In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

TANER BAYLEE NGUYEN,	*	No. 20-1719V
Petitioner,	*	Special Master Christian J. Moran
v.	*	
	*	Filed: June 22, 2026
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner;
Mitchell Jones, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING ENTITLEMENT TO COMPENSATION[1]

Taner Baylee Nguyen alleges that the hepatitis B vaccine caused him to develop a neurological condition known as Guillain-Barré syndrome ("GBS"). He seeks compensation pursuant to the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 et seq. Mr. Nguyen has retained a neurologist, David Simpson, who has written reports on his behalf. Mr. Nguyen advocated through two briefs.

The Secretary denies that Mr. Nguyen is entitled to compensation. The Secretary has also retained a neurologist, Brian Callaghan. The Secretary supported a denial of compensation through one brief.

The evidence does not preponderate in favor of compensation. The critical flaw is that Mr. Nguyen has not presented a reliable theory to explain how the hepatitis B vaccine can cause

[1] 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.

Guillain-Barré syndrome. Accordingly, the Clerk's Office is instructed to enter judgment in accord with this decision.

I. Facts

Events in Mr. Nguyen's life are not disputed and are straightforward. Thus, this decision does not set out the facts at length. For a longer presentation of factual material, see Pet'r's Br., filed Apr. 30, 2024, at 2-5; Resp't's Br., filed Sep. 10, 2024, at 2-7.

Mr. Nguyen was born in 1998. At the time of the allegedly causal vaccination, Mr. Nguyen was serving in the United States Army. In the month before the vaccination, Mr. Nguyen injured his ankle while training. However, the Secretary does not assert that any pre-existing problem contributed to Mr. Nguyen's GBS.

Mr. Nguyen received his third dose of the hepatitis B vaccine on February 14, 2018. Exhibit 1 at 1. As with the first and second doses, it appears that Mr. Nguyen did not suffer any adverse consequences immediately after the vaccination. For information about the manufacturing of the recombinant hepatitis B vaccine, see Exhibit 26 at 145[2]; Bourche v. Sec'y of Health & Hum. Servs., No. 15-232V, 2020 WL 571061, at *5 (Fed. Cl. Spec. Mstr. Jan. 7. 2020).

On March 31, 2018, Mr. Nguyen was having difficulty walking. He also was experiencing numbness and tingling in his lower extremities and hands. He sought assistance at Blanchfield Army Community Hospital. Exhibit 6 at 360. After receiving some treatment at Blanchfield, Mr. Nguyen was transferred to Vanderbilt Medical Center for a higher level of care. Exhibit 6 at 267; 375.

At Vanderbilt, Mr. Nguyen informed the doctor in the emergency room that in addition to his ankle problems, he had developed numbness in his lower extremities that was ascending for about 10 days. Exhibit 2 at 188. The doctor was concerned that Mr. Nguyen had GBS and ordered a lumbar puncture and a consultation with a neurologist.

The lumbar puncture showed that the protein level was 391 and Mr. Nguyen had albuminocytologic dissociation. Exhibit 2 at 196-97. These results are consistent with GBS.

On April 1, 2018, a neurologist, James Eaton, diagnosed Mr. Nguyen with GBS. Exhibit 2 at 197. The neurologists retained in this litigation agree with the diagnosis of GBS. Exhibit 16 (Dr. Simpson's first report) at 7; Exhibit A (Dr. Callaghan's report) at 4.

The remaining medical records detail how Mr. Nguyen recovered from his GBS. Unfortunately, Mr. Nguyen's recovery was prolonged as he had various outpatient and inpatient services. But, these medical records do not inform the question of whether the hepatitis B vaccine caused his GBS. Thus, they are not set forth in this decision.

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[2] Joerg-Patrick Stübgen, Immune-mediated myelitis following hepatitis B vaccination, 12 AUTOIMMUN. REV. 144 (2012).

II. Procedural History

The procedural history is not controversial. For sake of organization, it is divided into three parts.

A. Events before Expert Reports

Mr. Nguyen initiated this litigation by filing his petition on December 1, 2020. The petition alleged that the hepatitis B vaccine caused Mr. Nguyen to suffer GBS. Pet., filed Dec. 1, 2020, at Preamble. Although the petition states that the Vaccine Injury Table associates the hepatitis B vaccine with GBS, the Table does not. Mr. Nguyen periodically filed medical records and affidavits.

The Secretary reviewed this material and recommended against an award of compensation. Resp't's Rep., filed Oct. 25, 2021. The Secretary commented that Mr. Nguyen lacked support from an expert. Id. at 8.

Because it appeared that the parties were likely to seek reports from experts, draft instructions were issued. Order, issued Nov. 5, 2021.

B. Retained Experts and Their Reports

1. David Simpson and his First Report[3]

Background. Dr. Simpson graduated from SUNY at Buffalo School of Medicine in 1979. He had an internship in internal medicine, a residency in neurology, and a fellowship in clinical neurophysiology. He became board-certified in psychiatry and neurology in 1984. He has obtained board-certification in sub-disciplines as well.

Dr. Simpson held various academic positions, culminating in becoming a professor of neurology at the Icahn School of Medicine at Mount Sinai in 2001. His research has been supported by numerous grants and Dr. Simpson has written more than 250 articles, published in peer-reviewed journals. In his first report, Dr. Simpson stated that he has treated more than 100 patients with either acute inflammatory demyelinating polyneuropathy or chronic inflammatory demyelinating polyneuropathy in the last five years.

