# **United States Court of Appeals for the Federal Circuit**

2009-5052

MELISSA CLOER, M.D.,

Petitioner-Appellant,

٧.

### SECRETARY OF HEALTH AND HUMAN SERVICES.

Respondent-Appellee.

Mari C. Bush, Kaye and Bush, LLC, of Denver, Colorado, argued for petitioner-appellant. Of counsel was Robert T. Moxley, Robert T. Moxley, P.C., of Cheyenne, Wyoming.

<u>Lynn E. Ricciardella</u>, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With her on the brief were <u>Tony West</u>, Assistant Attorney General, <u>Timothy P. Garren</u>, Director, <u>Mark W. Rogers</u>, Deputy Director, and <u>Gabrielle M. Fielding</u>, Assistant Director.

Appealed from: United States Court of Federal Claims

Judge Lawrence J. Block

# **United States Court of Appeals for the Federal Circuit**

2009-5052

MELISSA CLOER, M.D.,

Petitioner-Appellant,

٧.

## SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Appeal from the United States Court of Federal Claims in case no. 05-VV-1002, Judge Lawrence J. Block.

DECIDED: May 6, 2010

Before MICHEL, Chief Judge, CLEVENGER and DYK, Circuit Judges.

Opinion for the court filed by <u>Chief Judge</u> MICHEL. Dissenting opinion filed by <u>Circuit Judge</u> CLEVENGER.

MICHEL, Chief Judge.

Petitioner-appellant Melissa Cloer, M.D., appeals the decision of the United States Court of Federal Claims. Cloer v. Sec'y of Health & Human Servs., 85 Fed. Cl. 141 (Fed. Cl. 2008). The decision affirmed the Chief Special Master's report, which denied Dr. Cloer's petition for compensation under the Vaccine Injury Compensation Program ("Vaccine Program") established by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act"), because it was time-barred. See

Cloer v. Sec'y of Dep't of Health & Human Servs., No. 05-1002V (Fed. Cl. May 15, 2008).

This case presents the question of whether the Vaccine Act's statute of limitations, 42 U.S.C. § 300aa-16(a)(2), begins running where a claimant experiences a symptom of injury, but where the medical community at large does not recognize that the symptom is related to a vaccine and the claimant has not received medical information suggesting a connection. We hold that the statute of limitations does not begin running in such cases. Thus, we reverse and remand.

### I. BACKGROUND

Plaintiff-appellant Melissa Cloer is a physician who is disabled due to multiple sclerosis ("MS"). She had no significant medical issues prior to exhibiting symptoms of demyelinating disease. Dr. Cloer received three Hepatitis B ("Hep-B") immunizations at the University of Missouri Student Health Center. After her first two vaccinations on September 3, 1996 and November 11, 1996, Dr. Cloer experienced some numbness and tingling. Dr. Cloer received her third Hep-B vaccination on April 3, 1997.

About a month after her final vaccination, Dr. Cloer began to experience an electric-like shock sensation in her spine. Medical professionals call this sensation a Lhermitte sign, a common symptom of MS. In September and October 1997, petitioner also lost sensation in her left arm and left hand. Dr. Cloer consulted with her primary care physician, Dr. Pereira, who prescribed Motrin. The symptoms resolved over a short period of time.

When Dr. Cloer experienced additional problems in 1998, she returned to Dr. Pereira. Dr. Cloer underwent further testing, including a magnetic resonance imaging

(MRI) scan on May 12, 1998. The MRI scan indicated that possible diagnoses for Dr. Cloer included MS, lyme disease, acute disseminating encephalomyelitis, or other demyelinating processes. A May 15, 1998 medical record specifically noted, "Probable early inactive non-progressive CNS [central nervous system] demylination/MS . . . ."

In 1998, Dr. Cloer was referred to a neurologist, Dr. Meyer, with a specialty in the diagnosis and treatment of MS. Dr. Meyer treated appellant in 1998 for "singular sclerosis" or "early inactive non-progressive CNS demyelinating disease." Dr. Cloer was given a "provisional" diagnosis of MS on November 26, 2003 by her treating neurologist Dr. Wood subsequent to his obtaining Dr. Cloer's medical history and the results of an MRI examination.

In May 2004, Dr. Cloer applied for and was awarded monthly Social Security disability benefits due to her medical condition. As part of her eligibility for benefits, James P. Metcalf, M.D., conducted a comprehensive medical examination and noted that appellant "first beg[a]n to have some symptoms consistent with MS in 1997," although her "symptoms waxed and waned until the fall of 2003 when she beg[a]n to have manifestations of the full blown disease."

Dr. Cloer first became aware of an association between MS and the Hep-B vaccine when she read an editorial and prospective French study in the September 2004 issue of Neurology. Dr. Cloer reported to the Vaccine Adverse Event Reporting System (VAERS) on October 11, 2004 that she experienced numbness and tingling after her first two Hep-B vaccinations.

On September 16, 2005, Dr. Cloer filed a claim for compensation under the Vaccine Act, alleging that her Hep-B vaccinations caused or significantly aggravated her

latent MS condition. On December 1, 2005, respondent-appellee Health and Human Services ("HHS") moved to dismiss the petition because it was filed after the expiration of the statutorily prescribed limitations period.

Dr. Cloer relied upon affidavits and testimony from Dr. Meyer, a recognized expert in MS. Dr. Meyer explained that when he evaluated Dr. Cloer in 1998 her symptoms were consistent with but not independently diagnostic for clinically definite MS. He noted that symptoms of MS could occur well before a diagnosis of MS is made. Dr. Meyer testified that, in retrospect, the first sign of MS was the Lhermitte sign that the appellant experienced in 1997.

Dr. Meyer did not believe, or even consider, that Dr. Cloer had suffered a vaccine injury when he evaluated her in 1998. Dr. Meyer did not become aware of the association between MS and Hep-B immunization until he was contacted by Dr. Cloer's counsel in late 2005. Dr. Meyer testified that a member of the medical community at large would not have recognized or believed Dr. Cloer had a vaccine injury as of 1999. Having reviewed Dr. Cloer's prior medical records, Dr. Meyer found no indication of a link between her MS and the Hep-B immunizations before 2004. Dr. Meyer's testimony was not rebutted by any expert.

