In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1174V

(not to be published)

MERRY WHELAN,	*	Special Master Corcoran
Petitioner,	*	Filed: January 28, 2019
v.	*	Influenza ("flu") vaccine; Dermatomyositis ("DM"); *Althen* Prong Three.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Martin J. Rubenstein, Martin Rubenstein, Staten Island, NY, for Petitioner.

Sarah C. Duncan, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On September 21, 2016, Merry Whelan filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Ms. Whelan alleged that her October 4, 2013 influenza ("flu") vaccine caused dermatomyositis ("DM"). Pet. at 1 (ECF No. 1).

Once the medical records, statement of completion, Respondent's Rule 4(c) Report, and expert reports were filed, I conducted a status conference, during which I recommended that this

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with Internet access.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "pf 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 in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–34 (2012) (hereinafter "Vaccine Act" or "the Act"). Individual section references hereafter shall refer to §300aa of the Act.

case be resolved without hearing. *See* Minute Entry, May 9, 2018. The parties agreed to this proposition, and Petitioner filed a brief in support of her claim on July 31, 2018. *See* Pet'r's Pre-Hr'g Mem. (ECF No. 30-1) ("Pet'r Br."). Respondent subsequently filed a brief arguing for dismissal of Petitioner's claim. *See* Resp't's Response to Pet'r's Br. in Support of her Claim, filed Sept. 21, 2018 (ECF No. 33) ("Resp. Br."). Petitioner filed a Reply on October 4, 2018 (ECF No. 34).

Having completed my review of the evidentiary record and the parties' filings, I hereby **DISMISS** Petitioner's claim, for the reasons stated below.

I. Factual Background

Before receiving the flu vaccine at issue, Ms. Whelan's medical history was largely unremarkable. She did, however, have polymorphic light eruption ("PMLE")[3] from ages thirteen to fifty, as well as a family history of cancer. Ex. 10 at 2 (ECF No. 6-10).

On October 4, 2013, Petitioner, then age fifty-four, received the Fluvirin flu vaccine at a Walgreens in Cherry Hill, New Jersey. Ex. 1 at 3 (ECF No. 6-1). There is some dispute about the situs of the vaccine's administration: the vaccination record states that she received it in her left shoulder (*id.*), but Petitioner later reported that she received the shot in her *right* shoulder. Ex. 15 at 2 (Expert Report of Dr. Arthur Brawer), filed July 5, 2017 (ECF No. 12-1) ("Brawer Rep.").

There are no medical records relevant to Petitioner's claim for the next two months. Then, on December 13, 2013, Petitioner saw her dermatologist, Emily Miller, M.D., for a mole check. Ex. 3 at 21–22 (ECF No. 6-3). Notes from that visit do not reflect concern about any muscle pain or a rash. *See id.* At a January 22, 2014 annual check-up with a gynecologist,[4] however, Petitioner was now noted (for the first time in the medical records in this case) to have left shoulder pain and a history of "frozen shoulder." Ex. 17 at 11–12 (ECF No. 13-2). This record does not specify when such pain began. *See id.*

On March 25, 2014, Petitioner returned to Dr. Miller with complaints of an itchy rash on her face and hands, which she stated had been present for approximately two months (meaning it began in late January). Ex. 3 at 19–20. She connected the start of her rash to a trip to Puerto Rico. *Id.* at 20. At this same visit, she denied muscle pain and weakness. *Id.* Dr. Miller noted that the rash could be evidence of PMLE, DM, or SCLE [subacute cutaneous lupus erythematous]. *Id.* At

[3] PMLE is skin rash resulting from exposure to sunlight. *Dorland's Illustrated Medical Dictionary* 642, 1538 (32nd ed. 2012) (hereinafter "*Dorland's*").

[4] Notes from this visit do not identify which physician Ms. Whelan saw. *See* Ex. 17 at 11–13.

a follow-up appointment with Dr. Miller on April 1st, examination revealed a worsening rash as well as a Gottron's papule[5] on Ms. Whelan's right hand. *Id.* at 10–11. Dr. Miller then ruled out PMLE and SCLE, diagnosing Petitioner with DM. *Id.* at 10.

Ms. Whelan's rash thereafter continued to spread, and she saw Dr. Miller for two additional follow-up visits in April 2014. Ex. 3 at 4–5, 8–9. Petitioner consulted with two rheumatologists and another dermatologist the following month: an in-person visit with rheumatologist Brian Grimmett, M.D., on May 5th; a telephone consultation with rheumatologist Preethi Thomas, M.D., on May 9th; and an in-person visit with dermatologist Victoria Werth, M.D., on May 13th. Ex. 9 at 4–5 (ECF No. 6-9); Ex. 10 at 2–3; Ex. 29b at 204–08 (ECF No. 20-2).

