In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

* *
MARIE BROWN, *
* No. 18-786V
Petitioner, * Special Master Christian J. Moran
*
v. *
* Filed: May 8, 2020
SECRETARY OF HEALTH *
AND HUMAN SERVICES, * Guillain-Barré syndrome ("GBS),
* alternative factor, infection,
Respondent. * surgery, statistics
* *

Leah V. Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner;
Linda S. Renzi, United States Dep't of Justice, Washington, DC, for respondent.

RULING FINDING ENTITLEMENT TO COMPENSATION[1]

Marie Brown alleges that within 42 days of receiving an influenza (flu) vaccination she developed a serious disease of her peripheral nervous system, Guillain-Barré syndrome (GBS). The Secretary agrees with this allegation, and, typically, this agreement would result in a finding that Ms. Brown is entitled to compensation because the Vaccine Injury Table associates flu vaccination with GBS that arises within 3-42 days of the vaccination. But, relying upon the reports of two experts, the Secretary has proposed alternative causes, a significant

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website (http://www.cofc.uscourts.gov/aggregator/sources/7). This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

infection and an operation Ms. Brown underwent approximately six weeks before she began to suffer from GBS.

Ms. Brown and the Secretary have filed briefs regarding the proposed alternative causes. Although the Secretary has demonstrated that an infection and an operation can cause GBS, the Secretary has not met his burden of establishing, by preponderant evidence, that either the infection or the operation did cause Ms. Brown's GBS. Therefore, Ms. Brown is entitled to compensation.

I. Medical and Procedural History

A. Medical History

Ms. Brown was born in 1955. Exhibit 21 (affidavit) ¶ 1. For more than 30 years, she taught in public schools before retiring in 2008. Id. ¶ 5. In 2015, she was independent, capable of driving, shopping, dancing, and attending football games. Id. ¶ 2.

On May 30, 2015, Ms. Brown sought assistance at a local emergency room, complaining of 5-6 days of abdominal pain with constipation. When the pain became too intense to tolerate, Ms. Brown went to the emergency room. Exhibit 2 at 169. She underwent an exploratory laparotomy. During this operation, the doctors removed an ovarian mass and she had a sigmoid resection. Ms. Brown was in septic shock and to maintain her blood pressure during the operation, the doctors gave her vasopressors and fluids. Id. at 176. The doctors left Ms. Brown's abdomen open for approximately two days. Id. at 168 (discharge report). Then, the doctors returned Ms. Brown to surgery for washout and closure. Id. at 173-74.

Ms. Brown's hospitalization lasted until June 6, 2015. While recovering, Ms. Brown's bowel function, diet, and level of activity improved. Id. at 168 (discharge report).

One day before leaving the hospital, Ms. Brown received two vaccines, the flu vaccine and the pneumococcal 13-valent vaccine. Exhibit 1 at 1. The flu vaccine is the basis of Ms. Brown's petition.

After discharge, Ms. Brown did well for a few weeks. However, around July 8, 2015, she stopped having output from her ostomy with intermittent abdominal pain. In addition, she experienced numbness in her hands and feet bilaterally. She, therefore, went to the emergency room on July 11, 2015. Exhibit

2 at 151. After an examination and work-up, the doctor discharged her home. Id. at 152.

Two days later, July 13, 2015, Ms. Brown returned to the emergency room because she was not feeling better and was still experiencing pain and nausea. She was admitted to the hospital. Id. at 26 (emergency room report).

During this July 2015 admission, a neurologist saw Ms. Brown. Ms. Brown told the neurologist that when she was admitted on July 13, 2015, she was weak in her lower extremities. Over the course of her hospitalization, she started to develop tingling of her lower extremities. After an examination, the neurologist diagnosed Ms. Brown as suffering from GBS. The neurologist ordered, among other things, plasma exchange. Id. at 37-39.

