

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-997V

(Not to be Published)

SHEILA GRAFFEO, on behalf of the
Estate of JESSICA GRAFFEO,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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* Filed: October 13, 2015
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* Entitlement; Ruling on the Record;
* Influenza (“Flu”) Vaccine; Acute
* Respiratory Failure; Pneumonia; Coma;
* Death.
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Sheila Graffeo, Metairie, LA, *pro se* Petitioner.

Gordon E. Shemin, U.S. Dep’t of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT AWARD¹

On December 17, 2013, Sheila Graffeo filed a petition on behalf of the estate of her deceased daughter, Jessica, seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”).² Petitioner alleges that Jessica’s acute respiratory failure, pneumonia, coma, and ultimate death were caused-in-fact by her receipt of the Pneumovax 23³ and influenza (“flu”)

¹ Because this decision contains a reasoned explanation for my actions in this case, I will post it on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (Dec. 17, 2002) (current version at 44 U.S.C. § 3501 (2014)). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published decisions inclusion of certain kinds of confidential information. Specifically, under 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 whole decision will be available to the public. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter “Vaccine Act” or “the Act”]. Individual section references hereafter will be to § 300aa of the Act.

³ Section 11(c)(1) of the Vaccine Act requires that the injured person have “received a vaccine set forth in the Vaccine Injury Table . . .” The Pneumovax vaccine, however, is not a vaccine listed on the Vaccine Injury Table (*see, e.g., Amin v. Sec’y of Health & Human Servs.*, No. 13-300V, 2013 WL 3994322, at *2 (Fed. Cl. Spec. Mstr. July 29, 2013)), so Petitioner cannot prevail with a claim regarding Pneumovax vaccine having caused her daughter’s alleged injuries and

vaccines on December 14, 2011. Pet. at 1 (ECF No. 1). Petitioner has now requested that I rule on her claim based solely on the record as it currently exists. *See* Order, dated July 29, 2015. For the reasons set forth below, and based on my review of the record⁴ filed in this matter, I find that the evidence offered is insufficient to meet Petitioner's burden to establish entitlement to compensation, and therefore her claim warrants dismissal.

I. BACKGROUND

A. *Factual History*

As noted above, Ms. Graffeo filed her petition in December of 2013, and spent the ensuing fourteen months obtaining and filing medical records.⁵ Pet'r's Exs. 1-7. The filed records plainly establish that Jessica (then 26 years old) received a flu vaccine on December 14, 2011, and that she became extremely ill thereafter, dying a little less than two years later, on November 2, 2013. *See* Iberia Medical Center, records dated Jan. 8, 2013 at 7-9, 52-53; Dauterive Hospital, records dated 2008 through 2013 at 119-20. The crux of the parties' dispute is whether the symptoms she suffered in 2011 through 2013 were caused by the flu vaccine, or were unrelated and/or simply reflected her pre-vaccination poor health.

The record establishes that at the time she received the flu vaccine, Jessica had a history of insulin-dependent diabetes (which was poorly controlled). Iberia Medical Center, records dated Jan. 8, 2013 at 7-9, 53-54. Jessica had been dealing with insulin-dependent diabetes (and associated complications) since she was seven years old. Iberia Medical Center, dated Dec. 11, 2011 through Mar. 6, 2012 at 11. Thus, when Jessica was admitted to a hospital in New Iberia, Louisiana through the emergency room on December 13, 2011 (the day prior to the vaccination at issue) after reporting that she had been experiencing nausea and vomiting over the last few days,⁶ her principal diagnosis

ultimate death. Accordingly, I will only provide further review going forward in my decision with regards to Petitioner's claim with that the flu vaccination was responsible for her daughter's injuries and ultimately her death.

⁴ Ms. Graffeo's petition is not supported by an affidavit, as the Vaccine Act requires. § 300aa-11(c)(1). Petitioner did, however, file medical records which themselves contain proof of vaccination, and also corroborate the facts pertaining to Jessica's alleged illness and its course in considerable detail. I therefore find that the failure to include an affidavit was a *de minimis* omission not prejudicial to the Petitioner. *See also* Vaccine Rule 2(B) (describing circumstances in which affidavits are required to supplement existing medical record).

