



On April 5, 2001, this case was transferred to the undersigned. On July 31, 2001, petitioner's counsel moved for authority to issue subpoenas. On August 8, 2001, the undersigned issued an Order granting petitioner's motion. On August 31, 2001, the undersigned issued an Order that petitioner file a single medical record by April 12, 2002 or his case would be dismissed for lack of prosecution.

On March 1, 2002, petitioner submitted Ex. 1, his affidavit stating he received a hepatitis B vaccination at Mt. Sinai Medical Center and, shortly after the vaccination, he started feeling strong pressure on his chest and could not breathe. He has since developed asthma.

Although petitioner submitted medical records, he did not submit an immunization record or a medical expert report. A status conference was held on January 24, 2003, and the undersigned issued an Order on January 28, 2003, that petitioner file an expert report. A status conference was held on April 8, 2003, and the undersigned issued an Order on April 9, 2003 that petitioner file an expert report. A status conference was held on May 13, 2003, and the undersigned issued an Order on May 14, 2003, that petitioner file all available medical records.

On July 8, 2003, a status conference was held and the undersigned issued an Order that day that petitioner file his prevaccination records and an expert report from Dr. Bellanti. On September 4, 2003, a status conference was held and the undersigned issued an Order that day that petitioner file his prevaccination records and an expert report from Dr. Bellanti.

---

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.

A status conference was held on November 5, 2003, followed by an Order dated November 6, 2003 that petitioner shall file Dr. Bellanti's expert report. A status conference was held on January 14, 2004, during which the undersigned gave the parties dates to select in order to have a hearing to take Dr. Bellanti's testimony, followed by an Order on January 15, 2004.

The undersigned issued an Order on February 10, 2004 that a status conference was to be held on February 12, 2004. A hearing was set for March 18, 2004, during which petitioner and Dr. Joseph A. Bellanti testified. This was followed by orders for further documentation.

On June 22, 2004, petitioner filed a Status Report that he was unable to secure documentation of petitioner's receipt of hepatitis B vaccine. On June 24, 2004, the undersigned issued an Order that petitioner file proof of vaccination by July 23, 2004 and additional literature in support of Dr. Bellanti's testimony. The undersigned set a status conference for July 20, 2004, during which conference the undersigned gave counsel dates for continuation of the hearing to take the testimony of respondent's expert. The hearing continued on October 18, 2004, during which Dr. Burton Zweiman testified. Both experts are immunologists.

On December 13, 2004, petitioner filed a Status Report and Request for Extension until the end of January 2005 within which to locate and file documentation supporting petitioner's receipt of hepatitis B vaccination and petitioner's prevaccination history of allergies.

The undersigned denies petitioner's motion and, for the purposes of this decision, will assume that petitioner received a hepatitis B vaccination and has a history of allergies and his family

has a history of allergies, both of which he denied to his doctors (except for his recollection of being allergic to penicillin, which is irrelevant to this case<sup>2</sup>).

### FACTS

Petitioner was born on July 5, 1960. He alleges he received hepatitis B vaccine on August 17, 1994. On September 1, 1994, he signed a Notice of Injury for the Department of Labor and Employment Security, Division of Workers' Compensation, that he received hepatitis B vaccine on **August 17, 1994 at 7:00 a.m.** from the Mt. Sinai Hospital, Employee Health Office, 4300 Alton Road, Miami Beach, FL 33139, and had a reaction to it on **August 18, 1994 at 7:00 a.m.** P. Ex. 6, p. 13. He returned to full duty as a policeman on September 1, 1994. Id. He states his whole body was affected and he requested and received medical care. Id. He saw Dr. Molina, 10141 SW 40 St., Miami, FL. Id.

On August 23, 1994, Dr. Molina wrote a "To Whom It May Concern" letter, stating that on that date, petitioner was suffering from severe dyspnea, short of breath. "This seems to appear after an immunization for hepatitis." Dr. Molina gave him bronchodilators and "mucolytics" which improved his condition. Med. recs. at Ex. 6, p. 28.

