

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 10-372V
Filed: March 29, 2012
Unpublished

MICHELLE GOULD,	*	
	*	
Petitioner,	*	
	*	Proof of vaccination receipt; Vaccine
v.	*	contaminated with purified protein
	*	derivative, PPD
SECRETARY OF THE DEPARTMENT	*	
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

James N. Gross, Philadelphia, PA, for Petitioner.
Lara A. Englund, U.S. Department of Justice, Washington, D.C., for Respondent.

FACT RULING AND ORDER¹

In this case, petitioner filed her Petition under the National Childhood Vaccine Injury Act² on June 16, 2010. Petitioner’s (“P”) Petition (“Pet.”), filed Jun. 16, 2010. Petitioner alleges she suffered from pleurisy³ as a result of a somehow tainted influenza (“flu”) vaccination that

¹ The undersigned intends to post this decision on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). **As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.**

² This Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) (hereinafter “Program,” “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

³ “Pleurisy is an inflammation of the lining around the lungs and the chest wall. The inflammation may be caused by an infection, an injury or from other diseases such as pneumonia, tuberculosis, infection or even the flu. Symptoms include a cough, fever, chills and sharp, stabbing pain that becomes worse with a deep breath or movement of the arms or upper body. Often, due to the pain, people may breathe quickly and very shallow. Pleurisy is a symptom of an underlying problem. The treatment is directed at finding the cause while the symptoms

she allegedly received on October 31, 2007. Pet. 1, filed on Jun. 6, 2010. Specifically, petitioner's theory of this case is that she received an influenza vaccine that "contained, or was comprised of, the purified protein derivative ("PPD").⁴ Pet. at ¶ 8. Petitioner attests she consulted with a doctor who reviewed the case and concluded "that there is no evidence to suggest a cause for [petitioner's] pleurisy *other than* the influenza virus vaccination which contained, or was comprised of, the [PPD]." Pet. at ¶ 8 (emphasis in original). However, petitioner did not provide this evidence. Respondent contests this case on several grounds: petitioner has provided no evidence that the flu vaccine can or did cause petitioner's pleurisy; petitioner failed to provide evidence that she received a flu vaccine contaminated with PPD; petitioner offered no evidence that a flu vaccine, even if contaminated with PPD, could cause pleurisy; and petitioner has not evidenced she suffered her alleged injury for more than six months as required by § 300aa-11(c)(1)(D). Respondent's ("R") Rule 4(c) Report, filed May 19, 2011. It appears, upon review of the Rule 4(c) Report, that respondent does not argue that petitioner did not receive a flu vaccine on October 31, 2007. R Rule 4(c) Report at 6-7 ("Based on the record as a whole, there are two possibilities: petitioner either received a flu vaccine as she intended on October 31, 2007, or she was mistakenly given an injection of PPD."). Respondent recommends the Petition be dismissed based upon petitioner's inability to prove causation and her failure to meet the six month requirement. R Rule 4(c) Report at 7-8.

Since the inception of this case, much dispute has taken place regarding whether petitioner has been able to show she received a vaccination covered by the Act. As discussed in the January 10, 2011 status conference and in the undersigned's Order, filed Jan. 10, 2011, there were three possibilities to consider: petitioner received an influenza vaccination, petitioner inadvertently received an injection of PPD, or – as alleged by petitioner – she received an influenza vaccination that "contained, or was comprised of, the purified protein derivative." Pet. at ¶ 7-8. The parties do not appear to argue over whether petitioner received some form of an injection at all on October 31, 2007. If petitioner inadvertently received an injection of PPD, her case is not covered by the Vaccine Act as she did not receive a vaccine set forth in the Vaccine Injury Table. § 300aa-11(c)(1)(A). In that circumstance, her Petition would be dismissed. If it is found that petitioner received an influenza vaccine or an influenza vaccination that somehow contained PPD, her case is covered under the Act and she then needs to prove by preponderant evidence causation and that the residual effects of the alleged injury were suffered for more than six months or resulted in hospitalization and surgical intervention. § 300aa-11(c)(1)(D); see, e.g., Althen v. Sec'y of the Dept. of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005)(discussing the requirements for compensation of a non-Table case causation-in-fact).

