No. 12-236

# In the Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MELISSA CLOER

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

## PETITION FOR A WRIT OF CERTIORARI


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## QUESTION PRESENTED

Whether a person whose petition under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs.

## PARTIES TO THE PROCEEDING

The caption of the case in this Court contains the names of all parties in the court of appeals.

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The Solicitor General, on behalf of Kathleen Sebelius, the Secretary of Health and Human Services, respectfully petitions for a writ of certiorari to review the order of the United States Court of Appeals for the Federal Circuit in this case.

### ORDER AND OPINIONS BELOW

The order of the en banc court of appeals (App., *infra*, 1a-21a) is reported at 675 F.3d 1358. A related opinion of the en banc court of appeals (App., *infra*, 22a-83a) is reported at 654 F.3d 1322. A related opinion of a panel of the court of appeals (App., *infra*, 88a-125a) is reported at 603 F.3d 1341. A related opinion of the United States Court of Federal Claims (App., *infra*, 126a-154a) is reported at 85 Fed. Cl. 141. A related decision of the Chief Special Master of the United States

Court of Federal Claims (App., *infra*, 155a-176a) is not published in the *Federal Claims Reporter* but is available at 2008 WL 2275574.

## JURISDICTION

The order of the en banc court of appeals was entered on April 11, 2012. On June 27, 2012, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 9, 2012. On July 27, 2012, the Chief Justice further extended the time to August 23, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATUTORY PROVISIONS INVOLVED

The pertinent statutory provisions are reprinted in an appendix to this petition. App., *infra*, 177a-182a.

## STATEMENT

This case presents the question whether a person whose petition under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs. Dividing 7-to-6, the en banc Federal Circuit held that such awards are available.

1. To stabilize the vaccine market and provide compensation for vaccine-related injuries and deaths, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U.S.C. 300aa-1 *et seq*. The Vaccine Act created the National Vaccine Injury Compensation Program (Compensation Program or Program), see 42 U.S.C. 300aa-10(a), which provides compensation for vaccine-related injuries and deaths through a no-fault system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011)

(quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)). Covered vaccines and injuries commonly associated with them are identified in a Vaccine Injury Table, and a causal connection between vaccine and injury is rebuttably presumed when a claim is based on an injury specified in the Table. *Whitecotton*, 514 U.S. at 270; 42 U.S.C. 300aa-14; 42 C.F.R. Pt. 100. If an injury falls outside the parameters of the Table, a claimant must establish that the injury "was caused by" the covered vaccine. 42 U.S.C. 300aa-11(c)(1)(C)(ii).

A person injured by a vaccine (or the representative of such a person) may file a petition for compensation in the United States Court of Federal Claims (CFC), naming the Secretary of Health and Human Services (Secretary) as respondent. *Bruesewitz*, 131 S. Ct. at 1073. A special master of the CFC then "makes an informal adjudication of the petition," *ibid.*, subject to further review by a judge of the CFC and by the United States Court of Appeals for the Federal Circuit, see 42 U.S.C. 300aa-12(e)(2)(B) and (f). "After judgment has been entered by the [CFC] or * * * after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11" must elect between accepting the CFC's judgment and pursuing a civil tort action instead. 42 U.S.C. 300aa-21(a).

The Vaccine Act provides in relevant part that "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 or of the significant aggravation of" the alleged injury for which compensation is sought. 42 U.S.C. 300aa-16(a)(2). The Act also provides for awards of attorneys' fees and costs in certain circumstances:

> (1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—
>
> (A) reasonable attorneys' fees, and
>
> (B) other costs,
>
> incurred in any proceeding on such petition. If the judgment of the [CFC] on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

42 U.S.C. 300aa-15(e)(1). Awards of attorneys' fees and costs, like awards of compensation on the merits, are paid from the Vaccine Injury Compensation Trust Fund, which is supported by an excise tax on each vaccine dose. See 42 U.S.C. 300aa-15(f)(4)(A); 26 U.S.C. 4131, 9510.

