

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

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| ISABEL ZAMORA,      | * | No. 21-1414V                      |
|                     | * |                                   |
| Petitioner,         | * |                                   |
|                     | * | Special Master Christian J. Moran |
| v.                  | * |                                   |
|                     | * | Filed: March 19, 2025             |
| SECRETARY OF HEALTH | * |                                   |
| AND HUMAN SERVICES, | * |                                   |
|                     | * |                                   |
| Respondent.         | * |                                   |

\* \* \* \* \*

Courtney Jorgenson, Siri & Glimstad, LLP, Phoenix, AZ, for petitioner;  
Naseem Kourosh, United States Dep’t of Justice, for respondent.

**DECISION DENYING ENTITLEMENT TO COMPENSATION<sup>1</sup>**

Isabel Zamora alleges that an influenza (“flu”) caused her to develop chronic fatigue syndrome. To support her claim, Ms. Zamora presented the opinion of a neurologist, Mitchell Miglis. The Secretary opposes Ms. Zamora’s claim and relies upon a contrary opinion from a rheumatologist, Roland Staud. After the experts disclosed all their opinions, the parties advocated through memoranda.

A review of the evidence and arguments shows that Ms. Zamora has not met her burden to show the flu vaccine caused her chronic fatigue syndrome. A basic

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<sup>1</sup> Because this decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

challenge is that the etiology of chronic fatigue syndrome is unknown. Ms. Zamora has not persuasively established that the flu vaccine can cause chronic fatigue syndrome. Without this showing, Ms. Zamora cannot be awarded compensation.

## **I. Facts<sup>2</sup>**

### **A. Before Vaccination**

Ms. Zamora was born in 1962 in Mexico. Exhibit 10 (affidavit regarding damages) ¶ 1. She averred that before the allegedly causal vaccination, she had “very controlled pre-diabetes.” Id. ¶ 3; Exhibit 48 (affidavit) ¶ 4. However, via her attorney, she also represented that she was not receiving much medical treatment. Pet’r’s Status Rep., filed Oct. 17, 2022.

In the years leading up to the allegedly causal vaccination, Ms. Zamora earned income, which was reported to the Social Security Administration. Exhibit 56. Ms. Zamora’s primary job was working on an assembly-line. Exhibit 10 ¶ 5.<sup>3</sup> Although Ms. Zamora earned some wages, she remained eligible for Medicaid, which largely paid her medical expenses. Id. ¶ 4.

On at least two occasions before the allegedly causal vaccination, Ms. Zamora received other doses of the flu vaccine. See Exhibit 4 at 82 (Jan. 26, 2018) and Id. at 63-64 (Oct. 12, 2017). In November 2018, Ms. Zamora went to Mexico for plastic surgery. Exhibit 4 at 94.

### **B. Vaccination and Afterwards**

On October 8, 2019, Ms. Zamora went to the place where she received her primary medical care, Salud Para La Gente, where she saw a nurse practitioner, RoseMarie Sandoval. Ms. Zamora received a dose of the flu vaccine. Exhibit 4 at 99. The specific type of flu vaccine was Flulaval. Id. at 28. Flulaval contains an inactivated form of the flu virus. Court Exhibit 1001 (Flulaval package insert) at 5.

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<sup>2</sup> Because the outcome of Ms. Zamora's case largely depends upon evidence not related to her personally, events in her life are presented summarily. For a more detailed account, see Pet’r’s Br., filed June 19, 2024, at 1-26; Resp’t’s Br., filed Aug. 19, 2024, at 1-18, and the exhibits cited therein.

<sup>3</sup> In her affidavit, Ms. Zamora estimated her annual earnings were in an amount that exceeded the earnings reported to the Social Security Administration.

Through an affidavit created during this litigation, Ms. Zamora averred that soon after the vaccination, she began to experience headaches. Exhibit 1 ¶ 1. Ms. Zamora further avers that she also developed fatigue. Id.

Within approximately two weeks of the vaccination, Ms. Zamora sought care at Salud Para La Gente for a lacerated finger. Exhibit 4 at 102 (Oct. 11, 2019 – initial visit) and at 104 (Oct. 18, 2019 – suture removal). Although a complaint about fatigue was not memorialized in the records created on these two dates, Ms. Zamora averred that she was experiencing fatigue, weakness, or confusion. Exhibit 14 ¶ 10. Likewise, Ms. Zamora attested that when she had a routine screening for breast cancer on October 31, 2019, she was feeling exhausted. Id. ¶ 11.

