United States Court of Appeals for the Federal Circuit

05-5106

LISA ANN PAFFORD
and RICHARD LEON PAFFORD,
Parents and Next Friends of
Richelle Lorrae Pafford, a minor,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Robert T. Moxley, Gage and Moxley, of Cheyenne, Wyoming, argued for petitioners-appellants.

Melonie J. McCall, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With her on the brief were Peter D. Keisler, Assistant Attorney General and Timothy P. Garren, Director, and Vincent J. Matanoski, Assistant Director.

Appealed from: United States Court of Federal Claims

Judge Lawrence J. Block

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DECIDED: June 20, 2006

Before LOURIE, RADER, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge RADER. Dissenting opinion filed by Circuit Judge DYK.

RADER, Circuit Judge.

Richelle Pafford (Pafford) alleges that her DTaP, MMR and OPV vaccinations resulted in the onset of systemic Juvenile Rheumatoid Arthritis.[1] Pafford v. Sec'y Of Health & Human Servs., 2004 WL 1717359 (Ct. Fed. Cl. 2004) (Trial Court Decision). Because the Special Master correctly interpreted and applied the relevant statutory test for proving causation in off-table cases, this court affirms.

[1] DTaP stands for diphtheria, tetanus (commonly known as lockjaw), and pertussis (commonly known as German measles.) OPV stands for oral poliovirus vaccine.

I

On March 24, 1998, Pafford received a series of vaccinations from her doctor, Dr. Jay Schmidt (Dr. Schmidt). Trial Court Decision, 2004 WL 1717359, at *1. The vaccinations administered by Dr. Schmidt during this office visit included a DTaP vaccination, Pafford's fourth OPV vaccination, and a second MMR vaccination. Id. Pafford had received routine childhood immunizations prior to this. Both her first and second DTP, OPV, and Hib vaccinations were normal.[2] Id. However, she developed a faint maculopapular rash approximately seventeen days after receiving her third DTP and OPV vaccinations and her first MMR vaccination. Id.

Earlier that month, on March 5, 1998, Dr. Schmidt had treated Pafford for a cold and diarrhea. Approximately one week later, on March 12, 1998, Pafford was seen by Dr. Schmidt for inflamed tonsils with white patches on them and a fever of 101-102 degrees Fahrenheit. Id. She tested negative for strep. Id. At her March 24, 1998 visit, Dr. Schmidt examined Pafford and noted that the tonsillitis had cleared. Id. As was the case throughout her early childhood years, Dr. Schmidt concluded that Pafford was showing normal growth and development without any unusual medical problems. Id.

On April 4, 1998, Pafford developed a fever and complained of neck pain. Id. The fever resolved itself, but the neck pain continued. Id. Dr. Schmidt saw Pafford on April 7, 1998 for her neck pain. Id. By that time, she had developed a diffuse, pink, macular rash, whitish spots on her tongue. Id. She also complained of limb pain. Id. Dr. Schmidt diagnosed her with a vaccine-induced rash and recommended that she avoid exposure to others for five days. Id. On April 13, 1998, Pafford was taken to a

[2] DPT is an older version of the DTaP vaccination. Hib stands for *Haemophilus Influenzae* Type b vaccine.

local hospital emergency room with a fever, vomiting, pain on being touched and a rash on her hands, legs, chest, and upper abdominal area. Id. at *2. The hospital doctor, Dr. Bell, noted that "[t]he rash was very viral in character and I did not feel it was related to her immunizations but suggested a CBC to see if it supported the viral picture." Id. Pafford was admitted and her symptoms quickly dissipated. Id. She tested positive for a bacterial infection known as "mycoplasma" which Dr. Bell determined to be the cause of Pafford's symptoms. Id. She was released from the hospital the next day because her rash and fever had disappeared. Id. On April 20, 1998, Dr. Bell saw Pafford for a recurrence of her symptoms. Dr. Bell diagnosed Pafford with systemic onset Juvenile Rheumatoid Arthritis, also known as Still's disease. Id.

Pafford's parents, on behalf of Pafford, brought a claim under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 34, in the Court of Federal Claims. They alleged that their daughter's development of Still's disease was a result of the vaccinations she received on March 24, 1998. Id. at *1. On July 16, 2004, Special Master Richard Abell issued a decision denying Pafford's claim. Id. Special Master Abell determined that a vaccine can cause Still's disease but that Pafford had not sufficiently demonstrated that in her case the vaccine did cause the development of Still's disease. Id.