This hospitalization lasted until August 4, 2015. When she was discharged, Ms. Brown was weak and lacked reflexes. Id. at 45-46. Upon leaving the hospital, she went to a long-term rehabilitation facility, where she stayed for approximately one month. Exhibit 3.

Ms. Brown continued to follow up with neurologists for her GBS. In December 2015, she reported that she was experiencing less pain and she could walk well with a walker. Exhibit 11 at 11. On March 21, 2017, approximately 20 months after Ms. Brown began to experience GBS, she saw a physician's assistant at her neurologist's office. Ms. Brown sought clearance for an operation to treat a compression fracture in her spine. Exhibit 6 at 27. Her strength in her upper extremities was 5/5 and 4/5 in both lower extremities. Id. at 24.

Ms. Brown had the operation, a lumbar kyphoplasty, for her compression fracture on April 4, 2017. Exhibit 2 at 246-47. While she was referred for neurosurgery for foraminal stenosis at L5/S1 and central canal stenosis at L1, she deferred the surgery because her lower extremity weakness from GBS was better. Exhibit 6 at 27.

The most recent medical record appears to be from May 2018. She reported back pain, balance problems, and a burning sensation in her feet and fingers. Exhibit 12 at 5.

B. Procedural History

The procedural history starts when the medical history ends. Ms. Brown filed her petition on June 4, 2018, alleging an on-Table case of flu vaccine—GBS.

Pet. ¶ 4. The case was originally placed in the Special Processing Unit. Ms. Brown filed medical records periodically and her statement of completion on September 3, 2018.

Approximately 11 months later, the Secretary completed his review of the medical reports and presented his evaluation. Resp't's Rep., filed Aug. 9, 2019. The Secretary conceded one aspect of the case, stating Ms. Brown "alleges that she suffered GBS within the Table time period set forth in vaccine Table for the flu vaccine, and the records support that allegation." Id. at 6.

The Secretary, however, declined to recommend that Ms. Brown was entitled to compensation. In the Secretary's view, Ms. Brown's GBS "was more likely than not caused by her severe abdominal infection and surgery, unrelated to the administration of her vaccinations." Id. at 7. The Secretary based his view on a report from a neurologist whom he retained for litigation, Dara Jamieson.

Dr. Jamieson opined that Ms. Brown met the diagnostic criteria for GBS. Exhibit A at 7. But, Dr. Jamieson asserted that "Given the lack of causative correlation between current influenza vaccination, and given the known causative correlation between both infections and surgery and the triggering of GBS, it is my opinion that Mrs. Brown's GBS was likely triggered by her prior overwhelming gastrointestinal infection and her extensive surgeries." Id.

Dr. Jamieson detailed the basis for her opinion. She stated that "GBS is often a post-infectious disorder . . . with two-thirds of patients reporting preceding respiratory or gastrointestinal symptoms within 4 weeks of the onset of weakness, usually by 10 to 14 days after the infection." Id. at 8. Dr. Jamieson continued, "While the triggering linkage with prior surgery is less robust than with gastrointestinal or respiratory infections, recent surgical procedures have been shown to increase the risk of GBS, with the possibility of a combined synergistic effect of infections and surgery." Id. at 9 (citing Yang and Rudent). Finally, Dr. Jamieson reached flu vaccinations. She recognized an increased incidence of GBS following the influenza A / H1N1 program in 1976. But, "Subsequent epidemiological studies of the incidence of GBS after influenza vaccination found slight to no increase in GBS risk with vaccination, depending on the type of vaccine and the method of analysis." Id. at 9-10.

After the filing of the Secretary's report and Dr. Jamieson's report, this case was transferred out of the Special Processing Unit. Order, issued Sept. 6, 2019. In the undersigned's first status conference, Ms. Brown contended that Dr.

Jamieson's report should be struck from the record because her opinion relied on statistical information to choose surgery over vaccinations as the causative agent. The Secretary was directed to clarify various aspects of Dr. Jamieson's opinion. Order, issued Oct. 11, 2019.

