IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

* *		
STACEY HEINZELMAN,	*	
	*	No. 07-01V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: December 11, 2008
	*	
SECRETARY OF HEALTH	*	entitlement, flu vaccine, Guillain-
AND HUMAN SERVICES,	*	Barré syndrome, burdens of proof,
	*	alternative factor, Shyface
Respondent.	*	distinguished.
	*	
* *		

Richard Gage, Richard Gage, P.C., Cheyenne, Wyoming for petitioner;
Ryan Pyles, United States Dep't of Justice, Washington, D.C., for respondent.

PUBLISHED RULING GRANTING COMPENSATION[*]

Petitioner, Stacey Heinzelman, alleges that the flu vaccine caused her to develop Guillain-Barré syndrome. She seeks compensation pursuant to the National Vaccine Injury Compensation Program ("the Program"), 42 U.S.C. § 300aa–10 et seq. (2006). She is entitled to compensation based on the evidence and the allocation of burdens of proof.

Ms. Heinzelman's case presents a challenging issue of law. Specifically, what happens when the petitioner establishes that the vaccine can cause her injury and the respondent identifies

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[*] Because this published decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

an independent factor that also may have caused the petitioner's injury. In this situation, as a matter of law, respondent bears the burden of establishing that it is more likely than not that the independent factor, and not the vaccine, caused the injury. In Ms. Heinzelman's case, as a matter of fact, respondent has not met his burden. Consequently, Ms. Heinzelman is entitled to compensation.

I. Facts and Procedural History

The facts of Ms. Heinzelman's case are straightforward. The parties agree that the medical records created contemporaneously with the events that they describe are accurate. These records reveal the following facts.

Ms. Heinzelman was born in 1971. Her medical history until December 2003 is not relevant. Respondent has not argued that any condition before December 2003 affects whether Ms. Heinzelman is entitled to compensation. See Resp't Rep't, filed April 25, 2007.

On December 10, 2003, Ms. Heinzelman received the flu vaccine. Exhibit 2. On approximately December 19, 2003, she started to have diarrhea, vomiting, chills, and fever. Exhibit 5 at 3-5; see also affidavit of Ms. Heinzelman, dated December 28, 2006, ¶ 3. As discussed below, the agent (whether virus or bacteria) responsible for Ms. Heinzelman's gastrointestinal illness was never identified specifically. See exhibit A at 7.

On December 30, 2003, Ms. Heinzelman saw her primary care doctor and complained that she had a headache, tingling in her hands and feet, and stiff legs. Exhibit 5 at 6; see also affidavit of Ms. Heinzelman, dated December 28, 2006, ¶ 4. The next day, Ms. Heinzelman was admitted to the hospital. She was diagnosed as having Guillain-Barré syndrome (GBS). Exhibit 1 at 15. Both the expert for petitioner and the expert for respondent retained in this case accept this diagnosis.

The details of Ms. Heinzelman's hospitalization are not relevant to determining whether the flu vaccine caused her GBS. She continues to suffer some residual effects of this disease.

The procedural history is also not controversial. Ms. Heinzelman filed her petition and two volumes of medical records on January 3, 2007. She added additional medical records about 60 days later.

Respondent filed his report, pursuant to Vaccine Rule 4. Respondent denied that Ms. Heinzelman was entitled to compensation and noted that Ms. Heinzelman had not filed an opinion of an expert. Resp't Rep't, filed April 25, 2007, at 13-14.

Ms. Heinzelman filed the report of Dr. Marcel Kinsbourne as exhibit 11 and a copy of Dr. Kinsbourne's curriculum vitae as exhibit 13. Ms. Henizelman also filed a statement from one of her treating doctors, Dr. Prince, as exhibit 12.

In turn, respondent filed a report from Dr. Gerald Winkler, associated medical articles, and his curriculum vitae as exhibits A-H. Dr. Winkler opined that an infectious agent was the more likely cause for Ms. Heinzelman's GBS. Exhibit A at 8.

To receive testimony from the experts, a hearing was conducted in Boston, Massachusetts on April 28, 2008. The transcript from this hearing is cited as "tr. __." Both Dr. Kinsbourne and Dr. Winkler testified credibly. Their demeanor did not enhance or reduce their persuasiveness.

Following the hearing, the parties filed briefs. This briefing process concluded on September 26, 2008. With the filing of these briefs, the case is ready for adjudication.

II. Analysis

To receive compensation under the Program, Ms. Heinzelman must prove either: (1) that she suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the flu vaccine, or (2) that she suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec'y of Health and Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, Ms. Heinzelman does not claim that she suffered a Table injury. Thus, she must prove causation in fact.

A. The Two Agents Are Independent, Not Collaborative

Preliminarily, before discussing what the parties are required to prove, it may be helpful to explain what is not at issue. Ms. Heinzelman's case involves two specifically-identified possible causes for her GBS – the flu vaccine or the cause of her gastrointestinal illness. The two potential factors makes Ms. Heinzelman's case somewhat comparable to Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344 (Fed. Cir. 1999). However, a close examination of Shyface shows that Ms. Heinzelman's case differs in significant ways.

The evidence in this case shows that the flu vaccine and the potential infection causing Ms. Heinzelman's gastrointestinal illness are unrelated and separate causes. Both Dr. Kinsbourne and Dr. Winkler testified that they are not aware of how the flu vaccine and the infection could have acted jointly. Tr. 41-42 (Dr. Kinsbourne), 56-57 (Dr. Winkler).

The lack of joint contributions from both the flu vaccine and the infection brings Ms. Heinzelman's case out of the framework established by Shyface. The facts of Shyface are distinguishable from Ms. Heinzelman's case.

In Shyface, the petitioners sought compensation because their son, an infant named Cheyenne, died approximately four days after receiving the DTP vaccine. Cheyenne's autopsy revealed that he was infected with E.coli bacteria. Shyface, 165 F.3d at 1345. At the hearing before the special master, the petitioner's expert (Dr. Torch) explained that the two agents (the

E.coli bacteria and the DTP vaccine) worked in conjunction. The Federal Circuit summarized his opinion as:

> Cheyenne's death was caused by the high fever, resulting from a combination of the DPT vaccination and the E.coli infection. Dr. Torch testified that Cheyenne would not have died but for the DPT vaccination, that he would not have died but for the E.coli infection, and that it was the combination of the two that caused his death. Dr. Torch testified that he could not determine whether the DPT vaccination or the E.coli infection was the predominant cause of Cheyenne's death.

Id. at 1345-46. After an initial decision by the special master and a remand by a judge of the Court of Federal Claims, the special master issued another decision, which ultimately was reviewed by the Federal Circuit.