Ms. Zamora averred that when she woke up on November 4, 2019, “everything was different. The headache was very intense in the back, but [she] had the sensation of being in another dimension as if it were disconnected.” Exhibit 1 ¶ 2. Ms. Zamora also asserted that she was “dizzy, confused and scared because [she] did not understand what was happening.” Id.

Ms. Zamora averred that during a trip to Mexico from November 16, 2019 to December 9, 2019 to visit her mother, she felt “very sad” because she didn’t know what was going on with her health. Exhibit 14 ¶ 18. In December 2019, Ms. Zamora scheduled an appointment with her doctor for January 2020. Exhibit 1 ¶ 3.

This appointment at Salud Para La Gente took place on January 2, 2020, when nurse practitioner Sandoval saw her. Exhibit 4 at 113. Ms. Zamora’s chief complaint included “headache, dizziness, and blurry vision on and off x 1 month.” Id. NP Sandoval assessed Ms. Zamora as suffering from adjustment disorder with anxiety. Id. at 114-15. NP Sandoval recommended that Ms. Zamora seek therapy. Id.

By February 2020, Ms. Zamora was working. Exhibit 1 (affidavit) ¶ 3; see also Exhibit 56 (Social Security Administration records). Ms. Zamora averred that working was difficult because she had no control over her headaches and fatigue. Exhibit 1 ¶ 3. In February 2020, Ms. Zamora worked between 40 and 50 hours per week. Exhibit 16 at 11-15.

Although not recounted in Ms. Zamora’s affidavit, the coronavirus pandemic was severely affecting this country by February or March 2020. Ms. Zamora avers that on “March 18, 2020 I decided to not go to work. I took refuge in my house and only woke up to do the necessary things.” Exhibit 1 ¶ 4. This account is

corroborated in her employer's pay records. Exhibit 16 at 8 (showing that for the week beginning March 15, 2020, she worked 0.00 hours). Ms. Zamora attested about the next steps with respect to her employment: "In April 2020, I applied for unemployment online. I argued that my work was a place with many risks of contagion, since we were too many people working very closely. They denied me unemployment and said that I had just quit my job." Id. ¶ 5. The employment records do not say anything about whether Ms. Zamora quit her job, whether she sought unemployment benefits, or whether she was sick. See Exhibit 16.

Ms. Zamora did not see any medical doctors during this time. In her affidavit, she explained that "I believed in the diagnosis of the doctor who said it was stress so I never thought it could be a disability." Id.

Ms. Zamora returned to work in May 2020. Exhibit 1 ¶ 6. (Apparently, Ms. Zamora changed employers because the employment records she filed do not contain any information about her returning to work at the company where she worked before the pandemic. See Exhibit 16.) She stated: "My headaches increased.... I only worked until June 6, because my headaches were getting more and more intense, my legs and arms had no energy, my tongue did not have the normal movement. I could talk but I had difficulty moving it and my fingers were numb." Id. Records from the California Unemployment Office confirm that she applied for benefits in June 2020. Exhibit 15 at 2.<sup>4</sup> Ms. Zamora received benefits for about one year. Id. at 3.

Approximately eight months after the flu vaccination, Ms. Zamora had a telemedicine appointment with a physician assistant at Salud Para La Gente, Alicia Potes. Exhibit 4 at 117. Ms. Zamora reported three weeks of bilateral hand cramping. She also complained about "some issues going back to the fall, Oct. 2019. She says her symptoms started after getting the flu vaccine. She was feeling confused and having headaches." Id. On exam, Ms. Zamora had normal cognitive function, but she had a depressed mood and flat affect. Id. at 118. PA Potes assessed Ms. Zamora as having a headache syndrome, depression and pain and she suspected that Ms. Zamora's "occurred symptoms are related to depression." PA Potes referred Ms. Zamora to neurology. Id. at 119.

Over the next three months, Ms. Zamora sought a variety of medical providers for a variety of complaints. However, these details do not affect whether

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<sup>4</sup> The completeness of the unemployment records is uncertain as these records do not reflect an application for benefits in April 2020.

Ms. Zamora has established whether the flu vaccine caused her to suffer chronic fatigue syndrome.

A more relevant record was created on September 26, 2020. On that date, a physician assistant (Caitlin Casey) diagnosed Ms. Zamora as suffering from chronic fatigue syndrome. Exhibit 4 at 141. Ms. Casey supported Ms. Zamora's request for disability benefits with an opinion regarding chronic fatigue syndrome. Exhibit 15 at 4. Ms. Zamora's expert, Dr. Miglis, agreed with the diagnosis of chronic fatigue syndrome. Exhibit 19 at 12. So, too, the Secretary's expert, Dr. Staud, agreed that Ms. Zamora suffered from chronic fatigue syndrome. Exhibit A at 12. However, as discussed below in section V.A.2, Dr. Staud places the onset of Ms. Zamora's chronic fatigue syndrome before (not after) her flu vaccination.