In 2007, the Chief Special Master conducted a telephonic hearing to take Dr. Meyer's testimony. The Chief Special Master issued his decision on May 15, 2008, determining that the first symptom, manifestation of onset, or significant aggravation of Dr. Cloer's MS was the Lhermitte's sign she experienced in 1997. Because Dr. Cloer filed her Vaccine Act petition on September 16, 2005, more than 36 months later, the

Chief Special Master dismissed the petition as untimely. The Court of Federal Claims affirmed the Chief Special Master's decision.

Dr. Cloer timely appealed to the Federal Circuit. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3).

#### II. DISCUSSION

Α.

Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005). We review legal determinations of the Court of Federal Claims de novo. Althen, 418 F.3d at 1278. To the extent that the Court of Federal Claims adopts factual findings made by the special master, we accord them the same deference as the Court of Federal Claims and review them under the arbitrary and capricious standard as provided in the statute. Munn v. Sec'y of the Dep't of Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992). While we owe no deference to either the special master or the trial court on questions of law, Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1106 (Fed. Cir. 1996), we review factual findings for clear error, Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1523 (Fed. Cir. 1991).

B.

Congress established the Vaccine Act to increase the safety and availability of vaccines. See 42 U.S.C. § 300aa-1. As part of the Vaccine Act, the Vaccine Program permits claimants to petition to receive compensation for vaccine-related injuries. See §

300aa-100(a). The Vaccine Injury Table lists vaccines that are covered under the Vaccine Act. See §§ 300aa-11(c)(1)(C)(ii), 300aa-14. The Vaccine Injury Table also lists injuries that may arise from these vaccines, which are referred to as Table injuries. § 300aa-14. Other injuries, including MS, are not listed in the Vaccine Injury Table and referred to as non-Table injuries. § 300aa-11(c)(1)(C)(ii).

The Vaccine Act sets forth a statute of limitations:

In the case of . . . a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.

§ 300aa-16(a)(2). The question in this case is whether the 36 month period commences where a petitioner experiences the first symptom of an injury, but where the medical community at large does not recognize that the symptom is related to a vaccine and the claimant has not received medical information suggesting such a connection. If so, Dr. Cloer's appeal is time-barred because she experienced the first symptom of MS in 1997 but did not file her claim until 2005.

Dr. Cloer argues that her appeal cannot be time barred because the "first symptom or manifestation of onset," for the purposes of § 300aa-16(a)(2), is "the first event objectively recognizable as a sign of vaccine injury by the medical profession at large." See Markovich v. Sec'y of Heath and Human Servs., 477 F.3d 1353 (Fed. Cir. 2007). Dr. Cloer interprets Markovich to mean that the medical community at large needs to recognize a link between the injury and the vaccine for the statute of limitations to begin running. We generally agree.

We begin with an analysis of Markovich, where this court considered the standard that should be applied in determining the date of "the occurrence of the first symptom or manifestation of onset . . . ." Id. at 1356. The Markoviches' daughter, Ashlyn, received a series of vaccinations on June 10, 2000, when she was approximately two months old. Id. at 1354. That same day, the Markoviches observed that Ashlyn began to rapidly blink her eyes, but they did not recognize that it was a first symptom of vaccine-related seizures. See id. On August 30, 2000, Ashlyn became unresponsive for about twenty minutes, during which time all of Ashlyn's extremities jerked aggressively. Id. at 1354-35. Ashlyn was treated at the Fairview Ridge Emergency Room, where she was diagnosed with having a grandmal seizure. Id. at 1355.

The Markoviches argued that the standard for the statute of limitations should be subjective and begin running on August 30, 2000, the date they became aware of an injury. Id. at 1356. This court disagreed, holding that an objective standard was consistent with the Vaccine Act language that the statute is triggered by the "first symptom or manifestation of onset." Id. at 1358, 1360. The use of the words "first" and "or" require that the statute of limitations commence with whichever event (i.e., symptom or manifestation of onset) occurs first. Id. at 1358. Thus, this court held that the "'first symptom or manifestation of onset,' for the purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." Id. at 1360. Because Ashlyn's eye blinking episode was objectively recognizable by the medical profession at large as constituting the first evidence of vaccine injury onset, the statute of limitations began on that date. Id.

Markovich confirms that, under § 300aa-16(a)(2), in general, a symptom must be recognizable by the medical community at large as constituting a vaccine-related injury. As this court expressly held, the limitations period begins at the "first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." See id. (emphasis added). This holding also is consistent with the plain language of the statue of limitations, which specifically applies to injuries that are vaccine-related:

In the case of . . . a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a <u>vaccine-related injury</u> occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of <u>such injury</u>.

§ 300aa-16(a)(2) (emphasis added). Thus, we hold that, in general, for the purposes of § 300aa-16(a)(2), to be "vaccine-related" the "first symptom or manifestation of onset or of the significant aggravation of such injury" cannot occur until the medical community at large objectively recognizes a link between the vaccine and the injury.

The government's arguments to the contrary are unpersuasive. First, HHS argues that "Congress chose to start the running of the statute before many petitioners would be able to identify, with reasonable certainty, the nature of the injury." See Markovich, 477 F.3d at 1358. However, as the preceding discussion demonstrates, the issue is not whether a petitioner subjectively recognizes an injury as vaccine-related, but rather whether the medical community at large objectively recognizes the injury as vaccine-related. Second, HHS argues that Dr. Cloer's position would essentially "eviscerate" the limitations period provided in the Vaccine Act for most non-Table injuries. HHS alleges that, in many non-Table cases, the first time an injury is causally associated with a vaccine is well after the petition has been filed. Be that as it may, the

relevant inquiry for determining when the limitations period begins to run is generally this: when does the medical community at large recognize that a vaccine is linked to an injury? That the statute of limitations may start running later for certain non-Table injuries does not "eviscerate" the statue of limitations.

