United States Court of Appeals for the Federal Circuit

MELISSA CLOER, M.D.,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2009-5052

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

Decided: August 5, 2011

ROBERT T. FISHMAN, of Denver, Colorado, argued for petitioner-appellant on rehearing en banc. With him on the brief was MARI C. BUSH, Kaye and Bush, LLC, of Denver Colorado. Of counsel on the brief was ROBERT T. MOXLEY, Robert T. Moxley, P.C., of Cheyenne, Wyoming.

ANISHA S. DASGUPTA, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee on rehearing en banc. With her on the brief were TONY WEST, Assis-

tant Attorney General, TIMOTHY P. GARREN, Director, MARK W. ROGERS, Deputy Director, GABRIELLE M. FIELDING, Assistant Director. Of counsel on the brief were THOMAS M. BONDY, Attorney, and LYNN E. RICCIARDELLA, Trial Attorney.

MARTIN JAMES MARTINEZ, Martinez Law Office, of Napa, California, amicus curiae on rehearing en banc.

THOMAS NEVILLE, Ogborn Summerlin & Ogborn, LLC, of Denver, Colorado, for amicus curiae Colorado Trial Lawyers Association on rehearing en banc.

CLIFFORD J. SHOEMAKER, Shoemaker & Associates, of Vienna, Virginia, for amicus curiae National Vaccine Information Center on rehearing en banc.

KEVIN P. CONWAY, Conway, Homer & Chin-Caplan, P.C., of Boston, Massachusetts for amici curiae the Vaccine Injured Petitioners' Bar Association, et al. on rehearing en banc.

Before RADER, *Chief Judge*, NEWMAN, LOURIE, CLEVENGER, BRYSON, GAJARSA,[*] LINN, DYK, PROST, MOORE, O'MALLEY, and REYNA, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* CLEVENGER, in which *Chief Judge* RADER and *Circuit Judges* LOURIE, BRYSON, GAJARSA, PROST, MOORE, and O'MALLEY join. Dissenting opinion filed by *Circuit Judge* DYK, in which *Circuit Judges* NEWMAN, LINN, and REYNA join.

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[*] Judge Gajarsa assumed senior status on July 31, 2011.

CLEVENGER, *Circuit Judge*.

This case involves the interpretation and application of the statute of limitations in the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act"). The statute of limitations provides that if a vaccine-related injury occurred as a result of the administration of a vaccine, "no petition may be filed for compensation under the Program for [a vaccine-related] injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such [vaccine-related] injury." 42 U.S.C. § 300aa-16(a)(2).

Dr. Melissa Cloer received three Hepatitis-B ("Hep-B") vaccinations in 1996 and 1997. Years later, in 2005, Dr. Cloer filed a claim under the National Vaccine Injury Compensation Program ("Vaccine Program"), established by the Vaccine Act, seeking compensation for a multiple sclerosis ("MS") injury she alleged was caused by the administration of the vaccine. The Chief Special Master and Court of Federal Claims dismissed Dr. Cloer's claim as untimely because it was filed more then 36 months after her first symptom of MS occurred in 1997. *Cloer v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 141 (2008). Dr. Cloer appealed the decision and a panel of this court reversed, ruling in her favor. *Cloer v. Sec'y of Health & Human Servs.*, 603 F.3d 1341 (Fed. Cir. 2010), *vacated*, 399 Fed. App'x 577 (Fed. Cir. Oct 25, 2010). Subsequently, we granted the petition of respondent and appellee Secretary of Health and Human Services ("the government") to rehear the case en banc, vacated the panel opinion, *Cloer*, 399 Fed. App'x at 577, and requested additional briefs from the parties.

Consistent with the plain meaning of the statute, we hold that the statute of limitations of the Vaccine Act begins to run on the calendar date of the occurrence of the first medically recognized symptom or manifestation of onset of the injury claimed by the petitioner. Because Dr. Cloer's first symptom of MS, recognized as such at the time she suffered the symptom, occurred more than 36 months before the filing of her petition for compensation, her claim is time-barred. We today also reverse our previous holding in *Brice v. Secretary of Health & Human Services*, 240 F.3d 1367 (Fed. Cir. 2001) ("*Brice*"), which precluded application of the doctrine of equitable tolling in Vaccine Act cases, but reject the ground upon which Dr. Cloer seeks the benefit of equitable tolling in this case. We thus affirm the judgment of the Court of Federal Claims dismissing Dr. Cloer's claim as untimely.

In Part I below, we briefly address the background against which Congress enacted the Vaccine Act and in particular the statute of limitations chosen by Congress. Part II sets forth the essential facts of the case. In Part III, we discuss the proceedings before the Chief Special Master and the Court of Federal Claims. Part IV states our standard of review. In Part V, we set forth and respond to the three arguments Dr. Cloer presented to the court in her initial briefs and at the initial panel hearing of the case. In Part VI, we address and answer the three specific questions on which we requested additional briefing to the en banc court. Our en banc hearing focused on these questions.

I

In 1986, Congress established the Vaccine Program to provide compensation for vaccine-related injuries and deaths. *See* 42 U.S.C. § 300aa-10. The Vaccine Act

creates a "no-fault" Federal program for compensating injuries that are either presumed or proven to be causally connected to vaccines. The Vaccine Act arose because "the Nation's efforts to protect its children by preventing disease have been [] a success," but "[w]hile most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured." H.R. Rep. No. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. However, "at least in part as a result of [the] increase in litigation, the prices of vaccines [] jumped enormously." *Id.* Congress created the Vaccine Program to balance these two primary concerns that the tort system was failing to adequately compensate persons injured from vaccinations that were undergone for the public good and that excessive tort liability was unsustainably raising prices and discouraging vaccine manufacturers from remaining in the market. *See id.* at 3–7, *reprinted in* 1986 U.S.C.C.A.N. at 6344–48.

Congress noted "for the relatively few who are injured by vaccines — through no fault of their own — the opportunities for redress and restitution [were] limited, time-consuming, expensive, and often unanswered." *Id.* at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347. In response, Congress created the Vaccine Program to be "simple, and easy to administer" while also being "expeditious and fair." *Id.* at 7, 12, *reprinted in* 1986 U.S.C.C.A.N. at 6348, 6353. To compensate injured persons quickly and fairly, the Vaccine Act exempted petitioners from the tort requirements of demonstrating that a manufacturer was negligent or that a vaccine was defective. *Id.* at 12–13, *reprinted in* 1986 U.S.C.C.A.N. at 6353–54. For some injuries which the medical profession at large recognized as especially likely to be caused by vaccine administration, Congress exempted petitioners from the burden of

proving causation. *Id.* In sum, while the Vaccine Act does not prohibit a petitioner from going to state court after completion or unfair delay of the compensation proceedings, the Vaccine Program was intended to "lessen the number of lawsuits against manufacturers" and "provide[] relative certainty and generosity" of compensation awards in order to satisfy petitioners in a fair, expeditious, and generous manner.[1] *Id.*

The legislative history shows that Congress considered alternative statutes of limitation for claims filed in the Vaccine Program. The House of Representatives version, H.R. 1780, introduced on March 27, 1985, provided that "any claim under this title that is filed more than two years after the first manifestation of a vaccine-related injury shall be barred." National Childhood Vaccine-Injury Compensation Act of 1985, H.R. 1780, 99th Congress § 2112(a) (1985). A subsequent Senate bill, S. 827, introduced on April 2, 1985, took a different approach. Unlike H.R. 1780, S. 827 did not trigger the statute of limitations upon the occurrence of the first manifestation of an injury. Instead, it provided that actions for compensation "shall be barred if the petitioner fails to file the action . . . within 5 years after the occurrence of the compensable complication or residual effect of the illness, disability [or] injury." National Childhood Vaccine Injury Compensation Act of 1985, S. 827, 99th Congress § 2106(a) (1985). In addition, the 5 year statute did not apply at all if a petitioner could demonstrate that she either (a) did not receive the parent information about vaccines required under the bill, or (b) did not know the

[1] The Supreme Court has held that the Vaccine Act preempts state law vaccine design defect claims. *See Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1075 (Feb. 22, 2011).

complication or effect of her injury was compensable under the program. *Id.* § 2106(b). S. 827 set forth a Vaccine Table, listing specific vaccines, specific injuries, and specific time periods for the first symptom or manifestation of onset of a listed injury after administration of a vaccine. Compensation was required if a petitioner could meet the specified time periods for a listed vaccine and injury. But if a petitioner could not meet the time period requirements, the petitioner could still prevail if "the petitioner demonstrates on the basis of credible evidence" that the injury "suffered by petitioner was caused by a vaccine listed in the Vaccine Injury Table." *Id.* § 2105(a)(2). The Senate bill thus incorporated both strict liability and causation in fact liability.

Ultimately, Congress settled on the former of the two approaches. H.R. 5546 (September 18, 1986) followed the approach of H.R. 1780, and provided that if a vaccine-related injury occurred as a result of the administration of a vaccine listed on the Vaccine Injury Table, "no petition may be filed for compensation under the Program after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury." National Childhood Vaccine Injury Act of 1986, H.R. 5546, 99th Congress § 2116(a)(1)(B) (1986). Both the House and Senate passed H.R. 5546, as incorporated into S. 1744, and the statute of limitations was signed into law on November 14, 1986 as part of the National Childhood Vaccine Injury Act of 1986. Pub. L. No. 99-660, 100 Stat. 3743 (1986).

The legislative record is thus clear that Congress chose to trigger the statute of limitations from the date of the occurrence of the first symptom or manifestation of onset of an injury, not from the date of the injury itself. Further, Congress was alerted to the consequences of its

choice. For example, at a July 18, 1985 Senate Hearing before the Committee on Labor and Human Resources, the president of Dissatisfied Parents Together ("DPT") submitted testimony comparing the different pending House and Senate bills. *See To amend the Public Health Service Act to provide for the compensation of children and others who have sustained vaccine-related injuries, and for other purposes: Hearing on S. 827 before the S. Comm. on Labor and Human Res.*, 99th Cong. 41 (1985) (statement of Jeffrey H. Schwartz, President of DPT). The testimony noted that under the Senate proposal, S. 827, a claim "must be filed within five years of occurrence of injury" but "[t]his limitation does not apply if claimant did not receive the required parent information packet or did not know the injury was compensable." *Id.* at 56. The testimony sharply contrasted this with the pending House proposal, H.R. 1780, under which a claim "must be filed within 2 years after first manifestation of injury" and "[t]his limit applies regardless of when claimant discovered the causal link between the injury and the vaccine." *Id.*

From the above, we note that the Vaccine Act, as enacted, reflects a specific decision by Congress that the Act's statute of limitations would begin to run not on the date of injury (as is sometimes seen in other contexts), but on the date that injury first became symptomatic or manifested.

II

The essential facts of this case are undisputed. Petitioner Melissa Cloer is a physician with MS.[2] Prior to

[2] MS is "a disease in which there are foci of demyelination of various sizes throughout the white matter of

receiving her Hep-B immunizations in 1996 and 1997, Dr. Cloer had no significant medical issues and enjoyed generally good health. Dr. Cloer received her first two doses of Hep-B vaccine without major incident and received her third and final vaccination on April 3, 1997. Approximately one month thereafter 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) (defining Lhermitte sign as the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord).