### *Chronic Fatigue Syndrome*

Chronic fatigue syndrome is "a serious, chronic, complex, and systemic disease that frequently and dramatically limits the activities of affected patients." Institute of Medicine Report at 5 / *pdf* 28.<sup>5</sup> Sometimes, "chronic fatigue syndrome" is joined with another condition, known as "myalgic encephalomyelitis," which is often abbreviated "ME." *Id.* at 27-28. / *pdf* 50. For the sake of simplicity and consistent with the parties' terminology, this decision labels Ms. Zamora's condition as "chronic fatigue syndrome." People with "chronic fatigue syndrome" have three symptoms: (1) a substantial reduction in the ability to engage in activities, which is accompanied by fatigue, (2) post-exertional malaise, and (3) unrefreshing sleep. *Id.* at 6 / *pdf* 29. They also have either cognitive impairment or orthostatic intolerance. *Id.*

Doctors have limited knowledge about what causes chronic fatigue syndrome. Dr. Staud stated that "The disease has an 'unknown etiology.'" Exhibit A at 9. Dr. Miglis did not profess to have any more knowledge. He wrote: "The cause of ME/CFS remains unknown, however multiple lines of evidence have demonstrated impairment in energy metabolism pathways, autonomic nervous system function, immune dysfunction, and neuro-inflammation." Exhibit 19 at 3.

Dr. Miglis presented various articles that found unusual immunologic results in people with chronic fatigue syndrome. Immunologic substances studied

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<sup>5</sup> Institute of Medicine, Beyond Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (2015); filed as Exhibit 21.

included: antibodies to EBNA (Loebel),<sup>6</sup> low amounts of natural killer cells (Strayer),<sup>7</sup> autoantibodies to nuclear envelope antigens (Konstantinov),<sup>8</sup> various cytokines (Montoya),<sup>9</sup> and autoantibodies to muscarinic cholinergic receptors (Tanaka, Chu).<sup>10</sup> Other articles have noted that some infections precede the onset of chronic fatigue syndrome. See Bateman,<sup>11</sup> White,<sup>12</sup> and Magnus.<sup>13</sup>

However, Ms. Zamora is not argued to have suffered from an infection before she developed chronic fatigue syndrome. Her medical records on this point are relatively muted.

After Ms. Zamora was diagnosed with chronic fatigue syndrome, she received medical treatment from many doctors. But, these more recent medical records do not help determine whether a flu vaccine can cause chronic fatigue syndrome. For more information about the course of Ms. Zamora's health, see Pet'r's Br. at 12-26; Resp't's Br. at 10-17 and the medical records cited therein.

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<sup>6</sup> Madlen Loebel et al., Serological profiling of the EBV immune response in Chronic Fatigue Syndrome using a peptide microarray, 12 PLOS ONE 1 (2017); filed as Exhibit 26.

<sup>7</sup> David R. Strayer, Low NK Cell Activity in Chronic Fatigue Syndrome (CFS) and Relationship to Symptom Severity, 6 J. CLIN. & CELLULAR IMMUNOL. 4 (2015); filed as Exhibit 28.

<sup>8</sup> K. Konstantinov et al., Autoantibodies to nuclear envelope antigens in chronic fatigue syndrome, 98 J. CLIN. INVEST. 1888 (1996); filed as Exhibit 31.

<sup>9</sup> Jose G. Montoya et al., Cytokine signature associated with disease severity in chronic fatigue syndrome patients, 114 PROC. NATL. ACAD. SCI. USA E7150 (2017); filed as Exhibit 34.

<sup>10</sup> Susumu Tanaka et al., Autoantibodies against muscarinic cholinergic receptor in chronic fatigue syndrome, 12 INT. J. MOL. MED. 225 (2003); filed as Exhibit 32.

Lily Chu et al., Onset Patterns and Course of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 7 FRONT. PEDIATR. 1 (2019); filed as Exhibit 39.

<sup>11</sup> Lucinda Bateman et al., Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Essentials of Diagnosis and Management, 96 MAYO CLIN. PROC. 2861 (2021); filed as Exhibit 22.

<sup>12</sup> P. D. White et al., Incidence, risk and prognosis of acute and chronic fatigue syndromes and psychiatric disorders after glandular fever, 173 BR. J. PSYCHIATRY 475 (1998); filed as Exhibit 23.