First Report. After describing his qualifications in about one page, Dr. Simpson's report opens with a recitation of events in Mr. Nguyen's medical history, ending in September 2018. Exhibit 16 at 2-5.

Dr. Simpson opines that the hepatitis B vaccine caused the onset of Mr. Nguyen's GBS. Consistent with the Expert Instructions, he discusses each of the prongs set out in Althen v. Sec'y of Health and Hum. Servs., 418 F.3d 1274 (Fed. Cir. 2005). For a theory to connect how the hepatitis B vaccine can cause GBS, Dr. Simpson sets out four topics: (1) molecular mimicry, (2)

[3] Information about Dr. Simpson's background can be found in his curriculum vitae, filed as Exhibit 40, which is nearly 100 pages.

neurotoxic effect, (3) immune complexes, and (4) loss of self-tolerance. Id. at 5-6. Although Dr. Simpson lists these separately, Mr. Nguyen argues for molecular mimicry. Pet'r's Br. at 11 ("Dr. Simpson proffers the theory of molecular mimicry").

For a logical sequence of cause and effect, Dr. Simpson wrote about one page. This one page basically restates the events in Mr. Nguyen's history. See Exhibit 16 at 8.

For the last Althen prong, Dr. Simpson stated that the interval between vaccination and the onset of GBS was appropriate. Id. at 7.

2. Brian Callaghan and his First Report[4]

Background. Dr. Callaghan graduated from the University of Pennsylvania Medical Center in 2004. He completed an internship and residency at the same institution. He also had a fellowship in neuromuscular medicine at the University of Michigan Health System, completing it in 2009. Dr. Callaghan became board-certified in psychiatry and neurology in 2008.

Starting in 2008, Dr. Callaghan taught neurology at the University of Michigan. Since 2018, Dr. Callaghan has worked as an associate professor there.

Dr. Callaghan has written more than 80 articles published in peer-reviewed journals. In his report, Dr. Callaghan stated that he has seen more than 50 patients with GBS.

First Report. As with Dr. Simpson, Dr. Callaghan set out his qualifications and Mr. Nguyen's medical history. Exhibit A at 1-3. Dr. Callaghan generally addresses Dr. Simpson's opinion that the hepatitis B vaccine can cause GBS via molecular mimicry. For many (but not all) of the articles Dr. Simpson cited, Dr. Callaghan summarizes the article in a single sentence.[5] In Dr. Callaghan's opinion, "there is no convincing evidence to support hepatitis B as a cause of GBS." Exhibit A at 5. One basis for this opinion is an article by McMahon. However, the Secretary did not submit any of the three articles Dr. Callaghan cited as exhibits. Thus, because the articles are not evidence, they will not be considered. More details about Dr. Callaghan's specific criticisms of Dr. Simpson's opinion will be provided in the analysis below. Dr. Callaghan did not directly address the second and third Althen prongs.

3. Dr. Simpson's Second Report, filed Feb. 14, 2023

Dr. Simpson attempted to respond to Dr. Callaghan. Dr. Simpson clarified that he is relying upon molecular and added more case reports. Exhibit 34.

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[4] Dr. Callaghan's curriculum vitae is Exhibit B.

[5] Although accurate, the short descriptions do not reveal much, if anything, about Dr. Callaghan's opinions about the articles. As such, the Secretary would be unlikely to elicit additional testimony from Dr. Callaghan about the articles. See Simanski v. Sec'y of Health and Hum. Servs., 671 F.3d 1368, 1382 (Fed. Cir. 2012).

C. Briefing

Dr. Simpson's second report was the final expert report. See Resp't's Status Rep., filed May 19, 2023 (declining to present additional expert reports). The parties were directed to file briefs. Order, issued Sep. 11, 2023. For approximately six months, the parties considered whether to resolve the case informally, but ultimately decided to proceed with litigation.

The parties advocated through briefs. Mr. Nguyen filed his primary brief on April 30, 2024 and his reply on October 10, 2024. In between, the Secretary submitted his brief on September 10, 2024. With the submission of Mr. Nguyen's reply, the matter is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his 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. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

IV. Elements of a Claim

The Vaccine Act requires that petitioners establish five elements. 42 U.S.C. § 300aa–11(c)(1)(A) through (E). Here, the dispute concerns the third element, causation. To establish causation, petitioners may rely upon the Vaccine Injury Table, which establishes a presumption of causation for certain vaccine-injury combinations. However, Mr. Nguyen has not submitted an on-Table claim. Thus, he is necessarily pursuing an off-Table claim. For off-Table cases, 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).

V. Analysis Part One: Qualifications

Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. See Depena v. Sec'y of Health & Hum. Servs., No. 13-675V, 2017

WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Hum. Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016).

Here, both parties retained doctors specializing in neurology and both Dr. Simpson and Dr. Callaghan are well-qualified neurologists. The problem, however, is that how vaccines affect the human body is primarily an immunologic topic. Dr. Simpson lacks any special qualifications in immunology. See Block v. Sec'y of Health & Hum. Servs., No. 19-969V, 2021 WL 5709764, *5 (Fed. Cl. Spec. Mstr. Oct. 29, 2021).

Dr. Callaghan, too, lacks any special qualifications in immunology. In the undersigned's experience, the Secretary often retains Dr. Callaghan and a person with expertise in immunology. See, e.g., Eloyan v. Sec'y of Health & Hum. Servs., No. 18-1450V, 2023 WL 9053983, at *1 (Fed. Cl. Spec. Mstr. Nov. 17, 2023).