On November 9, 1994, the Johns Eastern Company, Inc., insurance adjusters, prepared an initial report on the claim, enclosing a recorded statement summary of petitioner. Med. recs. at Ex. 6, p. 14. Christopher D. Nichols, an adjuster for Johns Eastern Company, Inc., met with petitioner on September 17, 1994 and secured his recorded statement. Petitioner saw a memorandum with a

---

<sup>2</sup> Dr. Bellanti testified that an allergy to penicillin has no relationship to having an atopic tendency to have IgE problems. In other words, an allergy to penicillin is unrelated to an allergy to weeds, foods, and aspirin, or to asthma. Tr. at 63.

list of names of people that the police department was sending to get hepatitis vaccinations because of exposure in their line of work. Med. recs. at Ex. 6, p. 15.

Petitioner called his supervisor for permission to go to the Employee Health Center at Mt. Sinai where he received hepatitis vaccine on August 17, 1994, before going to day court work. “The nurse explained that he would have some cold/flu like symptoms, and **Mr. Rezzonico felt nothing on the first day. By the second day, however, Mr. Rezzonico began to feel tightness in his chest and by the end of the day sought medical attention.**” *Id.*

On November 7, 1994, petitioner saw Dr. Mitchell L. Petusevsky, a pulmonary specialist, and stated that he was in his usual state of excellent health until two months previously when he noted chest tightness, wheezing, a nonproductive cough, and shortness of breath. **His symptoms began three days after hepatitis B vaccination.** He had no preceding upper respiratory infection, no prior history of asthma or allergies. His family had a negative history for asthma or allergies. He had never had an allergy to his pets (dogs and a bird). He was allergic to penicillin. Med. recs. at Ex. 2, p. 12. Dr. Petusevsky stated, “I doubt any serious relationship between the hepatitis vaccine and the development of his symptoms.” Med. recs. at Ex. 2, p. 13.

Petitioner was denied benefits from workers’ compensation on November 11, 1998, because his condition was due to natural causes, unrelated to his employment. Med. recs. at Ex. 6, p. 1.

#### **Other Submitted Material**

Petitioner submitted Ex. 14 (also Ex. 30), a Letter to the Editor entitled “Asthma and Urticaria After Hepatitis B Vaccination,” by Dr. Ghanshyam Lohiya, 147 *Western J Med* 3:341 (1987), stating that an employee experienced **within 30 minutes** of plasma-derived hepatitis B vaccine pruritus, dyspnea, urticaria, and infraorbital edema. She had extensive rhonchi in both lungs.

Petitioner submitted Ex. 15 (also Ex. 27), a brief report entitled “A Severe Allergic Reaction Presenting as an Asthma Exacerbation With Respiratory Failure Following Hepatitis B Vaccination,” by B.A. Becker, 109 *J Allergy and Clin Immunol* 1 (online), stating that a girl developed asthma exacerbation **four hours** after receiving recombinant hepatitis B vaccine.

Petitioner submitted Ex. 16 (also Ex. 28), an article entitled “Childhood vaccinations and the risk of asthma,” by F. DeStefano, et al., 21 *Ped Infect Dis J* 21:498-504 (2002), analyzing the risk of asthma after various vaccinations in a population aged 18 months to 6 years. The authors found a weak association between hepatitis B vaccine and asthma.

Petitioner submitted Ex. 22, a chapter entitled “Allergic Disease. Pathophysiology and Immunopathology,” by M.H. Moss, et al., from Allergic Diseases. Diagnosis and Treatment, 2d Ed., eds. P. Lieberman and J.A. Anderson (2000) 1-16. The authors describe allergic inflammation, which is a Th2-mediated response:

Just as IgE production and mast cell activation are key components to the initial allergic response, several other cells play a role in propagating this allergic inflammatory response. After the immediate release of mast cell mediators following allergen exposure, leukocytes influx into affected tissues. This occurs approximately **2-8 hr after allergen exposure** and has been termed the **late-phase** reaction (LPR) or the late allergic response (LAR). [emphasis added].

Id. at p. 13.