The undersigned herein examines a very basic factual underpinning for petitioner's case: did petitioner receive a vaccination covered by the Act? As will be discussed, the undersigned finds that petitioner did receive an influenza vaccine, which is covered by the Act. However, considering the record as a whole, petitioner falls tremendously short of preponderant evidence in her related allegation – that the influenza vaccine she received on October 31, 2007, somehow

are made better." P Ex. 3 at 101, filed on June 29, 2010 (Discharge papers provided by Chestnut Hill Hospital to petitioner to explain petitioner's condition.).

⁴ Purified Protein Derivative ("PPD") is "a sterile solution of a purified protein fraction precipitated from a filtrate of tubercle bacillus culture grown on a special medium, used for tuberculin tests." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1451 (30th ed. 2003).

contained or was comprised of PPD. Following this discussion, petitioner will be directed to review her case and present how she intends to proceed if she wishes to continue pursuit of compensation under the Act.

Procedural History

On June 16, 2010, petitioner filed a Petition for compensation for injuries resulting from the administration of a flu vaccination allegedly received on October 31, 2007. Pet. at 1. The petitioner alleges that this vaccination “which contained, or was compromised of, purified protein derivative,” caused her pleurisy. Pet. at 1. During the initial status conference call conducted on August 5, 2010, the respondent noted that there was a possible jurisdictional issue regarding whether petitioner received an influenza vaccine on October 31, 2007. Order, filed August 6, 2010. At that time, petitioner was ordered to produce evidence regarding the vaccination she allegedly received on October 31, 2007. Id. Subsequently, petitioner filed an invoice dated October 31, 2007 from Albert Einstein Healthcare network, billing her for an influenza vaccination. P Ex. 6.

Even with the invoice, in a status conference call held on November 5, 2010, the respondent again voiced confusion over what injection petitioner received, especially in light of the fact that petitioner alleged she received an adulterated flu vaccine. Order, filed November 5, 2010. The undersigned and the parties agreed that it would be beneficial to contact the treating medical facility seeking further assistance regarding the injection petitioner received on October 31, 2007. Id.

Subsequently, the parties jointly drafted questions, which were submitted to the facility, and the treating facility cooperated, providing responses to the parties’ questions. Joint Status Report as to Subject Injection, filed Dec. 3, 2010; Document 13-1, Letter from Marie Keeley, Senior Counsel at Albert Einstein Healthcare Network, dated December 3, 2010 (“Response Letter”); Document 13-2, Letter to Marie Keeley from petitioner and respondent, dated November 18, 2010.

Despite this new information provided by the treating facility, the parties were still in conflict regarding the type of injection petitioner received. Order, filed on January 10, 2011. During the January Status Conference Call, petitioner requested and received more time to investigate whether petitioner received an influenza vaccine, a PPD injection, or a tainted influenza vaccine. Id. However, to date, no additional evidence regarding the alleged injection has been filed. On March 2, 2011, petitioner filed her Status Report as to Petitioner’s Injection of 10/31/07. Status Report as to Petitioner’s Injection (“P Status Report regarding Injection”), filed on March 2, 2011. Petitioner “avers that she sustained an adverse reaction due to PPD being contained in the influenza vial which was used in the injection administered to petitioner on 10/31/07.” Id. Petitioner requested the opportunity to provide additional information regarding the injection. Id.

On March 24, 2011, respondent filed a Status Report providing argument and notice of respondent’s belief that “there is no reasonable basis for petitioner’s claim that she received a flu vaccine that contained PPD.” R Status Report, filed Mar. 24, 2011. This Status Report also noted respondent would challenge “any further attorneys’ fees or costs incurred pursuing this theory.” Id.