Following an appeal, Court of Federal Claims Judge Lawrence J. Block issued an opinion sustaining the Special Master's decision. Pafford v. HHS, 64 Fed. Cl. 19 (2005). Pafford filed a motion for reconsideration alleging "legal error with regard to standards of proof and the allocation of burdens" which was denied on March 8, 2005.

II.

This court reviews the United States Court of Federal Claims' review of the Special Master's decision without deference. Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1523-24 (Fed. Cir. 1991). Thus, this court examines the Special Master's legal determinations under a "not in accordance with law" standard and factual determinations under an "arbitrary and capricious" standard. Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

Generally a petitioner can obtain compensation under the vaccine injury program in two ways. See id. at 865. In a "table" case, the petitioner has an initial burden to prove an injury listed in the Vaccine Injury Table within the prescribed time period under the requirements of 42 U.S.C. § 300aa-14(a). See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319 (Fed. Cir. 2006) (citations omitted). Upon satisfying this initial burden, the petitioner earns a presumption of causation. At that point, the burden shifts to the respondent to prove that a factor unrelated to the vaccination actually caused the illness, disability, injury, or condition. 42 U.S.C. §§ 300aa-13(a)(1)(A),(B).

The other avenue for compensation does not involve the presumption of causation conferred by the table. In an "off-table" case (also known as a "causation-in-fact" claim), the petitioner cannot obtain a presumption of causation. Rather, the petitioner in an off-table case has the burden to prove the vaccination in question "caused" the illness, disability, injury, or condition. 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I). Pafford does not allege she suffered a table injury. Thus, Pafford must prove causation-in-fact or that the vaccine was actually the cause of her injuries.

Under this court's precedent, Pafford must prove by preponderant evidence both that her vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination. Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999) ("We adopt the Restatement rule for purposes of determining vaccine injury, that an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action."). This court recently articulated an alternative three-part test. To show causation in fact, the petitioner must show:

> (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 proximate temporal relationship between the vaccination and injury.

Capizzano, 440 F.3d at 1324 (citing Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Of course, as noted in Shyface, these prongs must cumulatively show that the vaccination was a "but-for" cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.

The Special Master applied the tests of Althen and Shyface correctly in this case. Specifically, the Special Master indicated:

> *First*, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. *In fine*, can [the] vaccine(s) at issue cause the type of injury alleged? *Second*, a petitioner must also prove that the vaccine actually caused the alleged symptoms in her particular case.

Trial Court Decision, 2004 WL 1717359, at *4 (emphasis in original). The first prong of the Special Master's test is identical to the first prong of the Althen test. Capizzano, 440 F.3d at 1324 (citing Althen, 418 F.3d at 1278). The Special Master's inquiry also gave

effect to the "logical sequence of cause and effect" at the heart of the second prong of the Althen test. Trial Court Decision, 2004 WL 1717359, at *6 (discussing Dr. Levin's testimony linking Pafford's March 1998 vaccinations to the onset of Still's disease). Most importantly, the second prong of the Special Master's test in this case restates correctly that the petitioner must show that the vaccine was the "but for" cause of the harm according to Shyface, or in other words, that the vaccine was the "reason for the injury" as stated in the second prong of the Althen test. Finally, the Special Master also required proof of a proximate temporal relationship between Pafford's vaccinations and the onset of Still's disease commensurate with the third prong of the Althen test. Trial Court Decision, 2004 WL 1717359, at *9 ("The link missing from Petitioner's argument . . . was the lack of any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event."). Thus, this court perceives no significant difference between the Special Master's test and that established by this court in Althen and Shyface.

III.

This court turns next to the evidence of record on causation-in-fact. Notably, the causation evidence of record consists primarily of testimony from two of Pafford's experts, Drs. Levin and Geier, and scientific literature on which their testimony was based. As discussed below, this court finds it was not arbitrary and capricious for the Special Master to conclude on this record that Pafford did not prove causation by preponderant evidence.

Applying the causation test to the facts before the court, the Special Master determined that Pafford proved only one of the two prongs of his test by preponderant

evidence. Specifically, the Special Master noted, while "it is biologically plausible that one or more of the vaccinations at issue could cause the onset of Still's disease[,]" Trial Court Decision, 2004 WL 1717359, at *5, Pafford did not prove that the vaccinations were a but-for cause of her contracting Still's disease (i.e., Pafford failed to satisfy the "but-for" prong of the Shyface test), id. at *9. The Special Master was particularly troubled by the lack of evidence demonstrating "any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event." Id.