At her visit with Dr. Grimmett, Petitioner reported that she had started experiencing weakness in her legs at least four months earlier (or January), with weakness in her arms and neck developing sometime thereafter. Ex. 9 at 4. During her telephone consultation with Dr. Thomas, by contrast, Petitioner stated that her symptoms began in December 2013 with left shoulder pain. Ex. 29b at 204. Ms. Whelan reiterated her belief that her rash began during a February 2014 vacation in Puerto Rico at these visits. Ex. 10 at 29; Ex. 29b at 204. All three physicians confirmed that Petitioner suffered from DM, noting a serious rash and weakness in multiple extremities that made even simple tasks difficult. Ex. 9 at 5; Ex. 10 at 30; Ex. 29b at 204. Furthermore, Dr. Thomas noted that many DM cases are indicative of the presence of cancer, and she accordingly recommended several cancer screenings. Ex. 29b at 208.

On June 12, 2014, Petitioner saw Allan Magaziner, D.O., at the Magaziner Center for Wellness. Ex. 2 at 10–11 (ECF No. 6-2). At this visit, she now informed Dr. Magaziner of her suspicions (for the first time in this medical record) that her symptoms "actually began in October 2013 when she felt she may have had a frozen shoulder as she had some discomfort in that area." *Id.* at 10. But this record makes no mention of the flu vaccine. *See id.* at 10–11. Ms. Whelan then underwent a colonoscopy on July 16, 2014, which was normal except for a finding of non-bleeding internal hemorrhoids. Ex. 5 at 5–6 (ECF No. 6-5). The colonoscopy was ordered due to treater concern that her DM diagnosis could be secondary to an "occult malignancy." *Id.* at 9.

Six months later, Petitioner experienced a DM flare-up in January and February of 2015. Ex. 10 at 14, 19–20. The record is otherwise silent as to any other subsequent flare-ups or DM symptom recurrence. In addition, nearly three years after her October 2013 flu vaccination, Petitioner was treated for breast cancer. An August 16, 2016 mammogram revealed a small mass in her right breast, and a September 1st biopsy confirmed the presence of a ductal carcinoma in situ ("DCIS").[6] Ex. 27 at 3 (ECF No. 19-4). The small tumor was removed on October 13th, after

[5] Gottron's papules are small, flat-topped, and discolored raised areas on the knuckles characteristic of DM. *Dorland's* at 1373.

[6] A DCIS is a malignant growth in a mammary duct that has not spread elsewhere in the body. *Dorland's* at 291, 569,

which Ms. Whelan underwent radiation therapy. *Id.* at 3, 12. She successfully completed radiation treatment on December 28, 2016. *Id.* at 12.

At a September 18, 2017 visit with Dr. Thomas, Petitioner was reported to have no weakness and that her rash was better. Ex. 29a at 4 (ECF No. 20-1).

II. Witness Statements

Only one statement[7] was filed in this case, from Petitioner's close friend, Gail Parker Krol. *See* Ex. 40, filed July 31, 2018 (ECF No. 30-2). In it, Ms. Krol stated that Ms. Whelan had complained to her of pain and weakness in her right upper arm in mid-October 2013. *Id.* at 2. Ms. Krol believed this to be "frozen shoulder," which she herself had previously experienced. *Id.* After Petitioner was diagnosed with DM, Ms. Krol conducted independent research that led her to believe that Ms. Whelan's condition may have resulted from her flu vaccine. *Id.* at 3–4. Ms. Krol's affidavit also provides corroboration for several points that are well-substantiated in Petitioner's medical record, including the fact that Petitioner developed a rash after her trip to Puerto Rico and had a small tumor removed from her breast in September 2016. *Id.* at 2–3.

III. Expert Reports

A. *Dr. Arthur Brawer*

Arthur Brawer, M.D., filed two reports on Petitioner's behalf. *See generally* Brawer Rep.; Ex. 38, filed Apr. 26, 2018 (ECF No. 27-1) ("Brawer Supp. Rep."). Petitioner did not file a curriculum vitae ("CV") for Dr. Brawer, but his letterhead indicates that he is a rheumatologist and serves as a diplomate to both the American Board of Internal Medicine and the American Board of Rheumatology.[8] Brawer Rep. at 1. Dr. Brawer opined that the flu vaccine caused Petitioner's DM through molecular mimicry.

i. *Dr. Brawer's First Expert Report*

571, 944.

[7] Contrary to Vaccine Act requirements, Petitioner did not file a sworn statement of her own to accompany her Petition. *See* Section 11(c)(1).