In the decision after remand, the special master found that the petitioners were not entitled to compensation because they failed to establish that the vaccine was a "but for" cause of Cheyenne's death. The Federal Circuit quoted from the special master's decision:

> Petitioners [sic] evidence of a vaccine-related cause stands possibly in equipoise, but no better. As even Dr. Torch conceded, it is impossible to know with any degree of confidence, which source is the predominant cause of death.
>
> Respondent's evidence is equally persuasive. Without the benefit of the statutory presumption conferred by the presence of a Table injury, and because petitioners have the burden of affirmatively proving a vaccine-related cause, it is my opinion that petitioners cannot prevail on the record as it stands. I base my conclusion on my determination that petitioners have failed to carry their burden of proof.

Id. at 1347.

On appeal, the Federal Circuit reversed the special master's decision. The primary issue on appeal was whether petitioners must establish that the vaccine was the predominant cause of Cheyenne's death or whether the petitioners must establish that the vaccine was a "but for" cause of the child's death. Id. at 1348-50 (setting forth parties' arguments).

To resolve this issue, the Federal Circuit cited the Restatement (Second) of Torts § 430 through § 433. Id. at 1351-52. The Federal Circuit noted that the "Restatement recognizes that concurrent forces may bring about a single harm, requiring weighing the contributing factors." Id. at 1352. The Federal Circuit further quoted the Restatement as stating:

> There are frequently a number of events each of which is not only a necessary antecedent to the other's harm, but is also recognizable as having an appreciable effect in bringing it about. Of these the actor's conduct is only one. Some other event which is a contributing factor in producing the harm may have such a predominant effect in bringing it about as to make the effect of the actor's negligence insignificant and, therefore, to prevent it from being a substantial factor. So too, although no one of the contributing factors may have such a predominant effect, their combined effect may, as it were, so dilute the effect of the actor's negligence as to prevent it from being a substantial factor.

Id., quoting Restatement (Second) of Torts § 433 cmt. d.

Under these circumstances, the Federal Circuit concluded that petitioners must establish that the vaccine was a "substantial factor" in causing Cheyenne's death. Having determined the legal test, the Federal Circuit also determined that the evidence demonstrated that "Cheyenne would not have died but for the DPT vaccination, and that the DPT vaccine contributed to Cheyenne's death by causing him to experience an exceptionally high fever." The Federal Circuit, thus, ordered that the petitioners receive compensation for Cheyenne's death. Id. at 1353.

The Federal Circuit's use of the "substantial factor" test from the Restatement (Second) of Torts stems from the underlying facts in which the E.coli infection and the vaccine contributed to Cheyenne's death. The decision in Shyface references, several times, passages that discuss joint causes. For example, the decision states the "Restatement recognizes that concurrent forces may bring about a single harm." Id. at 1352 (emphasis added).

In another case, the Federal Circuit clarified the importance of combined forces.

> The Restatement distinguishes between forces that combine to produce a harm, and forces that independently caused a harm. When a case involves multiple causes acting in concert (not the situation involved here), we recognized in Shyface that a petitioner need not show the asserted vaccine was the predominant cause, but must show that it was substantial.

Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1151 n.4 (Fed. Cir. 2007). This discussion confirms that the substantial factor test from Shyface is appropriate when two forces act in concert.[1] See Citizens Federal Bank v. United States, 474 F.3d 1314, 1318 (Fed. Cir.

[1] It is notable, although not dispositive, that the new edition of the Restatement of Torts: Liability for Physical Harm criticizes the substantial factor test in the Restatement (Second) of

2007) (stating "Our cases dealing with the proper standard of causation may appear superficially somewhat inconsistent in applying the 'substantial factor' and 'but for' theories. We discern a common thread among them, however: the selection of an appropriate causation standard depends upon the facts of the particular case and lies largely within the trial court's discretion.")

As discussed, here, each expert proposes an independent cause for Ms. Heinzelman's GBS. Tr. 41-42, 56-57. No expert proposes that the flu vaccine acted in conjunction with the cause of the gastrointestinal illness. Because the factual prerequisite for using the substantial factor test has not been established, Ms. Heinzelman must establish that the vaccine was a "but-for" cause of her GBS.

B. Elements of Petitioner's Off-Table Case

To prove causation in fact, a petitioner must establish at least three elements. The petitioner's

> burden is to show by preponderant evidence that the vaccination brought about [the] 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 and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Torts. The Restatement (Third) of Torts states that the

> [P]rimary function [of the substantial factor test] was to permit the factfinder to decide that factual cause existed when there were overdetermined causes--each of two separate causal chains sufficient to bring about the plaintiff's harm, thereby rendering neither a but-for cause. See § 27. The substantial-factor test has not, however, withstood the test of time, as it has proved confusing and been misused.

Restatement (Third) of Torts: Liability for Physical Harm (Proposed Final Draft No. 1) § 26 cmt. j; see also Restatement (Third) of Torts § 26 cmt. *l* (noting that illustrations 4 and 5 are loosely based upon the facts in Shyface.)

Thus, the Restatement (Third) of Torts limits the substantial factor test to relatively rare situations in which two forces combine to cause a harm. As explained in the text of this decision, Shyface presents one of those rare cases.

For reasons discussed at length below, this case turns on the second prong identified in Althen. The meaning of the phrase "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" has not been addressed. As discussed in part II.E. below, with regard to how other factors that could have possibly caused the injury, Federal Circuit precedent seems to run in different directions. That challenging legal issue is addressed after the discussion of Ms. Heinzelman's evidence.

C. Ms. Heinzelman's Evidence on *Althen* Prongs One and Three

Ms. Heinzelman has established the first and third prongs from Althen – the medical theory and the appropriate timing. Ms. Heinzelman was required to produce a medical theory. She did so. Dr. Kinsbourne asserted that "it is biologically plausible that [the] influenza vaccine could be responsible for some cases of GBS." Exhibit 11 at 3. Respondent's expert, Dr. Winkler, did not challenge this theory. Exhibit A at 7; tr. 56.

In addition, Ms. Heinzelman established that the onset of GBS was within the appropriate time after she received the flu vaccine. Exhibit 11 at 4. Dr. Winkler also agreed. Tr. 63.

For these two prongs, respondent did not challenge Ms. Heinzelman's proof. See Resp't Post Hearing Br., filed Aug. 15, 2008. For these reasons, Ms. Heinzelman has met her burden of proving the first and the third prongs from Althen.[2]

D. Ms. Heinzelman's Evidence Regarding *Althen* Prong Two

The question, then, remains did Ms. Heinzelman establish, by a preponderance of evidence, " a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. Ms. Heinzelman argues that she has. Respondent argues that "[t]here is evidence in the record, foremost of which is [Ms. Heinzelman's] antecedent gastrointestinal illness, that a logical sequence of cause and effect cannot be established in this case." Resp't Supp. Post-Hearing Mem., filed Sept. 26, 2008, at 4.