Ms. Brown developed and slightly modified her argument in a five-page motion for ruling on the record. Ms. Brown contended that "Respondent's defense of this Table case is legally impermissible. Dr. Jamieson's opinion is based on statistical evidence specifically forbidden by the Court of Appeals for the Federal Circuit." Pet'r's Mot., filed Oct. 14, 2019, at 2 (citing Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543 (Fed. Cir. 1994)).

Because Dr. Jamieson was already preparing a supplemental report in response to the October 11, 2019 order, the Secretary was instructed to file both her supplemental report and response to the motion for ruling on the record by November 25, 2019. Order, issued Oct. 31, 2019.

On the deadline, the Secretary filed a motion to amend the schedule in three respects. Ms. Brown's position regarding the requests was ambiguous. Regardless, the Secretary was permitted a short amount of additional time to file a supplemental report from Dr. Jamieson. The Secretary was allowed a longer amount of time to file a report from an immunologist. Lastly, the Secretary's deadline for responding to the motion for ruling on the record was extended until 14 days after the immunologist's report was filed. Order, issued Dec. 2, 2019.

The Secretary complied with the deadlines for his experts' reports. The Secretary filed a supplemental report from Dr. Jamieson on December 16, 2019. Exhibit C. The Secretary also filed a report from an immunologist, Dr. Kedl, on January 9, 2020. Exhibit D.

With respect to the pending motion for ruling on the record, the Secretary again requested additional time to file a response. Resp't's Mot., filed Jan. 23, 2020. The Secretary was given a limited amount of time because the motion to which the Secretary was responding was only five pages and had been pending since October 14, 2019. The Secretary was also restricted to filing any additional motions for enlargement to times that corresponded to the amount of time being requested. For example, if the Secretary was requesting one week of additional time, the Secretary was required to file that motion for enlargement of time one week in advance. Order, issued Jan. 28, 2020 (setting deadline of Feb. 14, 2020).

On February 7, 2020, the Secretary asked that the deadline for responding to the October 14, 2019 motion for ruling on the record be extended from February 14, 2020 to April 7, 2020. The Secretary proposed that the parties engage in settlement discussions. However, Ms. Brown opposed this enlargement. Because Ms. Brown opposed the enlargement and because the Secretary had extended the deadline for responding many times previously, the Secretary's motion was denied. Order, issued Feb. 10, 2020.

The Secretary filed a response to Ms. Brown's motion for ruling on the record on February 14, 2020. The Secretary argued that he "through his experts, has established by preponderant evidence that petitioner's GBS was likely caused by a factor unrelated to her vaccination." Resp't's Resp. at 6. The Secretary also "disagree[d] that the evidence relied upon by his experts is the type of bare statistical evidence rejected in Knudsen." Id. at 7.

After submitting two motions for enlargements of time, Ms. Brown filed a reply. Her motion for a ruling on the record is ready for adjudication.

II. Vaccine Injury Table and Alternative Factors

In enacting the Vaccine Act that included a Vaccine Injury Table, Congress turned on its head the maxim "post hoc ergo propter hoc." Shalala v. Whitecotton, 514 U.S. 268, 270 (1995). When a petitioner establishes that she "sustained . . . any illness . . . set forth in the Vaccine Injury Table in association with [a] vaccine, . . . and the first symptom . . . of the onset . . . of any such illness . . . occurred within the time period after the vaccine administration set forth in the Vaccine Injury Table," 42 U.S.C. § 300aa–11(c)(1)(C)(i), the petitioner gains a rebuttable presumption that the vaccination caused the injury. The Secretary may rebut this prima facie showing by proving that the illness was in fact caused by "factors unrelated to the administration of the vaccine." 42 U.S.C. § 300aa–13(a)(1)(B); accord Whitecotton, 514 U.S. at 270-71.

