

OFFICE OF SPECIAL MASTERS

**Nos. 00-759V; 01-221V; 99-609V;
99-591V; 99-628V**

(Filed: June 20, 2003)

CAPIZZANO, ASHBY, ANALLA, RYMAN, *
and MANVILLE, *

Petitioners, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED

ORDER

On June 11, 2003 and Jun 12, 2003 the undersigned conducted a hearing to address the general issue of whether the Hepatitis B vaccine can in fact cause rheumatoid arthritis. Rheumatoid arthritis is not an injury listed on the Vaccine Injury Table and thus does not benefit from the Act's presumed causation. 42 U.S.C. §300aa-14(a). Petitioners were represented by Mr. Ronald Homer and Ms. Sylvia Chin-Caplan. Respondent was represented by Ms. Catharine Reeves, Ms. Ann Donohue and Ms. Melanie McCall. The undersigned Chief Special Master also heard evidence in the five above captioned cases which argue that the Hepatitis B vaccine caused petitioner's rheumatoid arthritis. As discussed with the parties at the close of the hearing and in a subsequent conference call on June 18, 2003, this Order directs the parties to file various documents introduced and discussed during the hearing and to file post-hearing briefs.

Documents to be Filed

The parties are directed to file the following documents no later than July 25, 2003. Respondent shall file:

- a copy of the letter to the editor of The Journal of Rheumatology from Dr. Pope and Dr. Bell
- a copy of Dr. Phillip's chart comparing rheumatoid arthritis and reactive arthritis

- a copy of Dr. Zweiman’s Auto Safety Study along with related criticism by Dr. Halsey.

Petitioner shall file:

- medical records in Manville v. HHS for the period prior to the vaccine and up to March 23, 1993 and an affidavit attesting to the availability, or lack thereof, of such records
- copies of the slides presented by Dr. Bell.¹

Petitioner and Respondent shall file:

- any additional information that is more recent than respondent’s exhibit HH, a 1967 article, C.G. Barnes and H.L.F. Currey, *Carpal Tunnel Syndrome in Rheumatoid Arthritis. A Clinical and Electrodiagnostic Survey*, Ann. Rheum. Dis. 1967:26:226-233, previously filed by respondent.²

Petitioner and Respondent are urged to file:

- additional medical evidence in the form of peer-reviewed literature that discusses whether or not there is a possible association between the Hepatitis B vaccine and rheumatoid arthritis or other evidence that assists the court in determining what the medical community is “thinking” regarding the alleged association.

Causation in Fact

Post hearing briefs shall be filed no later than July 25, 2003. The briefs shall address the court’s criteria³ governing actual causation claims as discussed in Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001).

As the undersigned has commented on several occasions, causation in fact cases involve

¹Slide numbers 1, 3-6, 11-13, 15-16.

²This information is needed to assist the court in understanding the parties’ respective positions relative to the relationship between carpal tunnel syndrome and rheumatoid arthritis.

³Petitioner must provide proof of (1) medical plausibility, (2) confirmation of medical plausibility from the medical community and literature, (3) an injury recognized by the medical plausibility evidence and literature, (4) a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and (5) the elimination of other causes. Stevens 2001 WL 387418 at 23-26 as clarified in Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537 at *8 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), White v. Secretary of HHS, No. 98-426V, 2002 WL 1488764, at *5, n. 12 (Fed. Cl. Spec. Mstr. May 10, 2002) and Althen v. Secretary of HHS, No. 00-170V, 2003 WL –, slip op. at 18-22 (Fed. Cl. Spec. Mstr. June 3, 2003) (to be published).

the resolution of a critical legal/medical issue: how much and what type of medical evidence is required to meet the legal standard of preponderance? This issue bedevils the parties, the medical experts and the court in every causation in fact case. This case was no exception.