[8] Dr. Brawer has testified previously in the Vaccine Program. *See, e.g.*, *Cabrera v. Sec'y of Health & Human Servs.*, No. 13-598V, 2017 WL 510466, at *4 (Fed. Cl. Spec. Mstr. Jan. 12, 2017). As noted in *Cabrera*, he received his M.D. from Boston University, then completed a residency in internal medicine and a fellowship in arthritis. *Id.* As of early 2017, he was board-certified in internal medicine and rheumatology. *Id.* At that time, he served as an associate clinical professor at Hahnemann/Drexel University School of Medicine in Philadelphia, as well as an assistant clinical professor of medicine at Robert Wood Johnson University School of Medicine in New Brunswick, New Jersey. *Id.*

Dr. Brawer begins his six-page report by noting that he performed an in-person evaluation of Ms. Whelan, in addition to a review of her medical records. Brawer Rep. at 1. He provides an overview of Petitioner's medical history, noting that she received the October 4, 2013 flu vaccine in her *right* arm—contrary to what the vaccination record and other medical records state, although he asserts that such records are "in error." *Id.* at 1–2. Dr. Brawer describes Petitioner's post-vaccination course, stating that she began experiencing severe pain in her right shoulder one week after vaccination, which developed into progressive weakness in both upper extremities, a feeling of heaviness in her legs, and frequent fatigue. *Id.* He notes further that, in early 2014, she developed a rash on her forehead, followed by a generalized full-body rash. *Id.* With no specific reference to Petitioner's February 2014 trip to Puerto Rico, Dr. Brawer asserts that "[n]one of this rash was precipitated by sun exposure." *Id.* Dr. Brawer does not address the fact that Ms. Whelan's medical records are silent as to her claimed soreness, weakness, and fatigue in the final months of 2013. He next describes the results of his physical examination of her, concluding that she suffers from DM "directly initiated by and related to the influenza vaccination administered on October 4, 2013." *Id.* at 3.

Dr. Brawer then turns to his explanation of how the flu vaccine caused Petitioner's DM. Brawer Rep. at 4–5. He describes the theory of molecular mimicry, in which "antigens of infectious agents can cross react with self-antigens on a variety of body cells, including immunocompetent cells, thereby triggering systemic inflammatory reactions." *Id.* at 4. He alludes to "numerous reports" that purportedly provide support for the theory of molecular mimicry in general (though he specifically cites to only one item of medical literature), then proceeds to identity six scientific articles that ostensibly speak to the theory's applicability to DM. *Id.* at 5.

In the alternative, Dr. Brawer briefly touches on other theories of causation. Brawer Rep. at 5. In particular, he notes that vaccines can "alter the balance between helper and suppressor T-cells," and that "[p]olyclonal B-cell activation . . . can also occur following vaccination." *Id.* Furthermore, he alludes to "additional deleterious mechanisms of vaccine induced autoimmune diseases, including adjuvants such as aluminum, modification of surface antigens, induction of novel antigens, and exposure of sequestered antigens." *Id.* Dr. Brawer does not discuss any of these alternative theories in detail, however, nor does he discuss their applicability to the flu vaccine and DM.

Dr. Brawer turns next to the questions of whether there was a logical sequence of cause and effect and reasonable temporal relationship linking Petitioner's DM to the flu vaccine. Brawer Rep. at 5–6. Noting that Ms. Whelan did not experience other conditions likely to trigger DM prior to her diagnosis (such as systemic inflammatory arthritis), Dr. Brawer concludes that the sequence of cause and effect is logical. *Id.* He finds "complete concordance" between Petitioner's medical

records and her self-reported history, and based on this concludes with "an emphatic yes" that the October 4, 2013 flu vaccine is temporally related to Ms. Whelan's development of DM. *Id.* at 6.

ii. *Dr. Brawer's Second Expert Report*

Dr. Brawer's supplemental report was filed in response to the report from Respondent's expert (which is discussed below). Brawer Supp. Rep. at 2. He examined Ms. Whelan for a second time on April 11, 2018, and he begins his second report by providing an update on her condition. *Id.* at 1. He asserts that she experienced a DM flare-up in late fall of 2017, but does not identify medical records supporting this.[9] *Id.*

Dr. Brawer then responds to Dr. Matloubian's report. He discusses Petitioner's September 2016 lumpectomy in relation to her DM, noting that the almost three-year gap between her flu vaccine and lumpectomy makes it "far outside the realm of probability" that her carcinoma was present when her DM first began. Brawer Supp. Rep. at 3. However, he provides no explanation of what *would* constitute a reasonable time lapse in order for there to be a causal link between the cancer and the preceding DM, nor does he cite medical literature in support of his statements on this topic. *Id.* at 3–4. Finally, Dr. Brawer reiterates his conclusions from his first report and provides a brief rebuttal to criticisms raised by Dr. Matloubian, emphasizing the varied causes, presentations, and courses of inflammatory systemic connective tissue diseases.[10] *Id.* at 2.

B. *Dr. Mehrdad Matloubian*

Mehrdad Matloubian, M.D., Ph.D., provided one report on behalf of Respondent. *See* Ex. A, filed Dec. 1, 2017 (ECF No. 22-1) ("Matloubian Rep."). As reflected in his CV, Dr. Matloubian received his B.S., M.D., and Ph.D. (specializing in immunology and virology) from the University of California, Los Angeles. Ex. B at 1, filed Dec. 1, 2017 (ECF No. 23-6) ("Matloubian CV"); Matloubian Rep. at 1. He completed a residency in Medicine at the University of California, San Francisco ("UCSF"), followed by a fellowship in rheumatology at the same facility. Matloubian CV at 1.