To the Special Master, the absence of temporal linkage evidence prevented him from finding that a *vaccination* was the reason for the injury rather than other contemporaneous events unrelated to the vaccinations. Id. at *7 ("[A]bsent an appropriate time frame, the Court cannot find the mere temporal proximity of the vaccination and injury dispositive."). These contemporaneous events included: (1) a positive test for mycoplasma (a type of bacteria); (2) x-rays showing a thickening of the sinus membrane consistent with a sinus infection; (3) an earlier bout of tonsillitis; and (4) an earlier cold accompanied by diarrhea. Id. at *8. Thus, according to the Special Master, Pafford did not prove by preponderant evidence that one or more of her vaccinations were a "but-for" cause of her contracting Still's disease.

On appeal, Pafford argues "[t]he special master placed an untoward and legally impermissible burden on petitioners" as part of the but-for inquiry to prove it was the vaccinations rather than the other contemporaneous events that triggered her Still's disease. Brief for Pafford at 54, Pafford v. Sec'y of Health & Human Servs., No. 05-5106 (Fed. Cir. 2006) (Petitioner's Brief); see Trial Court Decision, 2004 WL 1717359, at *4 ("Ruling out other potential causes is an essential element but does not itself

establish causation."). Pafford argues that "[t]his is contrary to the express terms of the statute, whereby § 300aa-13 (a)(1)(B) contemplates the grant of compensation **unless** alternate causation by known factors is shown 'by a preponderance.'" Petitioner's Brief at 54 (emphasis in original). Pafford relies primarily on two of this court's cases, Shyface and Grant (as interpreted by Shyface) for the proposition that a petitioner need not rule out alternative causes in proving actual causation.

Contrary to Pafford's reading, Shyface and Grant do not stand for this premise. Shyface was a vaccine injury case involving an infant's April 1, 1993 DPT vaccination.[3] Shyface v. Sec'y of Health & Human Servs., 1997 WL 829404, at *1 (Ct. Fed. Cl. 1997), rev'd, 165 F.3d 1344 (Fed. Cir. 1999). Four days after inoculation, the infant was taken to a hospital with a fever hovering between 109 and 110° F; tragically the infant died from the fever the same day. Id. at *2. Subsequent tests revealed the presence of a bacterial infection that could not be ruled out as the cause of death. Id. Thus, at trial, petitioners' expert theorized the DPT vaccination "caused" the infant's fever, which was then significantly exacerbated by the infection. Id. at *5. In other words, petitioners' expert argued 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. When presented with this theory, the Special Master found preponderant evidence linking the DPT vaccination to the infant's death, but still rejected petitioners' claim because "it is impossible to know with any degree of confidence, which source is the predominant cause of death." Id. at *8.

[3] DPT is an older version of the DTaP vaccination. This vaccination is given for the prevention of diphtheria, pertussis, and tetanus.

On appeal, this court reversed. Shyface, 165 F.3d at 1353. This court held that, in order to establish a *prima facie* case, the petitioners had to show "that the DPT vaccine was both a but-for cause of and a substantial factor in [the infant's] death." Id. The court went on to explain that, while the vaccination must be a "substantial factor" in the infant's death, it need not be the sole factor or even the predominant factor. Id. at 1352-53. Thus, the court reversed the Special Master's decision in favor of respondent; the Special Master should have awarded compensation to the petitioners who had proven the DPT vaccine was both a but-for cause of and a substantial factor in the infant's death. Id. at 1353.

Unlike Shyface, the petitioner here 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 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." Trial Court Decision, 2004 WL 1717359, at *7. "Without such a defined time period, the link between the vaccinations and the injury is tenuous." Id. at *9. As noted earlier, this reasoning applies properly the tests of Althen and Shyface.

Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the "but-for" prong of the causation analysis. See Capizzano, 440 F.3d at 1326 (finding medical opinions that explain how a vaccine can cause the injury alleged coupled with evidence demonstrating a close temporal relationship "are quite

probative" in proving actual causation). If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury. Thus, it was entirely proper for the Special Master to require Pafford to prove but-for causation, including some showing of temporal relationship between the vaccination(s) and the onset of injury.

Moreover, the Special Master's requirement for strong temporal evidence is consistent with the third prong of the Althen test: demonstrating a proximate temporal relationship between the vaccination and the injury. See Althen, 418 F.3d at 1278. Again, without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.