In trying to establish a factor unrelated to the vaccination caused the injury, the Secretary's burden is a "preponderance of the evidence." Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007). A "preponderance of the evidence" is not the same as scientific certainty. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Congress authorized the Secretary to modify the Vaccine Injury Table. 42 U.S.C. § 300aa–14(c)(3); see also Terran v. Sec'y of Health & Human Servs., 195

F.3d 1302, 1312-14 (Fed. Cir. 1999) (upholding the constitutionality of this aspect of the Vaccine Act). As relevant in Ms. Brown's case, the Secretary proposed, on July 29, 2015, to modify the Vaccine Injury Table to link flu vaccine with GBS that arises in 3-42 days after vaccination. 80 Fed. Reg. 45132. The basis for this proposal was a set of "studies demonstrating a causal association between the 2009 H1N1 and 1976 swine flu vaccines and GBS." Id. at 45146. The Secretary recognized that "the degree of surveillance needed to detect an increased risk of one case per million vaccinations, as was seen with the monovalent 2009 H1N1 vaccine, is unlikely to be routinely performed as strains in the flu vaccines change from year to year." Id. The Secretary reasoned, "Although the scientific evidence does not show a causal association for current formulations of seasonal flu vaccines and GBS," a modification to the Table was "in accordance with the ACCV Guiding Principles." Id.

The Secretary announced he adopted this proposed modification on January 19, 2017. 82 Fed. Reg. 6294. But, this adoption was delayed and became effective on March 21, 2017. 82 Fed. Reg. 11321. The flu vaccine—GBS link continues to be on the Vaccine Table today, and the Secretary has not proposed any modifications to the Vaccine Table to remove this link.

III. Analysis

Ms. Brown grounds her motion for ruling on the record on the argument that the Secretary's experts are using statistical information improperly. In their briefing, the parties have identified three cases that discuss statistical information in the Vaccine Program. These are discussed in section A below. Following that discussion, section B below evaluates the opinions Dr. Jamieson and Dr. Kedl presented.

A. Vaccine Program Precedent on Statistical Information

The parties have identified three appellate cases that discussed the use of statistical evidence. These are reviewed below.[2]

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[2] The discussion does not rely upon isolated quotes extracted from the decisions because the context affects the meaning of a court's statement. Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc., 769 F.3d 1339, 1353 (Fed. Cir. 2014) (Taranto, J., dissenting from denial of a petition for rehearing en banc).

1. Knudsen

In 1956, seven-month-old Debra Knudsen received her third dose of the diphtheria-pertussis-tetanus ("DPT") vaccine. Later that day, she had a fever. That night, she woke with a high fever, troubled breathing and other more severe problems. Knudsen v. Sec'y of Health & Human Servs., No. 90-2067V, 1992 WL 395631, at *1 (Fed. Cl. Spec. Mstr. Dec. 17, 1992), rev'd, 35 F.3d 543 (Fed. Cir. 1994).

Additional evidence demonstrated that Debra suffered an encephalopathy that caused life-long problems. Because this encephalopathy occurred within the time associated with a pertussis vaccination listed on the Vaccine Injury Table, the Knudsens were entitled to a rebuttable presumption that the DTP vaccine caused Debra's encephalopathy. Id. at *9; see also Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 547 (Fed. Cir. 1994).

The Secretary disputed the Knudsens' right to compensation by arguing that Debra suffered a viral infection and this viral infection caused the encephalopathy. After considering Debra's medical records as well as the testimony from doctors, including a doctor who treated Debra, the special master found that Debra suffered from a viral infection. 1992 WL 395631, at *1-9. The special master was persuaded, in part, by the testimony of the Secretary's expert who had opined that a viral infection could explain all Debra's symptoms. Id. at *9. The special master also held, as a matter of statutory interpretation, that the Secretary was not required to specify what type of virus infected Debra. Id. at *9-10.