Dr. Matloubian's practice involves a combination of research and patient care. He has served as an associate professor of Medicine at UCSF since 2001. Matloubian CV at 2. In his research, Dr. Matloubian focuses on innate and adaptive immune responses to viral infections, and

[9] Petitioner has not otherwise filed medical records substantiating or providing details about this alleged DM flare-up.

[10] Dr. Brawer also dedicates a sizable portion of his supplemental report to criticizing Dr. Matloubian's report, largely by way of ad hominem attacks on Dr. Matloubian himself. *See* Brawer Supp. Rep. at 2–4 (characterizing Dr. Matloubian as having "little appreciation for the fact that the complexity of nature far transcends man's ingenuity," having "a cookie-cutter, one-size fits all approach to inflammatory systemic connective tissue diseases that is untampered by clinical reality," and having an "obsession with the deficiencies of molecular mimicry;" and asserting that "the usefulness and validity of Dr. Matloubian's report of November 28, 2017 is inversely related to its length").

he has published numerous articles in reputable medical journals on issues in this field. *Id.* at 7–8, 10–14; Matloubian Rep. at 1. In addition to teaching and research work, he also serves as associate director of the UCSF Molecular Medicine Consult Service, which is a recently-established hospital service involving both clinicians and research scientists, who work together to treat patients with a variety of unusual disorders. Matloubian CV at 3. Additionally, Dr. Matloubian has spent one month per year as an attending physician on the UCSF Inpatient Rheumatology Consult Service since 2001. *Id.*

In his fifteen-page report, Dr. Matloubian discusses Petitioner's medical history, opines that the flu vaccine played no role in her development of DM, and offers an alternative theory of causation. *See generally* Matloubian Rep. Unlike Dr. Brawer, Dr. Matloubian did not personally examine Ms. Whelan, but he provides a detailed review of her medical history. *Id.* at 1–3. In his view, no causal link exists between the flu vaccine and DM, and he discusses the weaknesses in Dr. Brawer's theory at length. *See id.* at 7–12.

DM, Dr. Matloubian explains, is one of the idiopathic inflammatory myopathies—a group of heterogeneous autoimmune diseases of unknown cause that affect both the skin and muscle function. Matloubian Rep. at 4. It presents with a rash (often in a specific pattern) after extensive sun exposure, as well as muscle weakness in the neck, shoulders, upper arms, and thighs. *Id.* The effects on the muscles are symmetric, meaning that both sides of the body are affected equally. *Id.*

Dr. Matloubian criticizes Dr. Brawer's assertion that the flu vaccine can cause DM through molecular mimicry. Matloubian Rep. at 7–12 (discussing Brawer Rep. at 4–5). He provides an overview of how molecular mimicry works, explaining that, regardless of whether a disease is mediated by B cells or T cells, the specific antibodies produced (whether in response to an infection or vaccination, as alleged here) to fight a particular pathogen must detect parallel structures to that pathogen in self-cells in order for molecular mimicry to occur. *Id.* at 8. Accordingly, in order for a vaccine to cause an autoimmune disease (such as DM), the pathogen from which the vaccine is derived must, in his opinion, be associated with the autoimmune disease in question. *Id.* at 8, 10. This means, he argues, that the wild virus (which the vaccine immunizes against) should *also* plausibly cause the same autoimmune disease in some individuals. *Id.* Against this backdrop, Dr. Matloubian proceeds to assess whether the wild flu virus has been shown to cause DM. *Id.* at 10. His research revealed no studies linking the two, which he finds particularly compelling given the high incidence of wild flu infections worldwide. *Id.* at 10–11.

Dr. Matloubian next considers the medical literature cited by Dr. Brawer in support of his assertion that the flu vaccine is associated with DM. Matloubian Rep. at 11–12. He discusses five of the six items of literature cited by Dr. Brawer (*see* Brawer Rep. at 5) in turn. Matloubian Rep. at 11–12. One was a letter to the editors of medical journal The Lancet aiming to *correct* the mistaken view that the flu vaccine and DM were associated. *Id.* at 11 (citing Richard K.

Winkelmann, *Influenza Vaccine and Dermatomyositis*, 320 The Lancet 495 (1982), filed as Ex. 20 (ECF No. 16-1) ("Winkelmann")). Another was a case report linking the Hepatitis B vaccine—which is entirely unrelated to the flu vaccine—to DM. *Id.* (citing Arie Altman et al., *HBV Vaccine and Dermatomyositis: Is There an Association?*, 28 Rheumatology Int'l 609 (2007), filed as Ex. 21 (ECF No. 16-2) ("Altman")). Collectively, three others referenced the *same* case report of a patient who experienced DM following a flu vaccination. *Id.* at 11–12 (citing F.M. Jani et al., *Influenza Vaccine and Dermatomyositis*, 12 Vaccine 1484 (1994), filed as Ex. 28 (ECF No. 19-5) ("Jani") (one flu-DM case report); Joerg-Patrick Stügben, *A Review on the Association Between Inflammatory Myopathies and Vaccination*, 13 Autoimmunity Rev. 31 (2013), filed as Ex. 23 (ECF No. 16-4) ("Stügben") (listing one flu-DM case report, which is the Jani report)[11]; H. Orbach & A. Tanay, *Vaccines as a Trigger for Myopathies*, 18 Lupus 1213 (2009), filed as Ex. 25 (ECF No. 19-2) (discussing one flu-DM report, which is the Jani report)). Furthermore, Dr. Matloubian opines that it would be improper to rely on case reports alone to support a theory of causation between the flu vaccine and DM, as they do not discuss the subjects' prior or subsequent medical history, and "provide no mechanistic evidence for causation and may simply reflect coincidental temporal association." *Id.* at 12. He also calls into question the accuracy of the DM diagnosis made in the Jani case report.[12]