Based upon a review of the evidence, the undersigned again voiced doubt that petitioner received an adulterated influenza vaccine. Minute Entry, entered May 2, 2011; Order, filed May 3, 2011. Petitioner requested fifteen days to decide how to proceed. Order, filed May 3, 2011. On May 18, 2011, petitioner filed a Status Report as to Petitioner's Intention to Proceed, in which petitioner requested a ruling on the record regarding her underlying claim. On May 19, 2011, respondent filed her Rule 4(c) Report, recommending that the Petition in this case should be dismissed. Rule 4(c) Report, filed May 19, 2011. See supra p. 2 (noting respondent's challenges to this Petition).

Background Facts

Petitioner was born on July 3, 1942. P Ex. 1 at 4. Prior to the vaccination and condition in question, petitioner had a complex medical history. See, e.g., P Ex. 1 at 26. On October 31, 2007, petitioner visited the doctor to receive an influenza vaccine.⁵ There is no notation – a doctor's order, the location of injection or vaccination lot number – of this vaccination in the medical records she submitted from Einstein Community Health Associates. See P Ex. 1. However, petitioner did submit a billing receipt, dated October 31, 2007, for a flu vaccination from her medical provider.⁶ P Ex. 6.⁷

Thereafter, in the evening on November 23, 2007, petitioner “experienced severe pain in her right lung area and had trouble breathing.” Pet. at 2. Petitioner sought help from Chestnut Hill Hospital on November 23, 2007.⁸ P Ex. 2 at 82-85, filed on Jun. 29, 2010. Petitioner's discharge noted a diagnosis of bronchitis and medication was prescribed. P Ex. 2 at 82-85; see also Pet at 2. On November 24, 2007, Petitioner returned to Chestnut Hill Hospital emergency room, complaining again of pain in her chest. P Ex. 3 at 88, filed on Jun. 29, 2010. Petitioner's Initial Assessment Form indicated that petitioner suffered no respiratory distress. P Ex. 3 at 87. The assessment demonstrated “clear breath sounds,” P Ex. 3 at 87, and “[r]espiratory effort is unlabored.” P Ex. 3 at 88. During the emergency visit, petitioner rated her pain as 10/10. P Ex. 3 at 88. Petitioner was diagnosed with pleurisy and bronchitis, and was prescribed medication. P Ex. 3 at 104-05.

Shortly thereafter, Albert Einstein Healthcare Network sent petitioner a letter dated November 27, 2011, regarding the flu vaccination petitioner “received as part of [her] care at a

⁵ Petitioner alleges that the influenza virus vaccine administered to her on October 31, 2007, was identified as Fluvrin. Pet. ¶ 3. The petitioner alleges that the vaccine was manufactured by Novartis Vaccines and Diagnostics Inc., 350 Massachusetts Avenue, Cambridge, MA 02139. Pet. ¶ 3.

⁶ These medical records do evidence a flu vaccination on December 11, 2007. P Ex. 1 at 2-3. Upon receiving the letter from the Albert Einstein Healthcare Network regarding the injection she received on October 31, 2007, petitioner returned for this “repeat” flu shot as was advised in the letter. P Ex. 1 at 1.

⁷ This medical record was filed on September 3, 2010. There was no exhibit number designated. The undersigned hereinafter references this exhibit at P Ex. 6. Petitioner's filing on October 10, 2010, is also not designated with an exhibit number and the undersigned refers to this filing as petitioner's Exhibit 7.

⁸ Petitioner provided only the discharge instructions from this visit. See P Ex. 2 at 82-85. Respondent noted in its Rule 4(c) Report previous requests for complete records for the November 2, 2007 visit. Rule 4(c) Report at 3 n. 2.