Finally, and most importantly for Ms. Brown's case, the special master found that "There is a preponderance of the evidence that the encephalopathy Debra suffered on April 22, 1956 was caused by the viral infection." Id. at *9. The special master's reasoning was contained in two sentences. "Here, the experts agreed that the pertussis vaccine encephalopathy is a rarer event than viral encephalitis." And, "Because viral infection is a more likely cause of the injury Debra suffered than DPT vaccine, having found that Debra suffered from a viral infection in April 1956, it is appropriate to conclude that it is more likely that Debra's encephalopathy was caused by the viral infection than by the DPT vaccine." Id. Thus, the special master concluded that the Knudsens were not entitled to compensation.

After a review by the Court of Federal Claims, the Knudsens brought their case to the Federal Circuit. It appears that on appeal, the parties did not challenge

the finding of fact that Debra suffered a viral infection. While the Knudsens did contest the holding that the Secretary was not required to identify the type of virus, the Federal Circuit affirmed the special master's holding. 35 F.3d at 548. This point was preliminary to the Federal Circuit's examination of the special master's finding regarding causation.

The Federal Circuit characterized the appeal as raising "the question of what evidence is relevant to determining under the Vaccine Act that a condition or injury is unrelated to administration of the DTP vaccine, a question of law which we review *de novo*." 35 F.3d at 547. The Federal Circuit "reject[ed] the government's argument, which again was relied on in the special master's decision, that evidence that there are more occurrences of encephalopathies caused by viral infections than there are encephalopathies caused by DTP vaccines is relevant." The Federal Circuit explained: "The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine." Id. at 550. The Federal Circuit, then, looked at the remaining evidence. "This conflicting record evidence does not in our view either compel a finding of viral alternative causation nor preclude one. If the evidence is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded." Id. Consequently, the Federal Circuit vacated the judgment, which had denied compensation, and remanded the matter back to the special master.

2. Hart

In the second case the parties identify as discussing statistics, Emma Hart, as the representative of the estate of her daughter, Manasseh Miclea, alleged that a measles-mumps-rubella vaccination caused Manasseh to suffer a disease known as hemophagocytic lymphohistiocytosis, abbreviated HLH. HLH is a disease that "seem[s] to be 'triggered' by some stimulus such as infection." Hart v. Sec'y of Health & Human Servs., No. 01-357V, 2003 WL 23218077, at *2 (Fed. Cl. Spec. Mstr. Nov. 24, 2003), mot. for rev. granted, 60 Fed. Cl. 598 (2004). The special master, preliminarily, gave some credit to the theory that the MMR vaccine, which contains attenuated (live) viruses, could be the source of an infection that triggers HLH. Id. at *3. However, the special master declined to find that the MMR vaccine triggered Manasseh's HLH because the Secretary presented evidence that persuaded the special master that an Epstein Barr viral infection caused

Manasseh's HLH. While conflicts in the evidence made the special master's decision "difficult," the special master ultimately found that Manasseh suffered from an active Epstein Barr infection. Id. at *4-8.

Between the two potential causes—the MMR vaccine and the Epstein Barr virus, the special master found that the Epstein Barr virus was more likely the cause because it "has been identified as by far the most common trigger for HLH." Id. at *4. The special master also ruled that Knudsen's commentary about the use of "bare statistical" evidence was distinguishable in that Knudsen's comments came in the context of an on-Table case. Because Ms. Hart was claiming an off-Table injury, the special master "conclude[d] that the approach [he] used in analyzing the evidence concerning the Epstein-Barr virus in this case is not contrary to the Knudsen decision." Id. at *11. The special master, thus, found that Ms. Hart was not entitled to compensation.