Dr. Matloubian also responds to one of Dr. Brawer's alternative theories of causation. Matloubian Rep. at 12 (discussing Brawer Rep. at 5). He notes that, while Dr. Brawer theorizes that adjuvants may play a role in vaccine-related harms, the flu vaccine received by Ms. Whelan (Fluvirin) contains no adjuvants. *Id.*[13]

Dr. Matloubian also discusses onset and the timing of Ms. Whelan's first DM-related symptoms. When an injury is driven by molecular mimicry, Dr. Matloubian noted, onset would be expected to occur within one to three weeks after vaccination. Matloubian Rep. at 14. He explained that this is the case because B- and T-cell responses peak ten to fourteen days after immunization. *Id.* at 13. In his view, however, the record establishes that Petitioner's DM symptoms did not begin until December of 2013, when she first experienced "musculoskeletal symptoms," more than eight weeks after immunization, making vaccine causation impossible even under Petitioner's proffered theory. *See id.*

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[11] Dr. Matloubian states that Stügben contains "a handful" of flu-DM cases, but in my own review of the article I found only one listed. Matloubian Rep. at 11; Stügben at 33.

[12] Dr. Matloubian does not discuss the final item of medical literature cited by Dr. Brawer in his first report, "an article in 1979 in the Scandinavian *Journal of Rheumatology* by E. Kass, entitled 'Dermatomyositis associated with BCG vaccination'" ("Kass"). Brawer Rep. at 5. That article does not appear to have been filed in this case. Regardless, based on its title, it appears to discuss the bacille Calmette-Guérin vaccine, which immunizes against tuberculosis and is thus not relevant to this claim. *Dorland's* at 2015.

[13] *See* Package Insert—Fluvirin at 8, *available at* U.S. Food & Drug Admin., *Fluvirin*, https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm112852.htm.

In addition to offering criticism of Dr. Brawer's theories of causation, Dr. Matloubian also puts forth an alternative theory linking Petitioner's DM to her subsequent breast cancer. Matloubian Rep. at 4–6. He cites epidemiologic studies in support of his position that DM is associated with cancer, even when the cancer is diagnosed for up to five years after the DM. *Id.* at 4–5. He explains how immune responses to cancer cells may also attack normal tissue, causing autoimmune diseases such as DM. *Id.* at 5. While he concedes that the link between cancer and DM is still not fully understood, Dr. Matloubian opines that it is likely a correct hypothesis, and that is accurately describes Petitioner's clinical course. *Id.* at 6. Noting that her carcinoma was detected approximately two years after her DM diagnosis, he finds it likely that her 2014-diagnosed DM was related to her then-likely subclinical breast cancer. *Id.* at 5–6.

IV. Procedural History

As noted above, Ms. Whelan filed her Petition on September 21, 2016. Respondent filed his Rule 4(c) Report on April 3, 2017. ECF No. 9. Petitioner's medical records were submitted sporadically over the course of many months, the last of which were filed on October 23, 2017. Dr. Brawer's initial expert report was filed in July 2017, followed by supporting medical literature two months later. Respondent filed Dr. Matloubian's report and accompanying medical literature in December 2017, and Petitioner filed Dr. Brawer's responsive report in April 2018. The parties submitted their respective briefs in the summer and fall of 2018. This case is now ripe for decision.

V. Parties' Respective Arguments

A. *Petitioner's Memorandum*

Petitioner asserts that she has satisfied all three prongs (discussed in detail below) of the Federal Circuit's test for determining Vaccine Act entitlement stated in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), and has thus demonstrated entitlement to an award of compensation on a theory of causation-in-fact. *See* Pet'r Br. at 1. Emphasizing that Dr. Brawer met with Ms. Whelan twice in person and has extensive clinical experience, she urges me to adopt his conclusion about the flu vaccine's causal role in her development of DM. *Id.* at 4–5.

Ms. Whelan contends that she has provided a theory of general causation through Dr. Brawer's explanation of molecular mimicry. Pet'r Br. at 2. She highlights a quotation from the Jani case study, whose authors opined that the patient's onset of DM shortly after vaccination and the disease's similar presentation to other vaccine-associated DM cases "do suggest a causal relationship" linking the flu vaccine and DM. *Id.* at 8 (citing Jani at 1484).