⁵ The individual exhibits filed by Petitioner do not contain exhibit numbers (on the actual documents) or page numbers. Accordingly, the exhibits are referred to by the naming conventions utilized by Petitioner when filing the compact disks in this case, and the page numbers cited correspond to the page number of the actual PDF document (as reflected in the PDF reader).

⁶ This was not the first time Jessica had presented to the emergency department in 2011. On August 15, 2011, Jessica noted that she had been experiencing nausea for the past three to four days and expressed concerns that she was pregnant. Iberia Medical Center, records dated Jan. 8, 2013, at 19-20, 24. On August 19, 2011, Jessica went to the hospital reporting that she had been experiencing body aches for two months and that she thought her blood sugar was low, and also repeated her pregnancy concern. *Id.* at 30. *Id.* Then, on November 2, 2011, Jessica went back to the emergency room complaining of a rash, hives, and itching that had occurred for the last two weeks. *Id.* at 41.

was uncontrolled diabetes mellitus (“DM”) with ketoacidosis. *Id.* at 7-9, 49, 51.

Jessica’s symptoms responded well to treatment during the time that she was in the hospital. Iberia Medical Center, records dated May 15, 2012 at 12. Because it was noted that the flu and pneumococcal vaccinations were indicated for Jessica, she received both vaccinations prior to being discharged from the hospital on December 14, 2011. Iberia Medical Center, records dated Dec. 11, 2011 through Mar. 6, 2012 at 23, 53, 78. Four days later, however, on December 18, 2011, Jessica returned to the emergency room with complaints of dyspnea (shortness of breath), as well as a fever. Iberia Medical Center, records dated May 15, 2015 at 89, 109. While at Iberia Medical Center, Jessica was intubated and received manual ventilation. *Id.* A chest x-ray revealed “bilateral patchy infiltrates throughout much of the lung fields.” *Id.* at 108. Under clinical impressions, pneumonia, diabetic ketoacidosis (“DKA”), hypotension, and uncontrolled DM were listed. Iberia Medical Center, records dated Jan. 8, 2013, at 133. She was subsequently transferred to Regional Medical Center in Lafayette, Louisiana for admission because they could provide her with a higher level of care. Iberia Medical Center, records dated May 15, 2015 at 78-83, 117; Iberia Medical Center, records dated Jan. 8, 2013 at 132.

At that time, the following were listed under the assessment of Jessica’s condition: (1) DKA; (2) acute respiratory failure with acute lung injury, and possible acute respiratory distress syndrome (“ARDS”); (3) possible healthcare acquired pneumonia with sepsis; (4) acute renal failure likely prerenal in organ; (5) shock of multifactorial origin, primarily metabolic at this point; (6) iatrogenic hypokalemia; (7) shock liver; (8) systemic inflammatory response syndrome (“SIRS”) (due to DKA and probable infection); (9) diabetes mellitus type 1; (10) volume overload; and (11) elevated liver function test consistent with liver shock. Regional Medical Center, records dated Aug. 16, 2012 at 3011-12. Although the contemporaneous medical records record the fact of Jessica’s receipt of the flu vaccine days before, no connection between Jessica’s receipt of vaccination and present condition was made by her treaters. *Id.* at 3012.

Jessica remained hospitalized through February 6, 2012, and upon discharge her diagnoses were “acute respiratory failure, resolved; Type 1 diabetes; and hypothyroidism.” Regional Medical Center, records dated Aug. 16, 2012 at 3009. She was thereafter transferred to inpatient rehabilitation at Regional Medical Center of Acadiana. *Id.* at 2007, 3009. Her diagnosis in rehabilitation was listed as “[d]ebilitation following diabetic ketoacidosis resulting [in] an ICU stay and mechanical ventilation due to respiratory failure,” with the contributing factor of a “[l]ong history of poorly controlled type 1 diabetes resulting in above and decreased ADL function endurance and strength secondary to recent illness.” *Id.* at 2015. No mention of her flu vaccine as having had any role in her symptoms or illness is set forth in these contemporaneous records, however. She remained an inpatient at the transfer medical facility through February 23, 2012. *Id.* at 2015-16.