Thus, for immunology, the experts stand on relatively similar ground. But, the lack of expertise in immunology is more a detriment to Mr. Nguyen because he, as the petitioner, bears the burden of presenting a persuasive case. See Pickens v. Sec'y of Health & Hum. Servs., No. 14-187V, 2021 WL 615218, at *15 (Fed. Cl. Spec. Mstr. Jan. 22, 2021); Dean v. Sec'y of Health & Hum. Servs., No. 13-808V, 2017 WL 2926605, at *18 n.12 (Fed. Cl. Spec. Mstr. June 9, 2017).

Regardless of the background, whether opinions are persuasive depends upon the justification for them. See Doyle v. Sec'y of Health & Hum. Servs., 92 Fed. Cl. 1, 8 (2010) ("Mere conclusory opinions—or ones that are nearly so as unaccompanied by elaboration of critical premises—will not suffice as proof of causation, no matter how vaunted or sincere the offeror").

VI. Analysis Part Two --- Medical Theory

Of the three Althen prongs, the parties most strenuously dispute the first prong, which is sometimes interpreted as asking, "can the vaccine cause the injury"? See Pafford v. Sec'y of Health and Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). Within this domain, three subtopics are relevant: burden of proof, appellate precedents regarding molecular mimicry, and evidence regarding molecular mimicry

A. Burden on Prong One Generally

Mr. Nguyen's position as to the level of proof is not crystal clear. Initially, he argued that a "Petitioner must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("Althen Prong One")." Pet'r's Br. at 6. Similarly, he also maintained that a "Petitioner must preponderantly establish that the Hepatitis B vaccine can cause GBS by providing a 'reputable medical or scientific explanation.'" Id. at 7, quoting Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019). Mr. Nguyen also cited W.C. v. Sec'y of Health and Hum. Servs., 704 F.3d 1352, 1356 (Fed. Cir. 2013) for the proposition that a petitioner cannot prevail by establishing his case with only a "plausible" causal link. Id. at 7-8. Nevertheless, in his second brief, Mr. Nguyen argues that "To satisfy the preponderance of

evidence standard in an 'Off-Table' case, Althen Prong One requires a biologically plausible mechanism." Pet'r's Reply at 2. In support of this argument, Mr. Nguyen cites Hoffman v. Sec'y of Health and Hum. Servs., 172 Fed. Cl. 477, 492-96 (2024).

Mr. Nguyen's cite to Hoffman is accurate in the sense that Hoffman does support biologic plausibility as the standard for Althen prong one. However, Hoffman, which is not binding precedent, represents a minority point of view among judges at the Court of Federal Claims. Many more judges have rejected "plausibility" as the level of proof for Althen prong one. See, e.g., Demore v. Sec'y of Health and Hum. Servs., 175 Fed. Cl. 756, 762-64 (2025); Munoz v. Sec'y of Health and Hum. Servs., 174 Fed. Cl. 276, 286-88 (2024); Stricker v. Sec'y of Health and Hum. Servs., 170 Fed. Cl. 701, 712-13 (2024).

B. Appellate Precedents regarding Molecular Mimicry

A slightly different question concerns the level of proof when petitioners rely upon molecular mimicry. Because molecular mimicry is advanced so frequently, appellate authorities have had opportunities to review how special masters have considered evidence about molecular mimicry.[6] 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 six 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.[7] 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

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[6] The briefs would have been improved if they had discussed any appellate cases about molecular mimicry.

[7] 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.

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).

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, Tulio, Yalacki, Stricker, Duncan, and Dennington, the undersigned will look to see whether any evidence supports the theory in this case.

C. Evidence regarding Molecular Mimicry between the Hepatitis B Vaccine and Guillain-Barré Syndrome

The evidence about the hepatitis B vaccine and GBS falls into three categories, which are (1) epidemiological studies, (2) case reports, (3) Dr. Simpson's opinion. A fourth consideration, which is not strictly evidence, concerns the results in similar cases.

1. Epidemiological Studies

For a lengthy discussion of the value of epidemiologic studies in the Vaccine Program, see Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *5-8 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448, 475 (2020).

Here, Mr. Nguyen and Dr. Simpson advance potentially three epidemiologic studies, one by Shaw and two others by Geier and Geier. The Shaw article is an interesting study, one that may have merited more attention than the parties and their experts gave to it. On the other hand, the studies by the Geiers received too much attention.

a) Shaw

Frederic E. Shaw, Jr., worked at the Centers for Disease Control. Before the article was published in 1988, Shaw and other colleagues from the CDC, people from the Food and Drug

Administration, and at least one person from the manufacturer of the vaccine investigated whether a hepatitis B vaccine was associated with an increased incidence of various diseases, most prominently GBS. The type of hepatitis B vaccine was the first hepatitis B vaccine that the FDA licensed and was known as "Heptavax." Exhibit 30 at 337-38.[8]

The manufacturer (Merck Sharp and Dohme) created Heptavax by purifying the plasma from carriers of the hepatitis B virus. "Each 1.0 ml of vaccine contains 20 μg of hepatitis B surface antigen (HBsAg) protein. The vaccine is given in a series of three injections; the second and third injections are given one and six months after the first." Id. at 338. In some cases, special masters have declined to rely upon Shaw because the vaccine was derived from plasma, unlike the current hepatitis B vaccine, which is a recombinant vaccine. E.g. Borrero v. Sec'y of Health & Hum. Servs., No. 01-417V, 2008 WL 4527837 at *14 (Fed. Cl. Spec. Mstr. Sept. 24, 2008). However, although Dr. Callaghan criticized Shaw in some respects as discussed below, Dr. Callaghan did not raise this particular point. Moreover, considering that both Heptavax and the current recombinant vaccine are based upon generating an immunologic response to the hepatitis B surface antigen, the differences in obtaining the surface antigens may not make a difference in assessing whether the vaccine could be harmful.