Turning to the evidence of record, neither of Pafford's two experts, Drs. Levin and Geier, provided sufficient evidence for the Special Master to conclude the onset of Still's disease occurred within the medically acceptable time frame. Dr. Levin explained that the DTaP, MMR and OPV vaccines can, in some individuals, trigger an

autoimmune inflammatory disorder that causes the release of cytokines,[4] which in turn cause the symptoms of Still's disease. Trial Court Decision, 2004 WL 1717359, at *5. Dr. Levin did not, however, provide any evidence about a medically acceptable time frame for the onset of the disease following the vaccination. Transcript of Record at 172-173, Pafford v. Sec'y of Health & Human Servs., No. 01-165V (Ct. Fed. Cl. 2004) (Trial Transcripts) (emphasis added). Dr. Levin also did not discuss in detail the other contemporaneous events unrelated to the vaccinations. Thus, the Special Master properly concluded, under our arbitrary and capricious standard of review, that Dr. Levin's testimony standing alone was not sufficient to prove the medically acceptable time frame or to link the onset of Still's disease to the vaccinations in this case.

In addition to Dr. Levin, Dr. Geier sought to provide testimony on this point. Specifically, Dr. Geier testified about the medically acceptable time frame for arthralgia episodes and joint syndromes generally. Trial Transcripts at 39-40; Petitioner's Brief at 10. The Special Master found Dr. Geier's testimony (and the scientific literature on which his testimony was based) insufficient for at least two reasons. In the first place, the Special Master noted correctly that evidence about the temporal relationship for arthralgia episodes and joint syndromes in general does not show the specific temporal relationship for Still's disease. Trial Court Decision, 2004 WL 1717359, at *7 n.42. The Special Master also questioned Dr. Geier's qualifications because he is not certified in the areas of rheumatology, pathology, or immunology. Id. at *1 n.2. Notably, this court accords great deference to a Special Master's determination on the probative value of

[4] Cytokine: "a generic term for non-antibody proteins released by one cell population on contact with a specific antigen, which act as intercellular mediators, as in the generation of an immune response." Trial Court Decision, 2004 WL 1717359, at *5 n. 29.

evidence and the credibility of witnesses. See Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (noting that the probative value of the evidence and the credibility of the witnesses are matters within the purview of the fact finder). On this record, the court cannot discern any reversible error in the Special Master's findings that Dr. Geier did not prove the temporal relationship between Still's disease and the vaccination.

Without credible testimony from either Dr. Geier or Dr. Levin on the medically acceptable time frame, the record contains little evidence linking Still's disease to the vaccinations in this particular case and leaves Pafford without adequate evidence to show "but-for" causation under this court's causation standards. See Trial Court Decision, 2004 WL 1717359, at *7 ("Petitioners provide no objective evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event."). Without a link between Still's disease and the vaccinations, the Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations. Id. at *8. Hence, petitioner did not show it was *more* likely that the vaccinations were a but-for cause of and a substantial factor in her contracting Still's disease.

IV.

In her final argument, Pafford alleges the Special Master committed a Due Process violation by raising the medically accepted time frame issue sue sponte at the close of trial, without providing her a full and fair opportunity to present evidence on this issue. The record, however, shows that the petitioner knew of the medically

accepted time frame issue well before the end of the trial and chose to rely on Dr. Geier to provide the required evidence. Response to Order to Show Cause & Motion for Inclusion in "Omnibus" Rubella Arthritis Cases at 1-2, Pafford v. Sec'y of Health & Human Servs., No. 01-165V (Ct. Fed. Cl. 2001) (asserting "the onset of Still's disease appears to fit within the bounds of biological plausibility and medically significant temporal relationship to vaccination" in view of literature associating the condition with rubella vaccine); Petitioner's Brief at 30 ("Petitioners' had determined the[y] would rely on Dr. Geier to address . . . the 'time frame' element . . . ."). While Dr. Geier did not supply sufficient admissible evidence to satisfy this critical portion of the causation test, Pafford's admitted reliance on Dr. Geier in this regard impeaches her Due Process argument.

V.

In summary, the Special Master did not err in requiring specific evidence about a medically acceptable time frame linking the onset of Still's disease to the vaccinations at issue. In the absence of such evidence, the court cannot say the Special Master's finding that Pafford failed to prove causation by preponderant evidence was arbitrary and capricious. Thus, this court affirms.