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

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the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term *multiple* also refers to remissions and relapses that occur over a period of many years." *Borrero v. Sec'y of the Dep't of Health & Human Servs.*, No. 01-417V, 2008 WL 4527837, at *1 n.4 (Fed. Cl. Sp. Mstr. Sept. 24, 2008) (quoting *Dorland's Illustrated Medical Dictionary* (30th ed. 2003) at 1669).

clinically definite MS." *Cloer*, 85 Fed. Cl. at 144. Even so, 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/or acute disseminating encephalomyelitis, along with other demyelinating processes. *Id.* at 143. Before the Chief Special Master, Dr. Meyer testified that Dr. Cloer suffered from MS in 1998 because "the first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997." *Cloer v. Sec'y of the Dep't of Health & Human Servs.*, No. 05-1002V, 2008 WL 2275574, at *6 (Fed. Cl. Sp. Mstr. 2008) ("*Special Master Opinion*"), *aff'd*, 85 Fed. Cl. 141 (2008).

On May 6, 1999, Dr. Cloer received a neurological examination from Dr. Ted Colapinto. *Cloer*, 85 Fed. Cl. at 144. 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. *Id.* 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." *Sp. Mstr. Op.*, 2008 WL 2275574, at *6. Dr. Cloer continued to suffer from numerous, but somewhat fleeting, symptoms. In May 2004, Dr. Cloer applied for and was awarded monthly Social Security disability benefits. Dr. James P. Metcalf conducted a comprehensive medical examination at the time 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." *Id.* at *2.

Dr. Cloer claims that even in 2003 upon receiving a diagnosis of MS she remained unaware of any causal association between the Hep-B vaccine and MS. Dr. Cloer testified that she first became aware of the possible link when she read an editorial and prospective French study in the September 2004 issue of *Neurology*. Cloer Aff., J. App'x 270–71; *see also* Robert T. Naismith, M.D. & Anne H. Cross, M.D., *Does the hepatitis B vaccine cause multiple sclerosis?*, 63 Neurology 772 (Sept. 2004); *and* Miguel A. Hernán, M.D. et al., *Recombinant hepatitis B vaccine and the risk of multiple sclerosis*, 63 Neurology 838 (Sept. 2004). On October 11, 2004, Dr. Cloer reported to the Vaccine Adverse Event Reporting System that she had experienced numbness and tingling after her first two Hep-B vaccinations, followed by "Lhermitte's" approximately one month after her third vaccination. *Sp. Mstr. Op.*, 2008 WL 2275574, at *1–2. Dr. Cloer subsequently filed her petition for compensation for a vaccine injury on September 16, 2005. *Cloer*, 85 Fed. Cl. at 144.

III

Before the Chief Special Master, Dr. Cloer did not challenge the evidence that she had suffered symptoms of MS, and likely the manifestation of onset of MS, more than three years before the filing of her petition, thus time-barring her petition. Instead, Dr. Cloer's primary argument to the Chief Special Master was that the statute of limitations did not begin to run against her until after receipt of a "clinically definite" diagnosis of MS. Dr. Meyer, Dr. Cloer's treating physician, explained that because Dr. Cloer's symptoms did not amount to a clinically definite diagnosis of MS until November 2003, Dr. Cloer was unaware of her injury until this time, and thus also could not have been aware that the Hep-B vaccine caused her injury. Since Dr. Cloer's petition was filed in

September 2005, she argued it was filed within the 3 year statute of limitations of when she was first diagnosed with MS. Essentially, Dr. Cloer asked the Chief Special Master to read the phrase "symptom or manifestation of onset" as only triggering upon a symptom or manifestation that is clinically diagnosed as the disease itself.

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 that the petitioner alleges has resulted from the vaccination. The Chief Special Master discussed at length our decision in *Markovich v. Secretary of Health & 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." *Sp. Mstr. Op.*, 2008 WL 2275574, at *5 (quoting *Markovich*, 477 F.3d at 1358). The Chief Special Master expressly dismissed Dr. Cloer's argument that a "clinically definite" diagnosis is required by *Markovich*:

> Petitioner misreads *Markovich*. 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." *Markovich*, 477 F.3d at 1360. There is no requirement that the *vaccine injury* be diagnosed.

Id. at *9.

Just as she did 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, elaborating that "because the first set of symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a 'vaccine injury.'" She also pointed to 42 U.S.C. § 300aa-11(c)(1)(D)(i), which contains a petition content requirement stating that "a petition for compensation . . . for a vaccine-related injury . . . shall contain . . . an affidavit, and supporting documentation, demonstrating that the person . . . suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after administration of the vaccine . . . ." Because of this requirement, she argued that the statute of limitations does not begin to run until a petitioner has suffered the residual effects or complications for more than 6 months after administration of the vaccine. She alleged as a matter of fact that she did not meet this requirement until late in 2003, which if true, would bring her 2005 petition within the statute of limitations. Finally, she asked for relief by way of equitable tolling, notwithstanding our opinion in *Brice* that equitable tolling is not available under the Vaccine Act. She sought relief under equitable tolling because she was not diagnosed with MS until 2003 and there was no reason for her to suspect a vaccine link to MS until 2004. *Cloer*, 85 Fed. Cl. at 145, 149.

The Court of Federal Claims rejected Dr. Cloer's arguments. The court understood Dr. Cloer's primary argument to be that a "vaccine-related" injury could not occur based on the first occurrence of a symptom of the injury, but instead would arise from "a physician's ultimate diagnosis" that the "vaccine caused the complained-of specific injury." *Id.* at 149. The court held her argu-

ment "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.* Referring to the trigger for the statute of limitations, the court quoted from *Markovich*: "Congress intended the limitations 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." *Id.* (quoting *Markovich*, 477 F.3d at 1358). The court also relied on the observation in *Brice* that the statute 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." *Brice*, 240 F.3d at 1373.

The court held that the Lhermitte sign in 1997 was the first symptom of Dr. Cloer's MS and triggered the statute of limitations, *Cloer*, 85 Fed. Cl. at 147–49, which the court held is unaffected by the 6 month requirement in 42 U.S.C. § 300aa-11(c)(1)(D)(i). The court found Dr. Cloer's petition is time barred and affirmed the Chief Special Master. The court also noted that *Brice* bars Dr. Cloer's request for relief by way of equitable tolling of the statute of limitations. *Id.* at 149, 152.

IV

We review the Special Master's decision under the same arbitrary and capricious standard as did the Court of Federal Claims. 42 U.S.C. § 300a-129(e)(2)(B); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). We owe no deference on questions of law, *Whitecotton ex rel. Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1106 (Fed. Cir. 1996), but

review factual findings for clear error, *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1523 (Fed. Cir. 1991). In this case we are concerned with issues of statutory interpretation: what constitutes a "vaccine-related injury" and what event triggers the running of the Vaccine Act's statute of limitations.

V

In her initial appeal briefs, Dr. Cloer abandons her argument that no vaccine-related injury can occur before a clinically definite diagnosis is made. Instead, she argues that a "vaccine-related injury" for purposes of the Vaccine Act and its statute of limitations cannot occur until the medical community at large understands and recognizes the causal relationship between the claimed injury and the administration of a vaccine. Dr. Cloer alleges that because an injury cannot be alleged as "vaccine-related" until after this recognition, any other interpretation of the statute of limitations would be unfair. Dr. Cloer also argues that the statute of limitations should not trigger until after a petitioner has suffered from six months of consistent, clinically-related symptoms, citing 42 U.S.C. § 300aa-11(c)(1)(D)(i). Otherwise, because a petitioner is required to attest, as a petition requirement, to residual effects or complications lasting "more than 6 months after the administration of the vaccine," Dr. Cloer argues the statute of limitations would be unfairly reduced to less than 36 months. Finally, Dr. Cloer requests that this court reconsider the holding in *Brice* that equitable tolling is not available under the Vaccine Act.

As noted above, the panel opinion ruled in Dr. Cloer's favor, accepting her argument that the statute of limitations begins to run upon formation of a consensus in the

medical community that a vaccine causes the injury claimed. The panel did not reach Dr. Cloer's other arguments. Because the panel opinion is vacated, we respond to her original arguments in subparts A, B, and C below.

A

We first address Dr. Cloer's primary argument on appeal that a "vaccine-related" injury only arises upon a medically established causal link between an injury and the vaccine in question. Our analysis must begin with the plain language of the statute. The Vaccine Act states that "if a vaccine-related injury or death 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" of injury. 42 U.S.C. § 300aa-16(a)(2). The plain language of the Vaccine Act thus requires injured parties to file Vaccine Program petitions within 36 months of the date of the first symptom or manifestation of onset of the "vaccine-related injury."

The Act defines "vaccine-related injury or death" as:

> [A]n illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

42 U.S.C. § 300aa-33(5). As both Dr. Cloer and the government recognize, this definition does not provide definitive guidance for us on the specific argument put forward by Dr. Cloer. However, "[a]s a rule, a definition which

declares what a term 'means' . . . excludes any meaning that is not stated." *Burgess v. United States*, 553 U.S. 124, 130 (2008) (quoting *Colautti v. Franklin*, 439 U.S. 379, 392–93 n.10 (1979)). Thus, we begin with a hesitation to read a causal link requirement into the term when no such link is included in the explicit statutory definition. Moreover, "[a] term appearing in several places in a statutory text is generally read the same way each time it appears." *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994). As the term "vaccine-related injury" appears throughout the Vaccine Act, we must analyze the effects of adopting Dr. Cloer's contention that the term always requires recognition in the medical community of a causal link between the vaccine and the injury.

The Vaccine Act provides a Vaccine Injury Table of vaccines and the injuries commonly associated with the use of each vaccine. *See* 42 U.S.C. § 300aa-14; *see also* 42 C.F.R. § 100.3(a) (containing updated Table). For injuries listed in the Table, generally referred to as "Table injuries," a petitioner need only prove that the first symptom or manifestation of onset occurred within the time period after vaccine administration set forth in the Vaccine Injury Table in order to receive compensation, *see* 42 U.S.C. § 300aa-11(c)(1)(C)(i), unless the government can prove that a factor unrelated to the vaccination actually caused the illness, disability, or condition. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing 42 U.S.C. § 300aa-13(a)(1)(A),(B)). For these injuries recognized by the medical community as linked to vaccine administration, Congress eliminated the petitioner's burdensome proof requirement. For "non-Table injuries," a petitioner must prove the injury was caused by the vaccine. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii).