In any event, the government officials and Merck "undertook the surveillance of illnesses reported after inoculation with the new vaccine." Exhibit 30 at 338. It appears that this surveillance system resembled the Vaccine Adverse Event Reporting System ("VAERS"), which was created in 1990. The researchers solicited adverse events from various sources, including letters to state epidemiologists. This process led to the submission of 41 reports, including nine cases of GBS.

The nine cases of GBS were further investigated by a group of four neurologists. Some of the neurologists questioned whether the person truly suffered from GBS. Exhibit 30 at 346 (Table 3). In addition, some of the people with GBS also had other factors that could have caused GBS. Id. at 345 (Table 3). But, ultimately, the researchers accepted all nine cases.

Those nine cases of GBS had to be placed in context. The researchers did not know exactly how many doses of Heptavax were administered. So, as a proxy, the researchers used the manufacturer's sales figures. Exhibit 30 at 339. The researchers estimated that 838,215 people received at least one dose of the vaccine.

The next step was trying to determine the background rate for GBS. Shaw and colleagues stated that: "Incidence rates for neurologic diseases in representative US populations are scarce." Id. Researchers found some information in two sources, one from Olmsted County,

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[8] Frederic E. Shaw, Jr., et al., Postmarketing surveillance for neurologic adverse events reported after hepatitis B vaccination. Experience of the first three years, 127 AM. J. EPIDEMIOL. 337 (1988).

Minnesota, where the Mayo Clinic is, and the other from the CDC. The incidence rates for GBS were 2.3 cases per 100,000 people and 1.2 cases per 100,000.

Based upon this information, researchers attempted to determine how the incidence of GBS in people who received Heptavax compared with the background rate of GBS (the rate among people who did not receive the vaccine). The results, unfortunately, were not consistent. The "incidence of Guillain-Barré syndrome was significantly higher than expected when compared with the Centers for Disease Control background rate of 1.2 per 100,000 person-years." Exhibit 30 at 344. But, the incidence was not significantly higher "when compared with the Olmsted County rate of 2.3 per 100,000 person-years." Id.

Shaw and colleagues recognized limitations to their analyses. One limitation was that "validation of diagnosis was problematic." Id. at 346. Another concern was "underreporting." Id. at 349. Other "components [were] open to interpretation, including the background rate, the hypothetical at-risk intervals, and biases attendant to the data." Id. at 349.

Ultimately, Shaw and colleagues did not draw any specific conclusions from their data. They did not reject outright the biological plausibility that a hepatitis B vaccine can cause GBS based upon reports of GBS after hepatitis B infection, the link between the swine flu vaccine and GBS, and other anecdotes about vaccines and GBS. Id. at 349. On the other hand, Shaw and colleagues saw their data as suggesting that any risk from Heptavax would be much smaller than the risk of developing hepatitis B infection. Id. at 350. Shaw and colleagues, accordingly, recommended additional surveillance and epidemiologic studies.

Except for the Geier studies discussed next, the record in this case does not contain any other epidemiologic articles. For example, again, although Dr. Callaghan cited McMahon, the Secretary's failure to submit McMahon as an exhibit prevents it from being considered. Also, in other cases, the Secretary's expert has cited an epidemiologic study by Baxter. That, too, is not in evidence and therefore plays no role in Mr. Nguyen's case.

While the Shaw article is intriguing, it is difficult to give Shaw much weight in either supporting or rejecting causation. The primary challenge is that the rate at which people developed GBS without receiving a hepatitis B vaccine was uncertain and this uncertainty led to inconsistent results. Additional questions concern the accuracy of the reports of nine cases of GBS among vaccinated people. Finally, Heptavax is a different vaccine.

b) Geier Studies

Dr. Simpson cited two studies by David A. Geier and Mark R. Geier. Exhibit 16 at 10 (reference 9, which is Exhibit 25, and reference 13, which is Exhibit 29). Mr. Nguyen did not cite either study in his primary brief. However, Mr. Nguyen cited the second Geier article in his reply. Reply at 4. They can be treated together.

In a study published in 2004, the Geiers searched VAERS and PubMed for situations in which a hepatitis B vaccine was given before people developed various problems, including

GBS. Exhibit 29.[9] In a study published in 2005, the Geiers used the VAERS database to compare the frequency of reports after a hepatitis B vaccine with the frequency of reports after a tetanus vaccine. Exhibit 25.[10]

This method of analysis, extracting data from the VAERS database, has been found to be unreliable:

> A primary flaw is using the VAERS database as a source. In multiple cases, special masters have rejected this methodology. See Tompkins v. Sec'y of Health & Hum. Servs., 117 Fed. Cl. 713, 721 (2014) (quoting special master's decision describing the VAERS database as a "stocked pond"); Analla v. Sec'y of Health & Hum. Servs., 70 Fed. Cl. 552, 558 (2006) (noting that the Court has uniformly upheld concerns of special masters about VAERS reports); see also Doe v. Ortho-Clinical Diagnostics, Inc., 440 F.Supp.2d 465, 475-76 (M.D.N.C. 2006) (noting that Dr. Geier's use of VAERS reports was not reliable).