Section 300aa-15(e)(1) is the sole source of compensation for attorneys in the circumstances described. See 42 U.S.C. 300aa-15(e)(3) ("No attorney may charge any fee for services in connection with a petition filed under [42 U.S.C. 300aa-11] which is in addition to any amount awarded as compensation by the special master or court under [42 U.S.C. 300aa-15(e)(1)]."). Section 300aa-15(e)(1) differs from most fee-shifting provisions in that it does not make success on the underlying claim a prerequisite to an award of fees. Rather, so long as

the special master or the court finds that a petition under Section 300aa-11 "was brought in good faith and there was a reasonable basis for the claim," the special master or the court may award attorneys' fees and costs even "[i]f the judgment * * * does not award compensation" to the claimant. 42 U.S.C. 300aa-15(e)(1).

2. After receiving three Hepatitis-B immunizations in 1996 and 1997, respondent experienced in mid-1997 what proved to be her first symptom of multiple sclerosis (MS). App., *infra*, 29a. In 2005, eight years after her first symptoms of MS, respondent filed a claim for compensation under the Vaccine Act. *Id.* at 31a. The special master dismissed her claim as time-barred (*id*. at 155a-176a), and the CFC affirmed (*id*. at 126a-154a).

3. a. A divided panel of the Federal Circuit reversed. App., *infra*, 88a-125a. The panel held that the Vaccine Act's limitations period does not begin to run until there is objective medical recognition of a link between the claimed injury and the vaccine. *Id*. at 93a-102a. In respondent's case, the panel concluded, such recognition had occurred (if at all) no earlier than 2004. *Id*. at 102a.

b. The court of appeals granted the government's petition for rehearing en banc and affirmed the CFC's dismissal of respondent's claim as time-barred. App., *infra*, 22a-83a. The en banc court rejected the panel's view that the Vaccine Act's statute of limitations is not triggered unless there is a medical recognition of a link between the claimed injury and the vaccine. The court held instead that, "[c]onsistent with the plain meaning of the statute, * * * 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." *Id.* at 23a-24a.

The en banc court of appeals further held that the Vaccine Act's statute of limitations is subject to equitable tolling, but that respondent had failed to identify a sound basis for tolling in her case. App., *infra*, 24a. Focusing on traditional circumstances warranting equitable tolling, the court explained that respondent "has put no argument before this court that, for example, she has been the victim of a fraud, or of duress." *Id.* at 65a. Respondent contended that applying the Act's time limits "is *ipso facto* unfair because it threatens to deprive her of her claim." *Ibid.* The court concluded that this was "not * * * the sort of circumstance that might merit equitable tolling." *Ibid.*

c. This Court denied respondent's petition for a writ of certiorari seeking review of the court of appeals' holding that her claim was time-barred. 132 S. Ct. 1908 (No. 11-832).

4. Respondent moved in the court of appeals for an award of $118,792.95 in attorneys' fees and costs for proceedings in the Federal Circuit. App., *infra*, 4a; *Cloer* v. *Secretary of HHS*, No. 2009-5052, Docket entry No. 79 (Fed. Cir. Sept. 6, 2011) (application for award of attorneys' fees and costs); *id.* Docket entry No. 75 (Sept. 12, 2011) (supplement to application). By a 7-6 vote, the court of appeals held that the dismissal of respondent's complaint as untimely did not preclude the possibility of a fee award under the Act. The court remanded for a determination whether respondent's claim had been brought in good faith and with a reasonable basis. App., *infra*, 1a-12a.

a. Seven members of the en banc court of appeals held that a person who files an untimely Vaccine Act

petition, but who "assert[s] a reasonable limitations argument" in connection with that claim, is eligible for an award of attorneys' fees and costs "absent a determination that [the] petition was not brought in good faith or that the claim for which the petition was brought lacked a reasonable basis." App., *infra*, 5a. The majority held "that Congress did not intend to require compliance with [42 U.S.C.] 300aa-16 as a prerequisite for the recovery of attorneys' fees." *Id.* at 6a. Rather, the majority concluded, "[t]he good faith and reasonable basis requirements apply to the claim for which the petition was brought; this applies to the entire claim, including timeliness issues." *Id.* at 9a.

The en banc majority recognized that, under 42 U.S.C. 300aa-15(e), a Vaccine Act fee award is available only in a case involving "a petition filed under section 300aa-11 of this title." App., *infra*, 6a. It also acknowledged the directive in 42 U.S.C. 300aa-16(a) that "no petition may be filed for compensation under the Program" after the Act's limitations period has expired. App., *infra*, 10a. The majority concluded, however, that for purposes of the Vaccine Act's attorneys' fees provision, an untimely petition qualifies as a "a petition filed under [42 U.S.C. 300aa-11]." *Id.* at 6a-7a.