The dissenting opinion argues that our interpretation of "vaccine-related injury" creates a substantial new hurdle for petitioners alleging non-Table injuries, suggesting that a claim could not be brought until the medical community had recognized a link between the vaccine and the injury. The dissent assumes that the time at which the right to bring suit for a non-Table injury accrues and the time of commencement of the limitations period are the same. They are not. The usual rule is that the right to bring suit and the commencement of the limitations period is the same, i.e., that the limitations period begins to run when the cause of action accrues. Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 545 U.S. 409, 418-19 (2005). But this presumption does not exist where statutory language is to the contrary. See id.; Dodd v. U.S., 545 U.S. 353, 360-61 (2005) (holding that the statutory language demonstrated that the limitations period and the petitioner's right to bring suit did not commence at the same time). Here, significantly, the statute relating to non-Table injuries uses quite different language to denote the commencement of the limitations period than it uses to describe the proof required to establish the vaccine injury. The statute of limitations subsection provides, "No petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or the significant aggravation of such injury," 42 U.S.C. § 300aa-16(a)(2) (emphasis added), whereas the non-Table proof of injury subsection provides,

"A petition . . . shall contain . . . an affidavit, and supporting documentation, demonstrating that the person who suffered such injury . . . sustained, or had significantly aggravated, any illness, disability, injury or condition . . . which was <u>caused</u> by a Vaccine referred to in subparagraph (A) . . . ." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (emphasis added). This difference in language is not inadvertent since in the statutory provisions relating to Table injuries, the right to bring suit depends on satisfying the "first symptom or manifestation" standard within the time period set forth in the Table. Thus, for Table cases, which do not require causation, the "first symptom or manifestation" language is used in both the statute of limitations and proof of injury subsections. In contrast, for non-Table cases, the "first symptom or manifestation" language is only used in the statute of limitation subsection and the "cause[s]" language applies to the proof of injury subsection. This deliberate choice of different language shows that the time one can bring suit for a non-Table injury (and prevail) is not the same as the time the limitations period begins. See Dodd, 454 U.S. at 361.

The dissenting opinion would require that the statute of limitations begin running even if there was no known medical association between a vaccine and an injury. A

See § 300aa-11(c)(1)(C)(i) (". . . sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the <u>first symptom or manifestation of the onset or of the significant aggravation of any such illness</u>, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table . . . .") (emphasis added).

<sup>§ 300</sup>aa-11(c)(1) provides the requirements for a Vaccine Act petition. § 300aa-13(a)(1) states that compensation shall be awarded if the special master or court finds on the record as a whole that the petitioner has demonstrated by a preponderance of the evidence the matters required by § 300aa-11(c)(1). Thus, § 300aa-11(c)(1) lists the requirements for a successful petition at trial.

petitioner who suffered a hypothetical injury in Year 1 would be required to file a petition within three years even if no one in the medical community knew of the association between the vaccine and the injury until Year 5. The general purpose of a statute of limitations is that a person should be diligent in pursuing her claim but, in this situation, it would be impossible for a petitioner — even if perfectly diligent — to know that she needed to file a claim. And if such a petitioner did bring a claim for her injury, it would probably be denied as she likely would be unable to prove causation-in-fact. Thus, the statute of limitations cannot begin to run when there is no medically recognized link between the vaccine and the injury.

Moreover, starting the running of the statute of limitations at the exact moment a person could prevail on a causation-in-fact claim would be unworkable. Causation-infact may be proven by medical opinion, such as medical testimony. See Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005). Thus, a petitioner could be required to bring immediate suit simply because she theoretically might be able to find and hire a medical expert to testify to such a link. This depends on the possible ability of a petitioner to find a pioneering medical expert rather than the objective medical community standard. Also, at the time a claim under the Vaccine Act is filed, it is unclear whether a hired medical expert could, in fact, prove causation-in-fact because such a determination is not made until the special master or court conducts a hearing and makes a ruling. See § 300aa-13(a)(1)(A). This necessarily constitutes a merits-based inquiry that should not preclude the filing of a claim.

Our decision does not conflict with <u>Brice v. Sec'y of Health & Human Servs.</u>, 240 F.3d 1367 (Fed. Cir. 2001), because our holding is based upon the proper interpretation

of § 300aa-16(a)(2). We do not need to equitably toll the limitations period to save Cloer's complaint because § 300aa-16(a)(2) permits her claim since the limitations period, properly interpreted, never began. In addition, while Brice noted that Congress had intended that Vaccine Act claims be resolved "as expeditiously as possible," this statement was in the broader context of replacing a traditional tort system that "was inadequate to compensate many who were injured by vaccines." See id. at 1368-69. As this court stated in Brice, "Congress noted that opportunities of those injured by vaccines to seek redress under the traditional tort system were 'limited, timeconsuming, [and] expensive,' and that for the injured, 'mounting expenses must be met." Id. at 1368 (quoting H.R. Rep. No. 99-908, at 6, reprinted in 1986 U.S.C.C.A.N. at 6347). Congress intended that awards under the Vaccine Act be made "quickly, easily, and with certainty and generosity." Id. at 1368-69 (quoting H.R. Rep. No. 99-908, at 3, reprinted in 1986 U.S.C.C.A.N. at 6344). Thus, generosity and reliability to petitioners were as much emphases of Congress as speed. The dissenting opinion, however, would not resolve Vaccine Act petitions generously or with certainty, given that one who is injured would be expected to predict whether there would be a medical linkage between a symptom and a vaccine by a pioneering expert within the next three years. Nor does it encourage expeditious resolution of the claims because a perfectly diligent person would still not know to file a claim any earlier than when the medical community recognizes a link. Thus, Congress could not have intended to prevent petitioners in such a situation from filing claims.

The dissenting opinion also argues that the majority opinion is inconsistent with Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353 (Fed. Cir. 2007).

However, as discussed above, <u>Markovich</u> is factually distinguishable from the instant case and thus compelled a different result. In <u>Markovich</u>, there was no dispute that the petitioner suffered from seizures as a result of the administration of the vaccine. <u>Id.</u> at 1356. The first symptom that Ashlyn experienced, a rapid eye blinking episode, was not normal childhood behavior and would have at the very least raised the suspicions of medical professionals. <u>See id.</u> at 1360. The central dispute was whether the statute of limitations should be objective or subjective. <u>See id.</u> at 1356-57. The Markoviches argued that the standard should be subjective, based solely on the view of a particular parent. <u>Id.</u> at 1356. The government argued that the standard should be objective, based on the recognized standards of the medical community. <u>Id.</u> at 1357. We held that the standard necessarily focused on the recognized standards of the medical community and apply that same holding to the facts here.