A "vaccine-related injury" is the subject of the petition for compensation in both Table and non-Table cases. For Table injury cases, the statute specifically defines for each vaccine the "vaccine-related" injuries for which compensation is assured. For example, a petitioner who suffers from a symptom of an anaphylactic shock injury within four hours of receiving a DTaP vaccine is presumed to have been injured by the vaccine. *See* 42 C.F.R. § 100.3(a). But for non-Table injuries, a petitioner must file an affidavit and supporting documentation demonstrating that the "vaccine-related injury" for which compensation is sought was caused by a vaccine.[3]

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[3] We note that a petitioner's pleading burden is, of course, lower than the preponderance burden that must be met in order to receive compensation. *See* 42 U.S.C. § 300aa-13(a)(1) ("Compensation shall be awarded to a petitioner if the special master or court finds . . . (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition."). To meet the preponderance standard, a petitioner must show that the vaccination brought about her injury by providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. A petitioner only needs to "provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case" and "the explanation need only be legally probable, not medically or scientifically certain." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quotation marks omitted).

Congress clearly contemplated that petitioners might not be able to meet the burden to demonstrate causation-in-fact by preponderance at the time the petition is filed. This is easily seen in the statute as a Vaccine Act petitioner, even if ultimately unsuccessful, can

The statute of limitations for the Act uses the same "vaccine-related injury" terminology.

> 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 . . . .

42 U.S.C. § 300aa-16(a)(2) (emphasis added).

Dr. Cloer would read "vaccine-related injury" throughout the Vaccine Act to require that the alleged injury must be objectively recognized by the medical community as related to the vaccine before it can be deemed a "vaccine-related injury." Accordingly, the statute of limitations would not begin to run on prospective petitioners until after this recognition is established. However, the statute is clear that only "*[a] person who has sustained a vaccine-related injury* . . . may, if the person meets the requirements of subsection (c)(1) of this section [listing the required elements of a petition], file a petition for compensation under the Program." 42 U.S.C. § 300aa-11(b)(1)(A) (emphasis added). Under Dr. Cloer's view that no vaccine-related injury exists until there is consensus in the medical community of a causal link between an injury and a vaccine, the key element of the

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still receive compensation to cover reasonable attorneys' fees and other costs incurred in the proceeding "if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim." 42 U.S.C. § 300aa-15(e)(1).

petition for compensation — the vaccine injury — does not arise until the requisite medical consensus exists. For example, in this case, it is agreed that even now there is not medical consensus of a causal link between the Hep-B vaccine and MS. Thus, under Dr. Cloer's definition of vaccine-related injury, she, like the great majority of non-Table injury petitioners, would lack standing to file a petition until the requisite medical consensus arises. Any construction that would result in a party suffering from a non-Table injury to be unable to file a petition because the alleged injury is not recognized by the medical community at large cannot be what Congress intended.[4]

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[4] The first time an injury is causally linked with a vaccine often occurs as a result of a successful non-Table petition. Over time, as injuries occur throughout the population and are linked to a vaccine, the medical community begins to recognize a link between the vaccine and the injury. This can occur through studies published in medical journals or as a result of government research. Often, however, before the link is sufficiently established to become generally recognized by the medical community, petitioners are able to muster enough evidence to receive compensation from the Vaccine Program. *See, e.g.*, *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) ("[R]equiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence . . . and negates the system created by Congress' through the Vaccine Act.") (quoting *Althen*, *supra* note 4, 418 F.3d at 1279–80) (omission in original); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) ("[R]equiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, *or general acceptance in the scientific or medical communities* to establish a logical sequence of cause and effect is contrary to [precedent].") (emphasis added). Finally, because a successful "causation in fact" petition can be the first established link between a vaccine and a non-Table injury, it must be allowed to be filed before an

Further, settled law establishes a firm default rule that a cause of action arises at the same time the statute of limitations begins to run on the cause. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 418 (2005) ("Congress generally drafts statutes of limitations to begin when the cause of

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objective recognition is understood by the medical community at large.

As noted above, *Althen* sets forth the three pleading requirements for a non-Table injury petition. These requirements have not been insurmountable for petitioners seeking compensation for MS caused by the Hep-B vaccine. At least 35 petitions alleging MS caused by the Hep-B vaccine have resulted in public opinions to date, and at least 14 of those petitioners have been successful. Many of the successful petitioners filed their petitions in 1999. *See, e.g.*, *Fisher v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-432V, 2009 WL 2365459 (Fed. Cl. Sp. Mstr. Jul. 13, 2009) (petition filed Jul. 2, 1999); *Adler v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-608V, 2008 WL 5068931 (Fed. Cl. Sp. Mstr. Nov. 18, 2008) (petition filed Aug. 4, 1999); *Doe/23 v. Sec'y of the Dep't of Health & Human Servs.*, 2008 WL 4865974 (Fed. Cl. Sp. Mstr. Oct. 16, 2008) (petition filed May 17, 1999); *Barillaro v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-408V, 2008 WL 2465794 (Fed. Cl. Sp. Mstr. May 28, 2008) (petition filed June 28, 1999); *Doe/13 v. Sec'y of the Dep't of Health & Human Servs.*, 2008 WL 926930 (Fed. Cl. Sp. Mstr. Mar. 31, 2008) (petition filed May 14, 1999); *Doe/07 v. Sec'y of the Dep't of Health & Human Servs.*, 2007 WL 3306493 (Fed. Cl. Sp. Mstr. Nov. 2, 2007) (petition filed Jul. 16, 1999); *Augustynski v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-611V, 2007 WL 3033614 (Fed. Cl. Sp. Mstr. Sep. 28, 2007) (petition filed Aug. 4, 1999); *Phippen v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-435V, 2006 WL 5631725 (Fed. Cl. Sp. Mstr. Dec. 5, 2006) (petition filed Jul. 2, 1999); *Werderitsh v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Sp. Mstr. May 26, 2006) (petition filed May 18, 1999).

action accrues."). The Supreme Court has recognized that Congress is free to provide the "odd result" of a cause of action that arises at a time different from the beginning of a statute of limitations, *see Reiter v. Cooper*, 507 U.S. 258, 267 (1993), but only by explicitly rejecting the default rule. *See Dodd v. United States*, 545 U.S. 353, 359–60 (2005). Under Dr. Cloer's interpretation of a vaccine-related injury, her claim for compensation would accrue (thus letting her petition go forward) before medical consensus as to causation exists. To succeed, she must show that Congress meant to divorce the date of accrual of her cause of action from the date that the statute of limitations begins to run. She faces the heavy burden of proving that Congress intended the odd result of breaching the firm default rule. Nothing in the text of the Vaccine Act demonstrates that Congress made a deliberate choice to allow a cause of action for a vaccine-related injury to accrue before the Vaccine Act's statute of limitations begins to run.[5]

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[5] The foregoing discussion responds to arguments made by Dr. Cloer in her initial briefs and at oral argument before the panel concerning the meaning of "vaccine-related injury." In the en banc proceedings, she preserved the consensus argument from her initial briefs, but retreated somewhat from her initial stance, arguing that the statute of limitations runs and her cause of action arises instead upon "recognition" by the medical community of a causal link between an injury and a vaccine. Her "recognition" trigger requires less proof than consensus in the medical community. Her rephrasing thus keys accrual of her claim not to medical agreement as to cause, but to whether there is reason to know that a vaccine may have caused her injury. As rephrased, her argument depends upon a discovery rule being found in the Vaccine Act statute of limitations. We address that question in part VI.A below.

In addition, we note an unintended result that would occur were we to accept Dr. Cloer's argument that the statute of limitations for a non-Table injury does not begin to run until the medical community at large recognizes a causal link between a vaccine and a claimed injury. Congress recognized that the Vaccine Injury Table could be revised such that a person not previously eligible for compensation might become eligible to seek compensation for the newly-recognized Table Injury. In such instances, Congress wrote a special statute of limitations that permits a claim for compensation under the revised Vaccine Injury Table if a vaccine-related death or injury occurred less than 8 years before the revision of the Vaccine Injury Table and the claim is filed within 2 years after the effective date of the revision. *See* 42 U.S.C. § 300aa-16(b). If Dr. Cloer's trigger for the statute of limitations for a non-Table injury were accepted, she and those similarly situated would enjoy a more generous statute of limitations than Congress provided for Table Injury petitioners, for whom causation is presumed. We do not think Congress would have intended such a result.

The correct interpretation of the term "vaccine-related injury" is plain from the language of the statutory provisions that set forth the statute of limitations and the requirements for a petition. For Table injury cases where causation is presumed, the vaccine-related injury is the injury specified in the Vaccine Injury Table for which a petitioner seeks compensation. For non-Table injury cases where the petitioner must establish causation, the vaccine-related injury is the injury which the petitioner avers is caused by the vaccine. The statute of limitations on its face requires a petition for compensation to be filed within 36 months after the date of occurrence of the first symptom or manifestation of onset of vaccine-related injury. The statutory language, however, begs the ques-

tion of the test for recognition of the existence of a symptom or manifestation of onset of an injury. In short, who decides if a symptom or manifestation of an injury has occurred? We were faced with, and decided, that question in *Markovich*. 477 F.3d at 1360.

In that case, the parents of a child sought compensation for seizure disorders suffered by the child after administration of a vaccine. On the day of administration of the vaccine, July 10, 2000, the child began to rapidly blink her eyes. The eye-blinking episodes continued for more than a month and culminated in a grand mal seizure. *Id.* at 1354–55. Under recognized standards of the medical profession at large, the eye-blinking episodes were symptoms of the seizure activity for which compensation was sought. The government argued that the first of such symptoms, on July 10, 2000, triggered the statute of limitations and required dismissal of the petition, which had been filed more than three years from the July 10 date. The petitioners argued for a subjective test to determine when the first symptom occurs. Accordingly, they argued that the symptom of the injury had to be understood as such by the parents. Because they thought the first blinking episodes were simply everyday events meaning the child was tired, they argued that the statute of limitations did not begin to run until August 30, 2010, when they became aware that their child had an injury. Under their view of how a symptom should be determined, their petition was timely. *Id.* at 1356–57.

Markovich thus resolved the dispute:

> A subjective standard that focuses on the parent's view would result in an uneven and perhaps overly broad application of the statute of limitations dependent entirely on the subjective percep-

> tions of lay persons having widely varying degrees of medical awareness or training. On the other hand, an objective standard that focuses on the recognized standards of the medical profession at large treats petitioners equally, without regard to their individual medical awareness. An 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, as well as the cases . . . that have consistently construed the Vaccine Act to include subtle symptoms that would be recognizable to the medical profession at large but not necessarily to the parent.

477 F.3d. at 1360.

We thus held that the first symptom or manifestation of onset of a vaccine-related injury is "the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Id.* The analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought, and the symptom or manifestation of onset must be recognized as such by the medical profession at large.

B

In order to file a petition, a claimant must attest, *inter alia*, that she has "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i). Dr. Cloer argues that because her symptoms were fleeting, she

could never have met this requirement until late 2003 when her symptoms were continuous and related enough to be deemed "residual effects or complications" of her Hep-B vaccinations. The government responds that the petition requirements are wholly separate from the statute of limitations and should not be read to extend the filing date of the petition beyond 36 months.

We agree with the government that the 6 month requirement is a condition precedent to filing a petition for compensation, not a limitation on the 3 year statute of limitations. The 6 month provision is a petition content requirement to which no reference is made in the statute of limitations. Had Congress intended to adjust the statute of limitations in light of the petition content requirement, we think it would have done so in the statute of limitations. We thus agree with the Court of Federal Claims that there is no support for Dr. Cloer's argument in the text of the Act, nor any in the case law. Congress included the 6 month petition requirement "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. Rep. No. 100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, -373. Thus, this provision, along with the other petition requirements, is intended to restrict eligibility to the compensation program, not to act as a statutory tolling mechanism for the statute of limitations.