<sup>13</sup> P. Magnus et al., Chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) is associated with pandemic influenza infection, but not with an adjuvanted pandemic influenza vaccine, 33 VACCINE 6173 (2015); filed as Exhibit 27. Magnus is discussed in more detail below.

## II. Procedural History<sup>14</sup>

Ms. Zamora started her claim by filing a petition on June 1, 2021. She was represented by Attorney Andrew Downing, who frequently represented petitioners in the Vaccine Program. Ms. Zamora periodically submitted medical records.

The Secretary reviewed this material and advised that Ms. Zamora was not entitled to compensation. The Secretary proposed that Ms. Zamora's chronic fatigue syndrome developed before the vaccination. Resp't's Rep., filed May 6, 2022, at 18. Because the parties appeared to be seeking reports from experts, a set of instructions for experts was issued. See Order, issued Aug. 9, 2022.

Ms. Zamora supported her claim with a first report from Dr. Miglis. Exhibit 19, filed Feb. 6, 2023. Dr. Miglis recounted Ms. Zamora's medical records. Id. at 5-11. He stated that she suffered from chronic fatigue syndrome. Id. at 12. The onset of this problem was "as early as October 2019, and as late as December 2019." Id.

Dr. Miglis provided background information about chronic fatigue syndrome. Id. at 2-5. As to how a flu vaccine can cause chronic fatigue syndrome, he wrote: "The mechanism of influenza vaccine-induced ME/CFS has not been described. However, given that ME/CFS has been described after influenza infection, a presumed theory is one of molecular mimicry."

In turn, the Secretary opposed Ms. Zamora's claim by presenting a first report from Dr. Staud. Exhibit A, filed June 6, 2023. Among the opinions that Dr. Staud presented was a view that Ms. Zamora developed chronic fatigue syndrome before the vaccination. Id. at 12. Dr. Staud also challenged the assertion that a flu vaccine can cause chronic fatigue syndrome.

Ms. Zamora attempted to address Dr. Staud's opinion by filing a second report from Dr. Miglis. Exhibit 38, filed Aug. 15, 2023. Dr. Miglis essentially maintained the opinions that he had expressed previously. For example, Dr. Miglis continued to assert that Ms. Zamora's chronic fatigue syndrome started after (not before) her vaccination. Id. at 1.

With the disclosure of opinions from experts completed, the parties were directed to file briefs. Order, issued April 4, 2024. As part of this process, Ms. Zamora was asked whether she wanted to pursue a claim that the vaccination

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<sup>14</sup> The course of Ms. Zamora's litigation has been straightforward.

significantly aggravated (as opposed to caused) her chronic fatigue syndrome. Via an affidavit, Ms. Zamora confirmed that she was pursuing an initial onset claim only. Exhibit 48.

As instructed, the parties advocated through memoranda. Ms. Zamora filed her initial brief on June 19, 2024, and her reply on September 17, 2024. In between, the Secretary filed his brief on August 19, 2024.

After the briefing ended, Mr. Downing stopped representing Ms. Zamora. He was replaced as counsel of record by Attorney Courtney Jorgensen. Attorney Jorgensen formerly was a partner of Mr. Downing. Thus, the appearance of a new attorney for Ms. Zamora does not necessarily require a delay in adjudication.

Resolving Ms. Zamora's case based upon the evidence and arguments presented so far is appropriate. Ms. Zamora has had a full and fair opportunity to present evidence. Her expert, Dr. Miglis, submitted the most recent substantive report and she submitted the last brief.<sup>15</sup> In other words, Ms. Zamora has had the final word. As discussed below, the flaws and gaps in Dr. Miglis's opinion cannot be solved with oral testimony. Thus, the case can be adjudicated now.

### **III. Standards for Adjudication**

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence.” Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed.

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<sup>15</sup> The parties each filed a “Statement From Testifying Expert” with their briefs, providing a short explanation of newly filed medical literature. These do not constitute substantive reports.

Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

In a case in which the vaccine-injury combination is not listed on the Vaccine Table, such as this one, petitioners are not afforded a presumption of causation. Rather, they must establish with preponderant evidence that the vaccine was the cause-in-fact of their injury. Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

#### **IV. Analysis – Althen Prong One**

As to whether the flu vaccine can cause chronic fatigue syndrome, the evidence falls into two broad categories. The first category consists of evidence that is generally applicable to any theory, such as epidemiological studies and case reports. The second category consists of evidence more specific to the theory that Dr. Miglis is offering, molecular mimicry.