Jessica’s subsequent medical history for the remainder of 2012 through 2013 is characterized by repeated visits to hospital emergency rooms, complaining of symptoms similar to those she had

previously reported as reflected in the medical history, as well as increasingly severe medical problems.⁷ When Jessica came into the emergency room on June 4, 2012, she reported a three-week history of left breast access and was at that time was noted to be suffering from uncontrolled Type I diabetes, resulting in nearly a three week long hospitalization during which she developed renal failure. Regional Medical Center, records dated Aug. 16, 2012 at 36-39. Upon discharge, it was noted that Jessica would likely require dialysis. *Id.*⁸

As per orders from her treaters, Jessica was thereafter to undergo dialysis treatments three times per week for three hours each time at a facility in Acadiana, Louisiana. Kidney Care of Acadiana, records dated Apr. 18, 2014 at 171. Jessica did initially do so, but thereafter often failed to show up for appointments or terminated treatment early against the advice of her treaters (despite having been repeatedly warned about the risk associated with doing so). *See, e.g.*, Kidney Care of Acadiana, records dated Apr. 18, 2014 at 37, 76; Kidney Care of Acadiana, records dated Apr. 28, 2014 at 325-29. Because of the above, Jessica received the dialysis she required only after new inpatient admissions, often in connection with additional emergency room visits.⁹ By the summer of 2013, Jessica had informed the Acadiana facility that she would no longer receive dialysis treatments there because she was moving, and signed a formal waiver indicating her awareness of the risks she ran in abandoning regular treatment. Kidney Care of Acadiana, records dated Apr. 28, 2014 at 323.

Jessica returned to yet another hospital emergency room on October 17, 2013, complaining of chest pain and shortness of breath. Dauterive Hospital, records dated 2008 through 2013 at 266. During her hospitalization, despite having the importance of compliance with her medical therapy repeatedly reinforced, Jessica “continued to refuse inpatient hemodialysis and oftentimes refused her insulin.” *Id.* at 266. Jessica was encourage to remain in the hospital until her glucose levels were closer to the goal, but she decided to leave against medical advice on October 21, 2013. *Id.* at 266-67.

⁷ For instance, she visited the emergency room on February 25, 2012, complaining of a three day history of chest pain and shortness of breath, but let the hospital on her own accord against her treater’s advice. Regional Medical Center, records dated Aug. 16, 2012 at 1992, 1981.

⁸ On July 10, 2012, Jessica was admitted to Dauterive Hospital in New Iberia, Louisiana after presenting to the emergency room “with generalized weakness,” and “was lethargic and oriented to person only.” Kidney Care of Acadiana, records dated Apr. 28, 2014 at 286-87. She remained hospitalized until August 4, 2012, and at the time of discharge her diagnoses included “[e]nd-stage renal disease, on hemodialysis, hyperkalemia secondary to end-stage renal disease, uncontrolled type 1 diabetes mellitus secondary to noncompliance, hyperphosphatemia, heart failure systolic with an ejection fraction of 10%, noncompliance with medications and diet, and mildly elevated liver function tests.” *Id.*

⁹ For instance, on January 24, 2013, Jessica was admitted to Dauterive Hospital because of “altered mental state.” *Id.* at 268. At that time, it was noted that she was “very acidotic and sugar is very high, and also [Jessica] did not show up for dialysis the past week, so [she] was admitted to the hospital for dialysis and also treatment of DKA.” *Id.* at 268. Similarly, on April 9, 2013, Jessica was admitted to Dauterive Hospital due to complaints of chest pain. *Id.* at 262. After initially refusing to undergo hemodialysis upon admission to the hospital, Jessica underwent hemodialysis the next morning. *Id.* at 262.