Stricker v. Sec'y of Health & Hum. Servs., No. 18-56V, 2024 WL 263189, at *13 (Fed. Cl. Spec. Mstr. Jan. 2, 2024). This analysis was sustained on a motion for review. Stricker v. Sec'y of Health and Hum. Servs., 170 Fed. Cl. 701, 717-18 (2024). At least one author of a medical article has reached a similar conclusion about relying upon VAERS reports: "It is also impossible to reliably estimate the incidence of vaccine-related adverse events because the data reported to VAERS consist of a collection of single case reports (without a case cohort control group) from an uncertain population." Exhibit 26 at 146-47.[11] In addition, the authors of these studies are not reliable:

> Geier and Geier have been repeatedly discredited in the Vaccine Program. See, e.g., America v. Sec'y of Health & Hum. Servs., No. 17-542V, 2022 WL 278151, at *8 n.16 (Fed. Cl. Jan. 4, 2022) ("the authors of the Geier Article have been almost wholly discredited as experts in the Vaccine Program") (citing Hooker v. Sec'y of Health & Hum. Servs., No. 02-472V, 2017 WL 3033940,

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[9] M.R. Geier and D.A. Geier, A case-series of adverse events, positive re-challenge of symptoms, and events in identical twins following hepatitis B vaccination: analysis of the Vaccine Adverse Event Reporting System (VAERS) database and literature review, 22 CLIN. EXP. RHEUMATOL. 749 (2004).

[10] David A. Geier and Mark R. Geier, A case-control study of serious autoimmune adverse events following hepatitis B immunization, 38 AUTOIMMUNITY 295 (2005).

[11] Joerg-Patrick Stübgen, Immune-mediated myelitis following hepatitis B vaccination, 12 AUTOIMMUN. REV. 144 (2012).

at *17 (Fed. Cl. Spec. Mstr. Apr. 11, 2017); King v. Sec'y of Health & Hum. Servs., No. 03-584V, 2011 WL 5926126, at *15 (Fed. Cl. Sept. 22, 2011); Doe/03 v. Sec'y of HHS, 2007 WL 2350645, at *3 (Fed. Cl. Spec. Mstr. July 31, 2007); and Daly v. Sec'y of HHS, No. 90–590V, 1991 WL 154573, at *7 (Cl. Ct. Spec. Mstr. July 26, 1991)).

Stricker, 2024 WL 263189, at *13; accord Garris v. Sec'y of Health & Hum. Servs., No. 22-1354V, 2025 WL 2401999, at *5 (Fed. Cl. Spec. Mstr. June 20, 2025) (stating that the Geiers "have been thoroughly discredited in Vaccine Program cases when offering testimony as experts, suggesting that their work merits little to no attention").

c) Summary on Epidemiology

In sum, the epidemiology balances as approximately neutral. The two studies by Geier and Geier use a flawed methodology and are not reliable. Thus, although the studies have been considered, they do not contribute to the analysis. See Vaccine Rule 8(b)(1) (requiring special masters to decide cases based upon reliable evidence). The Shaw study is inconclusive and does not preponderate in favor of finding causation or in favor of rejecting causation. Thus, the additional evidence will be analyzed.

2. Case Series and Case Reports

Much of Mr. Nguyen's prong one evidence consists of case reports and case series. See Pet'r's Br. at 12-18. Examples include articles by Khamaisi, Tabor, Sinsawaiwong, Ray, Wei, and Yiman.[12]

Various authorities have commented on the value of case reports. To start, the Federal Judicial Center has published a series of guides designed "to assist judges ... in reaching an

[12] Mogher Khamaisi et al., Guillain-Barré syndrome following hepatitis B vaccination, 22 CLIN. EXP. RHEUMATOL. 767 (2004). Filed as Exhibit 28.

Edward Tabor et al., GBS and other neurological syndromes in hepatitis A, B and non-A, non-B, 21 J MED. VIROL. 207 (1987). Filed as Exhibit 31.

S. Sinsawaiwong et al., GBS following hepatitis B vaccine and review of the literature, 83 J. MED. ASSOC. THAI 1124 (2000). Filed as Exhibit 27.

Gautam Ray, Acute Hepatitis B presenting as Guillain Barre, 22 INDIAN J. GASTROENTEROL. 228 (2003). Filed as Exhibit 37.

Jaijun Wei & Shenhan Duan, Severe Guillain–Barré syndrome associated with chronic hepatitis B, 100 MEDICINE e27989 (2021). Filed as Exhibit 38.

Kidist Yimam et al., Acute hepatitis B infection causing Guillain-Barré syndrome (GBS): A rare case, 9 Gastroenterol. Hepatatol. 121 (2013). Filed as Exhibit 39.

informed and reasoned assessment concerning the basis of expert evidence." Jerome Kassirer and Gladys Kessler, Reference Manual on Scientific Evidence, Preface (3d ed. 2011) ("Reference Manual"). The guidance from the Federal Judicial Center translates to the Vaccine Program because causation for off-Table injuries in the Vaccine Program is the same as traditional causation. See Moberly v. Sec'y of Health and Human Servs., 592 F.3d 1315, 1322-23; Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999) ("The absence of elaboration of the law of causation in the legislative history leads us to conclude that the Vaccine Act's requirement of causation in non-Table cases was not viewed as distinct from causation in the tort law."). For examples in which appellate authorities within the Vaccine Program have cited the Reference Manual, see Germaine v. Sec'y of Health & Hum. Servs., 155 Fed. Cl. 226, 228-29 (2021), and Hart v. Sec'y of Health & Hum. Servs., 60 Fed. Cl. 598, 607 n.20 (2004).