C

Finally, Dr. Cloer requested in her initial briefs that equitable tolling be made available and applied to the facts of her case, in spite of the binding precedent of *Brice*. Although the argument was rejected by the Chief Special Master and the Court of Federal Claims, and not ad-

dressed by the panel which initially heard the case, the en banc court decided to reconsider *Brice* through the lens of specific questions that were put to the parties. Equitable tolling is considered below, in parts VI.B and C.

VI

In an October 25, 2010 order, the court vacated its May 6, 2010 opinion and reinstated the appeal. We requested the parties to file new briefs addressing the following questions:

(a) Should the discovery rule, used for example in medical malpractice cases, *see United States v. Kubrick*, 444 U.S. 111, 120 (1979) and *TRW, Inc. v. Andrews*, 534 U.S. 19, 27–28 (2001), apply to 42 U.S.C. § 300aa-16(a)(2) so that the statute of limitations does not begin to run until the claimant has knowledge or reason to know of the cause of her injury?

(b) Should *Brice v. Secretary of Health & Human Services*, 240 F.3d 1367 (Fed. Cir. 2001) be overruled to permit equitable tolling of 42 U.S.C. § 300aa-16(a)(2)?

(c) If equitable tolling is permitted, do the circumstances of this case support equitable tolling?

Upon reviewing the briefs of the parties the court heard argument on May 10, 2011. We now address each question put to the parties.

A

Whether to incorporate a discovery rule in the Vaccine Act's statute of limitations requires us to decide when the

statute of limitations is triggered. Absent a discovery rule, the plain words of the statute trigger the statute of limitations on the date of the first symptom or manifestation of onset of the injury claimed. If, instead, the statute of limitations does not begin to run until a petitioner knows or has reason to know a vaccine has caused her vaccine-related injury, the plain words of the statute must be adjusted. Whether or not to incorporate a discovery rule boils down to a matter of interpretation of the statute of limitations.[6]

As previously stated, the statute of limitations contained in the Vaccine Act reads:

> In the case of—
>
> . . .
>
> (2) 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

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[6] As a matter of caution, we must recognize and respect that a "statute of limitations 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 what Congress intended." *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000) (quoting *Block v. North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273, 287 (1983) (internal quotation omitted)). We have consistently followed this admonition when interpreting the Vaccine Act's statute of limitations. *See, e.g.*, *Markovich*, 477 F.3d at 1360; *Brice*, 240 F.3d at 1370.

> manifestation of onset or of the significant aggravation of such injury[.]

42 U.S.C. § 300aa-(16)(a). Dr. Cloer makes two arguments for why a discovery rule should be read into the Vaccine Act. First, she argues that the text of the statute of limitations amounts to a discovery accrual rule requiring a claimant to know both the fact and the cause of her injury. Second, she argues that the language of the Vaccine Act is compatible with an implied discovery accrual rule. *See TRW*, 534 U.S. at 27 ("[L]ower federal courts generally apply a discovery accrual rule when a statute is silent on the issue.") (quotation marks omitted); *see also Rotella v. Wood*, 528 U.S. 549, 555 (2000) ("Federal courts, to be sure, generally apply a discovery accrual rule when a statute is silent on the issue.").

For the reasons that follow, we conclude that the Vaccine Act does not itself contain a discovery rule, and, applying the relevant analytic tools provided by the Supreme Court, conclude also that a discovery rule cannot be read by implication into the Vaccine Act's statute of limitations. We first address Dr. Cloer's argument that the Act contains its own discovery rule.

Dr. Cloer specifically highlights the phrase "if a vaccine-related injury occurred as a result of the administration of [the] vaccine" in the statute of limitations. Dr. Cloer argues that the inclusion of this phrase in the statute means that a non-Table injury claim does not accrue until the claimant has knowledge that the injury "occurred as a result of the administration of [the] vaccine." Otherwise, Dr. Cloer posits, the phrase would be superfluous. The government counters that the phrase is essential to breathe meaning into the term "vaccine-related injury" as used in the statute of limitations. The

government reads the accrual of a non-Table injury (and thus the beginning of the statute of limitations) to arise on the "date of occurrence of the first symptom or manifestation of onset" of the injury the claimant alleges to be "vaccine-related" for having "occurred as a result of the administration of [the] vaccine."

As an initial matter, Dr. Cloer is correct that "we construe statutes, where possible, so as to avoid rendering superfluous any parts thereof." *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991). However, the clearly dominant language in the statute of limitations is "the date of occurrence of the first symptom or manifestation of onset." As the Supreme Court has noted, the date of the occurrence of the first symptom is forceful — "[t]here cannot be two first symptoms or onsets of the same injury" — and the first symptom "signal[s] the injury's onset." *Shalala v. Whitecotton*, 514 U.S. 268, 274 (1995). We do not think that dominant phrase can be overcome by inferring a discovery requirement from the phrase "occurred as a result of the administration of [the] vaccine." We therefore reject Dr. Cloer's argument that the statute of limitations already contains a discovery rule that would key the accrual of a non-Table injury claim and the beginning of the statute of limitations to a claimant's discovery that the vaccine caused her injury.[7]

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[7] We note that Congress knows how to legislate an explicit discovery rule. For example, when providing a cause of action to quiet title of property in which the United States claims an interest, Congress mandated that "[a]ny civil action under this section . . . shall be barred unless it is commenced within twelve years of the date upon which it accrued. Such action shall be deemed to have accrued on the date the plaintiff or his predecessor in interest knew or should have known of the claim of the United States." 28 U.S.C. § 2409(g); *see also TRW*, 534

We now turn to whether the Vaccine Act statute of limitations is susceptible to an implied discovery rule. As a preliminary matter, we note that the Supreme Court has left open the question of whether a presumption exists that "all federal statutes of limitations, regardless of context, incorporate a general discovery rule unless Congress has expressly legislated otherwise." *TRW*, 534 U.S. at 27. Nonetheless, the Supreme Court noted in *TRW*, *id.*, that it had held in *Holmberg v. Armbrecht*, 327 U.S. 392 (1946), that "where a plaintiff has been injured by fraud and remains in ignorance of it without any fault or want of diligence or care on his part, the bar of the statute of limitations does not begin to run until the fraud is discovered." 534 U.S. at 27 (quoting *Holmberg*, 327 U.S. at 397). The Supreme Court proceeded to note in *TRW* that "[t]he only other cases in which we have recognized a prevailing discovery rule, morever, were decided in two contexts, latent disease and medical malpractice, 'where the cry for [such a] rule is loudest.'" *Id.* (quoting *Rotella*, 528 U.S. at 555) (second alteration in original). As the guide for deciding whether to read a discovery rule into a federal statute of limitations, the Supreme Court held in *TRW* that Congress can "convey its refusal to adopt a discovery rule . . . by implication from the structure or text of the particular statute." *Id.* at 27–28.

The question we must decide is whether, in the context of a no-fault vaccine-injury remedy statute Congress, in the text of the Vaccine Act and considering its overall structure, conveyed its refusal to permit an implied

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U.S. at 38 (Scalia, J., concurring) (discussing three additional examples of explicit discovery rules enacted by Congress).

discovery rule. We have already held that Congress did not write an explicit discovery rule into the statute.

Congress enacted the Vaccine Act statute of limitations against the backdrop of state law providing remedies for physical injuries. Indeed, Dr. Cloer points to that body of state law, noting that virtually all of the state laws on the subject incorporate discovery rules into their statutes of limitations. Those discovery rules look to the knowledge of a plaintiff to determine the date upon which the statute of limitations begins to run. From this body of state law, Dr. Cloer argues that Congress must have meant for the Vaccine Act statute of limitations to incorporate a discovery rule.

The contemporaneous existence of that body of state law, however, cuts against Dr. Cloer. First, that body of state law, dealing with fault liability, keys the accrual of the cause of action to the occurrence of the injury for which relief is sought. *See, e.g.*, Colo. Rev. Stat. §§ 13-80-106, 13-80-108 (enacting discovery rule for cause of action otherwise accruing at injury). As with the Federal Tort Claims Act, 28 U.S.C. § 2401(b), those state laws are understood to trigger their statutes of limitations upon the discovery of the existence and the cause of the injury. *See United States v. Kubrick*, 444 U.S. 111, 120 (1979). We may presume that Congress is generally aware of the consequences of enacting a statute of limitations that runs from the date of occurrence of an injury. As noted above, Congress was presented the option of enacting a statute of limitations that would have run from the knowledge of the occurrence of a vaccine-related injury. *See* S. 827, 99th Congress § 2106(a) (1985). Had it done so, the parallel between state law and the Vaccine Act sought by Dr. Cloer would have been plausible. Instead, Congress made the deliberate choice to trigger the Vac-

cine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury. This trigger confirms that a Vaccine Act cause of action accrues on that same date, not at a later date when a petitioner may have knowledge that the vaccine caused the injury. We need not decide whether the choice of Congress to bypass a statute of limitations comparable to the large body of state law shows a firm intent to bar, without more, a discovery rule in the Vaccine Act statute of limitations. But the choice made by Congress surely goes a long way to showing that Congress "conveyed its refusal to adopt a discovery rule."[8] *TRW*, 534 U.S. at 27.

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[8] The legislative history which we emphasize is not a matter of difference of opinion among legislators about what statutory language means, or individual statements by legislators. *See generally Garcia v. United States*, 469 U.S. 70, 75 (1984) (cautioning against reliance on legislators' "passing comments" and "casual statements" as indicating Congressional intent). Instead, it is a matter of pure fact that Congress had two clear and significantly differing concepts to choose from in writing the statute of limitations for the Vaccine Act. *Compare* H.R. 1780, 99th Congress § 2112 (1985) *with* S. 827, 99th Congress § 2106(a) (1985). Less significant but not unimportant is the additional fact that Congress was warned by Dissatisfied Parents Together, an interest group favoring the approach of S. 827, that the approach ultimately selected by Congress would trigger the statute of limitations regardless of when the claimant discovered the causal link between the injury and the vaccine. *See To amend the Public Health Service Act to provide for the compensation of children and others who have sustained vaccine-related injuries, and for other purposes: Hearing on S. 827 before the S. Comm. on Labor and Human Res.*, 99th Cong. 41 (1985) (statement of Jeffrey H. Schwartz, President of DPT).

Examination of the overall structure of the Vaccine Act and its text buttresses our conclusion that a discovery rule cannot be read into the Vaccine Act statute of limitations. First and foremost, Congress selected a specific textual calendar date to trigger the statute of limitations. Nothing in that date, the first occasion of a symptom or manifestation of onset of the injury for which compensation is sought, asks for information about how much knowledge a petitioner had. It is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition. We have recognized this in our previous cases. *See Markovich*, 477 F.3d at 1357 (rejecting the argument that eye blinking episodes were insufficient to start the statute of limitations because "the eye blinking symptom could not reasonably alert the Markoviches that anything was wrong."); *Wilkerson v. Sec'y of Dep't of Health & Human Servs.*, 593 F.3d 1343, 1345–46 (Fed. Cir. 2010) (rejecting a subjective standard for determining when the limitations period began to run based on the parent's perception and confirming an objective standard based on the medical profession's recognition of the existence of a symptom or manifestation of an injury).