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[2] In passing, respondent argues that the flu vaccine has not been shown to cause GBS in people less than 45 years old. Resp't Post-Hearing Br. at 5 n.2; Resp't Supp. Post-Hearing Br. at 4 n.3. Assuming that this observation is accurate, it is still not relevant. Dr. Winkler, respondent's expert, explicitly agreed with Dr. Kinsbourne's opinion that "a causative role for the influenza vaccine in the genesis of GBS is biologically plausible." Exhibit A at 7 (quoting exhibit 11 at 4). Thus, the evidence preponderates in favor of finding a biological theory linking the flu vaccine to GBS.

Ms. Heinzelman relies upon the opinion of Dr. Kinsbourne to meet her burden.[3] Dr. Kinsbourne believes that the flu vaccine did cause Ms. Heinzelman's GBS. Exhibit 11 at 4; tr. 6, 13-14.

Dr. Kinsbourne used the process of "differential diagnosis" to arrive at his conclusion that the flu vaccine caused Ms. Heinzelman's GBS. Tr. 13-14. Dr. Kinsbourne established that the flu vaccine can cause GBS. He did so because various articles show an increased risk of GBS following flu vaccine . Exhibits 22-26; tr. 7-11. In other words, the medical community has "ruled in" flu vaccine as a potential cause of GBS. Ruling in the potential cause is an important step in the process of differential diagnosis because without a determination that the potential causative agent actually can cause the injury, differential diagnosis is not a reliable method for determining causation. See Restatement (Third) of Torts: Liability for Physical Harm (Proposed Final Draft No. 1) § 28 Reporter's Note to comment (c)(4), citing, among other cases, Cavallo v. Star Enter., 892 F.Supp. 756, 771 (E.D. Va. 1995), aff'd in relevant part, 100 F.3d 1150 (4th Cir. 1996).

After ruling in the flu vaccine as a possible cause of GBS, Dr. Kinsbourne then ruled out other potential causes. Tr. 14 ("the last part of my opinion is that there is no reasonable alternative causation in the differential diagnosis of the cause of the GBS in this particular case.") Dr. Kinsbourne rejects the possibility that the cause of Ms. Heinzelman's gastrointestinal illness was also the cause of her GBS because the doctors did not identify the cause of the gastrointestinal illness. Tr. 14-15, 31-32.

Through Dr. Kinsbourne's opinion, Ms. Heinzelman has fulfilled her burden of proving that the flu vaccine, "was the reason," to quote from Althen, for her GBS. Dr. Kinsbourne's conclusion is based, in part, on his determination that other causes of GBS were not present in Ms. Heinzelman. However, for the reasons explored in the following section, respondent actually bears the burden of establishing that a factor other than a vaccine caused Ms. Heinzelman's illness.

E. Burden of Proof Regarding Possible Causes Other Than the Vaccine

The allocation of the burden of proof is a question of law. Fuji Kogyo Co., Ltd. v. Pacific Bay Intern., Inc., 461 F.3d 675 (6th Cir. 2006); see also Cromer v. Nicholson, 455 F.3d 1346 (Fed. Cir. 2006) (discussing presumptions and burden of proof when a veteran's records, while being held by the government, were destroyed in a fire); Navajo Tribe of Indians v. United States, 597 F.2d 1362, 1367 (Ct. Cl. 1979) (stating "we cannot say that the trial judge's allocation

[3] Ms. Heinzelman also submitted a one-paragraph letter from Darryl Prince, a neurologist who treated Ms. Heinzelman. Dr. Prince agrees with Dr. Kinsbourne's opinion. Exhibit 13. This statement has relatively little value independent from Dr. Kinsbourne's opinion. See 42 U.S.C. § 300aa–13(b) (stating that statements of treating doctors are not binding upon special masters).

of the burden of proof on the returned lands issue constituted legal error or abuse of discretion.") For the reasons that follow, it appears that the Federal Circuit has assigned the burden of ruling out other potential causes to the respondent.

The history of relatively older Federal Circuit decisions includes two different lines of cases. In one line of cases, the Federal Circuit uses the term "prima facie" case in the context of cases seeking compensation pursuant to the Vaccine Injury Table. In the other line, the Federal Circuit discusses the burden of ruling out alternative causes in the context of claims that a vaccine actually caused an injury, which are also known as Off-Table cases. Recently, these two lines of cases have blended, although the merger raises the challenging legal issue presented in Ms. Heinzelman's case.

1. On-Table Cases and Prima Facie Case

Because most of the parties' arguments focus on whether someone has established a "prima facie" case and what happens to a burden of persuasion, reviewing the history of Federal Circuit cases on these topics is instructive.

One of the earliest Federal Circuit cases that describe the parties' respective burdens of proof is Bunting, 931 F.2d 867, decided in 1991. (This case was litigated before Congress enacted some amendments affecting the relationship between special masters and judges at the Claims Court.) Mr. Bunting sought compensation for his son's injury, an encephalopathy, pursuant to the Table. Id. at 868. After the special master determined that Mr. Bunting was entitled to compensation because his son suffered an encephalopathy within the time specified on the Table, the respondent challenged this determination by presenting new evidence (a "Medical Review") to a judge of the Claims Court. The judge accepted this evidence and denied compensation to Mr. Bunting. Id. at 871.

On appeal, the Federal Circuit reversed the judge. In doing so, the Federal Circuit explained that "'[i]t is not plaintiff's burden to disprove every possible ground of causation suggested by defendant.'" Id. at 873, quoting Tinnerholm v. Parke Davis & Co., 285 F.Supp. 432, 440 (S.D.N.Y. 1968), aff'd, 411 F.2d 48 (2d Cir. 1969).

The earliest Vaccine Program case in which the Federal Circuit used the phrase "prima facie case" appears to be Whitecotton ex rel. Whitecotton v. Sec'y of Health & Human Servs., 17 F.3d 374 (Fed. Cir. 1994), rev'd sub nom. Shalala v. Whitecotton, 514 U.S. 268 (1995), proceeding after remand, 81 F.3d 1099 (Fed. Cir. 1996). In this decision, the Federal Circuit evaluated whether the special master was correct in determining that the petitioners' daughter, Maggie, did not suffer an encephalopathy within the time provided in the Vaccine Injury Table. Whitecotton, 17 F.3d at 376. Importantly, petitioners who seek compensation for an injury listed on the Vaccine Injury Table do not have to introduce any evidence regarding causation. The Vaccine Injury Table creates a presumption of causation. Id. Thus, for petitioners who seek compensation pursuant to the Vaccine Injury Table, petitioners establish that they are entitled to

compensation when they show that "the injured child received a vaccine enumerated in the Table, that the child sustained one of the injuries set forth in the Table within the statutory time period after vaccination, and that the effects of the injury lasted for more than six months, resulting in more than $1,000 of expenses." Id., citing 42 U.S.C. § 300aa–11(c) and 14(a).[4] "Once petitioners satisfy their burden of proving presumptive . . . causation, they are entitled to recover unless the Secretary shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." Id.[5]

The Supreme Court agreed with this aspect of the Federal Circuit's definition of a prima facie case. Shalala v. Whitecotton, 514 U.S. 268, 270 (1995), citing 42 U.S.C. § 300aa–11(c)(1)(C)(i). The Supreme Court also agreed that the respondent "may rebut a prima facie case by proving that the injury or death was in fact caused by 'factors unrelated to the administration of the vaccine.'" Id., quoting § 300aa–13(a)(1)(B).