A pertinent guide in the Reference Manual states "[a]necdotal evidence usually amounts to reports that events of one kind are followed by events of another kind. Typically, the reports are not even sufficient to show association, because there is no comparison group." David H. Kaye and David A. Freedman, Reference Manual on Scientific Evidence, Reference Guide on Statistics, at 218. These authors also state, "some courts have suggested that attempts to infer causation from anecdotal reports are inadmissible as unsound methodology under Daubert." Id. at 217 n. 14 (citing cases).

Within the Vaccine Program, the Federal Circuit has endorsed, albeit indirectly, a view that case reports merit little weight. In a series of five cases involving autoimmune hepatitis, the (undersigned) special master rejected case reports as evidence of causation. Porter v. Sec'y of Health & Hum. Servs., No. 99–639V, 2008 WL 4483740, at *13 (Fed. Cl. Spec. Mstr. Oct. 2, 2008). Under the caption of a different case, a judge at the Court of Federal Claims disagreed with this weighing of evidence. Rotoli v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 71, 86–87 (2009). When the Federal Circuit reviewed the special master's decision, the Federal Circuit stated that "[t]he special master found that the remaining two articles, both describing single case studies, did not contain any meaningful analysis about causation." Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1253 (Fed. Cir. 2012). The Federal Circuit also stated that the "decision reveals a thorough and careful evaluation of all the evidence including ... medical literature." Id. at 1254.

Similar indirect support from the Federal Circuit is found in W.C. v. Sec'y of Health & Hum. Servs., No. 07-456V, 2011 WL 4537877, at *13 (Fed. Cl. Spec. Mstr. Feb. 22, 2011), mot. for rev. denied on this point, 100 Fed. Cl. 440, 456 (2011), aff'd, 704 F.3d 1352 (Fed. Cir. 2013). At the trial level, the (undersigned) special master declined to rely upon case reports because, among other reasons, "case reports cannot distinguish a temporal association from a causal relationship." Id. at *13. At the Federal Circuit, the appellate court focused primarily upon epidemiologic studies, which undermined the claim that the vaccine significantly aggravated the petitioner's illness. W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1360-61 (Fed. Cir. 2013). However, at the end of its opinion, the Federal Circuit stated that it "cannot say that the special master's ... weighing of the scientific evidence was arbitrary or capricious." Id. at 1361.

Much of the foregoing analysis regarding case reports was set forth in K.O. v. Sec'y of Health & Human Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July

7, 2016). After K.O., the Federal Circuit has not discussed case reports in a precedential opinion, leaving Porter and W.C. as the leading, although muted, words on the subject.[13] Consequently, judges from the Court of Federal Claims have tended to defer to the special master's assessment of case reports. See, e.g., Kelly v. Sec'y of Health & Hum. Servs., 160 Fed. Cl. 316, 321 (2022) (indicating that the special master was not arbitrary in finding that case reports have limited or nonexistent value); Rus v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 672, 682 (2016) (noting the special master could reasonably afford little weight to the medical literature, including case reports). An exception to this trend is Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159 (2021). In Patton, the Court ruled that the special master "erred in his prong one analysis by discounting the evidentiary value of the case reports [petitioner's expert] submitted." Id. at 168. But, Patton does not discuss Porter or W.C. Instead, Patton relies upon Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 475 (2012).[14]

Outside of the Vaccine Program, district courts have examined the value of case reports in the context of claims that drugs or a medical device harmed a person. Examples include: In re: Abilify (Aripiprazole) Products Liability Litigation, 299 F.Supp.3d 1291, 1309 (N.D. Fla. 2018) ("The difficulty with case reports is distinguishing between association and causation"); In re Tylenol (Acetaminophen) Marketing, Sales Practice, and Products Liability Litigation, 198 F.Supp.3d 446, 461 (E.D. Pa. 2016) ("It is true that case reports and anecdotal evidence alone may not be sufficient support for a causation opinion.... However, case reports considered in conjunction with other evidence may be an appropriate basis for an expert's causation opinion."); In re Mirena IUD Products Liability Litigation, 169 F.Supp.3d 396, 451 (S.D.N.Y. 2016) ("Case reports are generally disfavored by courts as evidence of causation because they merely describe 'reported phenomena without comparison to the rate at which the phenomena occur in the

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[13] In a non-precedential opinion, the Federal Circuit held that the special master was not arbitrary in denying compensation. Kalajdzic v. Sec'y of Health & Hum. Servs., No. 2023-1321, 2024 WL 3064398 (Fed. Cir. June 20, 2024). In the underlying decision, the special master gave "little weight" to "case reports filed in support of Petitioner's theory." Kalajdzic v. Sec'y of Health & Hum. Servs., No. 17-792V, 2022 WL 2678877, at *23 (Fed. Cl. Spec. Mstr. June 17, 2022), mot. for rev. denied, 2024 WL 4524777 (originally issued Oct. 27, 2022), aff'd, 2024 WL 3064398 (Fed. Cir. 2024).

[14] Paluck states "case reports 'do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value. Nonetheless, the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight.'" Paluck, 104 Fed. Cl. at 475, quoting Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011). The case Paluck quotes, Campbell, cites to Rotoli v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 71, 86-87 (2009). However, the value of the opinion by the Court of Federal Claims seems questionable as the Federal Circuit, as noted above, reversed the outcome in Rotoli, and reinstated the special master's decision, which gave little weight to the case reports. Porter, 663 F.3d at 1253. Paluck, which cited Rotoli, was issued before the Federal Circuit reversed Rotoli.

general population or in a defined control group; [they] do not isolate and exclude potentially alternative causes; and [they] do not investigate or explain the mechanism of causation.' ") (citation omitted).