The date of the first symptom or manifestation resonates throughout the Vaccine Act. For example, with regard to Table injury cases, the petitioner is supplied in the Vaccine Injury Table with a list of symptoms or manifestations and a list of dates associated with the time of occurrence of each of those symptoms or manifestations. The Table Injury petitioner uses the same single statute of limitations as a non-Table injury claimant, and has 36 months from the date of the first symptom or manifestation in which to file a petition for compensation.

As noted in Part I above, a significant motive for Congress in enacting the Vaccine Program was to provide an efficient, simple, and easy to administer system for processing vaccine injury claims. We think the triggering mechanism selected by Congress for the statute of limitations promotes those goals, whereas a discovery rule may not. Once it is understood that Congress intended a specific date, rather than a date that would vary depending on the knowledge of a petitioner, to trigger the statute of limitations, it is easily understood that time-consuming debates over when the statute of limitations started to run would not likely occur in processing a petition for compensation. When the date a symptom first occurred might sometimes be in issue, but the more complicated inquiry about whether petitioner knew or reasonably should have known of a causal connection only arises under Dr. Cloer's view of the statute. Further, "the date of occurrence of the first symptom or manifestation of onset" treats all petitioners equally, whereas under a discovery rule, the otherwise neutral 36 month time limit will vary from petitioner to petitioner.

A discovery rule necessarily adjusts the beginning of a statute of limitations to the circumstances of an individual case. The rule typically asks when a plaintiff knew or reasonably should have known of enough facts to proceed with her case. *Kubrick*, 444 U.S. at 120–22; *see also Kach v. Hose*, 589 F.3d 626, 634–35 (3d Cir. 2009); *Rakes v. United States*, 442 F.3d 7, 20 (1st Cir. 2006); *Fries v. Chicago & Nw. Transp. Co.*, 909 F.2d 1092, 1095 (7th Cir. 1990); 2 Calvin W. Corman, *Limitation of Actions* § 11.1.1 (1991). The discovery rule tethers accrual of the cause, and with it the start of the limitations period, to the knowledge of the plaintiff or of a reasonable actor in the plaintiff's position. The discovery rule is therefore an inherently personal, plaintiff-specific one. As a matter of

both practice and design, a discovery rule treates different plaintiffs differently based on their personal circumstances. *Cascone v. United States*, 370 F.3d 95, 104 (1st Cir. 2004) ("The issue is whether a reasonable person *similarly situated* to the plaintiff would have known the necessary facts.").

In our view the personal, plaintiff-oriented approach of a discovery rule is antithetical to the simple, symptom-keyed test expressly required by the Vaccine Act's text. Such a conclusion is not surprising in light of the Vaccine Act's structure as a simplified no-fault administrative scheme. We note further that this conclusion is consistent with Congress's expressed desire that the Vaccine Act be "simple, and easy to administer" as well as "expeditious and fair." *See supra* part I (discussing legislative history). Under the Vaccine Act as written, two plaintiffs who receive the same vaccine on the same day, and who experience the same medically-recognized symptom of a vaccine-related injury shortly afterwards, also on the same day, begin their limitations periods simultaneously. But under the more capacious analysis of the discovery rule, the start of the limitations period could vary widely based on each plaintiff's personal circumstances. We think these two results so different as to make implication of a discovery rule fundamentally incompatible with the text Congress enacted.

We therefore hold that Congress "conveyed its refusal to adopt a discovery rule . . . by implication from the text and structure" of the Vaccine Act. *TRW*, 534 U.S. at 27–28. The statute of limitations begins to run on a specific statutory date: the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical profession at large.

B

In our second question for en banc briefing, we asked if *Brice* should be overruled to permit equitable tolling of 42 U.S.C. § 300aa-16(a)(2). We now answer that question in the affirmative. We therefore overrule *Brice* and hold that equitable tolling applies to the Vaccine Act. In Part C below, we reach and decide the ground on which Dr. Cloer seeks equitable tolling.

The Supreme Court observed in *John R. Sand & Gravel Co. v. United States*, 552 U.S. 130, 133 (2008), that "[m]ost statutes of limitations seek primarily to protect defendants against stale or unduly delayed claims." Limitations statutes of that nature do not implicate the jurisdiction of a court, and thus do not preclude relief from time filing limits by way of equitable tolling. The time limits in other statutes, the Supreme Court noted, have been read in the light of the statute's overall purpose as "more absolute, say as requiring a court to decide a timeliness question despite a waiver, or as forbidding a court to consider whether certain equitable considerations warrant extending a limitations period." *Id.* at 133–34. As examples of such more absolute statutes, the Supreme Court mentioned statutes that "achieve a broader system-related goal, such as facilitating the administration of claims, *see, e.g.*, *United States v. Brockamp*, 519 U.S. 347, 352–353 (1997), limiting the scope of a governmental waiver of sovereign immunity, *see, e.g.*, *United States v. Dalm*, 494 U.S. 596, 609–10 (1990), or promoting judicial efficiency, *see, e.g.*, *Bowles v. Russell*, 551 U.S. 205, 210–13 (2007)." *John R. Sand & Gravel*, 552 U.S. at 133. Whether a particular statute of limitations is treated as "jurisdictional" thus depends on the overall context of the statute. The term "jurisdictional" has no notable meaning in such contextual inquiries and is merely convenient

shorthand for statutory limits that are absolute and require a court to consider timeliness questions without reference to equitable considerations. *Id.* at 133–34. The "jurisdictional" determination thus merges into the question of whether Congress intended to allow equitable tolling of the Vaccine Act's statute of limitations.[9]

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[9] In *Martin ex rel. Martin v. Secretary of Health & Human Services*, 62 F.3d 1403 (Fed. Cir. 1995), the parents of a child injured by polio vaccine sought attorneys' fees and costs under the Vaccine Act. 42 U.S.C. § 300aa-11(a)(6) bars a petition for compensation if the petitioner has previously filed a civil suit for damages for the same injury. Because the Martins had filed such a suit, their petition was dismissed for lack of subject matter jurisdiction. We thus viewed the barrier to suit in § 300aa-11(a)(6) as jurisdictional, and consequently held that the absence of jurisdiction over the Martins' petition for compensation removed jurisdiction over their application for attorneys' fees and costs. 62 F.3d at 1407. After we held in *Brice* that equitable tolling does not lie under the Vaccine Act, the Brices sought attorneys' fees and costs. The Court of Federal Claims, in the light of *Martin*, treated the Brices' failure to meet the statute of limitations as jurisdictional, and thus dismissed the Brices' attorneys' fee and costs request for lack of jurisdiction. On appeal, we too assumed, without analysis, that compliance with the Vaccine Act's statute of limitations is a jurisdictional requirement, and affirmed the Court of Federal Claims decision. *Brice v. Sec'y of Health & Human Servs.*, 358 F.3d 865, 869–70 (Fed. Cir. 2004) ("second *Brice*").

Dr. Cloer brought *Martin* and the second *Brice* decision to our attention, pointing out that the second *Brice* decision merely assumed that the statute of limitations is jurisdictional, and asking that we clarify the issue. Notably, the government does not rely on the second *Brice* decision; indeed, it does not assert that the statute is "jurisdictional" and thus inhospitable to equitable tolling.

The only purpose of the statute of limitations in the Vaccine Act is to protect the government from stale or

Any analysis of whether equitable tolling lies against a federal statute of limitations begins with *Irwin v. Department of Veterans Affairs*, 498 U.S. 89 (1990). In that case, the Supreme Court established a presumption that all federal statutes of limitations are amenable to equitable tolling absent provision by Congress to the contrary. *Id.* at 95–96. *Irwin* left for decision in later cases whether when enacting specific statutes Congress rebutted the basic presumption in favor of equitable tolling. A leading case providing guidance on Congressional rebuttal is *United States v. Brockamp*, 519 U.S. 347 (1997). *Brockamp* framed the rebuttal question as "whether there is good reason to believe that Congress did not want equitable tolling to apply." 519 U.S. at 350. *Brockamp* detailed five factors for use in determining whether Congress rebutted the basic *Irwin* presumption: the statute's detail, its technical language, its multiple iteration of the limitations period, its explicit inclusion of exceptions, and its underlying subject matter. *See Brockamp*, 519 U.S. 350–52. These same factors were considered by this court when it previously decided that equitable tolling is not available. Indeed, at that time and again in this case, the government agrees that only two of the factors cut against equitable tolling. First, the government argues that the Vaccine Act includes two specific exceptions to the basic 36 month statute of limitations. And second, the government argues that the Vaccine Act's detail as a whole reveals multiple strict deadlines.

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unduly delayed claims. Whether viewed from the overall purpose perspective or, as demonstrated below, from the perspective of whether Congress barred equitable tolling by erecting a jurisdictional barrier, the answer is the same. There is no barrier to equitable tolling under 42 U.S.C. § 300aa-16(a)(2), and the statute of limitations is not jurisdictional. Previous law to the contrary is overruled.

The first exception to which the government refers provides for the situation when a petition for compensation is improperly filed as a tort claim in a state or federal court. Because a person seeking compensation for a vaccine-related injury must first file under the Vaccine Program, 42 U.S.C. § 300aa-11(a)(2), previous court filings elsewhere are improper and must be dismissed. The date such a dismissed action was filed "shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title [the 36 month period], be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action." 42 U.S.C. § 300aa-11(a)(2)(B).[10] This exception was relied on in *Brice* as a reason to deny equitable tolling.

The second exception to the basic limitations statute raised by the government concerns the provision in the Vaccine Act that deals with petitions for compensation filed after the Vaccine Injury Table is revised. For example, a person who was not eligible for compensation before the Vaccine Injury Table revision may file a petition for compensation under the revision, provided the petitioner's injury occurred no more than 8 years before the date of the revision and the petition is filed not later than 2 years

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[10] The relief afforded to petitioners by 42 U.S.C. § 300aa-11(a)(2)(B) was not available to the petitioner in *Martin*. *See supra* n.9. That case dealt with 42 U.S.C. § 300aa-11(a)(6), which completely barred access to the Vaccine Program if a petition was filed after November 15, 1988, for a vaccine-related injury or death associated with administration of a vaccine before November 15, 1988. In *Martin*, the vaccine was administered in 1986 and the state court suit was brought on November 15, 1989. *Martin*, 62 F.3d at 1404.

after the effective date of the revision. 42 U.S.C. § 300aa-16(b). This exception was not discussed in *Brice*.

As for the overall structure of the Vaccine Act, the government points to the many strict time deadlines that regulate cases once they are started. In particular, the government points to the need for special masters to decide cases within 240 days after the filing of a petition, and the bar to suspension of proceedings for more than 150 days. *See* 42 U.S.C. § 300aa-12(d)(3)(A)(ii),(C).