COSTS

Each party shall bear its own costs.

AFFIRMED

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DYK, Circuit Judge, dissenting.

The majority today holds that petitioners seeking compensation under the National Childhood Vaccine Injury Compensation Program (the "Vaccine Act") 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]," Ante at 6; and (2) an absence of "alternative causes" of the injury. Ante at 8. While there are some unfortunate dicta in our cases that might support the majority's approach, our earlier holdings and the statute itself are to the contrary. The majority's interpretation of the Vaccine Act approves the efforts of the Special Masters to impose unwarranted bright-line tests for causation under the statute. I respectfully dissent.

I

This case involves the five-prong test for causation in off-Table cases announced by the Chief Special Master in Stevens v. Secretary of the Department of Health and Human Services, No. 99-594V, 2001 WL 387418 (Ct. Cl. Spec. Mstr. Mar. 30, 2001). That test required petitioners to establish: (1) medical plausibility; (2) confirmation of medical plausibility from the medical community and literature; (3) an injury recognized by the medical plausibility evidence and literature; (4) a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) the elimination of other causes. Id. at *23-*26. We have already held that prongs (2) and (3) of this test are inconsistent with the statute. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279-81 (Fed. Cir. 2005). We have also held invalid a sixth Special-Master-created rule requiring petitioners, in order to demonstrate causation in fact in off-Table cases, to supply at least one of four types of evidence: "epidemiologic studies; rechallenge; presence of pathological markers or genetic predisposition; or general acceptance [of the causal relationship] in the scientific and medical communities . . . ." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1323 (Fed. Cir. 2006). This case for the first time presents the issue of the validity of prongs (4) and (5) of the Stevens test. The Special Master in this case rejected the petitioners' claim based on these two requirements. See Pafford v. Sec'y of Health & Human Servs., No. 01-0165V, 2004 WL 1717359, at *7, *9 (Ct. Cl. Spec. Mstr. July 16, 2004).

II

Here, the petitioners put on substantial evidence of causation. Their expert, Dr. Levin, testified that it is generally accepted in the medical community that "the

symptoms of Still's disease are caused by cytokine expression." Levin and the government's expert agreed that "vaccines induce cytokine production." See id. at *5. As to Richie Pafford's case, Levin stated that "'immune activation caused by DPT vaccinations is in turn caused by the release of the very cytokines that are elevated in Still's disease,'" and that although "the medical field had yet to develop testing sophisticated enough to identify specific cytokines" in patients, "indirect tests performed [on Richie] . . . correlate[d] with the clinical symptomatology." Id. at *6. Levin concluded that "'the only factor that seems associated with the development of this disease process [in Richie Pafford] is the vaccination.'" Id. The government did not introduce evidence to establish causation by any factor unrelated to the vaccinations. Id. at *8.

Acknowledging that it was a close case, the Special Master "painstakingly looked for the feather in Petitioners' argument that would tip the scales" as to causation in fact, but concluded that "the lack of any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event," and the petitioners' failure to rule out causation by other "contemporaneous events," required denial of compensation. See id. at *9. The majority holds that this was proper.

III

Prong (4) of the Stevens test requires evidence of "a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury" which "is defined through peer-reviewed literature . . . ." Stevens, 2001 WL 387418, at *25. To meet this requirement, "petitioners must satisfactorily prove that the onset occurred within a time frame deemed medically appropriate according to the scientific or medical evidence. . . ." Id. The Chief Special Master relied on no decision from this court for the

requirement, but rather on other Special Master decisions and reports issued by the National Academy of Sciences' Institute of Medicine ("IOM"). See id. at *25 n.78, *26 & n.79.

The majority states that "the Special Master also required proof of a proximate temporal relationship between Pafford's vaccinations and the onset of Still's disease commensurate with the third prong of the Althen test." Ante, at 6. The majority relies on the statement in Althen, 418 F.3d at 1281, that the "medically acceptable temporal relationship" requirement "is merely a recitation of this court's well-established precedent." The well-established precedent to which Althen was referring was apparently Lampe v. Secretary of Health and Human Services, 219 F.3d 1357 (Fed. Cir. 2000), Shyface v. Secretary of Health & Human Services, 165 F.3d 1344 (Fed. Cir. 1999), Hodges v. Secretary of Health & Human Services, 9 F.3d 958 (Fed. Cir. 1993), and Grant v. Secretary of Health & Human Services, 956 F.2d 1144, 1149 (Fed. Cir. 1992). These cases were cited in the Althen opinion.

