; onset was 21 days after second vaccination); Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006) (hepatitis B vaccine caused MS; onset was one month after second vaccination); Peugh v. Secretary of HHS, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007) (hepatitis B vaccine caused GBS and death; onset of GBS was eight days after fourth vaccination).

In another Omnibus case dealing with alternate diagnoses of ADEM or MS, the undersigned held, in ruling for petitioner, that the dispute between the parties over the diagnosis was puzzling since both were demyelinating diseases and evidence showed that doctors frequently confuse one with the other. Hawkins v. Secretary of HHS, No. 99-450V, 2009 WL 711931, at *21 (Fed. Cl. Spec. Mstr. 2009). The undersigned had no difficulty in applying to ADEM the principles she expounded in the Omnibus hepatitis B-demyelinating diseases proceeding concerning GBS, TM, CIDP, and MS. Id.

On June 4, 2009, in the instant action, respondent filed a Motion for Ruling on the Record, stating that medical personnel of the Division of Vaccine Injury Compensation, Department of Health and Human Services recently reexamined the record in this case. Motion, p. 1. Although respondent still contended the case was not compensable, respondent stated that an entitlement hearing “would not be an efficient use of Program resources and does not intend to further contest this case.” Motion, p. 2.

Experts

Dr. Eugene I. Tsimerinov

Petitioner filed the unpaginated letter of Eugene I. Tsimerinov, a neurologist, as exhibit 19, stating that the timing of onset was appropriate for causation and scientific literature strongly supported causation of MS from hepatitis B vaccination. He discusses an autoimmune response cross-reacting with myelin basic protein by molecular mimicry.

Dr. Martin A. Bielawski

Respondent filed the letter of Dr. Martin A. Bielawski, a neurologist, as exhibit A, stating there is no epidemiologic support for hepatitis B vaccine causing MS. Ex. A, p. 3. He granted

that molecular mimicry was a possible explanation of how immunization leads to autoimmune disease, but there were no animal studies to support that explanation and the medical community does not accept it. Ex. A, p. 4. The only relationship of petitioner's MS to hepatitis B vaccine, in Dr. Bielawski's opinion, is temporal. Ex. A, p. 5.

Medical Literature

As petitioner's Tab B to exhibit 18, petitioner attached the M.A. Hernán article: "Recombinant hepatitis B vaccine and the risk of multiple sclerosis. A prospective study," 63 Neurology 838-42 (2004). Hernán and his associates analyzed 163 MS cases and 1,604 matched controls. Id. at 839. They concluded that an increased risk lasted for three years post-hepatitis B vaccination. Id. at 840.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(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. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence

of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen. . . .”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148

Petitioner must show not only that but for the vaccine, she would not have had ADEM or MS, but also that the vaccine was a substantial factor in bringing about her ADEM or MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, 418 F.3d at 1278; Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal “compensation program” under which awards are to be “made to vaccine-injured persons quickly, easily, and with certainty and generosity.” House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.

The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

The undersigned has already ruled in the Omnibus paradigm case Werderitsh that hepatitis B vaccine can cause MS, and in Hawkins that hepatitis B vaccine can cause ADEM. The theory of molecular mimicry that Dr. Tsimerinov described in his report is biologically plausible. The Federal Circuit in Knudsen expressly stated that petitioners do not have to prove the specific biological mechanism in order to prevail. Petitioner has satisfied the first Althen criterion that there is a biologically plausible medical theory relating hepatitis B vaccine to her ADEM or MS.

There is a logical sequence of cause and effect that hepatitis B vaccine, which plausibly can lead to ADEM or MS, did lead to petitioner's ADEM or MS in this case. Petitioner has satisfied the second Althen criterion of a logical sequence of cause and effect.

The onset of two to three weeks is a medically appropriate time interval between vaccination and ADEM or MS. The Omnibus testimony of Dr. Vera Byers for petitioners and Dr. Roland Martin for respondent that the appropriate time interval for causation (if Dr. Martin were to accept causation of demyelinating disease from hepatitis B vaccine) was from three to 30 days. Petitioner has satisfied the third Althen criterion of an appropriate time frame.

Respondent has now decided not to expend any further resources in defending this case, asking for a ruling on the record, but maintaining that the case is not compensable. The evidence upon which the undersigned has already ruled in the Omnibus proceeding on hepatitis B vaccine and demyelinating diseases plus the evidence in this case supports a ruling for petitioner. The Federal Circuit has explicitly stated in Knudsen, Althen, and Capizzano that petitioners need not provide epidemiologic studies, animal experimentation, and general acceptance in the scientific and medical communities in order to prevail. The lack of epidemiologic studies, animal

experimentation, and general acceptance in the medical community constitute the precise basis of respondent's expert Dr. Bielawski's opinion in this case that hepatitis B vaccine did not cause petitioner's ADEM or MS. Legally speaking, his report is no defense at all in light of the Federal Circuit decisions listed.

Since petitioner has provided a biologically plausible medical theory linking hepatitis B vaccine to ADEM or MS, a logical sequence of cause and effect connecting her hepatitis B vaccination and her ADEM or MS, and a medically appropriate time frame between vaccination and illness, she has proved causation in fact.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will discuss damages during the telephonic status conference set for today.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master