Jessica had her final visit to an emergency room a little over a week later, on October 25, 2013, complaining of symptoms very similar to those she had reported in the past. Dauterive Hospital, records dated 2008 through 2013 at 119. After examination and testing, she was diagnosed with acute DKA and admitted to an intensive care unit. *Id.* During her hospitalization, Jessica's condition progressively worsened, requiring intubation, and she subsequently developed hypotension and sepsis. *Id.* She ultimately worsened to the point where she became unresponsive even without sedation. *Id.* at 120. Jessica had signed a "do not resuscitate" order, and she passed away on November 2, 2013. *Id.* at 119-20.

B. *Procedural History*

As noted above, Petitioner filed a number of medical records in the summer of 2014, and then filed her statement of completion in September of 2014 (ECF No. 15). I thereafter provided Ms. Graffeo the opportunity to locate and file additional medical records after Respondent indicated her belief that relevant materials were missing from the record. Order, dated Nov. 13, 2014 (ECF No. 21). Eventually, Respondent deemed the record sufficiently complete to address the merits of Petitioner's claim. Thus, on April 8, 2015, Respondent filed her Rule 4(c) report denying that Petitioner was entitled to compensation. Rule 4(c) Report (ECF No. 25).

Following the filing of Respondent's Rule 4(c) report, I urged Petitioner to consider what other proof she might offer to support her claim that the vaccines in question caused her daughter's alleged injuries and death – and in particular observed that an expert report might assist her in proving her case. *See* Status Conference Order, dated Apr. 23, 2015 (ECF No. 27). Despite being provided with an opportunity to do so (*see* Scheduling Order, dated Apr. 23, 2015 (ECF No. 27); Scheduling Order, dated June 24, 2015) (ECF No. 30)), however, Petitioner was unable to locate an expert to support her claim. Accordingly, on July 29, 2015, Ms. Graffeo contacted my chambers and orally requested a ruling on the record in this case as it then existed, foregoing the opportunity to present additional evidence in support of her claim. *See* Order, dated July 29, 2015 (ECF No. 31). I provided Respondent with an opportunity to reply to Petitioner's request for a ruling on the record, and she did so on August 8, 2015 (Response to Pet'r's Request for a Ruling on the Record (ECF No. 32)).

The parties' respective positions on the viability of Ms. Graffeo's claim were largely set forth prior to her request for a ruling on the record in this case.¹⁰ Petitioner had filed (on June 1, 2015) a document with six pages of information essentially consisting of her own review of available information regarding vaccine causation. *See* ECF No. 28. In it, Petitioner outlined information regarding two different medical conditions that could be attributable to the flu vaccine Jessica received. First, Petitioner provided information apparently copied from an unidentified internet source and pasted into a word document regarding ARDS, indicating that it "usually develops within

¹⁰ Indeed, in opposing Ms. Graffeo's request, Respondent simply referenced the arguments set forth in the earlier Rule 4(c) report. Resp. to Pet'r's Request for a Ruling on the Record (ECF No. 32).

a few hours to a few days after the original disease or trauma” and alleging that in this case, ARDS “[o]ccurred after Jessica received the two ordered vaccines.” Pet’r’s Statement of Additional Medical Information (ECF No. 28) at 2. However, as Petitioner also acknowledged, the most common underlying causes of ARDS are sepsis; inhalation of harmful substances; severe pneumonia; and head, chest, or other major injury (*id.*), and her report cited no other medical proof or literature causally connecting any vaccines to ARDS. Second, Petitioner provided information regarding Guillain-Barre syndrome (“GBS”), noting that it can be triggered by “recent surgery or immunization,” including “[r]arely, influenza vaccinations or childhood vaccinations,” and can result in death. *Id.* at 5. Petitioner, however, does not allege that Jessica suffered from GBS, nor do the medical records make any mention of it as a proposed or actual diagnosis for Jessica’s symptoms.