The authors continue describing early- and late-phase responses:

The mast cell activation pathway...occurs **within minutes** of allergen exposure. ...The LAR typically occurs **2-8 h after initial allergen exposure**. [T]he LAR represents the inflammatory phase of an allergic reaction....The late-phase response ... **peaks at 6-8 h** following allergen exposure and **lasts up to 24 h**. ...Clinically, isolated **immediate responses** are those that cause **airway obstruction** (with **wheezing, coughing, or shortness of breath**) **within minutes** of allergen exposure. They **typically resolve within 1 h**. **Late-phase reactions begin 3-4 h** after allergen exposure and **resolve within 24 h**. The symptoms associated with the late response

are similar to those of the immediate response, with dyspnea and cough predominating. [emphasis added].

Id. at 13, 14, 14, 15.

Petitioner submitted Ex. 31, an article entitled “Reactions to Thimerosal in Hepatitis B Vaccines,” by R.L. Rietschel and R.M. Adams, in a text entitled Contact Dermatitis. A Festschrift for Dr. Alexander A. Fisher, in 8 *Dermatology Clinics* 1:161-64 (Jan. 1990), describing two case reports, In the first, a man received hepatitis B vaccine and **within 6 hours**, noticed pruritus at the injection site. Id. at 161. In the second, a woman received hepatitis B vaccine and **a few hours** later, had a grapefruit-sized erythematous swelling at the infection site. Id. at 163.

Respondent submitted Ex. W, an article entitled “Systematic review of prevalence of aspirin induced asthma and its implications for clinical practice,” 328 *BMJ* 434 (Sept. 24, 2004), by C. Jenkins, et al., stating that individuals with aspirin-induced asthma have their reaction **within 30 minutes to three hours after the ingestion of aspirin**. Id. at 1.

### TESTIMONY

Petitioner testified that, to the best of his recollection, the onset of his asthma was two to three days after the vaccination. Tr. at 15. Dr. Joseph Bellanti, petitioner’s expert, accepted an onset of asthma from one to three days post-vaccination in finding a reaction to hepatitis B vaccine.<sup>3</sup> Tr. at 37, 94. He stated that the articles describing cases of asthma after an allergic reaction state the reaction occurs within the first 24 hours of exposure, but he would not be concerned if the reaction occurred two to three days later. Tr. at 94.

---

<sup>3</sup> In his report dated January 23, 2004, Dr. Bellanti stated that petitioner did not have any reaction on the first day following vaccination, but, on the second day, began to feel tightness in his chest and, by the end of that day, sought medical attention, suffering from severe shortness of breath. P. Ex. 12.

Dr. Burton Zweiman, respondent's expert, testified that, for many years, allergies were considered to be immediate hypersensitivity reactions which started within a few minutes of a challenge to a sensitized individual.<sup>4</sup> Tr. at 156. However, later, doctors realized that in many, but not all, individuals, this immediate reaction was followed within two to six hours by a recurrent reaction that was different in some respects than the immediate reaction and in the type of inflammation involved. Tr. at 156. Because this was later than the immediate reaction, it was called a late-phase response. Tr. at 157. It would peak typically at six to 12 hours, and was almost always gone by 24 hours after the reaction. Id. It rarely ever occurs without a prior immediate reaction. Chemicals released in the immediate reaction initiate the late-phase reaction. Id.

The immediate reaction is manifested by clinical signs and symptoms. Id. Dr. Zweiman has never seen a late-phase reaction without an immediate reaction and has trouble understanding how this could occur, although he has seen descriptions of it. Tr. at 158. At the time that petitioner took a pulmonary function test on November 15, 1994 (Ex. 6, pp. 33, 41), Dr. Zweiman testified that he had very, very mild obstruction of pulmonary function. The pattern suggests a small airways problem rather than typical asthma. Tr. at 164.