In fact, the precedent cited in Althen merely stands for the proposition that the temporal relationship between vaccination and injury may be a pertinent factor to consider in determining causation. In Lampe, for example, we stated only that "[t]he passage of time between an event and the consequences that are alleged to flow from it is often significant," not that a medically significant time interval is required. 219 F.3d at 1366. And in Hodges, we did not suggest that evidence of a temporal relationship is required -- we held only that where the petitioners failed to prove a Table injury, literal temporal proximity to vaccination and the absence of other possible causes, alone, were insufficient to establish causation in fact for an off-Table injury. See 9 F.3d at 960-

61. In Shyface, we addressed the standard for proving causation in off-Table cases in great detail and never once suggested a "medically established temporal relationship" requirement. Instead, we held that the petitioner must prove "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." 165 F.3d at 1352. Nor did we suggest in Shyface that a temporal relationship is necessary to establish either the but-for or substantial factor elements of causation. See id. at 1352-53.

Significantly, in Grant, we rejected a temporal requirement. There, the petitioner sought compensation for encephalopathy-induced infantile spasms that began 10 days after a Quadrigen vaccination.[1] Grant, 956 F.2d at 1146-47. Because the spasms occurred outside the Table time period (3 days, 42 U.S.C. § 300aa-14(a)), the petitioner was required to establish causation in fact. The Special Master nevertheless found causation, relying on "evidence that pertussis as part of the Quadrigen vaccine has a heightened potential to cause . . . exactly the symptoms that occurred to [the petitioner] . . . ." Id. at 1149. On appeal, we rejected the government's argument, based on epidemiological studies, that the "lack of statistical proof [of an association between DTP vaccine and infantile spasms 10 days later] . . . . is dispositive on the issue of causation." Br. of Secretary of Health & Human Servs., Grant, 956 F.2d 1144, at 15-17; see Grant, 956 F.2d at 1148. We concluded that "[t]hese epidemiological studies . . . are not dispositive of the actual causation question in this case." Grant, 956 F.2d at 1149. We affirmed the award of compensation, observing that:

[1] The Quadrigen vaccine combined diphtheria, pertussis, tetanus and polio vaccines in a single administration. Grant, 956 F.2d at 1145.

> [T]he Chief Special Master did not rely on expert testimony based on temporal association and studies of less direct relevance. Instead, the Chief Special Master relied on a preponderance of relevant scientific and medical evidence about the particular nature of Quadrigen. This court discerns nothing arbitrary, capricious, or unlawful in that reliance.

Id.

In rejecting a temporal requirement for off-Table cases, Grant was entirely consistent with the statute. Indeed, the "medically acceptable temporal relationship" requirement is plainly contrary to the Vaccine Act. As we have repeatedly recognized, the purpose of the Vaccine Injury Table was to afford petitioners a presumption of causation for particular types of injury for which there is a medically accepted temporal relationship with vaccination.[2] Every Table injury has an associated time period. See 42 U.S.C. § 300aa-14(a) (2000). Congress explained that scientific research might establish additional temporal relationships which, if found, would result in amendments to the time periods specified in the table:

> The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines . . . may propose to revise the Table . . . .

[2] See, e.g., Hodges, 9 F.3d at 961 ("Bring the case within the timetable and specifications of a Table Injury and the statute does the heavy lifting – causation is conclusively presumed."); Grant, 956 F.2d at 1147 ("The Vaccine Table, in effect, determines by law that the temporal association of certain injuries with the vaccination suffices to show causation."); Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1527-28 (Fed. Cir. 1993) (quoting Grant, 956 F.2d at 1147). Notably, the Chief Special Master in Stevens relied on the Secretary's 1995 explanation of the measles, mumps, and rubella vaccine/encephalopathy Table timeframe as an example of a "medically accepted temporal relationship." See 2001 WL 387418, at *25 (citing 60 Fed. Reg. 7678, 7692).

H.R. Rep. 99-908, at 18 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6359. Thus the Vaccine Act provides that the Secretary of Health and Human Services may by regulation "add to, or delete from, the list of injuries . . . or may change the time periods for the first symptom or manifestation of the onset . . . of any such injury . . ." in the Table. 42 U.S.C. § 300aa-14(c)(3) (2000); see 42 U.S.C. § 300aa-14(c)(1).