Ms. Hart filed a motion for review. The "primary thrust [of Ms. Hart's motion] [was] that the Special Master erred in relying on statistical evidence to conclude that EBV, rather than the MMR vaccine, was the most likely cause of Manasseh's HLH. According to petitioner, this reliance on statistics flies in the face of Knudsen." Hart v. Sec'y of Health & Human Servs., 60 Fed. Cl. 598, 604 (2004). To assess Ms. Hart's argument, the Court evaluated Knudsen, cited many cases from disparate jurisdictions that considered probabilistic evidence, and referenced multiple law review articles on this topic. After this scholarly analysis, the Court also analyzed the studies on which the Secretary's expert had relied. The Court concluded "In sum, while these studies certainly indicate that EBV can cause HLH, they provide no reasonable assurance that the observations extrapolated by [the Secretary's expert] and others therefrom could be projected validly to the particular facts" of Manasseh's case. Id. at 608. The Court elaborated, "additional evidence adduced must show that the probabilities expressed are extendable to the facts of a given case and link the so validated statistical evidence into an otherwise plausible chain of causation." Id. at 609. Ultimately, the Court found that the Secretary's evidence could not support the weight the special master had given it, vacated the special master's decision, and remanded for additional consideration. Id. at 610.

3. Holmes

In rebuttal, the Secretary relies on a case that resolved James Holmes's claim that a tetanus and diphtheria ("Td") vaccination caused him to suffer epilepsy. Mr. Holmes had received the Td vaccination at age 14. Holmes v. Sec'y of Health &

Human Servs., 08-185V, 2011 WL 2600612, at *1 (Fed. Cl. Spec. Mstr. Apr. 26, 2011). To support his claim, Mr. Holmes presented an opinion from Marcel Kinsbourne, a no-longer practicing neurologist. The Secretary retained Shlomo Shinnar, a practicing neurologist. Id. at *2 & n.9.

The special master concluded, "This case was more a rout than a 'battle of the experts.' Most of the 'facts' upon which Dr. Kinsbourne relied were not established; he either misread or misinterpreted the medical records." Id. at *20. In connection with the statistical information relevant to the issue in Ms. Brown's case, the special master stated, "Based on James' age and the lack of any febrile illness, I find the studies showing an increased risk of seizure disorders after complex febrile seizures are simply not relevant to his case." Id. This finding, in turn, was based upon research showing that "in the studies of febrile seizures, 99% of the children were below seven years of age." Id. at *17. Thus, for all these reasons, the special master denied compensation.

Mr. Holmes filed a motion for review. One argument was that the special master wrongly relied upon statistical information. Holmes v. Sec'y of Health & Human Servs., 115 Fed. Cl. 469, 482 (2014). The Court rejected that argument, stating "the statistics to which petitioner objects are relevant to determining whether a Td vaccination could ever be considered the cause of an adolescent's febrile seizures. The evidence that febrile seizures were not only phenomena of infancy and childhood but moreover were predominantly suffered by the very young has an obvious bearing on whether they could be the result of a vaccination administered to someone outside that age group." Id. at 486. Consequently, the Court denied the motion for review.

B. Reports from the Secretary's Experts

These precedents guide the evaluation of the reports from Dr. Jamieson and Dr. Kedl. Dr. Jamieson wrote two reports, exhibits A and C. Dr. Kedl wrote one, exhibit D.

While Dr. Jamieson offers infection and surgery as causes for GBS, she has not proposed any theory explaining how infection or surgery leads to GBS. Instead, her opinion rests upon epidemiologic studies. Exhibit A at 9; exhibit C at 2. In preferring infection and surgery over flu vaccination as the cause for Ms. Brown's GBS, Dr. Jamieson stated "the GBS risk with associated influenza vaccination is much less common, indicating a much more tenuous association than with infection and surgery." Exhibit C at 2. She added "[t]he difference in

the strengths of the linkage of the events indicate that it was the combination of surgery and infection, not vaccination that was the trigger for Mrs. Brown's GBS." Id.