Dr. Zweiman testified that asthma is a pathologically complex disease, not just one disease. The cause is not the same in every individual. It may or may not be due to allergy. Tr. at 168. Dr. Zweiman does not know the cause of petitioner's asthma. Tr. at 173. Dr. Zweiman stated that, if petitioner had had an allergic reaction to hepatitis B vaccine, he should have had a prior hepatitis B vaccination to sensitize him. Tr. at 175, 214. Moreover, his reaction should have occurred

---

<sup>4</sup> In his report dated June 18, 2004, Dr. Zweiman stated an earlier onset for causation of an allergic reaction (one hour after exposure, which may recur 6-12 hours later) could be medically plausible. R. Ex. B, pp. 8-9

immediately within minutes to an hour or two of vaccination. Id. If he had a late-phase reaction without an immediate reaction, it would have occurred six to eight hours at the latest after the vaccination, not a minimum of 24 hours later. Tr. at 175-76.

To have a chronic asthmatic reaction on an allergic basis, Dr. Zweiman said the person has to be repeatedly exposed to the offending allergen. Tr. at 177. Protein antigens such as the surface antigen of hepatitis B virus are broken down in the body, but for the allergic theory to work, the allergen has to persist in the body. Tr. at 178.

If petitioner had a Th2 predominant immune response (a skewing of the immune response), it would take a minimum of four to six weeks for him to get enough IgE antibodies to be clinically relevant. Id., tr. at 211, 212. It would not happen in one day. Id. Dr. Zweiman queried whether the hepatitis B vaccine could have been a non-immunologic trigger (not a theory that Dr. Bellanti postulated). Tr. at 215. He thought it unlikely because irritant-induced reactions always occur within an hour or two of exposure. Tr. at 215, 293.

Dr. Zweiman stated that if petitioner had had a reaction to hepatitis B vaccine within six hours of vaccination, he would certainly consider causation from the vaccine. Tr. at 282. If petitioner had an IgE-antibody mediated response with an immediate hypersensitivity reaction, it should have occurred within a couple of hours of vaccination. Tr. at 287.

## **DISCUSSION**

Petitioner is proceeding on a theory of causation in fact. To satisfy his burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148

(Fed. Cir. 1992). Agarwal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioner must not only show that but for the hepatitis B vaccine, he would not have had asthma, but also that the vaccine was a substantial factor in bringing about his asthma. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

The undersigned finds Dr. Zweiman's testimony more credible than Dr. Bellanti's on the crucial issue of onset because Dr. Zweiman's testimony is consistent with the medical literature that petitioner supplied. That medical literature shows that an asthma reaction to hepatitis B vaccine occurred within four hours of vaccination. Other types of reactions similarly occur within minutes to six hours of vaccination.

Petitioner's onset of symptoms occurred on the day after vaccination (the second day). He wrote on his workmen's compensation form that onset was 7:00 a.m. on the second day after vaccination, the vaccination having been administered at 7:00 a.m. on the prior day. He stated to the claims adjuster that he did not feel any symptoms on the first day of the vaccination.

Dr. Bellanti never explained his lack of concern if petitioner's onset were two to three days after vaccination regarding his conclusion that hepatitis B vaccine caused petitioner's asthma. In light of the medical literature, and Dr. Zweiman's persuasive discussion of Dr. Bellanti's theories, the undersigned finds Dr. Bellanti's lack of concern about an onset occurring after the first day makes no medical or scientific sense.

Dr. Zweiman’s description of Dr. Bellanti’s two theories of causation—either an allergic reaction or skewing of petitioner’s immune system—includes the appropriate onset times. For an allergic reaction to hepatitis B vaccine antigen, petitioner should have reacted within minutes and then possibly, for a late-phase reaction, within six to eight hours of vaccination. For an immune skewing type of reaction, petitioner would have needed four to six weeks to build up enough IgE antibodies to have a clinical response.

Petitioner’s onset of asthma is too late for a direct, allergic reaction to hepatitis B vaccine, and too early for a skewing of his immune response from hepatitis B vaccine. There is no logical sequence of cause and effect here that hepatitis B vaccine caused petitioner’s asthma.

Petitioner has failed to prove a prima facie case of causation in fact. Therefore, this case must be dismissed.

**CONCLUSION**

Petitioner’s petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.

**IT IS SO ORDERED.**

\_\_\_\_\_  
DATE

\_\_\_\_\_  
Laura D. Millman  
Special Master