Finally, the dissent points out that in <u>Wilkerson</u>, we stated that "[w]e do not read <u>Markovich</u> as requiring in each case a showing of the date on which the medical profession at large has such a recognition." Dissenting op. 9 (quoting (<u>Wilkerson v. Sec'y of Dep't of HHS</u>, 2010 WL 292661, at \*3 (Fed. Cir. Jan. 27, 2001)). Consistent with <u>Wilkerson</u>, we do not suggest that general medical community recognition of a link is required in every case in order for the statute of limitations to begin running. Where a claimant has received a medical opinion or medical knowledge that symptoms suggest a possible link between the vaccine and the injury, such notice will also suffice to trigger the statute of limitations.

When Dr. Cloer first experienced symptoms in 1997, the medical community at large did not recognize a link between MS and her vaccine. Dr. Meyer, a recognized

expert in neurology, testified that he was unfamiliar with any causal link between MS and a vaccine. HHS's own brief also notes that "the medical community at large does not accept a causal association between the hepatitis B vaccine and multiple sclerosis." Appellant's Br. at 16 n.4. In addition, the Vaccine Injury Table does not list MS as a vaccine-related injury. See §§ 300aa-11(c)(1)(C)(ii), 300aa-14.

Based on the record before us, the earliest <u>any</u> member of the medical community alleged he recognized a link between MS and a vaccine was September 2004, when an article was published in <u>Neurology</u>. Thus, the medical community at large could not have objectively recognized Dr. Cloer's symptoms as a vaccine injury any earlier than September 2004, if then. <u>See Markovich</u>, 477 F.3d at 1360. Usually more than one study or article is required. So too, in this case, at the earliest, Dr. Cloer (a medical professional) was put on notice about the possibility of a connection between MS and the vaccine due to the September 2004 <u>Neurology</u> article. As her petition was filed within 36 months of that time, the petition is timely.

Because Dr. Cloer filed her Vaccine Program petition on September 16, 2005, less than 36 months after September 2004, her petition is not time barred.

#### CONCLUSION

For the reasons provided above, the judgment of the Court of Federal Claims is <u>REVERSED\_AND\_REMANDED</u>

2009-5052

# **United States Court of Appeals for the Federal Circuit**

2009-5052

MELISSA CLOER, M.D.,

Petitioner-Appellant,

٧.

### SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Appeal from the United States Court of Federal Claims in 05-W-1002, Judge Lawrence J. Block.

CLEVENGER, Circuit Judge, dissenting.

Multiple sclerosis ("MS") is a horrible disease. In many cases, the disease manifests itself slowly. A person can experience a symptom of MS in a passing manner; a mild symptom can come and go with no apparent lasting effect. Some medically-recognized symptoms of MS are common events for many people: fatigue, numbness, dizziness, weakness, impaired mobility. Such events arising after a hepatitis B vaccination may not hamper a person enough to cause a visit to a doctor, let alone persuade one to file a lawsuit, even though the symptoms could be identified by any competent doctor as symptoms of MS. Until severe and repetitive symptoms arise, a confirmed diagnosis of MS is difficult, and to this day, there is no medical consensus establishing a causal association between the hepatitis B vaccine and MS.<sup>1</sup>

See Immunization Safety Review: Hepititis B Vaccine and Demyelinating Neurological Disorders 1, 8 (Kathleen Stratton et al. eds., The National Academies Press 2002).

In the past, persons suffering symptoms of demyelinating diseases have filed non-Table petitions, seeking to establish the required causal link between the hepatitis B vaccine and their disease.<sup>2</sup> Such cases were filed within three years of the first occurrence of a symptom or manifestation of onset of the demyelinating disease and those petitioners may have been successful. Dr. Cloer's case, had it been timely, was not necessarily doomed to failure.

For petitioners suffering from non-Table injuries who fail to bring suit within three years of onset, the majority provides the best possible solution, especially with regard to diseases that initially present with mild symptoms, such as MS. Under the majority's solution, the person suffering need not worry about the three-year statute of limitations in the Vaccine Act, unless there is consensus in the medical profession that the administered vaccine causes the adverse condition being experienced.<sup>3</sup> As there is no present medical consensus regarding almost all alleged non-Table injuries, injured

Due to the large number of related non-Table petitions, the Office of Special Masters created a Hepatitis B-Neurological Demyelinating Omnibus Proceeding to determine if the hepatitis B vaccine can cause demyelinating diseases. In four paradigm cases, Special Masters found that petitioners successfully demonstrated a causal link between the hepatitis B vaccine and demyelinating diseases even though no such causal link was objectively recognized by the medical profession. See Peugh v. Sec'y of Health and Human Servs., No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007) (hepatitis B vaccine caused Guillain-Barre Syndrome); Werderitsh v. Sec'y of Health and Human Servs., No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006) (hepatitis B vaccine caused MS); Gilbert v. Sec'y of Health and Human Servs., No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (hepatitis B vaccine caused Guillain-Barre Syndrome and chronic inflammatory demyelinating polyneuropathy); Stevens v. Sec'y of Health and Human Servs., No. 99-594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (hepatitis B vaccine caused transverse myelitis).

This is the "general" rule created by the majority. The majority's exception to its general rule is discussed in Part VI, <u>infra</u>.

persons can generally pick the time when they wish to bring their cases. For them, as for Dr. Cloer, the majority proposes that there is no applicable statute of limitations in the Vaccine Act.

As a matter of grace and perhaps public health policy, the majority has created a new statute of limitations for non-Table petitioners under the Vaccine Act. Neither I nor the majority have the slightest sense of whether this move is wise, but it is wrong as a matter of law, as I will now explain.

١

Dr. Melissa Cloer received her third and final hepatitis B vaccination on April 3, 1997. Before that time, she had no significant medical issues and enjoyed generally good health. About a month after her final vaccination, she began to experience numbness in her left forearm and hand. She also began to experience what she described as an "electric shock sensation" with "electric like sensations going down the center of her back to both feet with forward head flexion." This sensation is known as Lhermitte sign, long recognized by the medical profession as a common symptom of MS. See Dorland's Illustrated Medical Dictionary 1700 (30th ed. 2003).<sup>4</sup>

In 1998, about a year after her final vaccination, Dr. Cloer sought treatment from Dr. Michael Andrew Meyer, an expert in the field of neurology with a specialty in MS. After an MRI examination, Dr. Meyer noted "probable early inactive non-progressive CNS [central nervous system] demyelination/MS," although he explained that her situation did not meet "formal diagnostic criteria for clinically definite MS." Even so,

2009-5052

Lhermitte sign is defined as the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in MS but also in compression and other disorders of the cervical cord.

because the MRI revealed lesions on the white matter of her central nervous system, Dr. Meyer concluded that Dr. Cloer could have MS, Singular Sclerosis, Lyme Disease, and acute disseminating encephalomyelitis, along with other demyelinating processes. Before the Special Master, Dr. Meyer testified that "I think that the first MS related symptom was the [Lhermitte] phenomenon that she had in 1997."