Petitioner notes further that Dr. Brawer discusses alternative theories of vaccine-induced injury, including an altered balance between helper and suppressor T cells, "polyclonal T cell activation," the role of adjuvants, "modification of surface antigens," "induction of noval [*sic*] antigens and exposure of sequestered antigens." Pet'r Br. at 2. Petitioner does not identify which, if any, of these concepts applies specifically to her case, however, nor does she provide further detail or scientific support regarding any of their mechanisms of causation. *See id.*

Turning next to the question of whether Petitioner's flu vaccine is connected to her subsequent DM onset by a logical sequence of cause and effect, Petitioner cites to Dr. Brawer's conclusion that her DM cannot be attributed to other causes. Pet'r Br. at 3. In particular, she notes that she did not experience systematic inflammatory arthritis prior to developing DM. *Id.* She argues further that the close temporal nexus between her vaccination and DM onset, as well as the indefinite continued existence of her condition, illustrate the vaccine's causal role. *Id.*

Petitioner briefly discusses the temporal connection between the flu vaccination and her development of DM. Pet'r Br. at 3. Though she does not specify when her DM onset began, she restates Dr. Brawer's conclusion that her self-reported medical history at her in-person consultations with him is in "complete concordance" with her medical records. *Id.*

After laying out her case for compensation, Petitioner proceeds to criticize the alternative theory of causation put forth by Dr. Matloubian: that her DM could be linked to her 2016 breast cancer. Pet'r Br. at 4–5; 9–12. Ms. Whelan notes that her DCIS was "not a full blown disease process but a strictly localized process, which in any event was likely not present in the Fall of 2013." *Id.* at 4–5. She also asserts that her DM was not alleviated after the DCIS was excised. *Id.* at 12.

Petitioner also discusses evidence cited by Dr. Matloubian in support of his cancer-causation theory. Pet'r Br. at 9–12. She notes that Dr. Matloubian quotes a finding that between nine and thirty-two percent of DM cases are associated with cancer, which means that sixty-eight to ninety-one percent of DM cases are *not* cancer-associated. *Id.* at 9. With regard to the literature cited by Dr. Matloubian in support of his conclusions, Petitioner asserts that "[w]hile Dr. Matloubian refers to an extensive body of literature supporting an association between [DM] and cancer, only a minority of patients with [DM] have cancer diagnosed." *Id.* at 11–12. She criticizes the inadequacy of his discussion of DM and cancer, stating that he had failed to explain whether cancer causes DM, vice versa, or whether some additional factor plays a causal role in both conditions. *Id.* at 9. Finally, she criticizes his overall logical framework, arguing that his opinion that there is no cross-reactivity between the flu vaccine and relevant self-cells should undermine his conclusion that such cross-reactivity exists between tumor-specific immune cells and relevant self-cells. *Id.* at 12.

B. *Respondent's Response*

Respondent counters Petitioner's claim for entitlement, asserting that Petitioner has not satisfied any of the three *Althen* prongs. Resp. Br. at 1.

First, Respondent contends that Petitioner has failed to provide a sound and reliable theory of causation linking the flu vaccine to DM. Resp. Br. at 10. He urges me not to accept the theory of molecular mimicry without concrete support for a link between the specific vaccine and illness at issue, citing a previous Vaccine Program decision in which I stated that petitioners "cannot simply invoke the concept of molecular mimicry and call it a day." *Id.* at 10 (quoting *Johnson v. Sec'y of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018)). He notes that the literature cited by Dr. Brawer in support of his molecular mimicry theory largely does *not* actually support his conclusions. *Id.* at 10–11. Respondent notes that Dr. Matloubian's research revealed no association between the wild flu virus and DM, which he stated would be necessary in order for molecular mimicry to apply. *Id.* at 12.

Respondent also addresses the alternative theories of causation proffered by Petitioner. Resp. Br. at 10 n.8. He notes that Dr. Brawer's discussion of the adjuvant has no applicability to this case, as the flu vaccine Ms. Whelan received contains no adjuvant. *Id.* All other theories alluded to by Dr. Brawer and Petitioner should similarly be discounted, he asserts, due to Petitioner's failure to provide any additional explanation or supporting literature. *Id.*

Respondent criticizes Petitioner's proffered logical sequence of cause and effect, characterizing it as impermissible *post hoc ergo propter hoc* reasoning. Resp. Br. at 13–14. He asserts that Petitioner cannot simply rely on temporal proximity and elimination of other possible causes in order to show that the flu vaccine caused her injury. *Id.* Furthermore, he takes issue with Petitioner's failure to satisfactorily address the potential causal role of breast cancer. *Id.* at 14–15.

Finally, Respondent addresses the issue of timing, both with regard to the onset of Ms. Whelan's DM and what would constitute a medically-acceptable onset of an injury under a theory of molecular mimicry. Resp. Br. at 16–19. He contends that Petitioner's claimed DM onset in October 2013 is unsupported by contemporaneous medical records, and that the first recorded symptoms in fact occurred no less than eight weeks after vaccination. *Id.* Citing Dr. Matloubian's statement than a molecular mimicry-induced injury would occur within one to three weeks, Respondent contends that even if I find Petitioner's theory of causation credible, onset occurred too long after vaccination to find causation here. *Id.* at 19.