In support of that conclusion, the en banc majority observed that Vaccine Act proceedings can be initiated only by the filing of a petition. App., *infra*, 5a (citing 42 U.S.C. 300aa-11(a)(1)). The majority inferred from that fact that "[u]nless * * * [respondent's] filing was a 'petition filed,' neither we nor the [CFC] had jurisdiction over her appeal." *Ibid.* The majority also explained that another provision of the Vaccine Act (42 U.S.C. 300aa-11(a)(2)(A), relating to the conditions for filing a civil suit under state law) expressly cross-references the

limitations provision. App., *infra*, 6a. The majority stated that "[t]he absence of an analogous reference to [42 U.S.C.] 300aa-16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with [42 U.S.C.] 300aa-16 as a prerequisite for the recovery of attorneys' fees." *Ibid.* The majority also noted that the term "petition filed" is used in other Vaccine Act provisions and, in context, appears to encompass untimely petitions. *Id.* at 6a-7a.

The en banc majority also stated that "[r]emedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose." App., *infra*, 8a. The majority expressed the view that its interpretation of the Act's fee provision would "fulfill[] congressional intent and the Act's legislative purpose" because "having to shoulder attorneys' fees could deter victims of vaccine-related injuries from seeking redress." *Ibid.* The court of appeals remanded to the CFC for a determination "whether [respondent's] petition was brought in good faith and whether the claim for which her petition was brought had a reasonable basis." *Id.* at 12a.

b. Judge Bryson, writing for six judges, dissented. App., *infra*, 13a-21a. He explained that "[42 U.S.C. 300aa-16(a)] directs that 'no petition may be filed for compensation under the Program'—and thus under [42 U.S.C. 300aa-11]—after the expiration of the applicable time period." App., *infra*, 14a. He further observed that "[42 U.S.C. 300aa-15(e)(1)] allows an attorneys' fee award only when a petition is filed under [42 U.S.C. 300aa-11]." App., *infra*, 14a. The dissenting judges would have held on that basis that "an attorneys' fee award may be made only if the claimant files a timely petition, either by satisfying the applicable limitations

period of [42 U.S.C. 300aa-16] or successfully invoking equitable tolling." App., *infra*, 14a (citations omitted).

Judge Bryson noted as well that "it is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees." App., *infra*, 18a. He reasoned that, "because Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, [the court] should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended." *Id.* at 19a.

Judge Bryson also expressed concern about the practical difficulties that would arise in deciding a claim for attorneys' fees in a case dismissed on threshold timeliness grounds. He explained that, because Vaccine Act fees are available only for petitions brought in good faith and with a reasonable basis, the special master would be required to conduct "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." App., *infra*, 20a. He observed that "[q]uite apart from the burden on the special masters and the court, the amount of attorney time (and thus the accumulating fees) that would be consumed by such a proceeding would likely exceed the fees expended on the typically much simpler question whether equitable tolling is available to the claimant." *Id.* at 20a-21a. Judge Bryson reasoned that "it seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization, we should be cautious about engrafting one onto the statute." *Id.* at 21a.

## REASONS FOR GRANTING THE PETITION

By a 7-6 margin, the en banc Federal Circuit held that the United States is liable to pay the attorneys' fees of certain Vaccine Act claimants whose petitions for compensation do not even meet the Act's threshold timeliness requirement. That result departs from the Act's text and structure, it ignores applicable canons of statutory construction, and it threatens the efficient functioning of the Compensation Program. As the en banc majority recognized, the question whether fees may be awarded on untimely petitions "will frequently arise in vaccine injury cases." App., *infra*, 11a. Because the Federal Circuit has exclusive jurisdiction to decide the question presented, no circuit conflict is possible. This Court should grant review and correct the Federal Circuit's error.