The Supreme Court, however, disagreed with the Federal Circuit's determination that a petitioner's prima facie case, in a case in which the petitioners were seeking compensation pursuant to the Vaccine Injury Table, does not include a showing that the child "sustained no injury prior to administration of the vaccine." Id. at 273. The Supreme Court, therefore, reversed the decision of the Federal Circuit and remanded for additional considerations. Id. at 276.

When the case returned to the Federal Circuit, the Federal Circuit considered the elements of establishing a claim that a vaccine significantly aggravated an underlying condition. Again, this theory was discussed in the context of a claim pursuant to the Vaccine Injury Table. In this context, the Federal Circuit explained that when a petitioner establishes that first symptom or manifestation of an injury listed on the Table occurred within the time listed on the Table, "causation is presumed and petitioner is deemed to have made out a *prima facie* case of entitlement to compensation under the Act." Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1102 (Fed. Cir. 1996). This passage indicates that establishing a "prima facie case" means that a petitioner is entitled to compensation. However, as mentioned, the petitioners in Whitecotton were not required to present any evidence of causation because they were relying upon the presumption of causation created by the Vaccine Act.

Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543 (Fed. Cir. 1994), also involved a claim that a child suffered an encephalopathy as defined by the Vaccine Injury Table. The

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[4] An amendment to the statute eliminated the requirement to incur $1,000 in unreimbursed expenses. Pub. L. No. 105-277, § 1502, 112 Stat. 2681, 2681-741 (1998); see Lowery v. Sec'y of Health & Human Servs., 189 F.3d 1378 (Fed. Cir. 1999).

[5] The ellipses indicate that the phrase "or actual" has been deleted. Because the Federal Circuit's discussion is about whether the Whitecottons established a Table injury, comments about "actual causation" are dicta.

special master found that the child met this definition. However, the special master also "found that the government proved by a preponderance of the evidence that a factor unrelated to the vaccine – *i.e.*, a viral infection – in fact caused [the child's] table injury, encephalopathy." Thus, the petitioners were not entitled to compensation. Id. at 547.

The Federal Circuit vacated the special master's decision and remanded for additional consideration. The Federal Circuit discussed the government's burden of establishing an alternative factor. Id. at 549-50. These directions from the Federal Circuit are discussed in section II.F., below. For the present, it is sufficient to note that the statements regarding alternative causation were made in the context of a case in which causation was presumed because of the Vaccine Injury Table.

After Knudsen, cases based upon the Vaccine Injury Table have reached the Federal Circuit very rarely. A claim based upon the Vaccine Injury Table was also the context for a brief mention of the term "prima facie case" in Snyder by Snyder v. Sec'y of Health & Human Servs., 117 F.3d 545, 546 (Fed. Cir. 1997). However, Snyder does not advance the analysis beyond what Whitecotton stated.

More commonly, petitioners seek compensation pursuant to an off-Table theory. (Ms. Heinzelman's case is just one example.) The Federal Circuit has considered off-Table cases since at least 1992. This history is discussed in the following section.

2. Off-Table Cases and Alternative Causation

Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144 (Fed. Cir. 1992), is an early case in which the petitioners sought compensation for an off-Table injury. The chief special master determined "a preponderance of the evidence supports a finding that the vaccination caused Scott's injuries." Grant v. Sec'y of Health & Human Servs., No. 88-70V, 1990 WL 293410 *12 (Cl. Ct. Spec. Mstr. July 13, 1990). The chief special master, then, observed that the burden of showing that the injuries were due to factors other than the vaccine rested with respondent. Id. at *13. The chief special master determined that respondent did not meet this burden. Id. at *13-20. A judge at the Claims Court affirmed this decision.

The Federal Circuit also affirmed. First, the Federal Circuit affirmed the special master's determination that a preponderance of evidence supported a finding that the vaccine caused the child's encephalopathy, which had developed outside of the time specified on the Vaccine Injury Table. Grant, 956 F.2d at 1147-49. Second, the Federal Circuit also affirmed the special master's analysis of the alternative causation. However, the Federal Circuit did not address explicitly how the burden of proof operated. It quoted the special master as saying "Having found that the vaccine caused Scott's injuries necessarily precludes a finding that the injuries were due to unrelated factors." Id. at 1150. The Federal Circuit continued. "The Chief Special Master did not stop with that finding, but correctly proceeded to consider and reject evidence about alternative causes." Id.

The next Federal Circuit decision to discuss alternative causes was Munn v. Sec'y of Health & Human Servs., 970 F.2d 863 (Fed. Cir. 1992). For off-Table cases, "[t]he claimant must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury." Id. at 865.

This statement, however, is dicta. See Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1364-65 (Dyk, J., dissenting). The quoted language from Munn is dicta because Munn actually presented an on-table claim. The special master found that Chelsea suffered a hypotonia, which was included on the Vaccine Injury Table at that time. Munn, 970 F.2d at 865-66. The question was whether Chelsea's death was a sequella to that condition. The special master found that it was not, because Chelsea's death was caused by a factor unrelated to vaccine, pneumonia. Id. at 867. The Federal Circuit affirmed the special master's factual determinations. Id. at 872. Thus, the Federal Circuit in Munn was not required to set forth the elements of proof in an off-Table case.

Following Munn, the Federal Circuit decided a trio of cases with relatively similar facts in 1993. The first of this group of three was Jay v. Sec'y of Health & Human Servs., 998 F.2d 979 (Fed. Cir. 1993). In Jay, the special master determined, on a motion for summary judgment, that petitioners had not established that their child suffered an encephalopathy, which is an injury listed on the Vaccine Injury Table. A judge at the Court of Federal Claims agreed. Id. at 981.

The Federal Circuit reversed. The Federal Circuit stated in deciding whether the child suffered an encephalopathy, the special master "los[t] sight of the forest for the trees." The Federal Circuit found "nothing in the Vaccine Act which precludes death from being used as evidence of a table injury, here an encephalopathy." Id. at 984.

As part of its holding that the petitioners were entitled to compensation, the Federal Circuit considered whether the Jays had established that "the DPT vaccine in fact caused [their child] to die." The Federal Circuit ruled that on this issue, the Jays were entitled to summary judgment. Id.

Finally, the Federal Circuit reviewed whether there was any evidence of alternative causation because "[a]fter a petitioner establishes legal causation (table injury) or causation in fact, there still remains the statutorily separate inquiry under 42 U.S.C. § 300aa–13(a)(1)(B) whether an alternative causation has been proved by HHS." There was no such evidence. Thus, the Jays were entitled to compensation. Id.