On May 6, 1999, Dr. Cloer received a neurological examination from Dr. Ted Colapinto. Dr. Colapinto noted Dr. Cloer's medical history and recorded her complaints of numbness in her face, arms and legs, and her difficulty in walking. He concluded that Dr. Cloer's symptoms likely represented a demyelinating disease, commenting that "[Dr. Cloer] is having waxing and waning neurological symptoms in multiple areas of her body. I fear that this may likely represent demyelinating disease."

Notwithstanding the possibility that her vaccinations may have caused the symptoms of MS she displayed, Dr. Cloer did not file her petition for compensation for a vaccine injury until September 16, 2005, nearly two years after she received a definite diagnosis of MS in November 2003.<sup>5</sup>

Before the Chief Special Master, and then the Court of Federal Claims, Dr. Cloer did not challenge the uncontroverted evidence that she had suffered symptoms of MS, and likely the manifestation of onset of MS, recognizable as such by the medical

As the majority notes, Dr. Cloer did not think there was a link between the hepatitis B vaccine and MS until she read an article in the September 2004 issue of Neurology. The article reported on a prospective study in France on the possibility of a causal connection between the hepatitis B vaccine and MS, referring to statistics from studies with "substantial methodologic limitations" showing an increased risk of MS after receipt of the hepatitis B vaccine. As the majority must concede, the prospective French study cannot constitute recognition by the medical community at large of a causal link between the hepatitis B vaccine and MS, and to suggest otherwise would be irresponsible. As noted above, the medical community at large denies any such link.

profession, more than three years before the filing of her petition, thus time-barring her petition. Her primary argument to the Chief Special Master was that the statute of limitations should not begin to run until she received a "clinically definite" diagnosis of MS in 2003.

Relying on precedent of this court, the Chief Special Master rejected Dr. Cloer's theory and held that the statute of limitations begins to run on the occurrence of the first symptom or manifestation of onset of the injury which the petitioner alleges has resulted from the vaccination. The Chief Special Master discussed at length our decision in Markovich v. Secretary of Health and Human Services, 477 F.3d 1353 (Fed. Cir. 2007), quoting that "the terms of the Vaccine Act demonstrate that Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." Cloer v. Sec'y of Health & Human Servs., 2008 WL 2275574, \*5 (Fed. Cl. Sp. Mstr. May 15, 2008). The Chief Special Master expressly dismissed Dr. Cloer's argument that a "clinically definite" diagnosis is required by Markovich:

Petitioner misreads <u>Markovich</u>. The Court's holding was that for purposes of §300aa-16(a)(2), "the first symptom or manifestation of onset" is the "first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." <u>Markovich</u>, 477 F.3d at 1360. There is no requirement that the <u>vaccine injury</u> be diagnosed.

Id. at \*9 (emphasis in original).

Just as before the Chief Special Master, Dr. Cloer focused her argument at the Court of Federal Claims on her failure to receive a "clinically definite" diagnosis of MS until 2003. In addition, Dr. Cloer argued to the court that "because the first set of

symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a 'vaccine injury.'"

The Court of Federal Claims rejected Dr. Cloer's theory that a "vaccine-related injury" cannot arise until the time when a causal link is shown between the claimed injury and the administration of a vaccine. Initially, the court noted that Dr. Cloer's statutory argument was essentially the same as her main argument requiring a "clinically definite" diagnosis, but merely masked within an issue of defining the statutory term "vaccine-related injury." Cloer v. Sec'y of Health and Human Servs., 85 Fed. Cl. 141, 149 (Fed. Cl. 2008). The court pointed out that deferring the statute of limitations until after recognition that the vaccine causes the alleged vaccine injury necessarily requires the alleged vaccine injury to be definitively diagnosed prior to the triggering of the statute. Id. The court ruled that Dr. Cloer's argument is "contrary to Markovich, which held that the limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming." Id. The court concluded that "[t]he Federal Circuit was very clear that diagnosis is not the test for the purposes of the statute of limitations." Id.

On appeal, Dr. Cloer renews her statutory interpretation theory. She maintains that no "vaccine-related injury" arises, for purposes of having a cause of action under the Vaccine Act, and for triggering its statute of limitations, until the medical community at large confirms a causal relationship between the injury and the administration of a vaccine. She cites this court's opinion in Markovich for support.

The Vaccine Act requires injured parties to file petitions within 36 months of the first symptom or manifestation of onset of the vaccine-related injury regardless of whether the petitioner is aware that the vaccine caused the injury. The "vaccine-related injury" is the injury that the petitioner alleges was caused by the vaccine.

In <u>Brice v. Secretary of Health and Human Services</u>, 240 F.3d 1367 (Fed. Cir. 2001), this court buttressed its conclusion that the Vaccine Act's statute of limitations permits no equitable tolling as follows:

In addition, we note that the statute of limitations [under the Act] begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner would not have known at that time that the vaccine had caused an injury. It would have been quite odd for Congress to allow a limitations period to run in cases in which a petitioner has no reason to know that a vaccine recipient has suffered an injury, but to provide for equitable tolling when a petitioner is aware that a vaccine has caused an injury but has delayed in filing suit.

240 F.3d at 1373. <u>Brice</u> thus holds that the statute of limitations is triggered by the first symptom or manifestation of onset of the injury, even without a known connection between the symptom and the vaccine in question, and, moreover, holds that Congress intended this result. Further, we recognized in <u>Brice</u> that the statute of limitations is a condition on the waiver of sovereign immunity, and that the waiver cannot be broader than "that which Congress intended." Id. at 1370.