The correct analysis of the government's "exceptions" points is informed by the Supreme Court's recent decision in *Holland v. Florida*, 130 S. Ct. 2549 (2010), of which the *Brice* court did not have the benefit. *Holland* answered in the affirmative whether the one-year statute of limitations on petitions for federal habeas corpus relief by state prisoners under the Antiterrorism and Effective Death Penalty Act of 1996 ("AEDPA") is subject to equitable tolling. The respondent in *Holland* argued that the AEDPA should be interpreted to foreclose equitable tolling because the statute has explicit exceptions to the basic statute of limitations. 130 S. Ct. at 2561. The Supreme Court "concede[d] that [the AEDPA] is silent as to equitable tolling while containing one provision that expressly refers to a different kind of tolling." *Id.* at 2561–62 (citing the "exception" as 28 U.S.C. § 2244(d)(2), which does not count against the one-year statute the time a petitioner has a pending request for postconviction relief, because the federal petition cannot be brought before exhaustion of state remedies). The Supreme Court held that Congress had to balance the interaction of state and federal participation in the underlying subject matter, and the "exception" thus is a special need, and as such negates the significance of the special exception for *Brockamp* factor analysis purposes. 130 S. Ct. at 2562.

Holland teaches that exceptions to statutes of limitations do not necessarily rebut the bedrock *Irwin* presumption in favor of equitable tolling. Exceptions, instead, must be understood in context, for, as in *Holland*, an exception may signal a beneficent Congressional act, not a rebuttal of the *Irwin* presumption. In the context of the Vaccine Act, the "exception" seen in 42 U.S.C. § 300aa-11(a)(2)(B) does not counsel against equitable tolling.

As noted above, before a tort suit can be brought for damages, a claimant must seek relief under the Vaccine Program. If a would-be petitioner mistakenly first files a traditional tort suit, the tort suit must be dismissed. 42 U.S.C. § 300aa-11(a)(2)(B). Recognizing that the result of a rule requiring dismissal of premature suits could leave a petitioner nonsuited due to different statutes of limitations for state torts and the Vaccine Act, Congress included a special need provision that would allow the petitioner to benefit from the earlier state filing date when faced with the Vaccine Act's statute of limitations. Similarly, Congress included a provision that tolls state statutes of limitations during the pendency of Vaccine Program action. *See* 42 U.S.C. § 300aa-16(c). Thus, Congress created a system that provides for a petitioner to have equal access to the Vaccine Program and to state remedies once any filing occurs regardless of the forum.

We think it clear that Congress had a specific concern, unrelated to equitable tolling considerations, in enacting the "exception" in 42 U.S.C. § 300aa-11(a)(2)(B). This provision shows Congressional response to possible confusion regarding the new no-fault compensation system by minimizing the consequence of certain errors. This "exception" is driven by a special need, as was the case in *Holland*, and does not show a desire by Congress to bar equitable tolling.

We turn now to the statutory provision that permits a petition for compensation to be filed upon revisions to the Vaccine Injury Table. We reject the government's argument that this "exception" bars equitable tolling of the statute of limitations. This statutory provision is aimed at scientific advances in medicine that enable the establishment of new Table Injuries, for which causation will be presumed. Individual factual circumstances, the grist of equitable tolling claims, played no role in enactment of this provision. We think equitable tolling concepts lie in a different world from the opening to all vaccine recipients of a claim due to new medical knowledge. This "exception" too is easily understood as a special need provision to address a Vaccine Program that moves forward in time with advances in medicine. Equitable tolling is not defeated by the wisdom of Congress to see into the future.

The remaining factor urged by the government to support its view that Congress rebutted the *Irwin* presumption concerns the detailed time limits governing processing of cases under the Vaccine Program. Those factors, identified above, relate to the speed with which the special master must move in processing cases. Such limits are tight, to be sure, and they serve to meet the Congressional goal of swift and efficient disposition of claims once a petition is filed. These time limits are designed to benefit the petitioner. If a petitioner were to cause some delay in processing of her petition because the government resists her request for equitable tolling, she could not be heard to complain if the time to decide her claim is greater than a petitioner who filed her petition within the 36 month limit. And any delay in getting the merits of a petition underway because of equitable tolling is no greater, if as great, as the delay that would be inherent in resolving disputes about whether a petitioner reasonably should have known of a causal link between

her injury and a vaccination. Further, the 36 month period comports with traditional tort remedy statutes of limitations, and is not overly generous. *See United States v. Beggerly*, 524 U.S. 38, 48–49 (1998) (denying equitable tolling on an "unusually generous" 12-year statute of limitations.)

In sum, measuring the Vaccine Act by the standards in *Irwin*, *Brockamp*, and *Holland*, we see no reason to bar equitable tolling of the statute of limitations in the Vaccine Act, and therefore must conclude that there is not "good reason to believe that Congress did not want the equitable tolling doctrine to apply." *Brockamp*, 519 U.S. at 350.

C

In the order setting this case for en banc decision, we asked the parties to address whether, if equitable tolling is permitted, the circumstances of this case support equitable tolling. Dr. Cloer took advantage of our invitation and argued, as she has throughout these proceedings, that equitable tolling is appropriate in this case on the ground that she first became aware of the causal link between her MS and the Hep-B vaccine in 2004 when she saw an article in a journal suggesting such a link. She asserts that it is inequitable and unfair to hold her to the 36 month filing period when she had no reason to know, before 2004, of the causal link between her injury and the Hep-B vaccine. She thus posits that equitable tolling in her case, and presumably in other future cases with similar facts, should be a substitute for the discovery rule.

In other words, Dr. Cloer individually asks for the same relief as a matter of equity that Congress has withheld from all petitioners as a matter of law. But we find

no basis in equity for doing so. Dr. Cloer has put no argument before this court that, for example, she has been the victim of a fraud, or of duress. *See, e.g.*, *Bailey v. Glover*, 88 U.S. 342, 349–50 (1874). Instead, we understand her to argue that the result reached in the analysis above is *ipso facto* unfair because it threatens to deprive her of her claim. That is not, in our view, the sort of circumstance that might merit equitable tolling. *See Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005) (noting that equitable tolling requires a litigant to have diligently pursued his rights, but that "some extraordinary circumstance stood in his way"); *see also Irwin*, 498 U.S. at 96 (noting that equitable tolling is to be used "sparingly" in federal cases and has been limited to cases involving deception or the timely filing of a procedurally defective pleading).

While we recognize that our holding sharply limits Dr. Cloer's ability to be compensated under the Vaccine Act, this outcome is the result of a policy calculation made by Congress not to afford a discovery rule to all Vaccine Act petitioners and Dr. Cloer's failure to point to circumstances that could justify the application of equitable tolling to forgive her untimely claim. We thus hold that equitable tolling under the Vaccine Act due to unawareness of a causal link between an injury and administration of a vaccine is unavailable.[11]

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[11] In *Irwin*, the Supreme Court found for the first time that equitable tolling is presumptively available in all actions against the government, including the one asserted by Mr. Irwin. 498 U.S. at 95–96. Because the Court concluded that Mr. Irwin could not satisfy the stringent requirements of that doctrine, however, the Court affirmed the judgment the judgment against Mr. Irwin. *Id.* We follow a similar course here.

Accordingly, the judgment below is

AFFIRMED

United States Court of Appeals for the Federal Circuit

MELISSA CLOER, M.D.,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2009-5052

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

DYK, *Circuit Judge*, dissenting, with whom *Circuit Judges* NEWMAN, LINN, and REYNA join.

Contrary to the majority, I think it is quite clear that the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, 3755, Title III (1986) (codified at 42 U.S.C. § 300aa-1 to 34) [hereinafter the Vaccine Act], incorporates a discovery rule under which the limitations period does not begin to run until the claimant knew or should have known of a connection between the alleged injury and a vaccine.[1]

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[1] This does not mean, of course, that a definitive diagnosis of the alleged injury is required to trigger the statute of limitations, as this court made clear in *Mark-*

I

It is well established in both state and federal law that a discovery rule should be presumed for limitations purposes for claims similar to those under the Vaccine Act. The Supreme Court has "recognized a prevailing discovery rule . . . in [the] two context[s] of latent disease and medical malpractice, 'where the cry for [such a] rule is loudest.'" *TRW Inc. v. Andrews*, 534 U.S. 19, 27 (2001) (quoting *Rotella v. Wood*, 528 U.S. 549, 555 (2000)). Application of a discovery rule is necessary in these circumstances because the very fact that the plaintiff "has been injured . . . may be unknown or unknowable until the injury manifests itself; and the facts about causation may be in the control of the putative defendant, unavailable to the plaintiff or at least very difficult to obtain." *United States v. Kubrick*, 444 U.S. 111, 122 (1979). Where the plaintiff has knowledge of both the injury and its cause, however, "[t]he prospect is not so bleak" because the plaintiff is no longer at the mercy of the defendant, who possesses specialized medical knowledge. *Id.* Six of our sister circuits have similarly held that, in the case of medical malpractice and similar actions, the limitations period generally does not begin to run until the plaintiff knew or should have known of both the injury and its cause.[2] *See also TRW*, 534 U.S. at 27 ("[L]ower federal

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ovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1360 (Fed. Cir. 2007).

[2] *See, e.g.*, *Sell v. U.S. Dep't of Justice*, 585 F.3d 407, 409 (8th Cir. 2009) ("In medical malpractice cases . . . the cause of action accrues when the plaintiff discovers the nature and cause of his injury."); *Hensley v. United States*, 531 F.3d 1052, 1056 (9th Cir. 2008) (noting that, "[i]n certain circumstances, such as claims involving medical malpractice, accrual does not occur until a plaintiff knows of both the existence of an injury and its cause"); *Green v. United States*, 180 F. App'x 310, 313 (3d

courts generally apply a discovery accrual rule when a statute is silent on the issue.") (internal quotation marks omitted); *Rotella*, 528 U.S. at 555 ("Federal courts, to be sure, generally apply a discovery accrual rule when a statute is silent on the issue . . . .").

While the majority does not dispute that the Vaccine Act remedy is similar to, and replaces, a medical malpractice or similar remedy, it asserts that the application of a discovery rule to petitions under the Vaccine Act is inappropriate because such a rule would be inconsistent with the language and structure of the Act. Relying on the Supreme Court decision in *TRW*, the majority points out that "Congress can 'convey its refusal to adopt a discovery rule . . . by implication from the structure or text of the particular statute.'" Maj. Op. at 31 (quoting *TRW*, 534 U.S. at 27–28). The text and the structure of the Vaccine Act, however, do not suggest that Congress rejected a discovery rule. To the contrary, both the text and the

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Cir. 2006) ("[W]hen the fact of injury alone is insufficient to put an injured party on notice of its cause, the Supreme Court has indicated that the accrual of the claim is delayed until the injured party discovers that cause."); *Waggoner v. United States*, 95 F. App'x. 69, 71 (5th Cir. 2004) ("[A] claim under the FTCA accrues when a plaintiff knows or reasonably should have known of 'the existence and the cause of his injury.'"); *Mix v. Delaware & Hudson Ry. Co.*, 345 F.3d 82, 86 (2d Cir. 2003) ("[A]n FELA action accrues when the plaintiff in the exercise of reasonable diligence knows both the existence and the cause of his injury.") (internal quotation marks omitted); *Price v. United States*, 775 F.2d 1491, 1493-94 (11th Cir. 1985) ("[A] medical malpractice claim under the FTCA accrues when the plaintiff is, or in the exercise of reasonable diligence should be, aware of both [his] injury and its connection with some act of the defendant."); *see also Kubrick*, 444 U.S. at 120–21 (noting government concession that in medical malpractice cases plaintiff must know of both injury and its cause).

structure of the Act confirm that Congress adopted the prevailing discovery rule approach.