Approximately two weeks after Jay, the Federal Circuit decided Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565 (Fed. Cir. 1993). Like Jay, the petitioners claimed that their child died as a result of a vaccine and pursued both a claim based on the Table and a claim off the Table. The special master denied compensation but a judge of the Claims Court reversed. Id. at 1568. The Federal Circuit reversed the judge's decision based upon a different interpretation of how a Table injury is established. The Federal Circuit did not discuss how a

potential unrelated cause of death (Sudden Infant Death Syndrome) affected the burden of proof for an off-Table claim. Id. at 1569-71.

The final case in the trio of cases from 1993 is Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958 (Fed. Cir. 1993). The petitioners in Hodges also sought compensation for the death of their child by alleging a Table claim and an off-Table claim. The special master denied compensation and a judge at the Court of Federal Claims upheld the special master's decision. Id. at 959-60.

The Federal Circuit affirmed. With regard to the Table claim, the Federal Circuit followed the analysis used in Hellebrand. Id. at 960. With regard to the off-Table claim, the Federal Circuit found no error in how the special master evaluated the evidence. Id. at 961-62. The Federal Circuit did not discuss whether it was likely that another factor caused the child's death.

In sum, before 1996, only two Federal Circuit cases contained a holding about alternative causation in the context of an off-Table case. These are Grant and Jay, which relied upon Grant. Other cases, such as Munn, Hellebrand, and Hodges, either did not discuss other potential causes or discussed them in dicta.

3. Merger of Two Lines of Cases

The landscape began to shift, however, in Shyface. Shyface is unequivocally a case not based on the Vaccine Injury Table. Shyface, 165 F.3d at 1348 (stating "the Shyfaces appealed their non-Table claim"). The Federal Circuit observed, perhaps with some understatement, that "There is a dearth of precedent discussing the requirements for *prima facie* causation." Id. at 1350.

The Federal Circuit's use of the term "*prima facie* causation," arguably created confusion that latter cases are still resolving. Until Shyface, the Federal Circuit decisions using the term "prima facie case" were cases seeking compensation pursuant to the Vaccine Injury Table, the prime example being Whitecotton, 17 F.3d at 376. As discussed above, for a claim based on the Table, causation is presumed when the petitioner establishes certain facts – receipt of a particular vaccine and onset of a particular disease within a specified amount of time. For on-Table claims, petitioners are not required to submit any evidence that would establish causation as causation is used in traditional torts.

Because the petitioners in Shyface were pursing an off-Table case, their claim is comparable to a traditional tort. In this context, the Federal Circuit stated that "The Vaccine Act allows a petitioner to establish *prima facie* entitlement to compensation using the non-Table method, *i.e.*, by showing that the injury was 'caused' by the vaccine." Id. at 1350, citing 42 U.S.C. § 300aa–11(c)(1)(C)(ii). After establishing the rule for cases in which evidence indicates that two forces may have combined to cause a harm, the Federal Circuit held that the Shyfaces

had established a prima facie case that the vaccine was a substantial factor (along with an E.coli infection) in causing Cheyenne's death. Id. at 1352-53.

In Shyface, the Federal Circuit did not have occasion to consider whether a petitioner's prima facie case includes excluding other potential independent causes. This was because Cheyenne Shyface's case presented a situation in which two factors combined to cause his death. The facts, as established by the special master, did not show that it was either one factor (the vaccine) or another factor (the E.coli infection). Rather than being "either/or," it was "both/and." Therefore, Shyface is not comparable to Ms. Heinzelman's case. See section II.A., above.

Shyface did not spell out the elements of petitioner's proof for an off-Table case. To some extent, the Federal Circuit did that in Althen, 418 F.3d at 1278 (listing three elements). However, the Federal Circuit also approved some aspects of the special master's test for determining causation – "proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes" as a "recitation of this court's well-established precedent." Id. at 1281 (emphasis added). Other than this mention of "other causes," the Federal Circuit did not discuss potential alternative causes because it appears that the government had not explicitly argued that a factor unrelated to the vaccine caused the illness.

Another passing reference to alternative causes occurs in Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317 (Fed. Cir. 2006). Here, the Federal Circuit stated:

> A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Id. at 1327 (emphasis added). The underlined portion seems to indicate that "the claimant" is required to prove, by preponderant evidence, that "another cause" was not the reason for the injury. However, this reasoning may not be binding because Capizzano did not involve another cause.

The next significant case to discuss "prima facie case" was Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). Pafford begins a series of three cases, decided in three consecutive years, in which the Federal Circuit discussed both "prima facie case" and burden shifting. The other two cases are Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146 (Fed. Cir. 2007), and Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347 (Fed. Cir. 2008). All three cases warrant significant analysis.

In Pafford, the petitioners alleged that various vaccines caused their daughter, Richelle, to suffer juvenile rheumatoid arthritis. Pafford, 451 F.3d at 1353. Evidence indicated that around the same time as Richelle received the vaccinations, she also may have suffered from a bacterial infection, a sinus infection, an episode of tonsillitis, and a cold with diarrhea. Id. at 1356, citing special master's decision; see also Pafford v. Sec'y of Health & Human Servs., 64 Fed. Cl. 19, 26 (2005), citing special master's decision. The special master denied compensation. Pafford, 451 F.3d at 1353.

The Paffords appealed to a judge of the Court of Federal Claims, who affirmed the decision of the special master denying compensation. Pafford v. Sec'y of Health & Human Servs., 64 Fed. Cl. 19 (2005). Although the decision of the judge of the Court of Federal Claims is not binding precedent in this case, the judge's analysis is worthy of consideration because the issue in Pafford is comparable to the issue in Ms. Heinzelman's case. The Paffords argued that the special master committed an error of law by assigning them "the burden of proof as to potential alternative causes of Richelle's condition." Pafford, 64 Fed. Cl. at 27. The judge described the Paffords' argument as "focus[ing] squarely on the appropriate standard of proof to which a petitioner should be held in an off-Table Vaccine Program causation-in-fact case." Id. In a passage that foreshadows to some extent Ms. Heinzelman's case, the judge stated:

> To be sure, if the record indicates the existence of other possibilities as a reasonable culprit for the cause of the disease, it is very possible that the petitioner has not met either the "but for" or "substantial factor" requirement because those other possible culprits may well remain as viable alternatives that undercut the vaccine's causative role. In other words, as a practical matter, in such a circumstance, petitioners must eliminate other reasonably possible causes that exist in the record to meet its burden of establishing a *prima facie* case for causation-in-fact.

Id. at 30.

The judge determined that the special master used the correct standard of proof. The judge affirmed the special master's factual determination that the Pafford's evidence did not reach this level. Id. at 33.