### A. The Federal Circuit Erred In Holding That A Vaccine Act Claimant Whose Petition For Compensation Is Dismissed As Untimely May Recover From The United States An Award Of Attorneys' Fees And Costs

Under the most straightforward reading of the Vaccine Act's limitations and attorneys' fees provisions, an award of attorneys' fees and costs is unavailable when a petition is dismissed as time-barred. The cumbersome regime that results from the court of appeals' contrary holding—under which a special master must conduct "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding," App., *infra*, 20a (Bryson, J., dissenting)—is an obvious structural mismatch for a compensation system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011)

(quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)). Applicable canons of statutory construction reinforce the conclusion that fee awards are unavailable in these circumstances.

***1. The court of appeals misinterpreted the text and structure of the Vaccine Act***

a. The Vaccine Act requires the special master to award attorneys' fees and costs when "awarding compensation on a petition filed under section 300aa-11 of this title." 42 U.S.C. 300aa-15(e)(1). The Act permits (but does not require) a similar award of fees and costs "[i]f the judgment * * * on *such a petition* does not award compensation." *Ibid.* (emphasis added). Because the phrase "such a petition" refers back to "a petition filed under section 300aa-11 of this title," the court of appeals' decision in this case depends on the court's determination that an untimely Vaccine Act petition is a "petition filed under [42 U.S.C. 300aa-11]."

The Vaccine Act's limitations provision states, however, that "if a vaccine-related injury occurred as a result of the administration of [a covered] vaccine, *no petition may be filed* for compensation under the Program for such injury" after the expiration of the applicable time period. 42 U.S.C. 300aa-16(a)(2) (emphasis added). Because compliance with the limitations provision is a statutory prerequisite to the filing of a petition "for compensation under the Program," a petition that has been dismissed for failure to comply with the Act's time limits is not a "petition filed under [42 U.S.C. 300aa-11]." And in the absence of a petition filed under 42 U.S.C. 300aa-11, there is no statutory basis for awarding attorneys' fees and costs. See App., *infra*, 14a (Bryson, J., dissenting).

b. The result reached by the majority below is also incompatible with the structure and overall purpose of the Vaccine Act. Congress sought to establish a simple and efficient procedural mechanism for providing compensation to persons injured by vaccines. The court of appeals' decision, by contrast, will necessitate complex proceedings that cannot possibly result in compensation for injured persons.

In a case in which the judgment does not award compensation, a fee award is authorized only for a claim "brought in good faith" and with a "reasonable basis." 42 U.S.C. 300aa-15(e)(1). As Judge Bryson explained in dissent, "[i]n a case that has gone to judgment on the merits and the [Vaccine Act] petitioner has lost, it is fairly easy for the special master and the court to determine whether the petitioner's position on the merits was reasonable," because "the special master and the court will have the entire record of the case before them to enable them to make that determination." App., *infra*, 20a. The special master who has studied and resolved the pertinent merits issues can apply the knowledge acquired during that endeavor in deciding whether an award of attorneys' fees and costs is warranted. The special master is thus in a position similar to that of a district judge who has decided a case on the merits adversely to the government, and is therefore well-positioned to determine whether the government's position was "substantially justified" under the Equal Access to Justice Act (EAJA), 28 U.S.C. 2412(d). See *Pierce* v. *Underwood*, 487 U.S. 552, 560 (1988) (noting that a district judge deciding a request for EAJA fees has "full knowledge of the factual setting" and, by dint of experience with the case, "may have insights not conveyed by the record").

By contrast, a Vaccine Act petition submitted after the Act's limitations period has expired may be dismissed on threshold grounds without any meaningful analysis of the merits. When that occurs, the special master will have amassed no record, and will have acquired no case-specific expertise, that can be used to determine whether the claim was brought in "good faith" and had a "reasonable basis" on the merits. 42 U.S.C. 300aa-15(e)(1). To decide whether the claimant could satisfy those statutory prerequisites for a fee award, the special master therefore would be required to "conduct a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." App., *infra*, 20a (Bryson, J., dissenting).