recent visit” on October 31, 2007. P Ex. 1 at 1. The letter stated that “a small number of patients seen between 10/16/07 to 11/5/07 may have received PPD instead of the flu shot.” P Ex. 1 at 1 (emphasis added). The letter went on to explain the significance and risk of receiving a PPD injection, stating that PPD “will not harm you if you received it instead of the flu shot.” Id. The letter also discussed the risks associated with getting a second flu shot, noting it will “not cause any potential harm to you.” Id. The letter explained that the vaccine manufacturer, citing the Center for Disease Control and Prevention, recommends a second flu shot if “we were not certain that one of our patients was vaccinated for the flu.” P Ex. 1 at 1. The letter offered a second flu vaccination at no cost to petitioner. P Ex.1 at 1. The letter offered an apology on behalf of the practice and explained that Albert Einstein Healthcare Network “thought it was important for . . . [petitioner] to know about the possibility that . . . [petitioner] may not have actually received the flu shot.” P Ex. 1 at 1. Petitioner interprets the letter from Albert Einstein Healthcare Network as informing petitioner that the “influenza virus vaccine that had been administered to her on 10/31/2007 may have contained, or been compromised of, a purified protein derivative of tuberculin.” Pet. at 2. On December 11, 2007, petitioner received a flu vaccination. P Ex. 1 at 3. Respondent contests this interpretation.

On January 24, 2008, petitioner admitted herself to the Chestnut Hill emergency room complaining of “sternal chest pain moving from the right side.” P Ex. 4 at 112, filed on Jun. 29, 2010. “The right side pain started the night prior to admission when the patient was lying in bed, moved to substernal location and increased in intensity.” P Ex. 4 at 112. The pain was “described as chest pressure increased by deep inspiration, not exacerbated by activity.” P Ex. 4 at 112. A form created during this hospitalization notes that influenza vaccination is not indicated as petitioner had already received a flu vaccine that season. P Ex 4 at 160. Petitioner was admitted to the telemetry unit to rule out a myocardial infarction.⁹ P Ex. 4 at 113. Some cardiac concerns were ruled out and petitioner was discharged in stable condition on January 25, 2007, with instructions to seek an outpatient stress test. P Ex. 4 at 113.

Petitioner again went to the emergency room at Chestnut Hill Hospital on January 28, 2008. P Ex. 5 at 176, filed on Jun. 10, 2010. She complained of chills, headache, right-sided weakness, slurred speech and inability to walk. P Ex. 5 at 174, 176. She tried to walk, but was unable. P Ex. 5 at 176. During this visit, she was admitted to the hospital for further tests, notably to assess whether petitioner had a stroke or complicated migraine. P Ex. 5 at 177, 221. A brain MRI was performed on January 31, 2008. P Ex. 5 at 214. She had a temporal artery biopsy done on February 1, 2008. P Ex. 5 at 177. It was found that a stroke was unlikely and petitioner had abnormal liver function tests and a fatty liver upon ultrasound. P Ex. 5 at 177. Thereafter, petitioner was discharged in stable condition on February 1, 2008. P Ex. 5 at 177. The Discharge Summary shows a diagnosis of right-sided weakness, cholecystitis and giant-cell arteritis. P Ex. 5 at 176

After her discharge from Chestnut Hill Hospital, Petitioner was admitted to Chestnut Hill Lodge for rehabilitation on February 1, 2008. See Medical Records (“P Ex. 7”), at 22, filed on Oct. 5, 2010. At that point, she had the diagnosis of stroke and right sided weakness. Ex. 7 at

⁹ Myocardial Infarction (“MI”) “is gross necrosis of the myocardium as a result of interruption of the blood supply to the area; it is almost always caused by atherosclerosis of the coronary arteries, upon which coronary thrombosis is usually superimposed.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 928 (30th ed. 2003).

22. While at Chestnut Hill Lodge, petitioner was given a Mantoux test, P Ex. 7 at 6, which is “a type of intradermal tuberculin test . . . to determine whether the patient has had exposure to or infection with mycobacterium tuberculosis” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1917 (31st ed. 2003). The test was read three days later and was negative. Id. On February 16, 2008, petitioner was discharged home. P Ex. 7 at 31-33.

Petitioner thereafter sought consultation for gallbladder surgery and a follow up with a neurologist for a “complicated migraine.” P Ex. P Ex. 1 at 26-27, 29-30.