C. *Petitioner's Reply*

In a short Reply (just over one page in length), Petitioner reiterates that Dr. Brawer's conclusions are based on his in-person interactions with Petitioner, as well as on his extensive

clinical experience. Reply at 1. For this reason, Petitioner asks me to find his opinions more persuasive than those of Dr. Matloubian, which she contends are based "on speculation." *Id.*

VI. Applicable Legal Standards

A. *Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 11(c)(1), 13(a)(1)(A), 14(a); *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 (Fed. Cir. 2006).[14] In this case, Petitioner does not assert a Table claim. Furthermore, a petitioner must show that he has "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention." Section 11(c)(1)(D).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(a)(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enters. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal

[14] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues 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).

Circuit in *Althen*: "(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 proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biological plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States*, 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first Althen prong by preponderance; that standard applied only to second prong and petitioner's overall burden); *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)); *see also Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant's success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. *See, e.g., Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant vaccine to relevant injury]") (emphasis added). Regardless, petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations

omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, 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 Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" an injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without op.*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* 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 is a medically acceptable timeframe must also align with the theory of how the relevant vaccine can cause the injury in question. *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied 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 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub. nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight")).

In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Reports*

Establishing a sound and reliable medical theory often requires a petitioner to present statements from medical experts in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has been employed to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert reports, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories."

Broekelschen, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination or are central to Petitioner's case. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Determination to Resolve Case Without Hearing*

I have opted (without objection by either side) to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports, rather than after a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers when, in the exercise of their discretion, they conclude that such a means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Tiole v. Sec'y of Health & Human Servs.*, 726 F. App'x 809, 812 (Fed. Cir. 2018); *Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.,* 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his

discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

For the reasons set forth below, I find that Petitioner has failed to satisfy all three prongs of a causation-in-fact claim under *Althen*. I discuss each prong below in order of its significance to my determination.

A. *Althen Prong Three*

Even assuming that the flu vaccine could cause DM, Petitioner has failed to show that *her* injury occurred within a medically-acceptable time frame after vaccination. Petitioner's expert, Dr. Brawer, offers no opinion on the question of how long after vaccination one would expect DM to develop if caused through molecular mimicry. Rather, he states in conclusory fashion that there is "complete concordance" between Petitioner's contemporaneous medical records and her later-reported recollections that her symptoms began earlier than such records reflect. Brawer Rep. at 6. This assertion does not address the more fundamental question of *when* onset would be expected under Petitioner's proffered theory, and thus does not gain evidentiary weight simply from Dr. Brawer's pronouncement.

In addition, Petitioner's timing argument is contrary to the evidence offered in this case about what the reasonable timeframe for a vaccine-induced autoimmune reaction resulting in DM. In her brief, Petitioner asks me to adopt Dr. Matloubian's view that molecular mimicry-driven onset would occur one to three weeks after vaccination. Pet'r Br. at 14. This time period is consistent with the post-vaccination DM noted in the Jani case study. Jani at 1484 (DM began two weeks after vaccination).

But this onset is not reflected in Petitioner's medical record, which does *not* support the conclusion that Petitioner's DM began so quickly after vaccination. Neither her rash nor muscle pain clearly associated with DM was noted until *three* months after vaccination, in February 2014. This is consistent with other medical records. At all other visits with physicians in the intervening eight months, Petitioner consistently placed the onset of her rash as during her February 2014 vacation to Puerto Rico. *See, e.g.*, Ex. 3 at 20. Ms. Whelan's first statement to a treater indicating that her symptoms may have began closer in time to vaccination was not until her visit with Dr. Magaziner in June 2014. And Dr. Matloubian at best allowed for onset in December 2013—still too long after the October 4th vaccination to constitute a reasonable timeframe under Petitioner's causation theory.

In addition, it is unclear whether muscle pain or weakness that she may have experienced prior to this can fairly be attributed to her DM. Petitioner repeatedly denied muscle pain and

weakness at doctor's visits until long after vaccination. *See, e.g.*, Ex. 3 at 19–20 (denying muscle pain and weakness at March 25, 2014 visit with Dr. Miller). And while her later-in-time statements to treaters suggested that she began experiencing pain in *one* shoulder sometime around October or December 2013 (*see, e.g.*, Ex. 2 at 10–11 (stating to Dr. Magaziner at June 2014 visit that symptoms began with frozen shoulder in October 2013); Ex. 29b at 204 (informing Dr. Thomas during May 2014 conversation that symptoms began in December 2013 with left shoulder pain)), pain in one shoulder was not likely a symptom of DM, as Dr. Matloubian noted that DM-related muscle weakness is *symmetric*—that is, it presents on both sides of the body. Matloubian Rep. at 4.

