

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-603V

October 19, 2010

Not to be Published

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MORGAN BARNES, \*  
\*  
Petitioner, \*  
\*  
v. \*  
\*  
SECRETARY OF THE DEPARTMENT OF \*  
HEALTH AND HUMAN SERVICES, \*  
\*  
Respondent. \*  
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Denial of Motion to Stay  
Proceedings while science  
catches up to petitioner's  
allegation that Gardasil  
caused her fibromyalgia

## ORDER<sup>1</sup>

On September 15, 2009, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that her second Gardasil vaccination caused her chronic fatigue syndrome and/or fibromyalgia.

The Rule 4(b) Conference was held on November 4, 2009, during which petitioner's counsel stated she would file the medical records and an amended petition.

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<sup>1</sup> 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 constitute a clearly unwarranted invasion of privacy. When such a 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.

On November 4, 2009, petitioner filed medical records marked as Exhibits 1-10.

On December 30, 2009, petitioner filed medical records marked as Exhibits 11 and 12.

On January 12, 2010, petitioner filed medical records marked as Exhibit 13.

On January 13, 2010, petitioner filed medical records marked as Exhibit 14.

On March 4, 2010, petitioner filed an amended petition and her affidavits marked as Exhibits 15 and 16.

On March 26, 2010, the undersigned and the parties' counsel had a telephonic status conference. Petitioner's counsel stated she would file an expert report in 45 days. By Order dated March 26, 2010, petitioner's expert report was due May 10, 2010.

On May 10, 2010, petitioner filed a motion for an extension of time until July 9, 2010 to file a medical expert report.

On May 17, 2010, the undersigned granted petitioner's motion for an extension of time.

On July 9, 2010, petitioner filed a second motion for an extension of time until September 7, 2010 to file a medical expert report. This would mean that petitioner would have almost six months since the March 26<sup>th</sup> status conference to file an expert report.

On July 12, 2010, the undersigned granted petitioner's motion for another extension of time until September 7, 2010 to file a medical expert report.

On September 7, 2010, petitioner filed a Motion to Stay Proceedings on the ground that "additional time is necessary to allow the science surrounding the Gardasil vaccination to develop." Mot. to Stay, p. 4. Petitioner then refers to VAERS reports of an association between Gardasil and Guillain-Barré Syndrome (GBS), particularly if a vaccinee received Menactra vaccine. Mot. to Stay, p. 5. Petitioner in the instant action does not have GBS.

She then refers to VAERS reports of headaches, fever, nausea, myalgia, vomiting and warts after Gardasil. She mentions Indian Council reports of stomach disorders and epilepsy. Mot. to Stay, p. 6. Further, petitioner mentions an Australian study relating Gardasil to multiple sclerosis (MS). Mot. to Stay, p. 7. Petitioner in the instant action does not have warts, epilepsy, or MS.

She continues with a reference to Australian researchers reporting anaphylaxis after Gardasil vaccination. *Id.* Petitioner in the instant action did not have anaphylaxis. She mentions a report of 32 deaths after Gardasil. Mot. to Stay, p. 8. Petitioner in the instant action has not died. Petitioner continues with the list of reported illnesses post-Gardasil: gastroenteritis, appendicitis, pelvic inflammatory disease, urinary tract infection, pneumonia, pyelonephritis, bronchospasm, and asthma. Mot. to Stay, p. 9. Petitioner does not have gastroenteritis, appendicitis, pelvic inflammatory disease, urinary tract infection, pneumonia, pyelonephritis, and bronchospasm. Her exercise-induced asthma precedes her second Gardasil vaccination.

Petitioner asserts that the testing that Merck, the manufacturer of Gardasil, used in safety trials includes placebos contained aluminum adjuvants which themselves may have caused illness, making Gardasil look safe by comparison. Mot. to Stay, pp. 9-10. Petitioner states that Gardasil's safety has not been evaluated for pregnant women, immunocompromised individuals, and individuals 27 years of age and older. Mot. to Stay, p. 11. Petitioner in the instant action was not pregnant when vaccinated, is not immunocompromised, and was 16, not 27, years of age when she received her second Gardasil vaccination.

On October 7, 2010, respondent filed a Response to Petitioner's Request for an Indefinite Stay. Respondent discusses at length the general assertions petitioner makes in her motion to

stay. What is of more moment to this case, on page 6 of her response, respondent states “Petitioner seemingly ignores that her own treating doctors have suggested that her condition was likely caused by her severe, prolonged viral illness in January 2007. Notably, this opinion is shared by both petitioner’s PCP and Dr. Passo, her rheumatologist. *See* Pet. Exh. 1, pp. 34, 92.”

On October 19, 2010, the undersigned and counsel had a telephonic status conference during which the undersigned stated she was going to deny petitioner’s Motion to Stay Proceedings because it was the facts of petitioner’s case, not the absence of supportive medical research, that made it so difficult for petitioner to find an expert to support her allegations. In brief, all of petitioner’s contemporaneous medical records reflect that she gave a history to multiple providers that the onset of her symptoms was in late January-early February 2007 after she had a severe viral illness, which may or may not have been Epstein-Barr virus and could have been mononucleosis. Petitioner’s counsel asked for another two months (making a total of nine months) to find an expert or to file a status report if she could not find an expert. By Order of the same date, the undersigned gave petitioner until December 17, 2010 to file an expert report or, in lieu of one, a status report, and set the next telephonic status conference for January 4, 2011, at 11:00 a.m. (EST), unless petitioner requests a ruling on the record.

### **FACTS**

Petitioner was born on January 17, 1990.

On September 23, 2006, she received her first Gardasil vaccination. Med. recs. at Ex. 10, p. 1.