Most of Dr. Kedl's report focuses on presenting the opinion that "Any connection between vaccination and Mrs. Brown's GBS lacks reliable epidemiological, medical and scientific support." Exhibit D at 6. To support this opinion, he cites many studies, most of them published after 2013. Some of these studies evaluated the risk of GBS after seasonal flu vaccine. Other studies evaluated the risk of GBS after the H1N1 flu vaccine. Id. at 3-5.

Dr. Kedl also discusses epidemiological studies that have detected an increased risk of GBS after infections, particularly *Campylobacter jejuni*. Id. at 4. Dr. Kedl "conclude[s] therefore that the fecal matter in Mrs. Brown's abdominal cavity and ensuing life-threatening infection and septic shock, concomitant with her ovarian and adrenal masses and subsequent radical gynecological and gastrointestinal surgery, are considerably more than likely to have been the cause of her GBS than by any possible inflammatory consequences derived from her flu vaccine." Id. at 6.

Much of Dr. Kedl's opinion is not relevant. While Dr. Kedl may hold the opinion that (seasonal) flu vaccination does not increase the incidence of GBS, the Secretary has created a rule that eliminates any need for Ms. Brown to present evidence about how a flu vaccination can cause GBS. Cf. Summar v. Sec'y of Health & Human Servs., 24 Cl. Ct. 440, 443 (1991) (noting while whether diphtheria-tetanus-pertussis vaccine can cause a brain injury "may be a controversial question in the medical community, for this forum the question was already decided by Congress when it enacted the Vaccine Program").

Dr. Kedl and Dr. Jamieson both opine that infections and surgeries can cause GBS. On their surfaces, each opinion seems at least plausible. Thus, for sake of argument, the undersigned assumes that the Secretary has successfully established, through opinions supported by epidemiological studies, that infections and surgeries can cause GBS. See Pet'r's Reply, filed Apr. 20, 2020, at 6 ("Petitioner does not contest that petitioner experienced sepsis or that she underwent surgery, and that both of these things can be associated with GBS."). This use of epidemiological studies is consistent with the comment in Holmes, 115 Fed. Cl. at 486, that statistical evidence can be used to show whether something (in Holmes, a vaccine, and here, an infection or a surgery) can ever cause a disease.

Establishing an infection or a surgery *can cause* GBS is only one step in the Secretary's overall burden. The Secretary must also establish, by preponderant evidence, that the infection or surgery *did cause* Ms. Brown's GBS.

On this point, the opinions from Dr. Kedl and Dr. Jamieson resemble the opinions rejected in Knudsen and Hart. In both cases, the vaccine could have caused the injury. In both cases, the Secretary retained an expert who opined that a viral infection (unspecified in Knudsen and the Epstein-Barr virus in Hart) was the more likely cause. In both cases, the basic reasoning was that viral infections more frequently cause the injury than vaccines.

Dr. Kedl and Dr. Jamieson have essentially presented the same reasoning. See exhibit C at 2 (Dr. Jamieson: incidence of flu vaccination causing GBS is "much less common"); exhibit D at 3 (Dr. Kedl: describing the issue as whether "GBS as documented in the scientific literature is more commonly associated with infections or with vaccination").

Neither Dr. Kedl nor Dr. Jamieson have presented opinions that could support a finding in the Secretary's favor. Thus, Ms. Brown's motion for ruling on entitlement is GRANTED. She is entitled to compensation.

While Ms. Brown is entitled to compensation, this ruling does not specify the extent of compensation. Dr. Jamieson opined that Ms. Brown "has had [an] excellent recovery from GBS with documentation of normal motor, sensory, coordination, reflex and gait examinations by approximately a year after the diagnosis." Exhibit A at 10. In the damages phase of the case, Ms. Brown will be given an opportunity to connect her more recent problems to GBS.

A separate order to guide the parties in quantifying the amount of compensation to which Ms. Brown is entitled will issue shortly.

IT IS SO ORDERED.

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