Such a collateral proceeding would be wasteful, painful, and complex—the antithesis of the system that Congress "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 131 S. Ct. at 1073 (quoting *Whitecotton*, 514 U.S. at 269). Proceedings to decide whether there was a reasonable basis for a claim (had it been timely) would consume much of the effort that actually deciding the claim would have entailed, undermining the resource-conserving purpose of the limitations provision. Such proceedings would typically include review of the claimant's medical records, development of expert testimony, and briefing to the special master. Cf., *e.g.*, *Perreira* v. *Secretary of HHS*, 33 F.3d 1375, 1377 (Fed. Cir. 1994) (applying the "reasonable basis" requirement in an objective fashion taking into account the evidence offered in support of the Vaccine Act petitioner's merits claim). In cases where the special master held that a fee award was appropriate, the award could include attorneys' fees and costs for

the fee proceedings themselves. See App., *infra*, 20a-21a (Bryson, J., dissenting) (predicting that the amount of attorney time and consequent fees attributable to fee proceedings in this situation typically will be greater than the fees incurred while litigating the original timeliness question). That effort and those expenses, moreover, would be incurred *after* it had been definitively determined that the claimant was not entitled to compensation.

This shadow trial would be thoroughly unappealing to the claimant herself. Vaccine Act claimants often suffer from debilitating diseases or conditions that require lifelong intensive medical care and are sometimes terminal. Yet the attorneys' fee inquiry would call on the claimant to further expose her medical records (and perhaps herself) to expert examination, and face a trial of sorts. To be sure, a claimant who seeks Vaccine Act compensation must accept similar burdens in connection with the resolution of her claim on the merits. But while such merits proceedings may culminate in an actual award of compensation, the shadow trial necessitated by the decision below can produce no tangible benefit for the claimant herself, only for her lawyer.

Moreover, the determination whether a claimant had reasonable arguments as to both timeliness and the merits can be particularly delicate and complex in Vaccine Act cases because there will sometimes be tension between a claimant's merits and timeliness theories. To establish that a particular medical condition resulted from administration of a covered vaccine, it is typically helpful to show that the first manifestations of the condition were perceived soon after the vaccine was administered. See, *e.g.*, *Althen* v. *Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (explaining that a "showing

of a proximate temporal relationship between vaccination and injury" tends to support a claim under the Vaccine Act). But because the Vaccine Act's limitations period begins to run on "the date of the occurrence of the first symptom or manifestation of onset" of the pertinent condition, 42 U.S.C. 300aa-16(a)(2), a claimant's effort to establish the reasonableness of her position with regard to timeliness will often involve an attempt to dispute the relevance of any early-occurring symptom. Thus, in considering a fee request after dismissal of an untimely Vaccine Act petition, a special master would need to determine not only whether the claimant had reasonable arguments on both timeliness and the merits, but also whether those arguments were internally consistent.

The facts of *Smith* v. *Secretary of HHS*, No. 02-93V, 2006 WL 5610517 (Fed. Cl. July 21, 2006), sustained, 2006 WL 5624674 (Fed. Cl. Nov. 16, 2006), aptly illustrate the problem the court of appeals' decision creates. There, the Vaccine Act petitioner alleged that her son had developed diabetes as a result of a series of vaccinations ending in late 1998. *Id.* at *1-*2. In January 1999, the boy experienced symptoms including excessive thirst and frequent urination. *Id.* at *2, *6. In February 1999, the boy was hospitalized with dangerously high blood sugar and diagnosed with diabetes. *Id.* at *2. The Vaccine Act petition was filed in late January 2002, within the 36-month limitation period as measured from the hospitalization and diagnosis of diabetes, but outside the period as measured from the earlier symptoms. *Id.* at *2-*3. The claim was held to be time-barred, based on the special master's finding that the earlier symptoms were "the first symptom or manifestation of onset," 42 U.S.C. 300aa-16(a)(2), of the boy's diabetes. 2006 WL 5610517, at *7.

Under the decision below, resolving whether the claimant was entitled to an award of attorneys' fees and costs would entail a collateral proceeding to determine whether there was a reasonable basis for believing that the boy's vaccinations in 1998 caused diabetes that was first manifested in February 1999, with coincidental and unrelated symptoms of excessive thirst and frequent urination in January 1999. That inquiry is substantially more complex than the inquiry called for if the claim had been timely (*viz.*, simply whether there was a reasonable basis for a claim that the boy's vaccinations caused his diabetes). "[I]t seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization," the court of appeals should not have "engraft[ed] one onto the statute." App., *infra*, 21a (Bryson, J., dissenting).