##### **A. Epidemiological Studies and Case Reports**

These types of evidence are joined together because they may present evidence that the flu vaccine causes chronic fatigue syndrome without necessarily investigating the method by which the flu vaccine causes chronic fatigue syndrome.

##### **1. Epidemiologic Studies**

The study receiving the most attention from the parties is an article by Per Magnus.<sup>16</sup> Magnus and colleagues accessed computerized medical records for about essentially the entire population of Norway, which exceeds more than four million people. Magnus at 6174. The researchers determined how many Norwegians suffered from chronic fatigue syndrome and the percentage who had either been infected with an influenza virus or had received a vaccination against

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<sup>16</sup> Filed as Exhibit A-16 and Exhibit 27; *supra* note 13.

H1N1. Id.<sup>17</sup> The researchers found that people who suffered an H1N1 infection had a “two-fold increased risk” of chronic fatigue syndrome. Id. at 6173. In contrast, for vaccination, the researchers found “no increased risk” of chronic fatigue syndrome. Id. The Magnus study, therefore, tends to undermine the claim that flu vaccines can cause chronic fatigue syndrome, although this single study is not dispositive.<sup>18</sup>

In response to the Magnus study, Dr. Miglis and Ms. Zamora make two points. They contend that epidemiological studies are limited. Exhibit 19 (Dr. Miglis’s report) at 4; see also Pet’r’s Br. at 52-53 and Pet’r’s Reply at 15-17. As support, they pointed out that Magnus and colleagues recognized that: “there is still a lack of large, well-characterized cohort studies with [chronic fatigue syndrome] as an end point.” Magnus at 6176. This point is accurate in the sense that additional studies might be informative. However, special masters must decide cases based upon the evidence before them.

Although Ms. Zamora downplays the results in Magnus about the influenza vaccination, she emphasizes the results regarding influenza infection. She maintains that if an infection is associated with an adverse consequence, then the vaccination against this infectious organism should be presumed to be capable of causing the same adverse consequence. Pet’r’s Br. at 39. In response, the Secretary argued that this assertion was unsupported, “offered without any scientific testimony or literature.” Resp’t’s Br. at 34. In reply, Ms. Zamora did not identify any support from her expert, Dr. Miglis. Instead, Ms. Zamora cited a case decided by another special master. Pet’r’s Reply at 11, quoting Ahlum v. Sec’y of Health & Human Servs., No. 12-763V, 2018 WL 4323623, at \*44 (Fed. Cl. Spec. Mstr. Aug. 16, 2018).

The attempted analogy between flu infection and flu vaccination has not been persuasively established. A basic difference is that special masters have consistently found that inactivated flu vaccines do not replicate in a person’s body. See Greenslade v. Sec’y of Health & Hum. Servs., No. 14-1140V, 2024 WL 3527665, at \*24 (Fed. Cl. Spec. Mstr. June 28, 2024) (summarizing expert

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<sup>17</sup> The specific brands of flu vaccine were Pandemrix and Celvapan. Magnus at 6174. Ms. Zamora received a different type of flu vaccine. However, neither party developed any arguments regarding the difference in flu vaccines.

<sup>18</sup> It appears that one special master (the undersigned) discussed Magnus previously. See McCabe v. Sec’y of Health & Hum. Servs., No. 13-570V, 2018 WL 3029175, at \*28 (Fed. Cl. Spec. Mstr. May 17, 2018).

opinion); Martin v. Sec’y of Health & Hum. Servs., No. 17-250V, 2020 WL 4815840, at \*28 (Fed. Cl. Spec. Mstr. July 17, 2020); see also Miller v. Sec’y of Health & Hum. Servs., 172 Fed. Cl. 762, 782 (2024) (ruling special master did not err in rejecting theory based upon an assertion that a flu vaccine can replicate); D’Tiolo v. Sec’y of Health & Hum. Servs., No. 15-085V, 2016 WL 7664475, at \*1 n.4 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (discussing a live attenuated flu vaccine), mot. for rev. denied, 132 Fed. Cl. 421 (2017), aff’d, 726 Fed. App’x 809 (Fed. Cir. 2018). By way of contrast, the measles-mumps-rubella vaccine contains attenuated viruses, which do replicate in a person’s body. Therefore, Ms. Zamora’s reliance on Ahlum, which involved an MMR vaccine, is misplaced.