A

Section 300aa-16(a)(2) of the Vaccine Act provides:

> [I]f 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.

42 U.S.C. § 300aa-16(a)(2). Notably, the statute does not provide that the limitations period commences on the date of the injury. Instead, the limitations period commences on the date of the "first *symptom or manifestation*" of a "*vaccine-related* injury," making clear that the statute of limitations is triggered only where the claimant knew or should have known of both the injury and its connection to the vaccine. 42 U.S.C. § 300aa-16(a)(2) (emphases added). As the majority recognizes, the terms "symptom" and "manifestation" suggest knowledge or reason to know on the part of the claimant.[3] Maj. Op. at 25. That knowledge requirement refers not merely to the existence of a vaccine-related injury, but to knowledge that the injury was related to the vaccine. In other words, the limitations period is not triggered by knowledge of the injury itself, but by the first event which would put the claimant on notice that a vaccine-related injury has occurred.

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[3] *See* Webster's Third New Int'l Dictionary 1375, 2318 (1986) (defining "manifestation" as "something that manifests or constitutes an expression of something else: a perceptible outward, or visible expression," and "symptom" as "something that indicates the existence of something else").

Indeed, the limitations provision makes clear that it is not triggered merely by the first symptom of an injury—the injury itself must be *related* to the vaccine (i.e., a "vaccine-related injury") and must occur "*as a result* of . . . a vaccine." 42 U.S.C. § 300aa-16(a)(2) (emphasis added). The statutory definition of "vaccine-related injury" confirms this point, defining "vaccine-related injury" as "an illness, injury, condition, or death *associated with* one or more of the vaccines set forth in the Vaccine Injury Table." *Id.* § 300aa-33(5) (emphasis added). At the time the Vaccine Act was passed, the word "associated" was defined as "closely connected, joined, or united." Webster's Third New Int'l Dictionary 132 (1986). Thus, in order for an injury to be "associated with" a vaccine, there must be some connection between the injury and the vaccine, and there must be a manifestation or symptom of such an injury, i.e., there must be knowledge or reason to know that the injury is vaccine-related.

The majority asserts that the text of the Vaccine Act is inconsistent with the application of a discovery rule because "the clearly dominant language in the statute of limitations is 'the date of occurrence of the first symptom or manifestation of onset.'" Maj. Op. at 30 (quoting 42 U.S.C. § 300aa-16(a)(2)). Because the majority finds this phrase to be "dominant," it fails to recognize that the phrase "first symptom or manifestation of onset" means nothing standing alone. It can be understood only by looking to the remainder of the language in the limitations provision, which links the "first symptom or manifestation" to "a vaccine-related injury" and requires that such injury occur "as a result" of a vaccine. *See* 42 U.S.C. § 300aa-16(a)(2).

The majority's novel "dominant language" approach to statutory interpretation is plucked out of thin air and is contrary to Supreme Court precedent, which makes clear

that when interpreting a statute, the "[i]nterpretation of a word or phrase depends upon reading the whole statutory text." *Dolan v. United States Postal Serv.*, 546 U.S. 481, 486 (2006); *see also U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (explaining that "we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy"); *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991) ("[W]e construe statutes, where possible, so as to avoid rendering superfluous any parts thereof."); *Hornback v. United States*, 601 F.3d 1382, 1385 (Fed. Cir. 2010) (quoting *U.S. Nat'l Bank of Or.*, 508 U.S. at 455). The majority's rule that the limitations period begins to run on the "date of the occurrence of the first medically recognized symptom or manifestation of onset of the injury claimed by the petitioner," Maj. Op. at 4, simply rewrites the statutory language by leaving out the requirement that the injury be "vaccine-related" and occur "as a result" of a vaccine.

In an effort to support its decision to ignore the statutory text, the majority relies on legislative history supposedly demonstrating that Congress deliberately chose to trigger the limitations period from the date of the first symptom or manifestation of the alleged injury, regardless of whether there is an objective reason to suspect a causal connection between the alleged injury and the vaccine. Even under the questionable assumption that legislative history could support a reading contrary to the text of the statute, there is no such legislative history here. The majority cites two alternative pieces of legislation considered by Congress—H.R. 1780 and S. 827. The House of Representatives version required, in language similar to that finally enacted, that claims under the Act be brought within "two years after the first manifestation of a vaccine-related injury," a formulation that also re-

quired the "first manifestation" be "vaccine-related." National Childhood Vaccine-Injury Compensation Act of 1985, H.R. 1780, 99th Cong. § 2112(a) (1985). The Senate version required that claims be brought "within 5 years after the occurrence of the compensable complication or residual effect of the illness, disability, injury, or condition listed in the Vaccine Injury Table." National Childhood Vaccine-Injury Compensation Act of 1985, S. 827, 99th Cong. § 2106(a) (1985). In the Senate bill, as in the final version of the Act, causation was presumed for injuries listed in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(i). The Senate version also permitted the filing of a petition after the time period specified if it was demonstrated that the claimant "did not know that such complication or effect was compensable under the program," or the claimant "was not provided the information required by section 2143." S. 827, § 2106(b). Section 2143(c)(9) required that persons receiving a vaccine listed in the Vaccine Injury Table be provided certain information, including "information on . . . the availability of the Program."

The majority urges that Congress' rejection of the limitations provision set forth in the Senate bill demonstrates that Congress intended the limitations period to be triggered by the first symptom or manifestation of the alleged injury, regardless of whether there is any reason to suspect a connection between the alleged injury and the vaccine. But Congress' rejection of the exception contained in the Senate bill in no way demonstrates that Congress intended to reject the application of a discovery rule.

First, unlike the Vaccine Act, the Senate bill did not permit a claimant to recover for an injury unless the

injury was listed in the Vaccine Injury Table.[4] The only role of causation was to permit claimants to recover for Table injuries even though the time requirements for onset of the injury were not met. *See* S. 827, § 2105(a)(2).[5] The Senate bill did not, however, in this or any other respect, provide an exception to the limitations period based on the claimant's lack of knowledge or reason to know that there was a causal connection between the alleged injury and the vaccine. Thus, the rejection of the Senate bill hardly suggests a rejection of a discovery rule requiring that the claimant know or have reason to know of a causal connection between the alleged injury and the vaccine.

Second, the exception to the limitations period in the Senate bill was not a discovery rule. It did not depend on what the claimant knew or should have known, but on what the claimant actually knew. The exception permitted the filing of a petition after the time period specified only if it was demonstrated that (1) at the time of the

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[4] Section 2103 permitted the award of compensation only where "there is an adequate demonstration that . . . the [claimant] sustained, or had significantly aggravated, any of the illnesses, disabilities, injuries, or conditions listed in the Vaccine Injury Table." S. 827, § 2103(a)(2)(A). Additionally, the bill defined the term "vaccine-related injury" only in terms of injuries appearing in the Vaccine Injury Table, stating specifically that "the term 'vaccine-related injury' means any injury . . . listed in the Vaccine Injury Table." *Id.* § 2164(20).

[5] The Senate bill set forth a Vaccine Injury Table containing specific vaccines, injuries, and time periods for the first symptom or manifestation of onset of a listed injury. *Id.* § 2105(a)(1). Where the claimant's first symptom did not occur within the specified time period, the claimant could nonetheless recover upon demonstrating that the injury was caused by the vaccine.

vaccine, the petitioner was not provided with, among other things, information about the Vaccine Injury Compensation Program; or (2) that the petitioner did not know that the complication or effect of the injury was compensable under the Program. *Id.* §§ 2106(b), 2143(c)(9). Neither of these exceptions was designed to address a situation in which the claimant had no reason to suspect a causal connection between the alleged injury and the vaccine. Instead, they were designed to deal with circumstances in which the claimant had no knowledge of the availability or scope of the Vaccine Injury Compensation Program. As a result, Congress' rejection of the Senate limitations provision, does not suggest that Congress rejected a discovery rule or intended the language in the limitations provision of the Vaccine Act to be read to mean something different than the plain language conveys.

B

The application of a discovery rule is compelled by both the structure and history of the Vaccine Act, as well as its language. If the limitations provision were interpreted not to incorporate a discovery rule, claimants like Dr. Cloer would be faced with the odd result that the limitations period would begin to run before a petition could be filed under the Act., i.e., before the cause of action accrued. The majority itself recognizes that "settled law establishes a firm default rule that a cause of action arises at the same time the statute of limitations begins to run on the cause." Maj. Op. at 21 (citing *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 418 (2005)). Thus, absent an indication to the contrary, the limitations period begins when the cause of action accrues. *Graham Cnty.*, 545 U.S. at 418; *see also Reiter v. Cooper*, 507 U.S. 258, 267 (1993) (declining to permit the "odd result" that

the accrual of a federal cause of action and the start of the limitations period arise at different times without "any such indication in the statute").

The Vaccine Act divides vaccine-related injuries into two types—those which appear in the Vaccine Injury Table ("Table injuries") and those that do not ("non-Table injuries"). *See* 42 U.S.C. § 300aa-11(c)(1)(C). The same limitations period applies to both Table and non-Table injuries. *See id.* § 300aa-16(a)(2). For Table injuries, there is no need for the petitioner to establish causation because causation is presumed for injuries listed in the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i). But where, as here, a claimant seeks compensation for a "vaccine-related injury" not listed in the Table, the petition must contain, among other things, "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 *caused by* a vaccine." *Id.* § 300aa-11(c)(1)(C)(ii) (emphasis added). A claimant's cause of action does not accrue until the time at which the claim becomes enforceable.[6] Claims under the Vaccine Act become enforceable, or accrue, only when a claimant can file a petition demonstrating that the alleged injury was "caused by a vaccine." *Id.* §§ 300aa-11(a), (c). The legislative history makes clear that this requirement is not satisfied by a mere allegation that the injury was caused by the vaccine, i.e., the usual pleading standard. Instead, "evidence in the form of scientific studies or expert medical testimony is necessary." H.R. Rep. No. 99-908, at 15 (1986). Thus, in order for the limitations period to commence, the claimant must be able to file a petition. And

[6] To "accrue" in the sense of a cause of action means "[t]o come into existence as an enforceable claim or right." *Black's Law Dictionary* 23 (9th ed. 2009).

in order to file a petition, the claimant must demonstrate a causal connection between the vaccine and the injury using "scientific studies or expert medical testimony." *See id.* As a result, the limitations period cannot begin to run until "scientific studies or expert medical testimony" demonstrating a possible connection between the vaccine and the injury are known or should be known to the claimant.