The judge also discussed "alternative causation." The judge held that "the overwhelming weight of authority in this Circuit is consistent with traditional notions of tort law that place an initial burden of proof regarding alternative causation on the petitioner-not as part of the § 300aa-13(a)(1)(B) 'factor unrelated' test, but rather as part of establishing a *prima facie* case of causation-in-fact." Id. at 35. (Notably, the judge decided Pafford before the Federal Circuit decided Walther and Bazan, which are discussed below.) Ultimately, the judge affirmed the decision of the special master. Id. at 36. The Paffords then appealed to the Federal Circuit.

On appeal, the Federal Circuit affirmed the judge's ruling, although the Federal Circuit decision contains different reasoning. In describing petitioner's obligation to prove their entitlement to compensation in an off-Table case, the Federal Circuit cited Shyface. The Federal Circuit stated that a petitioner "must prove by preponderant evidence both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." Pafford, 451 F.3d at 1355 (emphasis added), citing Shyface, 165 F.3d at 1352.

The Federal Circuit continued its explanation of petitioner's burden. It stated that "This court recently articulated an alternative three-part test." Pafford, 451 F.3d at 1355, citing Capizzano, 440 F.3d at 1324 and Althen, 418 F.3d at 1278. The use of the word "alternative" is surprising because the three-part test from Althen was seen as the (singular) way to establish that the vaccine caused the illness in off-Table cases. That is, if a petitioner succeeded in meeting the three prongs described in Althen, then the petitioner would have shown that the vaccination was the "but-for" cause of the illness. However, the term "alternative" implies that petitioners could show "but-for" causation without meeting the three-prong test in Althen.

The Paffords argued that the special master erred by requiring them "as part of the but-for inquiry to prove it was the vaccinations rather than the other contemporaneous events that triggered [Richelle's] Still's disease." Pafford, 451 F.3d at 1357. The Federal Circuit rejected the Paffords' argument, which was based primarily on Shyface.

Pafford interpreted Shyface as presenting a situation in which "there were two 'but-for' causes, the vaccination and the infection, each of the 'but-for' causes being a substantial factor in the infant's death." Id. The Federal Circuit reversed the special master's decision in Shyface because the petitioners had established that the vaccine "was both a but-for cause of and a substantial factor in the infant's death." Id.

Pafford, then, distinguished the facts in Shyface from the facts for Richelle Pafford. The Federal Circuit explained that the Paffords

> never established that the vaccinations were a but-for cause of her contracting Still's disease. Thus, this case does not feature several "but-for" causes, one of which is a vaccination. Rather, the Special Master concluded that he was unable to tell whether any of the vaccinations made any contribution to her contracting Still's disease due, in part, to the absence of "evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event."

Id. at 1357-58, (quoting special master's decision).

Pafford also explained that the special master was correct as a matter of law in requiring that the petitioners establish an appropriate temporal relationship. The special master's requirement was "consistent with the third prong of the Althen test." Id. at 1358. The Federal Circuit determined that the record contained little evidence about the temporal relationship. Therefore, the Federal Circuit affirmed the special master's decision that the Paffords were not entitled to compensation.

In Pafford, one judge dissented. The dissent challenged the majority's holding that "petitioners . . . must establish, as essential elements of a *prima facie* showing of causation in off-Table cases, both (1) a 'proximate temporal relationship between [the] vaccinations and the onset of [injury]' . . . and (2) an absence of 'alternative causes' of the injury." Pafford, 451 F.3d at 1360 (J. Dyk, dissenting) (brackets in original, citation omitted).

The majority's discussion in Pafford about the sinus infection and bacterial infection that could possibly have caused Richelle to contract Still's disease could constitute dicta. In the latter portion of the decision, the majority noted that the Paffords had failed to establish the third prong from Althen. This deficiency in the petitioners' proof would seem to end the inquiry. When petitioners do not meet their burden as stated in Althen, considering whether another factor, such as an infection, could have caused a disease is unnecessary. Pafford's statements about alternative causes, however, are a prominent part of the next Federal Circuit case, Walther.

In Walther, Ms. Walther received five vaccinations on the same day. Walther, 485 F.3d at 1146 (Fed. Cir. 2007). Only two of these vaccines (the tetanus-diphtheria "Td" vaccine) are listed on the Vaccine Injury Compensation Table. The other three vaccines (yellow fever, typhoid, and meningitis) are not listed. See id. at 1149; see also 42 C.F.R. § 100.3. Approximately four and a half months later, a doctor diagnosed Ms. Walther as having acute disseminated encephalomyelitis (ADEM), a neurological disease. Walther, 485 F.3d at 1147. Ms. Walther sought compensation for this injury. To support her claim, Ms. Walther relied upon the opinion of Dr. Vera Byers.

The special master found that Ms. Walther was not entitled to compensation. The special master required Ms. Walther to submit "'proof eliminating other potential causes for the injury.'" Id., quoting special master's decision. The special master stated that Ms. Walther "'has not adequately eliminated the other vaccines that she received . . . as causative agents for her condition.'" Id. at 1148, quoting special master's decision. A judge at the Court of Federal Claims affirmed. Walther v. Sec'y of Health & Human Servs., 69 Fed. Cl. 123 (2005). Ms. Walther appealed to the Federal Circuit.

The appeal concerned the other potential causes of Ms. Walther's injury. Ms. Walther's "primary contention [was] that the special master applied an incorrect standard requiring her to eliminate other potential causes in order to establish a prima facie case of causation." Walther, 485 F.3d at 1148. On this issue, the Federal Circuit concluded "that the special master's

decision, to the extent that it did place a requirement on the petitioner to establish a lack of alternative causation, was erroneous." Id. at 1149.

The Federal Circuit's analysis begins by mentioning the recent decision in Pafford because the panel deciding Walther was bound by the holding of Pafford. South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982)(en banc). Walther states:

> While our recent decision in Pafford held that a petitioner as a practical matter may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is insufficient, 451 F.3d at 1359, we conclude that the Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case.

Walther, 485 F.3d at 1149-50.

As discussed above, it is not entirely clear that the discussion in Pafford about other potential alternative causes constitutes a holding. The discussion could be considered dicta (and thus, not binding) because Richelle Pafford was not entitled to compensation because she failed to meet one of the elements required by Althen. The aspect of Pafford that discusses the temporal relationship is probably the true holding of Pafford. According to precedent existing before Pafford, the elimination of other potential causes does not entitle a petitioner to compensation. Grant, 956 F.2d at 1149 (stating "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation.")

In Walther, after acknowledging the earlier decision in Pafford, the Federal Circuit analyzed the statute, in particular 42 U.S.C. § 300aa–13(a)(1); earlier decisions, including Shyface, Althen, Shalala v. Whitecotton; and the Restatement (Second) of Torts. These authorities led the Federal Circuit to conclude that "the petitioner does not bear the burden of eliminating alternative independent potential causes." Walther, 485 F.3d at 1152. Ultimately, the Federal Circuit vacated the special master's decision and remanded the case for additional consideration. Id. at 1153.