Although most attention was on Magnus, the parties also addressed some other articles that discussed whether vaccines can cause chronic fatigue syndrome. Appel<sup>19</sup> and Ortega-Hernandez<sup>20</sup> were both written more than 15 years ago. As such, the assessments are somewhat dated. Moreover, these articles are not original studies. Rather, they cite to other works. For example, Appel summarized findings from a Canadian Working group. Appel at 51.<sup>21</sup> Ultimately, both articles tend to exonerate the flu vaccine as a potential cause of chronic fatigue syndrome. Ortega-Hernandez at 603, Table 2 (stating that the influenza virus is not a risk for chronic fatigue syndrome); Appel (stating “there is no study that found induction of CFS by vaccination”). This lack of association is surprising because Yehuda Shoenfeld, who has often testified in the Vaccine Program that vaccines caused an injury, was a co-author on both articles.

Finally, in a report filed in conjunction with Ms. Zamora’s brief, Dr. Miglis cited an article published in June 2024. Exhibit 58, citing Arron.<sup>22</sup> This group of authors recognized that cases of chronic fatigue syndrome have occurred after vaccination, but the only study they cited, which evaluated the human papilloma

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<sup>19</sup> S. Appel, Joab Chapman, & Yehuda Shoenfeld, Infection and Vaccination in Chronic Fatigue Syndrome: Myth or Reality?, 40 AUTOIMMUNITY 48 (2007); filed as Exhibit A-22.

<sup>20</sup> Oscar Danielo Ortega-Hernandez & Yehuda Shoenfeld, Infection, Vaccination, and Autoantibodies in Chronic Fatigue Syndrome, Cause or Coincidence?, 1173 ANN. N.Y. ACAD. SCI. 600 (2009); filed as Exhibit 40.

<sup>21</sup> The paper from the Canadian working group is not an exhibit in this case, but it has been filed as an exhibit in other cases. See Doe 54 v. Sec’y of Health & Hum. Servs., No. 99-454V, 2009 WL 5196160, at \*21 (Fed. Cl. Spec. Mstr. May 28, 2009).

<sup>22</sup> Hayley E. Arron, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: the biology of a neglected disease, 15 FRONT. IMMUNOL. 1 (2024); filed as Exhibit 57.

virus vaccine, did not find an increased risk of chronic fatigue syndrome. Arron at 7.

## 2. Case Reports

The Arron article is not the only article that reports that people received a vaccination before developing chronic fatigue syndrome. For other examples, see Ortega-Hernandez at 602; Appel at 51.

The parties dispute the value of case reports. Ms. Zamora contends that case reports have more value than epidemiologic studies. Pet'r's Br. at 43-44. She does so, however, without citing any legal authority. In contrast, the Secretary maintains that case reports have limited utility. Resp't's Br. at 35. n.3. Despite the Secretary's citation to many cases that minimize the value of medical case reports, Ms. Zamora did not address this argument by identifying cases that support her position. See Pet'r's Reply at 12.

In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at \*11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports). In accordance with this precedent, the undersigned declines to afford the various case reports much weight. Thus, neither the epidemiologic studies nor the case reports carry Ms. Zamora's burden to establish that the flu vaccine can cause chronic fatigue syndrome.

### **B. Molecular Mimicry**

The presence of epidemiological evidence pointing away from vaccines as a cause for chronic fatigue syndrome does not necessarily mean Ms. Zamora is not entitled to compensation automatically, as epidemiology is not dispositive by itself. Therefore, the specific theory that Ms. Zamora's proposes, molecular mimicry, is evaluated. Because molecular mimicry is often invoked, appellate authorities have reviewed this theory. Accordingly, this appellate precedent is reviewed before the specific evidence Ms. Zamora's case is analyzed.

#### 1. Appellate Precedent regarding Molecular Mimicry

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their

appellate role of reviewing opinions.<sup>23</sup> In December 2019, the undersigned identified the leading precedents as W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec’y of Dep’t. of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff’d sub nom., 463 F. App’x 932 (Fed. Cir. 2012). Tullio v. Sec’y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at \*12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately five years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.<sup>24</sup> Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner’s burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec’y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff’d in non-precedential opinion, 850 F. App’x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: “the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it.” Id.

The Federal Circuit also evaluated the Chief Special Master’s approach in Morgan. The Federal Circuit concluded: “We discern no error in the special master’s causation analysis.” 850 F. App’x 775, 784 (Fed. Cir. 2021).

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<sup>23</sup> The briefs would have been improved if they had discussed any appellate cases about molecular mimicry.

<sup>24</sup> The term “homology” is used when discussing molecular mimicry. “Homology” is defined as “the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form.” *Dorland’s* at 868.