Respondent’s Rule 4(c) report contended that Ms. Graffeo could not establish her burden of proof by preponderant evidence, referencing the Federal Circuit’s conception of a vaccine injury claimant’s burden as stated in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In support of this argument, Respondent observed that no treater had identified the flu vaccine as the cause of Jessica’s death, and deduced from the record that Jessica’s pneumonia and respiratory failure in late 2011 was more likely attributed to a respiratory infection. ECF No. 25 at 7. Moreover, Respondent proposed that Jessica’s uncontrolled diabetes was the trigger for her intervening infections, episodes of diabetic ketoacidosis, and renal failure.¹¹ *Id.* at 7-8.

Respondent also asserted that Ms. Graffeo lacked a reliable medical or scientific theory explaining how the flu vaccine could cause Jessica’s sickness and death. ECF No. 25 at 6-8. And Respondent disputed whether Petitioner had satisfied the third *Althen* prong, arguing that to the extent Petitioner is alleging that Jessica’s shortness of breath in October of 2013, the time period immediately preceding her death, was caused by the flu vaccine, the nearly two years from when she received the flu vaccine in December of 2011 was too long a period to allow the inference that such a temporal period was medically acceptable. *Id.* at 7-8.

II. Analysis

To receive compensation under the Vaccine Program, a petitioner must prove either: (1) that she suffered a “Table Injury” – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question, or (2) that her illnesses were actually caused by a vaccine (a category of claim often referred to as a “Non-Table Injury”). See §§ 13(a)(1)(A), 11(c)(1), 14(a), and 11(c)(1)(C)(ii)(I); 42 C.F.R. § 100.3; see also *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320

¹¹ Respondent also questioned whether Petitioner met the six-month requirement (*see* 42 U.S.C. § 300aa-11(c)(1)(D) (requiring that the injured individual “suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine”)), because the medical records suggest that “following her discharge from Regional Medical Center in February 2012, Jessica likely returned to the baseline health status she had [experienced] prior to receiving the flu vaccine.” ECF No. 25 at 7, n. 8.

(Fed. Cir. 2006).¹² Ms. Graffeo has not alleged a Table Injury in this case (and in fact there are no Table Injuries specified for the flu vaccine, although the vaccine itself can be the basis for a claim).

I must therefore consider the requirements needed to prove a Non-Table Injury. Under such circumstances, the petitioner bears the burden of demonstrating actual causation by preponderant evidence. *Cedillo v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); § 13(a)(1). To do so, a petitioner must provide: “(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*, 418 F.3d at 1278. Under this evidentiary standard, a petitioner must demonstrate that the injury claimed was “more likely than not” caused by the alleged vaccine. *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner who successfully does so is entitled to compensation, unless the Respondent can then demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *Althen*, 418 F.3d at 1278.

Petitioners may be awarded Vaccine Program compensation based on “medical records *or* . . . medical opinion.” Section 13(a)(1) (emphasis added); *see also Althen*, 418 F.3d at 1279-80. Although expert testimony may be helpful and may be considered, there are no “hard and fast *per se* scientific or medical rules” for finding causation under the Vaccine Act, and thus no requirement that a petitioner offer expert testimony to prevail. *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Indeed, a special master may determine that a petitioner has carried his or her burden of proof sufficient to receive a Vaccine Program award even where the claim is not supported with conclusive medical literature, epidemiological studies, and/or theories enjoying general acceptance in the scientific or medical communities. *See Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009). Often, however, establishing a sound and reliable medical theory requires that the parties present expert testimony in support of their claims. *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000).

I have reviewed the entire record as required by the Vaccine Act (§ 300aa-13(a)(1)). Based upon that review, I find that Petitioner has failed to meet her burden of proof under any of the *Althen* prongs. Under its first prong, Petitioner was required to set forth a medical theory explaining how the flu vaccination that her daughter received could have caused her alleged injuries. *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Petitioner did not offer an expert report, but she has submitted information regarding various medical conditions (ADRS and GBS), as well as potential causes of and complications associated with those medical conditions. However,