Walther and Pafford were discussed in the most recent Federal Circuit decision arising out of the Vaccine Program, Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347 (Fed. Cir. 2008). This decision again addressed the petitioner's prima facie case and the burden of proof regarding other potential causes.

Adela Quintana de Bazan received the tetanus-diphtheria ("Td") vaccine and experienced the first symptoms of what was later diagnosed as ADEM approximately 11 hours later. She sought compensation for this injury, claiming that the Td vaccine caused her ADEM.

The special master found that Ms. Bazan was not entitled to compensation because she did not prove that 11 hours is a medically appropriate time frame in which the Td vaccine can cause ADEM. A judge of the Court of Federal Claims reversed the special master's determination. The Federal Circuit stated the judge's decision "held that the finding that the eleven- hour onset of ADEM was not within a medically appropriate timeframe to attribute to the vaccine was tantamount to finding that Bazan had failed to prove that no other cause could have caused her injuries." Bazan, 539 F.3d at 1350; see also de Bazan v. Sec'y of Health & Human Servs., 70 Fed. Cl. 687, 694 (2006). After additional proceedings producing a final judgment, the respondent eventually appealed to the Federal Circuit.

The Federal Circuit reversed the judge's decision and found no error in the special master's decision. The Federal Circuit stated that the judge "misunderstood" Federal Circuit precedents relating to alternative causation. Bazan, 539 F.3d at 1353.

Bazan noted that "a finding that the administration of a vaccine was not a cause-in-fact of an injury necessarily implies that some other cause resulted in the injury, assuming the injury itself is proven." Id. This observation was not explicitly made in any earlier Federal Circuit decision. However, the logic underlying this statement is implicit in the statement that "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149.

Practically, a petitioner cannot truly rule out all potential causes. For the diseases typically at issue in cases in the Vaccine Program, including GBS, medical science does not know the causes of the disease. (If science knew the cause of the disease, then there would be no litigation over whether the vaccine caused the disease – either the vaccine was a cause or it was not.) This idea, in turn, is reflected in the many decisions that hold a plaintiff in the traditional tort system seeking compensation must "rule in" the proposed tortious agent as capable of causing harm. It is not sufficient for the plaintiff to attempt to use a doctor's differential diagnosis to "rule out" other potential causes. See, e.g., Ruggerio v. Warner Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005).

In Bazan, the Federal Circuit held that the special master did not err by implicitly finding that something other than the Td vaccine caused Ms. Bazan's ADEM. The Federal Circuit ruled that the respondent may attempt to undermine the persuasiveness of the evidence a petitioner offers on one of the three Althen prongs. In doing so, respondent does not take on the burden of showing that "a particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor)." Bazan, 539 F.3d at 1354 (emphasis in original). The Federal Circuit explained that "the government's evidence did not concern any factors unrelated to the vaccine."

4. Analysis of Existing Case Law

"The special master's role is to apply the law." Althen, 418 F.3d 1280. With regard to how the possible presence of a potential factor unrelated to the vaccine affects the analysis of off-Table cases, Federal Circuit precedent is not especially clear.[6] More precise guidance, perhaps even a determination en banc, might be helpful. See Strickland v. United States, 423 F.3d 1335, 1338 n.3 (Fed. Cir. 2005) (noting that a trial court may urge en banc review of circuit court precedent).

The earliest Federal Circuit case resolving an off-Table claim, Grant, separates the determination that the vaccine did cause the petitioner's injury from the determination that an alternative factor did (or did not) cause the injury. Grant, 956 F.2d at 1149-50.

The most recent Federal Circuit case for off-Table claims, Bazan, is consistent with Grant. In Bazan, the Federal Circuit's description of the respondent's case implies that if the government's evidence did concern a factor unrelated to the vaccine, then the respondent does take up the burden to show the particular agent was "in fact the sole cause" of the injury.

Assuming that the Federal Circuit actually created a distinction between situations in which the government challenged the persuasive value of petitioner's evidence on a particular prong and situations in which the government put forth a particular agent as the cause of petitioner's injury, then the distinction is important. In contrast to how the Federal Circuit characterized the government's evidence in Bazan, the government's evidence here concerns a factor unrelated to the vaccine – Ms. Heinzelman's gastrointestinal illness.

Consequently, Ms. Heinzelman's burden of proving "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" does not include the obligation to negate possible alternative causes for her GBS. This holding is also consistent with Walther, 485 F.3d at 1149-50 ("the Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case.").[7]

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[6] For example, compare Althen, 418 F.3d at 1278 (listing three elements of petitioner's burden of proof and indicating that the government bears the burden of establishing factors unrelated to the vaccine caused the injury) with Althen, 418 F.3d at 1281 (stating that a claimant bears the burden to eliminate other causes).

[7] The quote from Walther, in some ways, encapsulates the legal issue. Although Walther states that petitioners are not required to rule out other causes when their evidence establishes a prima facie case, Walther does not define what constitutes a "prima facie case." The term "prima facie case" could be interpreted to include an obligation to rule out possible alternative causes. See Grant, 956 F.2d at 1149.

Here, Ms. Heinzelman has met her burden of establishing, by a preponderance of evidence, the second Althen prong, as this prong has been defined in the preceding two paragraphs. Because Ms. Heinzelman has established, by a preponderance of the evidence, each of the prongs required by Althen, she is entitled to compensation unless the respondent establishes a factor other than the vaccine caused Ms. Heinzelman's GBS. Respondent's obligation is taken up in the next section.

F. Respondent's Case

1. Overview

Respondent presented evidence and argument that a factor unrelated to the flu vaccine caused Ms. Heinzelman's Guillain-Barré syndrome. Specifically, respondent argues that an infectious agent, possibly the campylobacter jejuni bacteria, caused Ms. Heinzelman's Guillain-Barré syndrome.

A petitioner is not entitled to compensation when "a preponderance of the evidence that the illness . . . described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. § 300aa–13(a)(1)(B).

The Federal Circuit explained respondent's burden in Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). Knudsen stated that "the standards that apply to a petitioner's proof of actual causation in fact in off-table cases should be the same as those that apply to the government's proof of alternative actual causation in fact." As noted above, Althen establishes the basic elements of petitioner's case for an off-Table claim. Thus, Knudsen dictates that respondent is required to satisfy the same basic elements from Althen when he proposes an alternative factor.

The phrase "alternative factor" can be substituted for the term "vaccination," in the summary passage from Althen, which was quoted above. Thus, respondent's burden is to establish "(1) a medical theory causally connecting the [alternative factor] and the injury; (2) a logical sequence of cause and effect showing that the [alternative factor] was the reason for the injury; and (3) a showing of a proximate temporal relationship between [the alternative factor] and injury." Althen, 418 F.3d at 1278. Again, the burden of proving these factors is a preponderance of the evidence. Bunting, 931 F.2d at 873.