Treating Facility’s Answers to Questionnaire

As stated, the issue of whether petitioner received a vaccination covered by the Act was discussed since the inception of this case. In a letter dated November 18, 2010, petitioner and respondent jointly submitted questions to petitioner’s medical facility, the Albert Einstein Healthcare Network, in an attempt to learn more about the injection administered to petitioner on October 31, 2007. Joint Status Report as to Subject Injection, filed Dec. 3, 2010. The parties’ questions and the facility’s answers are filed as attachments to the December 3 Joint Status Report. Document 13-1, Letter from Marie Keeley, Senior Counsel at Albert Einstein Healthcare Network, dated December 3, 2010 (“Response Letter”); Document 13-2, Letter to Marie Keeley from petitioner and respondent, dated November 18, 2010.

The facility’s responses noted that, besides the bill, there is no other record of petitioner receiving an influenza vaccine and the support staff who may have been present at petitioner’s visit on October 31, 2007, were no longer with the facility. Response Letter at ¶ 1-2. Also, the facility’s PPD log does not indicate that petitioner received PPD on the day in question. Id. at ¶ 1. Despite receiving her bill for the October 31, 2007 flu vaccine, the facility says it can only be positive that she received a flu vaccine on December 11, 2007, when she returned after receiving the November 27 letter about the possible injection with PPD. Id. at ¶ 3. The facility also estimated that six patients between October 16, 2007, and November 5, 2007, received PPD instead of the flu vaccine and none of these were invoiced for PPD. Id. at ¶ 3-4. In response to the question asking if they were aware of a possibility that petitioner may have received an influenza injection that contained PPD, the facility replied in the negative, noting the flu vaccine and PPD are packaged separately. Id. at ¶ 5.

Petitioner’s Argument

The petitioner avers that “she sustained an adverse reaction due to purified protein derivative being contained in the influenza vial which was used in the injection administered to the petitioner on 10/31/07.” Status Report of Injection (Docket #18). The petitioner interprets the letter from her treating facility dated November 27, 2007, as informing the petitioner “that the influenza virus vaccine that had been administered on 10/31/2007 may have contained, or been compromised of, a purified protein derivative of tuberculin.” Pet. ¶ 7. In addition, petitioner references the medical opinion of Dr. Adejare, which is not included in the record. Pet. ¶ 8. Petitioner attests that this doctor “concluded that there is no evidence to suggest a cause for the pleurisy **other than** the influenza virus vaccination which contained, or was compromised of, the purified protein derivative.” Pet. at 2 (emphasis in original). Without providing further evidence, petitioner continues to argue she received an adulterated form of the influenza vaccine.

Respondent's Argument

Respondent asserted in her Rule 4(c) Report that petitioner is simply unable to show she received a flu vaccine containing PPD. Respondent more generally stated that “petitioner is not entitled to compensation because she has not met her burden of proof.” Rule 4(c) Report at 4. Regarding petitioner’s assertion of a contaminated flu vaccine, the respondent quoted language from the letter sent by Albert Einstein Healthcare Network on November 27, 2007. “[A] small number of patients seen between 10/16/07 and 11/5/07 may have received PPD **instead** of the flu shot.” Rule 4(c) Report at 6 (emphasis added by respondent)(citing P Ex. 1 at 1). Further, respondent pointed to the Response Letter from petitioner’s treating facility. When asked if petitioner may have received a flu vaccination containing PPD, the answer was definitively “No. They are packaged separately.” Rule 4(c) Report at 6 (citing Response Letter). Regarding this information, respondent characterizes it as unambiguous. Id. at 6. Respondent concludes petitioner either received a flu vaccine or an injection of PPD, not a contaminated flu vaccine.

Legal Discussion

The Vaccine Act states that compensation shall be awarded if a petitioner proves by preponderant evidence the requirements found under § 300aa-11(c)(1) of the Act. One requirement is that petitioner must show she “received a vaccine set forth in the Vaccine Injury Table” § 300aa-11(c)(1)(A). A preponderance of the evidence requires petitioner to adduce evidence that makes the existence of her receipt of a vaccine covered by the Act more likely than not.¹⁰ Also, petitioner may utilize circumstantial evidence to show proof of vaccination. E.g., Centmehaiey v. Sec’y of the Dept. of Health & Human Servs., 32 Fed. Cl. 612, 623-34 (Fed. Cl. 1995), aff’d 73 F.3d 382 (Fed. Cir. 1995).