Thus, in accord with these judicial authorities, the undersigned declines to give the various case reports much, if any, weight. In addition to the overarching point that case reports are generally not reliable of causation, there are smaller individual weaknesses about some case reports.

Exhibit 31 (Tabor). Tabor reports about cases of GBS that followed infections with hepatitis, either hepatitis A or hepatitis B. However, the hepatitis B vaccine differs from a hepatitis B infection. Bourche, 2020 WL 571061, at *5; Bigbee v. Sec'y of Dep't of Health & Hum. Servs., No. 06-663V, 2012 WL 1237759, at *35 (Fed. Cl. Spec. Mstr. Mar. 22, 2012).

In addition, Mr. Nguyen filed the abstract, not the whole article. The submission of an abstract does not comply with the November 5, 2021 Expert Instructions, page 8 ¶ 3.

Exhibit 27 (Sinsawaiwong). Mr. Nguyen also filed an abstract.

Exhibit 37 (Ray). This case report is about hepatitis B infection, not vaccination.

Exhibit 38 (Wai). This case report is about chronic hepatitis B infection, not vaccination.

Exhibit 39 (Yiman). This case report is about hepatitis B infection, not vaccination.

These points further diminish the already limited value of case reports.

3. Dr. Simpson's Opinion

Although the epidemiology and the collection of case reports are not particularly supportive for Mr. Nguyen's claim that the hepatitis B vaccine can cause GBS, Mr. Nguyen might prevail based upon the opinion of his expert. See Althen, 418 F.3d at 1278. Thus, his opinion is analyzed.

Dr. Simpson begins with a basic and basically accurate definition: molecular mimicry "suggests that epitopes of a virus or vaccine, results in development of immune antibodies and/or T cells that could cross-react with epitopes on myelin or axonal glycoproteins of nerves, leading to neuronal damage." Exhibit 16 at 5. In the context of molecular mimicry, Dr. Simpson discusses that an infection with *campylobacter jejuni* can lead to GBS. Id. at 6. Dr. Simpson does not propose any homologies, that is, Dr. Simpson does not identify any portions of the hepatitis B vaccine that share sufficient molecular structure with a component of the peripheral nervous system. See id.

Based upon this case's evidence, Mr. Nguyen has not met his burden of proof to present a reliable medical theory to explain how the hepatitis B vaccine can cause GBS. To be sure, molecular mimicry has been proposed as a way for infectious agents and vaccines to cause autoimmune diseases. See W.C. There is even some evidence that shows that molecular mimicry has been put forward in the context of the hepatitis B vaccine and GBS. See, e.g., Exhibit 28 (Khamaisi) at 769. But, Dr. Simpson is lacking any evidence that could make this

theory reliable. In this sense, Dr. Simpson's opinion regarding molecular mimicry resembles Dr. Tornatore's opinion in Dennington. Just as Dr. Tornatore's simple invocation of molecular mimicry was found insufficient in Dennington, so, too, Dr. Simpson's opinion is not credited here.

For these reasons, the evidence submitted in this case fails to demonstrate that molecular mimicry is a reliable theory to explain how the hepatitis B vaccine can cause GBS. Nevertheless, one additional point (a precedent favoring Mr. Nguyen's position) is discussed below.

4. Another Case with the Hepatitis B Vaccine and GBS

The September 11, 2023 order for briefing (page 6) invited the parties to cite similar cases. In response, Mr. Nguyen cited Osso v. Sec'y of Health & Hum. Servs., No. 18-575V, 2023 WL 5016473 (Fed. Cl. Spec. Mstr. July 13, 2023). Thus, a discussion of Osso is worthwhile. The Secretary, however, did not cite any cases in which a special master evaluated whether the hepatitis B vaccine can cause GBS.

Osso has some similarities and some differences with the present case. One difference is that Ms. Osso relied upon opinions presented by Dr. Marcel Kinsbourne. 2023 WL 5016473, at *8-14 (summarizing Dr. Kinsbourne's background and qualifications). The special master in Osso appears to have accepted Dr. Kinsbourne's qualifications in immunology, unlike the present case in which Dr. Simpson's background in immunology seems limited. Furthermore, Dr. Kinsbourne presented information showing homology between the hepatitis B virus and a portion of the peripheral nervous system potentially involved in GBS, myelin basic protein. Id. at *21.

One point of similarity between Mr. Nguyen's case and Osso is that the epidemiologic study, Shaw, was not viewed as determinative. As stated in Osso, "'[r]equiring epidemiologic studies ... impermissibly raises a claimant's burden under the Vaccine Act.'" 2023 WL 5016473, at *23 (quoting Andreu v. Sec'y of Health and Hum. Servs., 569 F.3d 1367, 1378 (Fed. Cir. 2009)).

The undersigned and the special master in Osso part company, however, with respect to the significance of the lack of supportive epidemiology. Osso states: "where robust epidemiology studies are not available, [case reports] provide some evidence of causation." 2023 WL 5016473, at *24. The undersigned, respectfully, disagrees with this reasoning. Case reports generally do not provide persuasive evidence of causation because the case report presents only a sequence of events. As discussed in Section VI.C.2 above, this criticism of case reports has been noted in multiple cases. This limitation is inherent in case reports. The problem with case reports does not go away simply because other evidence (such as epidemiologic studies) is not available. See Cress v. Sec'y of Health & Hum. Servs., No. 18-1369V, 2025 WL 2855161, at *11 (Fed. Cl. Spec. Mstr. Sep. 23, 2025) (stating "petitioners' burden to present preponderant evidence explaining how a vaccine can cause a disease is not reduced simply because there is a lack of information available about the disease" and citing cases).