Most other recent appellate cases follow this path. See, e.g., Stricker v. Sec’y of Health & Hum. Servs., 170 Fed. Cl. 701, 720-21 (2024); Duncan v. Sec’y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry and stating “there is an important difference between the general theory of molecular mimicry and the more specific theory that the vaccine at issue is capable of triggering an autoimmune response that culminates in the petitioner's injury”); Caredio v. Sec’y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at \*11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec’y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Patton v. Sec’y of Health & Hum. Servs., 157 Fed. Cl. 159, 169 (2021) (finding that a special master erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

The Court of Federal Claims explained why petitioners must present some evidence to show the persuasiveness of molecular mimicry as a theory in their cases. Dennington v. Sec’y of Health & Hum. Servs., 167 Fed. Cl. 640 (2023), appeal withdrawn, No. 2024-1214 (Fed. Cir. Mar. 25, 2024). There, Ms. Dennington alleged that a tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine caused her to develop GBS. Id. at 644. She supported her claim with two reports from a neurologist, Carlo Tornatore, who put forward molecular mimicry. Id. at 647-49. The Chief Special Master denied entitlement. Id. at 656.

The Court of Federal Claims denied a motion for review because the Chief Special Master did not commit any error in evaluating Ms. Dennington’s prong one evidence. The Court emphasized the lack of evidence supporting Dr. Tornatore’s opinion:

- “While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore’s expert reports, nor in Petitioner’s briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry.” Id. at 653.
- “Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS.” Id.

- “There is nothing in Dr. Tornatore’s report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress.” Id. at 654.
- “The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine.” Id.

Based upon these observations, the Court criticized the lack of specificity in Dr. Tornatore’s opinions:

In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap, molecular mimicry, and GBS, one could take Dr. Tornatore’s causation theory and substitute any table vaccine (e.g., the measles vaccine) and any autoimmune disorder (e.g., autoimmune encephalitis) and Dr. Tornatore’s expert report’s discussion of molecular mimicry would require absolutely no changes. That is how general her molecular mimicry theory is—it does not matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

Id.

In accordance with precedents such as W.C., Caves, Tullio, Yalacki, Stricker, Duncan, and Dennington, the undersigned will look to see whether any evidence supports the theory that the flu vaccine can cause chronic fatigue syndrome.

## 2. Ms. Zamora's evidence

Doctor Miglis’s opinion regarding molecular mimicry is thin. Part of the trouble is medical officials know very little about that causes of chronic fatigue syndrome. For example, whether chronic fatigue syndrome is autoimmune in origin is unclear as multiple different pathologic processes have been proposed.

As discussed, some studies have detected abnormal antibodies in people with chronic fatigue syndrome. However, whether these antibodies cause chronic fatigue syndrome has not been established with preponderant evidence. Moreover,

even if the antibodies were causative, Dr. Miglis does not connect the flu vaccine to the development of the (assumed) causative antibodies.

In supporting Dr. Miglis's opinion, Ms. Zamora relies, in part, on an attempted analogy to the influenza virus. See Pet'r's Br. at 43; Pet'r's Reply at 11-12. However, this argument is unpersuasive for the reason explained above---the flu virus, unlike Flulaval, replicates.

In short, Ms. Zamora has not persuasively established that molecular mimicry explains how the flu vaccine can cause chronic fatigue syndrome. Accordingly, she has failed to meet her burden of proof with respect to Althen prong one.

## V. Additional Comments / Questions

Although Ms. Zamora's failure with respect to Althen prong one is dispositive, the additional elements merit a short discussion.

### A. Althen Prong Three

One portion of a petitioner's burden is to show with preponderant evidence, "a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

#### 1. Expected Interval

The expected interval depends, at least in part, upon the theory being offered. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013); see also Resp't's Br. at 46. Here, the theory is molecular mimicry.

To assist with the submission of useful reports from experts, instructions for these reports were issued on Aug. 9, 2022. One portion was devoted to having the experts discuss the appropriate interval between a vaccination and the onset of chronic fatigue syndrome. ¶ 7.a.

Doctor Miglis's first report stated that the appropriate interval was "several weeks to several months." Exhibit 19 at 12. No explanation was given beyond his

own words. More clarification was sought. Order for Briefs, filed Aug. 4, 2024, at 7.

The briefs add very little, unfortunately. Ms. Zamora quotes portions of Dr. Miglis's two reports. Pet'r's Br. at 51. She proposes neither a minimum number of weeks nor a maximum number of months. The Secretary challenged Ms. Zamora's evidence on this point. Resp't's Br. at 46 ("petitioner's vague and varied assertions of an onset timeframe are conclusory and unsupported, and do not amount to a preponderant showing of a medically appropriate timeframe for post-flu-vaccination onset of ME/CFS"). In reply, Ms. Zamora analogizes the time for the flu vaccine to potentially cause chronic fatigue syndrome to the time listed in the Vaccine Table for the flu vaccine to cause Guillain-Barré syndrome. Pet'r's Reply at 5. But, this appears to be more of an argument from an attorney, rather than an argument based upon evidence from Dr. Miglis.