This court attempted to tackle the issue in Stevens. The undersigned has clarified the Stevens' five-prong test in subsequent decisions. Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537 at *8 (Fed. Cl. Spec. Mstr. Dec. 18, 2001); White v. Secretary of HHS, No. 98-426V, 2002 WL 1488764, at *5, n. 12 (Fed. Cl. Spec. Mstr. May 10, 2002); Althen v. Secretary of HHS, No. 00-170V, 2003 WL –, slip op. at 18-22 (Fed. Cl. Spec. Mstr. June 3, 2003) (to be published). In this case, much of the discussion concerned Prong 1– medical plausibility. However, **tentatively**, the undersigned finds the issue of medical plausibility moot. That is because respondent's exhibit L, "Rheumatic Disorders Developed After Hepatitis B Vaccination" related four "rechallenge"⁴ cases to the Hepatitis B vaccine. R. Ex. L (J.F. Maillefert, J. Sibilia et al., Rheumatic Disorders Developed After Hepatitis B Vaccination, *Rheumatology*, 1999:38:978-983 at 979). The Institute of Medicine (IOM) has stated that rechallenge is proof of causation. See Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines, 48, 53 (1991). The IOM has also stated that where causation is proven, biologic plausibility is a given. Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 21 (1994). Therefore, if the court affirms this tentative determination, petitioners will have met Prong 1 of Stevens and any rechallenge rheumatoid arthritis case, if proven successfully to be a rechallenge case, will be compensated.

That leaves us with the non-rechallenge cases. The critical issue remaining from the hearing is Prong 2 of Stevens. To assist the court with this issue, as indicated above, the parties are asked to 1) file additional medical evidence in the form of peer-reviewed literature that discusses whether or not there is a possible association between the Hepatitis B vaccine and rheumatoid arthritis or other evidence that assists the court in determining what the medical community is "thinking" regarding the alleged association and 2) address in their briefs, in addition to the general causation issue, what types of medical reports, studies or literature support Prong 2.

Confirmatory Evidence

The Second Prong of Stevens requires petitioner submit confirmation from peer-reviewed literature or proof that the medical community is "thinking about" or "seeing and reporting a suspected or potential association." Stevens 2001 WL 387418 at 24; Althen, No. 00-170V at 18-22. The court is looking for additional confirmatory evidence because a serious issue regarding causation was raised during the hearing. Testimony during the hearing presented difficult facts. Petitioner's expert testified that 18 cases of rheumatoid arthritis following the

⁴A rechallenge case is one where adverse symptoms are noted after a dose of the vaccine, an additional dose of the vaccine is given, and the symptoms worsen.

Hepatitis B vaccine have been reported. However, respondent's expert testified that millions of people have received the vaccine without reported evidence of contracting rheumatoid arthritis.⁵

Types of Medical Evidence

During the hearing, the court also heard testimony on a range of medical evidence relating to Prong 2 from individual case studies, to a report on a series of such cases, to a controlled study that showed a negative relationship between the vaccine and rheumatoid arthritis. P. Ex. 19 Tab D (G. Vautier and J.E. Carty, Letters to the Editor: Acute Sero-Positive Rheumatoid Arthritis Occurring after Hepatitis Vaccination, Brit. J. Rheumatol., at 991 (1994)); P. Ex. 19 Tab E (Yehuda Carmeli, Ran Oren, Letters to the Editor: Hepatitis B Vaccine Side-Effect, Vol. 341 Lancet, at 250-1 (Jan. 1993)); P. Ex. 19 Tab C (Janet Pope, et al., The Development of Rheumatoid Arthritis After Recombinant Hepatitis B Vaccination, J. Rheumatol. at 1687-1693 (1998)); R. Ex. L (J.F. Maillefert, J. Sibilia. et al., Rheumatic Disorders Developed After Hepatitis B Vaccination, Rheumatology. 1999:38:978-983). Furthermore, the expert witnesses failed to agree as to what type of medical evidence would be convincing. Respondent's expert Dr. Moulton testified that the gold standard for proof of causation would be a double-blind controlled study with a statistically significant sample. Both parties agree such proof is lacking for a rheumatoid arthritis injury following Hepatitis B vaccine.⁶ Respondent's expert Dr. Phillips testified that he would like to see more case studies to support a causal relationship between the vaccine and rheumatoid arthritis. Petitioner's expert Dr. Bell argued that the case series study was sufficient.