Osso actually goes a step further in that Osso relied, in part, on case reports about "GBS cases associated with hepatitis B infection." 2023 WL 5016473, at *24. But, the proposition

that hepatitis B infection causing GBS is not robustly developed beyond case reports in the present case. See Exhibit 32 (Peter D. Donofrio, Guillain-Barré Syndrome, 23 CONTINUUM 1295 (2017)) at 1295 (listing infections associated with GBS but not listing hepatitis B). Osso also did not explain why (assuming that the hepatitis B virus can cause GBS) it is reasonable to infer that the hepatitis B vaccine can cause GBS. Some explanation might have addressed the difference between a replicating organism and a non-replicating substance.

The Federal Circuit has recognized that special masters enjoy "very wide discretion" in how they weigh evidence. Whitecotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996). The Federal Circuit has similarly commented that special masters may weigh evidence differently. Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000). This difference in weighing evidence, particularly the value of case reports, appears to be a primary difference in outcome between Ms. Osso's case and the present decision.

Accordingly, for these reasons, Mr. Nguyen has not met his burden for Althen prong one.

VII. Remaining *Althen* Prongs

Because Mr. Nguyen can prevail only if he establishes all Althen prongs, the lack of preponderant proof on prong one means that he is not entitled to compensation. Nevertheless, the remaining Althen prongs are discussed briefly, if only to demonstrate that the whole record has been considered.

A. Logical Sequence of Cause and Effect

The second Althen prong requires preponderant evidence for "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Mr. Nguyen's arguments on this prong are thin as well. In his primary brief, across about one page, Mr. Nguyen essentially sets forth a chronology of events in which Mr. Nguyen received the hepatitis B vaccine before he developed GBS. Pet'r's Br. at 19. A simple recitation of events in which a vaccination preceded the start of a disease and no other cause for the disease has been identified does not, without more, show that a petitioner is entitled to compensation. Moberly, 592 F.3d at 1323.

Mr. Nguyen also argues that his doctors exempted him from receiving the flu vaccine. Exhibit 5 at 65. Pet'r's Br. at 19. However, the flu vaccine is not the hepatitis B vaccine. One notable difference is that the Secretary has associated the flu vaccine with GBS on the Vaccine Injury Table. 42 C.F.R § 100.3. Thus, the recommendation not to receive the flu vaccine seems more like a precaution than a statement that the hepatitis B vaccine caused Mr. Nguyen's GBS. In this regard, the parties were encouraged to identify any evidence that a treating doctor linked Mr. Nguyen's GBS to the preceding vaccinations. Order for Briefs, issued Sep. 11, 2023, at 7 (requesting this information). But, Mr. Nguyen has not identified any doctor's comments with respect to the hepatitis B vaccine.

Accordingly, Mr. Nguyen has not met his burden of proof for the second Althen prong.

B. Timing

The remaining Althen 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).

Here, for onset, there is a minor, but undecisive, dispute. Here, Dr. Simpson maintains that the onset was approximately two weeks after vaccination. Exhibit 16 at 7. Dr. Callaghan places the onset of Mr. Nguyen's GBS at approximately five weeks. Exhibit A at 5. This disagreement seems unimportant because Dr. Callaghan has not persuasively shown that five weeks is an excessively long latency such that an inference of causation would not be appropriate.

Thus, Mr. Nguyen is found to prevail upon the third Althen prong, which concerns timing. But, this limited success does not entitle Mr. Nguyen to receive compensation. Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992) ("Temporal association is not sufficient, however, to establish causation in fact.").

VIII. Resolution on the Papers is Appropriate

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020). A consideration is whether both parties, especially the losing party, had a fair opportunity to present its evidence and arguments.

Here, Mr. Nguyen enjoyed ample opportunities to present his evidence. Before the parties consulted any experts, they were advised that the reports could constitute the expert's testimony. Draft Instructions, issued Nov. 5, 2021. Mr. Nguyen had the last word regarding experts as Dr. Simpson wrote two reports as opposed to Dr. Callaghan who wrote a single report.

Similarly, Mr. Nguyen also enjoyed ample opportunities to argue his case. In the context of briefing, he again had the last word. He filed a reply brief.

An evidentiary hearing is not likely to change the outcome for Mr. Nguyen. Dr. Simpson's relative lack of experience in immunology will not change. See Section V above. Dr. Simpson's reports have not provided an adequate basis for finding molecular mimicry to be a reliable theory in the context of hepatitis B vaccine causing GBS. Dr. Simpson ordinarily would not be allowed to express a new basis for his opinion for the first time in any oral testimony. Simanski v. Sec'y of Health & Hum. Servs., 671 F.3d 1368, 1382 (Fed. Cir. 2012) ("the special master can order the experts to confine their testimony to the issues addressed in their reports"). In addition, the lack of support from treating doctors would not change with an evidentiary hearing.

IX. Conclusion

Mr. Nguyen suffered from GBS that developed no more than five weeks after he received the third dose of the hepatitis B vaccine. Thus, it is understandable that Mr. Nguyen may contend that the vaccine caused his GBS. However, Mr. Nguyen is required to support his case with evidence and in his case, preponderant evidence is lacking. Thus, he 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