In 1995, for example,[3] the Secretary changed the Table time interval between administration of pertussis vaccines and "anaphylaxis or anaphylactic shock" from 24 hours to 4 hours, explaining that "the pediatric literature is clear in stating that severe anaphylactic reactions occur immediately with antigen exposure and rarely show their first manifestation after 4 hours." 60 Fed. Reg. 7678, 7686 (Feb. 8, 1995). The Secretary also changed the Table time interval between administration of the measles, mumps, and rubella vaccine and the onset of encephalopathy from 15 days to "5 to 15 days," explaining that "[s]ince viral replication is required for a viral vaccine-associated encephalopathy, a window for the expected time of onset is appropriate. . . . [and] the 1991 [National Vaccine Advisory Committee] Subcommittee felt there was strong support in the literature to narrow the timeframe as above." Id. at 7692.

However, scientific research on vaccine-related injuries remains incomplete; thus it is not always possible to identify the "medically accepted temporal relationship." In a 2000 report on the progress of the Vaccine Act, Congress noted that "[o]f the 76 adverse events IOM reviewed [in 1991 and 1994] for a causal relationship [with vaccination], 50 (66 percent) had no or inadequate research." H.R. Rep. 106-997, at 5 (2000).

[3] The Table was also revised in 1997 and 2002, 62 Fed. Reg. 7685 (Feb. 20, 1997); 67 Fed. Reg. 48558 (July 25, 2002), and is codified at 42 C.F.R. § 100.3.

In recognition of the uncertain state of scientific knowledge, the statute provides what is known as an off-Table remedy, allowing recovery where the petitioner can establish that the injury "was caused by a vaccine" listed in the Table, even though the particular injury is not listed in the Table. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I) & (II) (2000). Another important purpose of allowing recovery for off-Table injuries was to allow a petitioner to make a claim for an injury listed in the Table where the injury was not manifested during the medically accepted time frame set forth in the Table.[4] The Vaccine Act specifically authorizes compensation for petitioners who "sustained . . . any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset of . . . which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A)." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(II) (2000) (emphasis added). Thus the statute clearly contemplates that causation in fact may be established in off-Table cases without showing the "medically accepted temporal relationship" listed in the Table.[5]

This purpose would be directly thwarted if proof of a medically accepted timeframe were required to show causation in off-Table cases. But that is exactly what the majority requires here. In this case, there was substantial evidence regarding the biological mechanism of causation, even though the experts did not identify a medically accepted temporal relationship. See Pafford, 2004 WL 1717359, at *5-*6. Under the

[4] The Secretary, in reducing the pertussis vaccines/anaphylaxis Table time interval from 24 hours to 4 hours, noted that "[p]etitioners may receive compensation under the [Vaccine Act] if they prove their injury was caused by the vaccination, even if onset was after the 4 hours specified in the Table." 60 Fed. Reg. at 7678.

[5] Congress made clear that it did "not intend . . . to suggest that variance from the Table should act as a presumption against the petitioner but rather only that such a petitioner is not to be deemed eligible for compensation without further showings of causation." H.R. Rep. 99-908, at 15.

majority's holding, any petitioner who fails to establish a medically accepted temporal relationship automatically lacks an essential element of their prima facie case for causation in fact. That holding is inconsistent with the clear provisions of the statute and our prior holdings interpreting it.

III

The Special Master here concluded that "[r]uling out other potential causes is an essential element" of the petitioner's case. Pafford, 2004 WL 1717359, at *4. The Court of Federal Claims, after reviewing our cases and the Chief Special Master's decision in Stevens, concluded that in off-Table cases, the "initial burden of proof regarding alternative causation [is] on the petitioner . . . as part of establishing a prima facie case of causation-in-fact." Pafford v. Sec'y of Health & Human Servs., 64 Fed. Cl. 19, 35 (2005).[6] The majority, in sustaining the Special Master's decision here, appears to agree. As with the temporal relationship prong, there is at least a fragment of dictum supporting this view. See Munn v. Sec'y of Health & Human Services, 970 F.2d 863, 865 (Fed. Cir. 1992) ("The claimant must prove by a preponderance of the evidence