Petitioner was unsuccessful in varying these medical records. She offered no witness statement of her own, and Ms. Krol's statement contradicts the existing record (like Ms. Whelan's after-the-fact statements to treaters) without corroboration. It is well-established Vaccine Program law that contemporaneous medical records are presumed accurate, meaning that later-in-time statements at odds with such records may be given very little weight. *See, e.g.*, *Burns*, F.3d at 417.

Accordingly, I cannot conclude that Petitioner's symptoms began within three weeks after vaccination. Because the record for onset is inconsistent with Petitioner's causation theory, and because Petitioner has otherwise established that a longer time period would be medically appropriate for vaccine-induced DM, she has failed to satisfy the third *Althen* prong.

B. *Althen Prong Two*

In addition to failing to explain how the flu vaccine could cause DM (as discussed below), Petitioner has failed to show that it *did* so in her case. There is significant disagreement in the record as to when Petitioner's DM began, but even if I assume for the sake of argument that it began the week after vaccination as alleged, it is well-established in the Vaccine Program that mere temporal proximity between vaccination and onset of injury does not suffice to demonstrate causation-in-fact. *See McCarren v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 142, 147 (1997).

As noted above, the evidence supporting the idea that Petitioner developed pain in *one* shoulder in late 2013 (consisting largely of later-in-time statements to treaters and Mr. Krol's affidavit, *not* contemporaneous medical records) does not actually support a diagnosis of DM, as Dr. Matloubian persuasively established that DM presents with *symmetrical* muscle weakness. The symptoms more clearly associated with DM—a rash and symmetrical weakness—were not present until late January or early February 2014, approximately three months after vaccination. Petitioner has not demonstrated a logical sequence of cause and effect explaining how a process of molecular mimicry could cause onset so long after vaccination, and no other signs or symptoms of an autoimmune process were visible in the intervening months between vaccination and DM onset. Indeed, the record is wholly silent on whether Petitioner experienced any symptoms between

October 2013 and the end of that year. Nor did any treater propose the flu vaccine was causal of her DM.

Additionally, Petitioner did not fully succeed in rebutting Respondent's argument that her subsequently-diagnosed breast cancer may have been associated with her DM. Dr. Brawer made the argument that the timeframe was entirely too long to link the cancer to the prior DM, but neither provided evidence in support of his conclusions nor addressed the literature offered by Dr. Matloubian. For example, Dr. Brawer disputed Dr. Matloubian's statement that cancer related to DM could present up to five years after DM diagnosis (Brawer Supp. Rep. at 3, discussing Matloubian Rep. at 5), but failed to address an article cited by Dr. Matloubian finding that "DM patients remain at increased [cancer] risk for at least 5 years *after* their initial diagnosis of myositis." Ex. A Tab 2 at 11 (ECF No. 22-3) (emphasis added). In response, Petitioner has simply asserted that Dr. Matloubian failed to substantiate the causal role and sequence of events connecting DM and cancer (Pet'r Br. at 9), ignoring Dr. Matloubian's explanation of these very issues. *See* Matloubian Rep. at 5–6. While I cannot on this record determine what the evidence suggests the true cause of Petitioner's DM was, this argument further undermined the sufficiency of Petitioner's "did cause" showing.

C. *Althen Prong One*

Dr. Brawer reasonably invoked molecular mimicry as a mechanism explaining the pathogenesis of autoimmune conditions like DM, but he did not in the first instance adequately establish that the flu vaccine *itself* (or the more potent wild virus) has been associated with DM. The literature he cited in support of that contention either directly undermines the conclusion or provides only tenuous, indirect support. Winkelmann, for example, states that there is *no* association between the flu vaccine and DM, while Altman and Kass discuss different vaccines. In addition, the remaining three items of literature cited by Dr. Brawer all involved the same individual case report of DM following flu vaccine. As Dr. Matloubian noted, however, the association proposed therein should be viewed with skepticism due to its questionably accurate diagnosis. Moreover, case reports are themselves not deemed robust evidence of causation in the Vaccine Program, a precept recognized Stügben's authors. Stügben at 33 ("case reports . . . provide[] only limited potential to establish causal effects" and thus "should not be interpreted as proof of cause"); *see also Crutchfield v. Sec'y of Health & Human Services*, No. 09-0039V, 2014 WL 1665227, at *19 (Fed. Cl. Spec. Mstr. Apr. 7, 2014). Otherwise, there were too many ways in which this causation theory wills its sub-components to be true without substantiating them with reliable evidence, or evidence pertaining to this case. *See* Brawer Rep. at 5 (discussing potential causal role of adjuvant, but failing to note that relevant formulation of flu vaccine in this case is unadjuvanted).

CONCLUSION

Having reviewed the medical records, expert reports, medical literature, and arguments put forth by the parties, I do not find that Petitioner has established with sufficient preponderant evidence that the flu vaccine she received on October 4, 2013, could have caused, or did cause, her DM. Accordingly, she has not established entitlement to a damages award and I must **DISMISS** her claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk **SHALL ENTER JUDGMENT** in accordance with this decision.[15]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master

[15] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.