In Markovich v. Secretary of Health and Human Services, 477 F.3d 1353 (Fed. Cir. 2007), the plaintiff argued that eye blinking episodes were not enough to trigger the statute of limitations because "the eye blinking symptom could not reasonably alert the Markoviches that anything was wrong." 477 F.3d at 1357. Rejecting the argument that "the standard for statute of limitations purposes should be a subjective one, focusing on

the particular view of a specific parent," <u>id.</u> at 1356, the court instead found that "[a]n objective standard is consistent with the statutory requirement that the first symptom or manifestation of onset of the injury begins the running of the statute of limitations." <u>Id.</u> at 1360 (emphasis omitted). Thus, "the first symptom or manifestation of onset, for the purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." <u>Id.</u> The court in <u>Markovich</u> did not require an objectively recognized causal link between the vaccine and the injury. In a nutshell, the dispute in <u>Markovich</u> only concerned recognition of the symptom or manifestation as related to the injury claimed. We held that the statute of limitations begins to run upon the occurrence of the first symptom or manifestation recognized by the medical profession at large as a symptom or manifestation of the injury claimed, in this case, MS. We expressly rejected any notion that the statute of limitations would start to run when a petitioner had reason to believe the vaccine had caused the injury.

When <u>Brice</u> and <u>Markovich</u> are read in tandem, the law is clear. "[T]he Vaccine Act's statute of limitations must be strictly and narrowly construed because it is 'a condition on the waiver of sovereign immunity by the United States and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended." <u>Markovich</u>, 477 F.3d at 1360 (quoting <u>Brice</u>, 240 F.3d at 1370). Thus, though the eye blinking in <u>Markovich</u> was "a symptom of a seizure disorder without any diagnosis," <u>id.</u> at 1357, it "was objectively recognized by the medical profession at large as constituting the first evidence of vaccine injury onset, i.e., the first symptom" of the seizure disorder suffered by the petitioner. <u>Id.</u> at 1360. It did not matter that the eye blinking was not recognized as being causally linked to

administration of a vaccine. <u>Id.</u> It only mattered that the eye blinking episodes were "connected to the injury of seizure disorder within ample time to have filed a timely claim." <u>Id.</u> at 1359. The court found the petition time-barred under section 300aa-16(a)(2). <u>Id.</u>

The court recently reaffirmed that Markovich keys to medical recognition of a link between the symptom and the injury claimed, not to medical recognition of a causal link between the injury and administration of a vaccine. See Wilkerson v. Sec'y of Dept. of Health and Human Servs., 593 F.3d 1343, 1345-46 (Fed. Cir. 2010). In Wilkerson, the petitioner argued that the court's holding in Markovich that the statute of limitations triggers upon "the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large" requires a contemporaneous recognition in the medical community that the symptom is linked to the alleged vaccine injury. Id. at 1345. This, of course, is the same argument Dr. Cloer makes in this appeal. The court flatly rejected Wilkerson's argument and stated that:

That statement in <u>Markovich</u>, however, was made to explain the court's rejection of a subjective standard for determining when the limitations period began to run based on the parent's perception of when that occurred, and adopting instead an objective standard based on the medical profession's recognition of when that occurred. We do not read <u>Markovich</u> as requiring in each case a showing of the date on which the medical profession at large had such a recognition.

<u>Id.</u> at 1345-46. Notwithstanding <u>Wilkerson</u>, the majority wants to interpret the same statement in <u>Markovich</u> as holding that <u>Markovich</u> requires a contemporaneous recognition in the medical community of a link between the vaccine and the injury. To do so, the court simply ignores the holding in <u>Wilkerson</u> that "the Act's time for filing

runs from 'the date of the occurrence of the first symptom or manifestation of onset,' not the date of its recognition." <u>Id.</u> at 1346.

Under the court's precedent, the Vaccine Act's statute of limitations starts running upon occurrence of the first symptom or manifestation of the alleged injury that is objectively recognized by the medical community as a symptom of the injury for which the petitioner seeks compensation. Putting this case into the correct Markovich analysis, the first objectively recognizable symptom of Dr. Cloer's MS by the medical profession at large was her Lhermitte sign in 1997. As correctly found by the Chief Special Master and the Court of Federal Claims, the statute of limitations began running on Dr. Cloer's Vaccine Program claim in 1997.

Ш

The Supreme Court has "repeatedly recognized" that "Congress generally drafts statutes of limitations to begin when the cause of action accrues." Graham County Soil & Water Conservation Dist. V. United States, 545 U.S. 409, 418 (2005). Indeed, the Supreme Court has refused to permit "the odd result" that a federal cause of action and statute of limitations arise at different times, "in the absence of any such indication in the statute." Reiter v. Cooper, 507 U.S. 258, 267 (1993). In Graham County, the Supreme Court was faced with a statutory scheme in which the relevant statute of limitations was subject to two plausible constructions. 545 U.S. at 419. The Supreme Court held that when differing but plausible constructions are possible, "we should adopt the construction that starts the time limit running when the cause of action [] accrues." Id.

In <u>Dodd v. United States</u>, decided the same day as <u>Graham County</u>, the Supreme Court was confronted with the one-year statute of limitations imposed by

2009-5052

Congress on habeas corpus petitions based on rights newly recognized by Supreme Court decisions. 545 U.S. 353 (2005). The statutory language provided that the oneyear period began to run on "the date on which the right asserted was initially recognized by the Supreme Court, if that right has been newly recognized by the Supreme Court and made retroactively applicable to cases on collateral review." Id. at 356-57 (quoting 28 U.S.C. § 2255 ¶ 6(3)). The Supreme Court held that the only natural reading of the statutory limitations period was for it to trigger upon the issuance of the decision initially recognizing the right in question. Id. at 357-58. Because the Supreme Court rarely determines retroactivity in its decisions initially recognizing a right, the Court acknowledged that when retroactivity is established more than one year after initial recognition of the right, the limitations period expires for petitioners before the cause of action accrues. Id. at 358-59. The Supreme Court held, however, that the general rule that a cause of action accrues at the same time the limitations period begins could be disregarded because Congress expressly and unambiguously provided for a different result. Id. at 359-60. The majority contends, wrongly I think, that Congress made a "deliberate choice" in the Vaccine Act to allow the cause of action for petitioners alleging non-Table injuries to accrue long before the statute of limitations begins to run, but to leave the general rule in force for petitioners alleging Table injuries.