2. Evidence on First and Third Prongs of Respondent's Case

The evidence demonstrates that respondent has established the first and third prongs by a preponderance of the evidence. On the first prong, respondent has met his burden of establishing, by a preponderance of the evidence, that a medical theory links a gastrointestinal illness to GBS. See exhibit A (report of Dr. Winkler) at 7-8, exhibit F (B.C. Jacobs, The Spectrum of Antecedent Infections in Guillain-Barré Syndrome, 51 Neurology 1110 (1998), tr.

56-59 (Dr. Winkler). Even petitioner's expert, Dr. Kinsbourne, agreed with the validity of this medical theory. Tr. 24-26.

There is also no dispute about the timing between when Ms. Heinzelman had her gastrointestinal illness and when her GBS began. Furthermore, both experts agreed that the fact that Ms. Heinzelman's gastrointestinal illness occurred closer in time to the onset of GBS was not a reason to discount the possibility that the flu vaccine, which was more remote in time, caused the GBS. Tr. 42-43 (Dr. Kinsbourne), tr. 69-70 (Dr. Winkler).

3. Evidence of Second Prong of Respondent's Case

When the respondent attempts to demonstrate a particular agent (other than the vaccine) caused the injury, respondent is obligated to establish " a logical sequence of cause and effect showing that the [alternative factor] was the reason for the injury." Althen, 418 F.3d at 1278; Knudsen, 35 F.3d at 549.

Here, respondent fails to meet his burden of proof. Respondent offers a form of evidence that is not persuasive.

Before turning to respondent's affirmative evidence, a preliminary point raised by Dr. Kinsbourne must be addressed. Dr. Kinsbourne opined that the special master should not consider Ms. Heinzelman's gastrointestinal illness because the specific organism was never identified. Tr. 14-15, 31-32. Of course, Dr. Kinsbourne is not an attorney and, therefore, he is not well-position to guide the legal analysis of special masters. It is unlikely that an attorney would offer this argument (and Ms. Heinzelman's attorney has not) because Federal Circuit precedent forecloses this argument. "[A] 'viral infection' *can* be an alternative causation, even though the viral infection is not in the particular case specifically identified by type or name." Knudsen, 35 F.3d at 549 (emphasis in original).

In essence, respondent argues that probabilities support a finding that the gastrointestinal illness caused Ms. Heinzelman's GBS. It appears uncontested that gastrointestinal illnesses cause more cases of GBS than the flu vaccine. Tr. 24-26 (Dr. Kinsbourne's testimony); exhibits B and F. This fact is at the core of Dr. Winkler's opinion. Tr. 57-58, 62.

Respondent's argument has some appeal. If the vaccine causes one of every million cases of GBS and a gastrointestinal illness causes one-third of every million cases of GBS, then the odds weigh quite heavily that the gastrointestinal illness was the cause. See Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1573 (Fed. Cir. 1993) (Newman, J., concurring).

The Federal Circuit, however, has rejected the use of statistical probabilities to determine whether a vaccine or some other factor caused an adverse reaction:

> 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.

Knudsen, 35 F.3d at 550. This holding, not Judge Newman's concurring opinion in Hellebrand, is binding precedent for special masters.

Respondent offers some arguments for distinguishing Knudsen from the present case. Resp't Post-Hearing Br. at 9-10. However, these arguments lack merit. The Federal Circuit in Knudsen did not rule against using statistics because the basis for the statistical information was unsound. Instead, the Federal Circuit addressed the question of probabilities more generally. See Hart v. Sec'y of Health & Human Servs., 60 Fed. Cl. 598, 604-10 (2004) (discussing statistical evidence and explaining why Knudsen rejected "bare statistical" evidence).

For these reasons, respondent has not met his burden of establishing, by a preponderance of the evidence, that the gastrointestinal illness caused Ms. Heinzelman's GBS. "If the evidence [regarding alternative causation] is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded." Knudsen, 35 F.3d at 550. Because Ms. Heinzelman has met her burden of proof and respondent has not met his burden of rebutting her case, Ms. Heinzelman is entitled to compensation.

G. Summary

Most cases in the Vaccine Program turn on the factual question of whether petitioners presented enough evidence to satisfy their burden of proving that the vaccine caused them a particular injury. Ms. Heinzelman's case, however, is unusual because the outcome is determined by a legal question – how the assertion of a particular agent, which is unrelated to a vaccine, affects the relative burdens of proof between the parties.

Both parties have identified an agent (either the flu vaccine or a gastrointestinal illness) that a reliable medical theory connects with Guillain-Barré syndrome. Both parties have established that the temporal relationship between each agent and the onset of the Guillain-Barré syndrome fits within the time medical science expects.

Under these circumstances, the dispositive question is does the petitioner bear the burden of ruling out the gastrointestinal illness as the cause of her injury or does the respondent bear the burden of ruling in the gastrointestinal illness?

Determining which party bears the burden of proof is necessary because the evidence is balanced. Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 824 (Fed.Cir.1988); Cook v.

United States, 46 Fed. Cl. 110, 113 n. 5 (2000); see also Director, OWCP v. Greenwich Collieries, 512 U.S. 267, 272-76 (1994) (discussing difference between burden of persuasion and burden of producing evidence). Both the flu vaccine and gastrointestinal illnesses can cause GBS and Ms. Heinzelman experienced both the flu vaccine and a gastrointestinal illness within the month before developing GBS. Setting aside the statistical information, no evidence points to either the flu vaccine or the gastrointestinal illness as the more likely cause of the GBS. Therefore, this case turns on the question of who bears the burden of proof. Because the respondent bears the burden of proving that the gastrointestinal illness was the cause of Ms. Heinzelman's GBS and respondent has not met his burden, respondent loses.[8]

III. Conclusion

Ms. Heinzelman is entitled to compensation. A status conference will be held shortly to discuss the process for quantifying the amount of damages to which she is entitled.

IT IS SO ORDERED.

_____
Christian J. Moran
Special Master

[8] An argument could be made that Ms. Heinzelman is entitled to compensation merely because the evidence balances. Such an argument would be based upon the Federal Circuit's statement that "close calls regarding causation are resolved in favor of injured claimants." Althen, 418 F.3d at 1280.

How this statement fits within the system of shifting burdens of proof is not entirely clear. For example, it is clear that petitioner bears the burden of establishing a prima facie case (whatever is encompassed by that term) by a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Bunting, 931 F.2d at 873.

In contrast, for people claiming veterans' benefits, Congress has explicitly given them in the statute the "benefit of the doubt" when "there is an approximate balance of positive and negative evidence." 38 U.S.C. § 5107(b); Ortiz v. Principi, 274 F.3d 1361 (Fed. Cir. 2001).

Because this decision holds that the burden of proving that the gastrointestinal illness rests with the respondent and, therefore, Ms. Heinzelman is entitled to compensation, discussion of whether the statement regarding "close calls" in Althen is dicta or is binding on special masters is not necessary.