The majority urges that a discovery rule would make "the otherwise neutral 36 month time limit . . . vary from petitioner to petitioner," Maj. Op. at 35, and thus undermine this court's decision in *Markovich* that the statute of limitations begins to run at "the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large," 477 F.3d at 1360. Under a discovery rule, however, the statute of limitations is triggered when the claimant knew or should have known that an injury was vaccine related. Though a claimant's subjective knowledge is certainly sufficient to trigger the statute of limitations, *Markovich* makes clear that subjective knowledge is not required.

The remedial nature of the Vaccine Act also supports a discovery rule. The Supreme Court has long recognized the canon of construction that remedial legislation should be construed liberally. *See, e.g.*, *Atchison, Topeka & Santa Fe Ry. Co. v. Buell*, 480 U.S. 557, 561–62 (1987); *Peyton v. Rowe*, 391 U.S. 54, 65 (1968); *Cosmopolitan Shipping Co. v. McAllister*, 337 U.S. 783, 790 (1949); *Stewart v. Kahn*, 78 U.S. 493, 504 (1870). The Vaccine Act, which created "a new system for compensating individuals who have been injured by vaccines," H.R. Rep. No. 99-908, at 3, clearly falls into the category of remedial legislation. The Vaccine Act's compensation program was intended to be a "program under which awards [could] be made to vaccine-injured persons quickly, easily, and with

certainty and generosity." *Id.* (emphasis added). It was "designed to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) (citing H.R. Rep. No. 99-908, at 3–7). Thus, it is clear from the legislative history that Congress intended the Vaccine Act's compensation program to be *more generous* than the civil tort system.[7]

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[7] Developments in the past few years have demonstrated the importance of the right to sue for non-Table injuries. The Secretary has revised the Vaccine Injury Table to add only four vaccine-related injuries since the Vaccine Act was enacted in 1986. *See* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7694 (Feb. 8, 1995) (adding "Chronic arthritis" as an injury associated with the MMR vaccine); National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II, 62 Fed. Reg. 7685, 7688 (Feb. 20, 1997) (adding "Brachial neuritis" as an injury associated with the DTP vaccine, "Thrombocytopenic purpura" and "vaccine-strain measles virus infection" as injuries associated with the MMR vaccine, and "vaccine-strain poliovirus infection" as an injury associated with the live poliovirus vaccine); National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table, 67 Fed. Reg. 48558, 48559–60 (Jul. 25, 2002) (adding "intussusception" as an injury associated with the live, oral, rhesus-based rotavirus vaccine). In each case, the Secretary noted that the addition of a particular injury is appropriate only where it "can reasonably be determined . . . to be caused . . . by certain vaccines." 62 Fed. Reg. at 7685; *see also* 67 Fed. Reg. at 48558 (stating that the proposed revisions were "based upon the Secretary's determination that the [injury] can reasonably be determined in some circumstances to be caused by [a specific vaccine]"); 60 Fed. Reg. at 7681 (declining to add certain injuries allegedly related to the DTP vaccine because the Secretary "could not 'reasonably determine' that a causal connection exists"). Additionally, the Secretary has stated that the addition of an injury to the Vaccine Injury Table

At the time the Vaccine Act was enacted, a large number of states recognized a discovery rule under which the limitations period did not begin to run until the plaintiff knew or should have known of both the injury and its cause.[8] Thus, in these states, the statute of limi-

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is inappropriate "[w]here [the] scientific research concerning the relationship between a disorder and a vaccine is incomplete or nonexistent." 62 Fed. Reg. at 7686.

[8] *See, e.g.*, *Anson v. Am. Motors Corp.*, 747 P.2d 581, 584 (Ariz. Ct. App. 1987) (holding that "a cause of action does not 'accrue' until a plaintiff discovers or by the exercise of reasonable diligence should have discovered that he or she has been injured by the defendant's negligent conduct"); *Yamaguchi v. Queen's Med. Ctr.*, 648 P.2d 689, 693 (Haw. 1982) (same); *Barnes v. A.H. Robins Co.*, 476 N.E.2d 84, 87–88 (Ind. 1985) (same); *Louisville Trust Co. v. Johns-Manville Prods. Corp.*, 580 S.W.2d 497, 501 (Ky. 1979) (same); *Penn v. Inferno Mfg. Corp.*, 199 So.2d 210, 219 (La. Ct. App. 1967) (same); *Baysinger v. Schmid Prods. Co.*, 514 A.2d 1, 3–4 (Md. 1986) (same); *Olsen v. Bell Tel. Labs., Inc.*, 445 N.E.2d 609, 611–12 (Mass. 1983) (same); *Cullender v. BASF Wyandotte Corp.*, 381 N.W.2d 737, 739 (Mich. Ct. App. 1985) (same); *Ahearn v. Lafayette Pharmacal, Inc.*, 729 S.W.2d 501, 503–504 (Mo. Ct. App. 1987) (same); *Thompson v. Neb. Mobile Homes Corp.*, 647 P.2d 334, 338 (Mont. 1982) (noting that statute of limitations begins to run on products liability claims when the plaintiff knew or should have known of both the injury and the defect); *Vispisiano v. Ashland Chem. Co.*, 527 A.2d 66, 71–72 (N.J. 1987) (holding that the statute of limitations begins to run when the plaintiff knew or should have known of both the injury and its cause); *O'Stricker v. Jim Walter Corp.*, 447 N.E.2d 727, 732 (Ohio 1983) (same); *Daugherty v. Farmers Coop. Ass'n*, 689 P.2d 947, 950–51 (Okla. 1984) (same); *Burnside v. Abbott Labs.*, 505 A.2d 973, 987–88 (Pa. Super. Ct. 1985) (same); *Woods v. Sherwin-Williams Co.*, 666 S.W.2d 77, 78–79 (Tenn. Ct. App. 1983) (same); *Olson v. A.H. Robins Co.*, 696 P.2d 1294, 1298–99 (Wyo. 1985) (same).

tations on a vaccine-injury claim would not run until the claimant knew or should have known that there was a causal connection between the alleged injury and the vaccine. Under the majority's reading of the limitations provision, however, the Vaccine Act may be far less generous than the remedy afforded by the civil tort system, which generally applies a discovery rule to injuries like the ones at issue here. A claimant who is legitimately injured by a vaccine will nonetheless be barred from filing a petition simply because science has not advanced enough prior to the end of the three-year period following his or her first symptom to furnish a reason to suspect a connection between the injury and the vaccine. This simply cannot be the result intended by Congress when it set out to establish a "program under which awards [could] be made to vaccine-injured persons . . . with certainty and generosity." H.R. Rep. No. 99-908, at 3.

In any event, it seems quite unlikely that Congress intended the Vaccine Act's statute of limitations to effectively bar more generous state remedies that utilize a discovery rule, but that is also the effect of the majority's decision. The Vaccine Act was not intended to bar state remedies, but to provide an *additional* system for vaccine injury compensation which would "lessen the number of lawsuits against manufacturers." H.R. Rep. No. 99-908, at 12 (1986). This was accomplished by "requir[ing] that a person with an injury resulting from a vaccine . . . file a compensation petition and go through the compensation program before proceeding with any litigation against the manufacturer." *Id.* Congress' intent to preserve state law remedies is clearly expressed in § 300aa-16(c) of the Vaccine Act, which provides for a stay of state limitations periods when a petition for compensation is filed under the Vaccine Injury Compensation Program. *See* 42 U.S.C. § 300aa-16(c). But in states that recognize a discovery

rule, that remedy is likely unavailable under the majority's view.

The Vaccine Act plainly requires that a claimant seek a remedy from the Vaccine Injury Compensation Program before attempting to pursue state law claims. *See* 42 U.S.C. § 300aa-11(a)(2); H.R. Rep. No. 99-908, at 14 (stating that claimants "must complete the compensation proceeding . . . *before* pursuing a civil action"); *see also Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1075 (2011). Where the claimant does not do so, the Act requires that the suit be dismissed by the state court. 42 U.S.C. § 300aa-11(a)(2)(B); *see also* H.R. Rep. No. 99-908, at 14. But the remedies available under the Vaccine Act are barred by the majority's view if more than thirty-six months have passed since the claimant's first symptom or manifestation of the injury. Thus, without the benefit of a discovery rule under the Vaccine Act, the claimant will be barred from filing a federal petition even though the state statute of limitations incorporating a discovery rule will not have run. The apparent result is that the state remedy will be barred for failure to file a petition under the Vaccine Act. It is incredible to think that the Vaccine Act was intended to foreclose the very state law remedies that it was designed to preserve and augment.[9]

In the end, there is nothing in the structure or history of the Vaccine Act that renders a discovery rule inappropriate. In fact, the structure and history of the Act not

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[9] The majority makes the strange argument that the failure of the Vaccine Act to tie the limitations period to "occurrence of the injury," as do state discovery statutes, somehow manifests a rejection of the discovery rule. Maj. Op. at 32. The fact that Congress chose to be more explicit about the discovery rule than state statutes hardly reflects a different policy choice.

only confirm, but compel the conclusion that a discovery rule is appropriate.[10] Failure to adopt a discovery rule will create a situation in which a claimant will be unfairly barred from filing a petition even if he or she never knows or has reason to know that a claim exists. Contrary to the majority's assertion, a discovery rule does not result in disparate treatment of similarly situated claimants, but ensures equitable treatment of all claimants.

II

The injustice of the majority's approach is amply demonstrated by the circumstances in this case. In Dr. Cloer's case, there is no dispute that the first symptom or

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[10] The majority's sole structural argument is based on the fact that a discovery rule would provide claimants like Dr. Cloer with a more generous limitations period than that provided for claimants seeking compensation when a new injury is added to the Vaccine Injury Table. The majority asserts that it would be incongruous for claimants asserting non-Table injuries to "enjoy a more generous statute of limitations than . . . Table Injury petitioners, for whom causation is presumed." Maj. Op. at 23. But the different treatment of the statute of limitations for Table and non-Table injuries makes eminent sense. Claimants asserting Table injuries have constructive notice of the vaccine-related nature of their injuries. Claimants asserting non-Table injuries, however, have no such notice. Based on the standards espoused by the Secretary, an injury may be added to the Vaccine Injury Table only where there is sufficient evidence to support a determination that the injury is caused by a certain vaccine. *See supra* note 7. If evidence of a causal connection has not advanced to that point, claimants will not have the benefit of constructive notice or any presumption of causation. In those circumstances, it is not at all incongruous that the statute of limitations should not begin to run until the claimant knew or should have known that the injury is vaccine-related.

manifestation of injury occurred in May 1997 when she experienced a Lhermitte sign, which is recognized by the medical profession as a common symptom of MS. The government has submitted no evidence, however, that Dr. Cloer had reason to suspect a connection between multiple sclerosis ("MS") and the Hepatitis B vaccine before 2004. Under the majority's reading of the Act, the limitations period on Dr. Cloer's claim began running on the date of her first symptom of MS, which occurred more than four years before her cause of action accrued. There is simply no indication that Congress intended that the limitations period begin before she had the information necessary to file a petition.