***2. Applicable canons of statutory construction reinforce the conclusion that attorneys' fees are not available when a Vaccine Act petition is dismissed as untimely***

For the foregoing reasons, the court of appeals' decision is inconsistent with the text and structure of the Vaccine Act. To the extent that any ambiguity remains, established canons of statutory construction should inform this Court's understanding of the Act's fee-shifting provision. Three such canons reinforce the conclusion that fees are not available when a Vaccine Act petition is dismissed as untimely.

First, the Vaccine Act authorizes monetary claims against the United States by way of a suit against the Secretary in her official capacity. "Caution is especially warranted in a case authorizing a monetary award against the government in light of well-settled principles of sovereign immunity." App., *infra*, 21a (Bryson, J.,

dissenting). That principle applies even when (as in the Vaccine Act) Congress has unambiguously waived sovereign immunity from *some* monetary claims. See, *e.g.*, *FAA* v. *Cooper*, 132 S. Ct. 1441, 1448 (2012) ("For the same reason that we refuse to enforce a waiver that is not unambiguously expressed in the statute, we also construe any ambiguities in the scope of a waiver in favor of the sovereign."). Accordingly, the scope of the Vaccine Act's waiver of sovereign immunity—including the United States' liability to pay respondent's attorneys' fees and costs—should be strictly construed. *E.g.*, *United States* v. *Nordic Vill. Inc.*, 503 U.S. 30, 34 (1992) ("[T]he Government's consent to be sued must be construed strictly in favor of the sovereign and not enlarged beyond what the language requires.") (alterations, citations, and internal quotation marks omitted).

Second, "statutes which invade the common law . . . are to be read with a presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident." *United States* v. *Texas*, 507 U.S. 529, 534 (1993) (citation omitted). In certain respects, the Vaccine Act's remedial provisions unambiguously deviate from prevailing legal practices. The very existence of a fee-shifting provision reflects a departure from the "American Rule," under which each party pays its own fees, *e.g.*, *Alyeska Pipeline Serv. Co.* v. *Wilderness Soc'y*, 421 U.S. 240, 247 (1975), and the Vaccine Act's fee-shifting provision is especially unusual because it does not make success on the merits a prerequisite to an award of fees. See App., *infra*, 18a (Bryson, J., dissenting) ("[I]t is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees."). Thus, even as construed by the govern-

ment and by the dissenting members of the en banc court of appeals, Section 300aa-15(e)(1) exposes the United States to much more expansive potential fee liability than does the typical federal statute. That fact counsels particular hesitation before reading Section 300aa-15(e)(1) to authorize fee awards in additional situations that the provision does not clearly cover. See *id.* at 19a ("[B]ecause Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, [the courts] should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended.").

Third, this Court has cautioned that ambiguous language in federal fee-shifting provisions should be construed, when the text of the statute permits, to limit the length and complexity of fee litigation. In *Pierce*, the Court concluded that "the text of the statute permits, and sound judicial administration counsels, deferential review of a district court's decision regarding attorney's fees under the EAJA." 487 U.S. at 563. The Court based that conclusion in part on the assessment that a deferential approach "will implement [the Court's] view that a 'request for attorney's fees should not result in a second major litigation.'" *Ibid.* (quoting *Hensley* v. *Eckerhart*, 461 U.S. 424, 437 (1983)).

That principle is directly applicable here. In a case where the special master has already conducted the inquiry needed to reject a Vaccine Act claim on the merits, the further determination whether the petition was brought in good faith and with a reasonable basis can typically be made in an expeditious manner. By contrast, when a Vaccine Act petition has been dismissed as untimely, the determination required by 42 U.S.C. 300aa-15(e)(1) will often require fee litigation of a length

and complexity that outstrips the underlying proceedings. See App., *infra*, 20a-21a (Bryson, J., dissenting); pp. 12-16, *supra*.