In sum, although no definitive finding is reached, Ms. Zamora's evidence and argument regarding the appropriate interval appears to lack persuasiveness. Dr. Miglis's reports seem to be too vague to be creditable. See Hennessey v. Sec'y of Health & Hum. Servs., 91 Fed. Cl. 126, 142 (2010) (the expert's "overly broad" opinion on timing effectively "renders Althen's third prong a nullity").

## 2. Onset

The second aspect of the third prong of Althen is when the condition developed. Here, too, there are questions about Ms. Zamora's evidence.

Before problematic areas are set out, two foundational points need to be established. First, determining when chronic fatigue syndrome begins can be difficult. See Pet'r's Reply at 7; Yalacki, 146 Fed. Cl. at 93-94; McCabe, 2018 WL 3029175, at \*37. Second, the parties agree that chronic fatigue syndrome is an appropriate diagnosis for Ms. Zamora. Thus, there is no dispute about diagnosis.

However, a diagnosis of chronic fatigue syndrome on September 26, 2020 does not mean that Ms. Zamora's chronic fatigue syndrome began on that date. See Rocha v. Sec'y of Health & Hum. Servs., No. 16-241V, 2024 WL 752787, at \*33 (Fed. Cl. Spec. Mstr. Feb. 1, 2024) (stating "As a matter of logic, a doctor's detection of a disease does not establish the date the disease began" and citing appellate cases affirming findings regarding date of onset). Indeed, both experts maintained that Ms. Zamora began suffering from chronic fatigue syndrome months and months earlier. Dr. Miglis places onset somewhere between October and December 2018. Exhibit 19 at 13 cited in Pet'r's Br. at 51. By contrast, Dr.

Staud places onset before vaccination. Exhibit A at 10-12 cited in Resp't's Br. at 41.

In resisting the argument that she suffered from (undiagnosed) chronic fatigue syndrome before vaccination, Ms. Zamora cites medical records describing her employment. Pet'r's Reply at 3, citing Exhibit 4 at 60 (September 6, 2017) and Exhibit 4 at 68 (Jan. 26, 2018). This is a fair critique of the Secretary's position. Yet, the evidence shows that Ms. Zamora continued to work throughout 2019 and into 2020. This level of activity appears inconsistent with an assertion that Ms. Zamora was suffering chronic fatigue in October, November, or December 2019. See McCabe, 2018 WL 3029175, at \*58 (questioning onset of chronic fatigue syndrome when petitioner went to work two days after the alleged onset); D'Angiolini v. Sec'y of Health & Hum. Servs., No. 99-578V, 2014 WL 1678145, at \*36 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (noting that petitioner's extensive exercise called into question whether petitioner was suffering from chronic fatigue syndrome), mot. for rev. denied, 122 Fed. Cl. 86 (2005), aff'd without op., 645 Fed. App'x 1002 (Fed. Cir. 2016).

Based upon the existing record, the undersigned declines to make any finding regarding onset. Ms. Zamora's lack of success on prong one is dispositive. However, if the undersigned were required to determine how the evidence preponderates, the undersigned would be inclined to hold a hearing to receive oral testimony. See Vaccine Rule 8(a).

## **B. Althen Prong Two**

An analysis of the second Althen prong likewise is not required. As explained above, Ms. Zamora has not established with persuasive evidence a theory by which the flu vaccine can cause chronic fatigue syndrome. As such, prong two does not factor into the outcome. Stricker, 170 Fed. Cl. at 721-22.

Furthermore, whether the sequence of events between the flu vaccine and the onset of chronic fatigue syndrome is logical depends in part on when her chronic fatigue syndrome began. See Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (stating evidence can be related to more than one prong). As set forth in section V.A.2, several questions prohibit an easy determination about onset. These questions also contribute to a reluctance to analyze prong two in detail.

**VI. Conclusion**

Ms. Zamora's chronic fatigue syndrome has taken a toll on her, and this disruption in her health entitles her to sympathy. However, special masters are required to resolve claims based upon the evidence presented. Ms. Zamora has not presented evidence of sufficient quality or quantity to establish that the flu vaccine can cause chronic fatigue syndrome. As such, she is not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

**IT IS SO ORDERED.**

s/Christian J. Moran  
Christian J. Moran  
Special Master