First and foremost, the undersigned finds that petitioner did in fact receive an influenza vaccine, covered by the Act, on October 31, 2007. Petitioner asserts she received a vaccination on October 31, 2007. Pet. at ¶¶ 2-3. Her proof of vaccination amounts to a bill for the influenza vaccine on October 31, 2007. P Ex. 6 at 3. One more piece of evidence that petitioner received the flu vaccine is the November 27, 2007 letter from her treating facility, which warned some patients may have received a PPD injection. The letter states, “I am writing you about the flu shot you received as part of your care at a recent visit” Although this letter may be based solely on the invoice petitioner submitted, P Ex. 7, receipt of it is further corroboration of the alleged vaccination. Vaccination receipt has been proven in this Program upon similar levels of evidence. E.g., Brown v. Sec’y of the Dept. of Health & Human Servs., 18 Cl. Ct. 834 (Cl. Ct. 1989)(finding vaccine receipt based upon parent’s personal calendar and doctor invoice), rev’d

¹⁰ See, e.g., Centmehaiey v. Sec’y of the Dept. of Health & Human Servs., 32 Fed. Cl. at 624 (Fed. Cl. 1995)(“The preponderance of the evidence standard requires the petitioner to ‘adduce evidence that makes the existence of a contested fact more likely than not.’”(citing Arrowood v. Sec’y of the Dept. of Health & Human Servs., 28 Fed. Cl. 453, 458 (1993)(quoting McClendon v. Sec’y of the Dept. of Health & Human Servs., 23 Cl. Ct. 191, 195 (1991)(citing Black’s Law Dictionary 1064 (5th ed., 1979)))); see also Doe/70 v. Sec’y of the Dept. of Health & Human Servs., 2011 WL 539133, *7, n.17 (Fed. Cl. Spec. Mstr. Feb. 9, 2011)(“A preponderance of the evidence standard requires a trier of fact to ‘believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact’s existence.’”).

on other grounds, 920 F.2d 918 (1990); Taylor v. Sec’y of the Dept. of Health & Human Servs., No. 90-857V, 1991 WL 1115031 (Fed. Cl. Spec. Mstr. 1991)(finding vaccine receipt based upon testimony corroborated by a baby book); Wonish v. Sec’y of the Dept. of Health & Human Servs., No. 90-667V, 1991 WL 83959 (Fed. Cl. Spec. Mstr. 1991)(finding vaccine receipt based upon parental testimony and references in medical records referring back to vaccination); Alger v. Sec’y of the Dept. of Health & Human Servs., No. 89-31V, 1990 WL 293408 (Fed. Cl. Spec. Mstr. 1990)(finding vaccine receipt upon testimony of mother and physician who alleged to administer the vaccine and was the infant’s routine physician); Groht v. Sec’y of the Dept. of Health & Human Servs., No. 00-287V, 2006 WL 3342222 (Fed. Cl. Spec. Mstr. 2006)(finding vaccine receipt based upon statements from treating physician given prior to litigation and given for the purpose of seeking medical treatment).

As for the evidence that calls the October 31, 2007 influenza vaccine in doubt, the letter from her treating facility, dated November 27, 2007, notes a three week period of time in which the facility suspects some patients **may** have instead received an injection of PPD. P Ex. 1 at 1. Thus, it is possible that instead of the flu immunization, petitioner received an injection of PPD. When questioned, the facility estimates six patients in that time period inadvertently received the PPD injection. Response Letter. Notably, the time period in which this occurred was October and November of 2007, a time of year when a large number of seasonal influenza vaccines are given; although speculation, the undersigned cannot imagine six patients is a very high percentage of the total patients who received the flu vaccine during this period at this facility. Therefore, the likelihood that petitioner was actually one of those six patients appears minimal. This inconclusive evidence is simply not enough to counter petitioner’s allegation and evidence of flu vaccine receipt. As such, it is found that the evidence preponderates in petitioner’s favor; petitioner has proven she received a flu vaccine, which is covered by the Act, on October 31, 2007.