IV

Under the Vaccine Act, there are two types of petitions, both of which are defined in the section of the Act titled "Petitions for Compensation." See 42 U.S.C. § 300aa-11. A person sustaining any "vaccine-related injury" must allege in their petition that they received a vaccine set forth in the Vaccine Injury Table. See 42 U.S.C. § 300aa-11(c).

For harms already recognized by the medical community, the Vaccine Act identifies the injuries commonly associated with each vaccine in the Vaccine Injury Table. See 42 U.S.C. § 300aa-14. If the alleged injury is listed in the Vaccine Injury Table then the petitioner can file a Table petition; otherwise the petitioner must file a non-Table petition.

A petitioner filing a Table petition must allege that he sustained, or significantly aggravated, an illness, disability, injury or condition set forth in the Vaccine Injury Table. See 42 U.S.C. § 300aa-11(c). The petitioner must also allege that the first symptom or manifestation of any such illness, disability, injury, or condition occurred within the time period after vaccine administration set forth in the Vaccine Injury Table. Id. These Table Injuries arise from an adequate consensus in the medical profession that a particular vaccine causes certain injuries. After a vaccine has been found often enough to have caused defined injuries with defined symptoms and manifestations occurring at defined times after vaccination, a Vaccine Injury Table entry is created. A petitioner seeking relief for any such injury no longer is required to allege that the vaccine caused the injury. A presumption of causation lies at the heart of Table Injury cases.

The Act also provides recovery for "non-Table" vaccine-related injuries. The required elements of a non-Table petition of course differ from the elements of a Table Injury petition. With regard to the "vaccine-related injury," a non-Table petitioner must allege that he "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine . . . . " 42 U.S.C. § 300aa-11(c). A non-Table petitioner must aver and demonstrate that a vaccine has caused the vaccine-related injury for which he seeks compensation.

In sum, the Act creates a cause of action for persons suffering a "vaccine-related injury." See 42 U.S.C. § 300aa-11(a). The Act specifies the required contents of the petition for compensation. 42 U.S.C. § 300aa-11(c). For injuries listed in the Vaccine Injury Table the petitioner merely identifies his vaccine and alleged injury and benefits from a presumption of cause, but the Act leaves it to the non-Table petitioner to specify his own vaccine-related injury and to shoulder the burden of proof of causation. Id.

The Act contains a single statute of limitations for all persons suffering a "vaccine-related injury," regardless of whether they file Table or non-Table petitions.

See 42 U.S.C. § 300aa-16(a)(2). The limitations statute applies "if a vaccine-related injury occurred as a result of the administration of [a] vaccine." Id. The phrase "occurred as a result of" necessarily refers to causation; presumptive causation in the instance of a Table Injury and alleged causation in non-Table petitions. In either instance, the petition must be filed within three years of "the date of the occurrence of the first symptom or manifestation of onset" of the claimed vaccine-related injury. Id.

For both Table and non-Table petitioners, the "occurrence of the first symptom or manifestation of onset" is a date on a calendar when an event occurred. In Table cases, the symptoms or manifestations of onset, and the timeframe during which the symptoms or manifestations must have occurred, are defined with specificity in the Table. See 42 U.S.C. § 300aa-14. For non-Table cases, the first symptom or manifestation of onset, under our precedent, requires consensus in the medical community that the symptom or manifestation reflects the specific injury claimed to have been caused by the vaccine. See Markovich, 477 F.3d at 1360. The cause of action

accrues, in both cases, upon the calendar date of the first symptom or manifestation, and the law requires the statute of limitations to begin to run on the same calendar date.

V

In light of the clear and binding precedent and the text of the Vaccine Act, the reader is surely asking how Dr. Cloer could possibly prevail. The answer lies in two steps taken by the majority. First the majority proposes: "Dr. Cloer interprets Markovich to mean that the medical community at large needs to recognize a link between the injury and the vaccine for the statute of limitations to begin running. We generally agree." See Maj. Op. at 6. As our recent decision in Wilkerson confirms, the majority and Dr. Cloer misread Markovich. As explained above, Markovich holds that the statute of limitations cannot run from just any symptom or manifestation; the triggering symptom or manifestation has to be one that the medical community at large recognizes as a sign of the claimed injury. Markovich does not help the majority because, under our precedent, the statute of limitations begins to run before the medical profession at large concludes that the vaccine has caused the injury claimed; the lack of consensus exists in nearly every non-Table case ever brought before this court. In short, under our precedent, specifically Brice, Markovich, and Wilkerson, Dr. Cloer cannot prevail.

Second, the majority is forced to confront the general rule that a statute of limitations begins to run at the same time the cause of action arises because the term "vaccine-related injury" appears throughout the Vaccine Act. It appears in the provisions creating the cause of action and specifying the statute of limitations. A petitioner cannot file a petition seeking relief under the Act unless a "vaccine-related injury" has occurred, see 42 U.S.C. § 300aa-11(a)(1), and the statute of limitations

begins to run three years after "the date of the occurrence of the first symptom or manifestation of onset. . .of such [vaccine-related] injury." See 42 U.S.C. § 300aa-16(a)(2). Because the majority defines a "vaccine-related injury" for purposes of the statute of limitations to mean "an injury that is causally connected by medical consensus to the vaccine in question," it necessarily understands that it can be criticized for erecting a bar that prevents petitioners (including Dr. Cloer) from filing causation-in-fact Vaccine Act petitions until such a time as there is consensus in the medical profession that the vaccine has caused the injury claimed. This would be so because if there is no "vaccine-related injury" without medical consensus on causation for statute of limitations purposes, see 42 U.S.C. § 300aa-16(a)(2), there can also be no "vaccine-related injury" for a cause of action until the medical consensus is formed, see 42 U.S.C. § 300aa-11(a)(1).

The majority, however, appreciates the effect of the general rule, which would bar the public from filing non-Table petitions until after a medical consensus states that a vaccine causes a particular injury. To avoid the general rule, the majority separates the time of accrual of non-Table causes of action from the time on which the statute of limitations begins to run for such cases. In short, the majority dictates that the general rule which links accrual with initiation of the statute of limitations applies for Table Injury petitions, but does not apply to non-Table petitions. As a practical matter, there no longer will be any statute of limitations for non-Table petitions, as they by definition allege injuries that the Secretary has not added to the Vaccine Injury Table due to a lack of consensus on causation. As a legal mater, this ignores the plain language of the

statute that creates a single cause of action for both Table and non-Table petitions. See 42 U.S.C. § 300aa-11(a)(1).