[6] See also Pafford, 64 Fed. Cl. at 30 ("The Federal Circuit has instructed that an actual-causation vaccine petitioner 'must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual case of the injury.' Munn, 970 F.2d at 863 (emphasis added). This would seem to engender the need for a petitioner to eliminate other possible causes of the condition (other than the vaccine) that exist in the record."); id. (". . . petitioner[] 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 35 ("[T]he 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 . . . as part of establishing a prima facie case of causation-in-fact."); id. at 36 ("[I]n establishing his prima facie case of entitlement, the petitioner must discount other potential causal factors that the record reveals, because the required 'substantial factor' analysis requires as much."); id. at 36 (". . . it was incumbent upon [the petitioners] to discount the role of these potential alternatives in order to prove that the vaccines were, more likely than not, the cause of Richelle's Still's disease.").

that the vaccine, and not some other agent, was the actual cause of the injury."). Since the dictum in Munn, however, we have unequivocally held that, under section 300aa-13(a)(1)(B), the government bears the burden of proof regarding causation by "factors unrelated" to vaccination.

Section 300aa-13(a)(1) of the Vaccine Act provides, in pertinent part:

> Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole –
> (A) that the petitioner has demonstrated by a preponderance of the evidence [a Table injury or causation in fact], and
> (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death 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) (2000) (emphasis added). As we have recognized, the plain language and structure of this provision establish that the petitioner's burden to make a prima facie showing of either presumptive or actual causation set out in section 300aa-13(a)(1)(A) does not include the burden of proof regarding "factors unrelated" to vaccination set out in section 300aa-13(a)(1)(B) – "[t]hese are two separate inquiries under the statute." Grant, 956 F.2d at 1149 ("The Vaccine Act expressly separates the inquiry for alternative etiologies from the inquiry for causation.").

We have repeatedly held that the separate burden of proof regarding "factors unrelated" to vaccination belongs to the government in both Table and off-Table cases. See, e.g., Jay v. Sec'y of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993) (section 300aa-13(a)(1)(B) requires a "statutorily separate inquiry . . . [as to] whether an alternative causation has been proved by [the government]." (emphasis added)). In Knudsen v. Secretary of Health & Human Services, 35 F.3d 543 (Fed. Cir. 1994), a Table case, the petitioners argued that the government failed to satisfy its burden of

proof for its argument that the injury was caused by a viral infection rather than the vaccine. In defining the government's burden under section 300aa-13(a)(1)(B), we held that "[t]he government was required not only to prove the existence of an infection (here viral), but also to prove by a preponderance of the evidence that the particular viral infection present in the child actually caused the table injury complained of." Id. at 549. And in Shyface, an off-Table case, we rejected the government's argument that the statute requires the petitioner to establish "'that the vaccine is more likely than any other factor to have been directly responsible for the injury,'" 165 F.3d at 1349, and concluded that compensation was warranted because the petitioners made a prima facie showing of causation and the government "failed to prove that factors unrelated to the vaccine were principally responsible . . . ." Id. at 1353.

Indeed the Second Restatement of Torts, which we held in Shyface to be controlling in off-Table cases, 165 F.3d at 1351-52, provides that the defendant bears the burden of proof on alternate causation. The Restatement describes the prima facie showing of causation in cases involving more than one possible cause: "[i]f two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself is sufficient to bring about harm to another, the actor's negligence may be found to be a substantial factor in bringing it about." Restatement (Second) of Torts § 432(2) (1965). "[T]he burden of proof that the tortious conduct of the defendant has caused the harm to the plaintiff is upon the plaintiff." Id. § 433B(1). But in cases involving multiple causes, the Restatement places the burden on the defendant to prove either "the apportionment" of the harm among the causes, or that one of the causes other than the defendant's conduct

actually caused the entirety of the harm to the plaintiff. Id. §§ 433B(2) & (3). Contrary to the majority's view, the same allocation of burdens is required under the Vaccine Act.

IV

In summary, the majority incorrectly holds that petitioners, in order to make a prima facie case in off-Table cases, must establish a "medically accepted temporal relationship" between vaccine and injury and eliminate other possible causes of the injury. In doing so, the majority perpetuates causation requirements imposed on vaccine petitioners by the Special Masters, whose "role is to assist the courts by judging the merits of individual claims on a case-by-case basis, not to craft a new legal standard to be used in causation-in-fact cases." Althen, 418 F.3d at 1281. This case should be remanded for adjudication under the correct legal standard.

United States Court of Appeals for the Federal Circuit

E R R A T A

June 27, 2006

Appeal No. 05-5106

Precedential Majority Opinion, Pafford v HHS

Decided June 20, 2006

Page 1, footnote 1, line 2: please delete “German measles” and insert “whooping cough”.