However, petitioner’s allegation takes the question of vaccine receipt much further. Petitioner alleges her pleurisy was caused by a flu vaccine that somehow contained PPD. Petitioner references a doctor, Dr. Adejare, as finding no other cause for her pleurisy other than a flu vaccine containing PPD. Pet. at 1-2. Again, no evidence or statement was submitted by Dr. Adejare. It is noted that there is one other possibility – that petitioner is one of the six people who inadvertently received a PPD injection. If so, petitioner’s case is not covered by the act as PPD is not a Table vaccine. Apparently, this was not addressed by Dr. Adejare. Thus, there is no reliable support for Dr. Adejare’s alleged finding. See Moberly v. Sec’y of the Dept. of Health & Human Servs., 592 F.3d 1315, 1325-26 (holding special masters “are entitled – indeed, expected – to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting the evidence”).

The undersigned finds there is no evidence to support the belief that petitioner received an adulterated vaccination. As pointed out by respondent, the November 27, 2007 letter says some patients may have received PPD **instead of** the flu vaccine. P Ex. 1 at 1. It does not say patients may have received a flu vaccine containing PPD. In fact, the letter continues on to recommend another flu vaccination to provide immunity in case petitioner received PPD. Id. The letter also allayed fears of potential harm from a second vaccination in case petitioner actually received a flu vaccine on the October 31, 2007 visit. The letter characterizes a “one or the other” scenario. Also, in the Response Letter following the parties’ questions, the treating facility stated they are not aware of any possibility that petitioner received a flu vaccine

containing PPD, noting the vials are **packaged separately**. Beyond petitioner's speculation, there is no evidence that petitioner received a flu vaccination that contained PPD. In fact, there is no evidence that the possibility exists of a flu vaccination being given at the Einstein facility with PPD contamination.

At this juncture, the undersigned points out another potential flaw in petitioner's case. As noted in respondent's Rule 4(c) Report, petitioner has provided no evidence that her alleged injury lasted six months following vaccination or required hospitalization and surgical intervention. R Rule 4(c) Report at 7 (citing § 300aa-11(c)(1)(D)). The submitted medical records conclude approximately five months after vaccination and contain no specific mention of pleurisy after diagnosis in November 2007¹¹ or surgical intervention for the alleged pleurisy. Beyond the allegation in her Petition, petitioner has provided no evidence to fulfill this requirement. See § 300aa-13(a)(1) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.").

In conclusion, it is found that petitioner received a vaccine covered by the Act, an influenza vaccine, but has failed to show that vaccination contained PPD. As such, petitioner will need to investigate her case in order to continue. Petitioner must reexamine her present theory of the case, which presently rests on the allegation that an adulterated flu vaccine caused her pleurisy. Petitioner will have to produce a reliable expert opinion explaining how a flu vaccine can and did cause petitioner's pleurisy. See, e.g., Moberly, 592 F.3d at 1324 (discussing the requirement that petitioner provide reliable evidence of a theory of causation and that this theory is at work in the case). In addition, petitioner faces the requirement to present evidence to satisfy § 300aa-11(c)(1)(D) of the Act. Petitioner must prove that the residua of that injury lasted for six months following the receipt of the vaccine or required hospitalization and surgical intervention. Accordingly:

- **Petitioner shall file within thirty (30) days, by no later than April 30, 2012, an amended Petition consistent with the above findings and petitioner's evidence supporting a finding required under § 300aa-11(c)(1)(D). If petitioner is unable to file an amended petition and the required evidence, petitioner shall instead file a status report on what efforts are being made to comply with this Order.**

Any questions regarding this Order shall be directed to my law clerk, Danielle Strait, at (202) 357-6343.

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Special Master

¹¹ The undersigned does note that the symptoms petitioner suffered when she was admitted to the hospital on January 24, 2008, were similar to those she suffered when she was diagnosed with pleurisy in November 2007.