Both parties are urged to discuss the evidence and testimony presented at the hearing on various types of medical evidence in relation to Prong Two of Stevens.⁷ Respondent is urged to state the requirement for proof under the Second Prong of Stevens in the absence of

⁵The court is mindful of the IOM's cautioning that such absence of reporting may be due to "an extremely rare adverse even and the notorious problems of underreporting in passive surveillance systems." Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 22 (1994).

⁶However, as the IOM recognized, the absence of such reports is not sufficient to reject a causal relation. Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, at 21 (1994).

⁷The court in Althen emphasized the importance of the second prong. Althen, No. 00-170V at 24 ("petitioner [must] show a recognition or a suspected association (the "thinking about it" concept expressed by Dr. Safran), through the medical community or literature, of a causal relation between the vaccine and injury. It is the satisfaction of this second prong which moves the petitioner's case beyond the theoretical causative connection towards the real of probable or preponderance").

epidemiological evidence dispositively. As the court said in Althen: “Respondent has stated consistently that epidemiological evidence is not required to prove causation-in-fact.” Althen, No. 00-170 at 25; White, 2002 WL 1488764 at *5, n. 12. In other matters, respondent has argued that epidemiologic studies are not required to prove causation in fact. Stevens, 2001 WL 387418; Watson, 2001 WL 1682537 at *8 (“respondent concedes that epidemiology is not the only way petitioner can prove actual causation”).

Individual Case Disposition

Three additional observations are offered. The undersigned is “painfully” aware of respondent’s criticism of Stevens. See Althen, No. 00-170V at 14, n.21. However, respondent’s experts, along with petitioner’s experts frequently testify utilizing the very evidence that Stevens used in setting out the five prongs. Of course, that is the genesis of Stevens – the undersigned’s experience with expert testimony in cause in fact cases over a 14-year tenure. Respondent’s expert, Dr. Phillips, confirmed the arguable correctness of Stevens. The court asked Dr. Phillips whether he would find the Hepatitis B vaccine causative of rheumatoid arthritis if the patient met the following criteria:⁸

- symptoms of inflammatory arthritis within one month of vaccination
- symptoms develop after dose number 2 or 3
- no previous joint pain
- no flulike symptoms
- no reactive arthritis
- no diagnosis of Reiter’s syndrome
- no familial history of rheumatoid arthritis

Dr. Phillips stated that with those facts it would be “highly suggestive” that the vaccine caused the rheumatoid arthritis. The court asked “what additional information would be needed to say the vaccine probably caused the rheumatoid arthritis? Dr. Phillips replied: “more case reports”.

Thus, Dr. Phillips both identified the critical issue remaining in this case, the strength of the medical evidence produced to meet Prong 2, and affirmed the reasonableness of Stevens’ approach in answering the question we began with: How much and what type of medical evidence is required to meet the legal standard of preponderance?

Secondly, the court observes that Dr. Bell’s testimony was supported largely by his own case series study. Thus if petitioners initially prevail on the remaining Prong 2 issue, the court intends to apply the criteria discussed above and utilized post hoc in the study to define a

⁸These criteria are essentially the criteria outlined in Dr. Bell’s study, petitioner’s exhibit 19, tab C, Janet Pope, et al., The Development of Rheumatoid Arthritis After Recombinant Hepatitis B Vaccination, J. Rheumatol., at 1687-1693 (1998).

Hepatitis B caused rheumatoid arthritis case. The court notes that those criteria are entirely consistent with the Stevens standards. Thus, petitioners should begin to measure their cases against Dr. Bell's criteria. If a case cannot meet Dr. Bell's criteria, unfortunately, it will be dismissed for failure of proof.

Lastly, these cases benefitted greatly from an excellent presentation by counsel, credible testimony from well-credentialed experts and solid medical literature. Despite these benefits, the ultimate outcome remains problematic. The court in this Order, and in previous conversations with counsel, has attempted to focus the resolution of these cases through eliminating some issues and narrowing others. The court strongly urges the parties to begin reviewing the individual cases against this guidance to determine the weak cases – which should be dismissed, the cases with strong evidence – which should be compensated, and lastly those cases with evidentiary “holes” – which may either be settled or litigated. The court stands ready to assist the parties in any way the parties find appropriate.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master