On November 7, 2006, she saw her doctor for polycystic ovary syndrome, exercise-induced asthma, and dysmenorrhea. Med. recs. at Ex. 1, p. 69.

On November 24, 2006, she received her second Gardasil vaccination. Med. recs. at Ex. 10, p. 1.

On February 9, 2007, she saw Dr. Alexius M. Bishop, complaining of being sick for one week, with dizziness, headache, bellyache, chills (hot and cold), two episodes of vomiting, nausea, decreased appetite, and fatigue. She told Dr. Bishop she had been exposed to mononucleosis. Med. recs. at Ex. 1, p. 26. This puts onset at around the beginning of February 2007.

On March 6, 2007, she saw Dr. Hillard, complaining of a four-week history of generalized body aches, and occipital and neck pain. Dr. Hillard noted her symptoms were consistent with a viral illness. Med. recs. at Ex. 1, p. 82. This puts onset at around the beginning of February 2007.

On March 28, 2007, petitioner saw Dr. Donald Gilbert, complaining of fatigue for about eight weeks, headaches, sleep problems, nausea, and joint or muscle pains. Med. rec. at Ex. 1, p. 85. This puts onset at around the end of January 2007.

On June 14, 2007, petitioner saw Dr. Tracy Ting and Dr. Murray H. Passo, a rheumatologist, complaining of myalgias all over. Since January 2007, she had muscle aches particularly in her calves. She reported that she had a significant illness in January 2007 which included fatigue, headache, sore throat, chills, and myalgias. She had poor sleep habits. She had posterior occipital headaches in January and February 2007. She had difficulty remembering things due to stress. Med. recs. at Ex. 1, p. 88. Petitioner had some numbness and tingling which was brief. Her grandmother had a possible diagnosis of fibromyalgia. On physical

examination, petitioner had several tender points throughout. The diagnosis was symptoms classic for fibromyalgia syndrome. Med. recs. at Ex. 1, p. 89.

On June 14, 2007, Dr. Passo wrote a letter to Dr. Alexius Bishop, stating that petitioner had a mono-like illness in January 2007 and, since then, had fatigue, headaches, throbbing, aching, occasional dizziness, sleep disturbance, and a mildly elevated sedimentation rate. Med. recs. at Ex. 1, p. 91.

On February 23, 2008, Dr. Passo wrote another letter to Dr. Bishop, stating that since petitioner's last visit, her fibromyalgia was worsening. He states that petitioner's upper respiratory syndrome in January 2007 set off her downward spiral. Her fibromyalgia syndrome flare was coincident to viral illnesses and school problems. Med. recs. at Ex. 1, pp. 98, 99, 101.

To four treaters (Drs. Bishop, Hillard, Gilbert, Passo), petitioner reported the onset of fibromyalgia was in late January or early February 2007, after she had a severe viral illness, possibly mononucleosis. As Dr. Passo, a rheumatologist, noted to Dr. Bishop, petitioner's upper respiratory illness in January 2007 set off her downward spiral.

### **DISCUSSION**

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence "(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. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y 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. Sec’y of HHS, 440 F.3d 1317, 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 . . . .” Such an approach is inconsistent with the use of circumstantial evidence. *Id.* The Federal Circuit stated in Althen, 418 F.3d at 1280, that “the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.”

The whole basis for petitioner’s Motion to Stay Proceedings is that unless she obtains an indefinite stay of proceedings, she will not be able to prove Prong 1 of Althen, *i.e.*, that Gardasil can cause fibromyalgia.

For the sake of this Order, the undersigned will assume that Gardasil can cause fibromyalgia. Petitioner’s problem is that she cannot avoid the four treating physicians to whom she told that the onset of her fibromyalgia symptoms occurred in late January or early February 2007, after she had a severe viral illness in January 2007. The onset of those fibromyalgia symptoms was two months after she received her second Gardasil vaccination. Petitioner is understandably having a difficult if not impossible time finding an expert who will say that Gardasil caused her fibromyalgia two months after her vaccination, but in close proximity to a severe upper respiratory infection. Petitioner is unlikely to fulfill Prong 2 of Althen.

Moreover, petitioner is understandably having a difficult if not impossible time finding an expert to say that an interval of two months is an appropriate time period for causation in fact, particularly with an intervening viral illness. Petitioner is unlikely to fulfill Prong 3 of Althen.

The undersigned has given petitioner from March 26, 2010 to today (almost seven months) to find a medical expert. At petitioner's counsel's request, the undersigned is giving petitioner two more months to find a medical expert. It should be apparent to petitioner, as it is apparent to the undersigned, that on the facts of this case, petitioner is unlikely to prevail and this state of affairs has nothing whatsoever to do with the nascent research that may or may not connect Gardasil to fibromyalgia. Since whether or not petitioner fulfills Prong 1 of Althen is unlikely to assist petitioner's prevailing because of the extreme unlikelihood that she will fulfill Prongs 2 and 3 of Althen, the undersigned denies petitioner's Motion to Stay Proceedings.

If, on the other hand, petitioner produces an expert report stating that the upper respiratory infection has nothing to do with petitioner's fibromyalgia, regardless of the opinion of petitioner's treating rheumatologist Dr. Passo, and that two months is an appropriate time interval for causation of fibromyalgia from Gardasil, the undersigned assumes the same expert will have a medical theory that links the vaccination to the condition without the need for epidemiological reports and other medical literature. As petitioner knows, the Federal Circuit does not require substantiation from medical literature, animal research, in vitro testing, or general acceptance in the medical or scientific communities, in order for petitioner to prove Prong 1 of Althen. See Capizzano, *supra*.

Petitioner's Motion to Stay Proceedings is hereby DENIED.

**IT IS SO ORDERED.**

October 19, 2010  
DATE

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s/Laura D. Millman  
Laura D. Millman  
Special Master