The majority seeks to justify its bifurcation by pointing out that, for Table petitions, the requirements include pleading the occurrence of a first symptom or manifestation of a defined vaccine injury within the Table-specified time, and the Vaccine Act statute of limitations uses the same language to trigger the running of the three-year period for bringing Vaccine Program claims. The majority then points out that the requirements for non-Table petitions, though arising under the same cause of action, do not mention "first symptom or manifestation" and instead require a petitioner to plead that the vaccine caused the claimed injury. This "deliberate choice" of different language for the contents of Table and non-Table petitions, according to the majority, proves beyond question that Congress intended to produce the "odd result" that for non-Table petitioners the cause of action can arise before the statute of limitations begins to run, and that, in fact, there may not even be a statute of limitations for most non-Table cases as the alleged injuries may never be objectively recognized as caused by the vaccine.

Notably, there is no evidence whatsoever in the legislative history of the Act that Congress made a "deliberate choice" of different language in the petition requirements in order to reject the normal rule that a cause of action arises at the same time the statute of limitations begins to run. The difference in language is required because the Vaccine Injury Table only contains injuries that the medical community has concluded are likely to be caused by certain vaccines. Thus, petitioners alleging a Table Injury must comply with the requirements of the Vaccine Injury Table, and the statute of

limitations runs from the defined time of the relevant symptom or manifestation listed in the Table. See 42 U.S.C. § 300aa-14. For non-Table injuries, there are no such medically agreed-upon symptoms or manifestations that appear within a defined timeframe after administration of the vaccine. Because Congress provided a single limitations period to run for all vaccine cases from the date of the first symptom or manifestation, see 42 U.S.C. § 300aa-16(a)(2), Congress left it to petitioners alleging non-Table injuries to prove when their first symptom or manifestation of onset occurred. Our case law has defined that date to require that the symptom or manifestation of onset be recognized by the medical profession as a symptom or manifestation of the injury claimed.

The Vaccine Act does not express a "deliberate choice" by Congress to enforce the statute of limitations for Table Injury petitioners, but indefinitely suspend or eliminate it for non-Table petitioners. Nor does the Vaccine Act present more than one interpretation of how its single statute of limitations works. There is simply no statutory support for the majority's reasoning that the single statute of limitations in the Vaccine Act somehow applies differently to petitioners depending on whether they allege Table or non-Table injuries.

The majority is plainly wrong to read the same statutory language to have two quite different meanings. Only by refusal to abide by our precedent (Markovich and Wilkerson), by misapplication of Supreme Court law (Dodd), and by creating two definitions for a single statutory term, can the majority save Dr. Cloer from the expired statute of limitations.

The majority conditions its "general rule" (that the statute of limitations does not run until a medical consensus recognizes a causal link between a vaccine and an injury) with what seems to be an afterthought. The condition is that, even if there is no medical consensus on causation, the statute of limitations may begin to run if a person has reason to believe that a vaccine caused the injury claimed.

Here, the majority stubs its toe over <u>Markovich</u> for the second time. If <u>Markovich</u> makes nothing else clear, it surely teaches that subjective considerations have no place in determining when the statute of limitations in the Vaccine Act begins to run.

The majority's add-on test is full of subjective issues: what did the would-be petitioner understand, and from where, and what was the basis for the supposed linking information, and would a reasonable person have so interpreted the information when other similarly situated persons understood the information differently? The only objective thing about the add-on test is that it triggers the statute of limitations on the date when the "medical information" is received. But under Markovich, the trigger date has to be the date upon which a symptom or manifestation occurred. Under the add-on test, Markovich's trigger is eviscerated.

Further, the add-on test ignores (and overrides) the plain holding in <u>Brice</u> that the statute of limitations begins to run before a petitioner suspects a causal link between a vaccine and the injury claimed. Instead, the majority's add-on test triggers the statute of limitations on the date that the petitioner first suspects a causal link.

Enough said. I need not belabor the wrongness of the majority's bewildering exception test for starting the statute of limitation on non-Table petitioners. I might add,

as a possible explanatory note to the readers, that Ms. Cloer did not present the majority's exception theory below, nor in the briefs or at oral argument here. Ms. Cloer argued only that the statute should not begin to run until the medical community arrived at a consensus causally linking the hepatitis B vaccine to MS. The illogic of her position and the chaos it would cause for bringing non-Table cases are evident, given the rule that a cause of action accrues and the statute of limitations begins to run at the same time. The majority overcomes Dr. Cloer's flawed argument first by refusing to follow Brice, Markovich and Wilkerson and by misapplying Dodd, and finally by trying to limit the damage done by its general rule by hiving onto it a subjective condition.

VII

The law of this circuit is clear: the statute of limitations in the Vaccine Program begins to run upon the first symptom or manifestation of a claimed vaccine injury, where that symptom or manifestation is recognized by the medical profession as a symptom or manifestation of the injury claimed. Requiring consensus in the medical profession that there is a causal link between the vaccine in question and the non-Table injury claimed has no place in the Vaccine Act. Such consensus arises, inter alia, from successfully litigated non-Table petitions.

A rule that the statute of limitations cannot begin to run for petitioners alleging non-Table injuries until medical consensus of a causal link arises creates havoc with the public's opportunity to file non-Table cases. Congress did not make a deliberate choice to bifurcate the Vaccine Act's non-Table petition requirements from the statute of limitations, and Congress surely could not have intended to so limit the availability of non-Table injury petitions as with the majority's definition of "vaccine-related injury."

To be correct, the court should define "vaccine-related injury" in the Vaccine Act to mean "the injury claimed by a petitioner to have been caused by administration of a vaccine." This matches the plain language of the Act and the general rule requiring Vaccine Program causes of action to accrue on the same date that the statute of limitations begins to run. This date is defined as the date of occurrence of the first symptom or manifestation of onset of the injury claimed, recognized as such by the medical profession. Under the correct test, Dr. Cloer's petition is time-barred.

For the foregoing reasons, I would affirm, and thus respectfully dissent.

20

2009-5052