¹² In this decision, I reference published decisions of other special masters, which constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). I also cite Federal Circuit decisions, which are binding on special masters. *Guillory v. Sec’y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d*, 104 F. App’x 712 (Fed. Cir. 2004); *see also Spooner v. Sec’y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

even if such information supports the conclusion that in certain cases vaccinations (including the flu vaccine) can result in illness, it does not bulwark her argument that the flu vaccine could cause the kinds of symptoms Jessica experienced in the almost two years following her receipt of that vaccine. She has not offered sufficient reliable scientific or medical evidence pertinent to the circumstances herein (for example, literature dealing with the effects of vaccination on individuals suffering from diabetes, or proposing some other theory by which the flu vaccine could cause the cascade of problems Jessica evidently experienced). Ms. Graffeo was not obligated to obtain an expert opinion to make her case, but given the nature of Jessica's overall health as reflected in the records, and lack of a treating physician that Jessica's vaccination was related to her symptoms, such support would have greatly assisted her in carrying her burden of proof. I find that she has not demonstrated how the flu vaccine could cause her daughter's alleged injuries (and ultimately her death).

I similarly find (even if the showing she made with respect to her theory of causation was deemed sufficient) that Ms. Graffeo has not established with preponderant evidence that the flu vaccine did cause Jessica's illness and/or death. Under the second prong of *Althen*, Petitioner is required to establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Here, however, none of Jessica's treaters speculated as to any connection (beyond the temporal) between her receipt of a flu vaccine and subsequent complications. *Moberly*, 592 F.3d at 1325 (although evidence from a treating physician regarding causation is not required, such evidence can be probative with regards to causation).

The record far more likely suggests that Jessica's underlying health problems (in particular, her diabetes) were the instigating factor for her symptoms. Jessica had a long history of diabetes, dating back to her childhood that predates administration of the flu vaccination at issue in this case. And Petitioner has not offered a more persuasive, contrary reading of the medical record (whether based on her own analysis or that of a competent medical expert). Accordingly, Petitioner has also failed to offer sufficient evidence to satisfy the second *Althen* prong.

I conclude the same with respect to the third component of a petitioner's burden under *Althen*, which requires a petitioner to show that there was a proximate temporal relationship¹³ between the vaccination and injury. *Althen*, 418 F.3d at 1279, 1281. To the extent Petitioner is alleging that

¹³ That term has been equated to the phrase "medically-acceptable temporal relationship." *Althen*, 418 F.3d at 1279, 1281. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what constitutes a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury set forth by the petitioner (*Althen* prong one's requirement). *Id.*; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (Fed. Cl. 2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877, at *27 (Fed. Cl. Spec. Mstr. May 30, 2013), *aff'd*, No. 2014-5054, 2014 WL 6804880 (Fed. Cir. Dec. 4, 2014).

Jessica's shortness of breath in October of 2013 (the time period immediately preceding her death) was caused by the flu vaccine, the nearly two years from when she received the flu vaccine in December of 2011 is too long to be medically appropriate to infer vaccine causation, and Ms. Graffeo has not offered any scientific or medical explanation for how this could have occurred. Nor has Ms. Graffeo offered an explanation for how the flu vaccine could have resulted in the symptoms that led to her daughter seeking medical intervention on December 18, 2011 (four days after receipt of vaccination). At bottom, she seems to be relying on the fact that her daughter became ill subsequent to receipt of the vaccination – but a temporal association alone is insufficient to establish entitlement to compensation. *Moberly*, 592 F.3d at 1323.

CONCLUSION

I have great sympathy for Ms. Graffeo's suffering at the loss of her daughter, and have no doubt this action has been pursued in a good faith desire to seek redress for that tragedy. However, I must make entitlement decisions on the basis of the legal standards applicable in the Vaccine Program regardless of the sympathy I have for petitioners. Having considered the evidence in the record in its totality, I am persuaded that despite her best efforts Ms. Graffeo has failed to offer sufficient evidence to meet her burden of proof. Accordingly, Petitioner is not entitled to an award of compensation under the Vaccine Program, and this case is hereby **DISMISSED**.

IT IS SO ORDERED.

Brian H. Corcoran
Special Master