***3. The reasons given for the en banc majority's holding are unpersuasive***

The court of appeals' resistance to the most natural construction of the Act's fee-shifting provision rests principally on indirect inferences from other parts of the statute. Those inferences are unpersuasive even on their own terms.

a. The majority below first noted that, whereas a different Vaccine Act provision (42 U.S.C. 300aa-11(a)(2)(A)) contains a cross- reference to Section 300aa-16's limitations provision, the Act's fee-shifting provision does not. App., *infra*, 6a. The court inferred that "[t]he absence of an analogous reference to [42 U.S.C.] 300aa-16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with [42 U.S.C.] 300aa-16 as a prerequisite for the recovery of attorneys' fees." *Ibid.* By its terms, however, the fee-shifting provision requires "a petition filed under section [42 U.S.C.] 300aa-11 of this title," see 42 U.S.C. 300aa-15(e)(1), and the limitations provision states that "no petition may be filed for compensation under the Program" after the expiration of prescribed time periods, 42 U.S.C. 300aa-16(a)(2). The fee-shifting provision's requirement of "a petition filed under [42 U.S.C.] 300aa-11" thus obviates the need for any direct cross-reference to the limitations provision itself. Cf. *Astrue* v. *Capato*, 132 S. Ct. 2021, 2031 (2012) ("Respondent notes the absence of any cross-reference in § 416(e) to § 416(h). She overlooks, however, that § 416(h) provides the crucial link * * * [by making] reference to 'this

subchapter' [which] includes * * * [§] 416(e). Having explicitly complemented § 416(e) by the * * * provisions contained in § 416(h), Congress had no need to place a redundant cross-reference in § 416(e).") (citation omitted).

b. The court of appeals was also wrong in stating that "[u]nless * * * [respondent's] filing was a 'petition filed,' neither we nor the [CFC] had jurisdiction over her appeal." App., *infra*, 5a. For two reasons, holding that a time-barred claim is not a "petition filed under section 300aa-11" would create no "jurisdictional impasse." *Id.* at 14a & n.1 (Bryson, J., dissenting). First, any court involved would have "jurisdiction to determine its jurisdiction." *Harmon* v. *Brucker*, 355 U.S. 579, 582 (1958) (per curiam). Second, 42 U.S.C. 300aa-12(a) alleviates the majority's specific concern by giving special masters broad jurisdiction "over proceedings to determine if a petitioner under [42 U.S.C. 300aa-11] is entitled to compensation under the Program." That authority logically includes the power to decide whether the claimant "is eligible under [42 U.S.C. 300aa-16] to file a petition for compensation." App., *infra*, 14a n.1 (Bryson, J., dissenting) (quoting 42 U.S.C. 300aa-12(a)).

c. The court of appeals also expressed concern that if the phrase "petition filed under section 300aa-11" is understood to exclude time-barred petitions, the Secretary and special masters will be unable to perform various statutory obligations with respect to "petitions filed" under the Act "until a determination is made as to the timeliness of the petition." App., *infra*, 6a-7a. But the obligations to which the court referred apply at the commencement of the action, when the claimant's allegations are taken as true and treated as sufficient to warrant further proceedings. For purposes of those require-

ments, a Vaccine Act petition can appropriately be treated as timely until the special master has definitively made a contrary determination. That is no different from ordinary litigation, in which, "[a]t the pleading stage, general factual allegations * * * may suffice," even though "at the final stage, those facts (if controverted) must be supported adequately by the evidence." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal quotation marks and citations omitted).

d. The en banc majority also believed its decision to be supported by prior Federal Circuit decisions (see, *e.g.*, *Shaw* v. *Secretary of HHS*, 609 F.3d 1372 (2010)) holding that "interim" fees may be awarded in Vaccine Act cases before the entry of judgment on the merits. The court stated: "Holding that attorneys' fees are only available where a petition has been subjected to a final adjudication on the merits is also inconsistent with the recognized practice of awarding interim attorneys' fees, which by definition does not require a final adjudication on the merits." App., *infra*, 10a-11a. For two reasons, prior Federal Circuit decisions allowing interim fees in Vaccine Act cases provide no sound basis for the decision below.

First, the Federal Circuit precedents allowing interim fees cannot be reconciled with the statutory text. The Vaccine Act authorizes the special master or court to award attorneys' fees either "[i]n awarding compensation on a petition filed under section 300aa-11" or, under certain circumstances, "[i]f the judgment of the [CFC] on such a petition does not award compensation." 42 U.S.C. 300aa-15(e)(1). Neither of those statutory conditions for a fee award—*i.e.*, an award of compensation, or a judgment that does not award compensation—can be satisfied until the claimant's entitlement to

compensation for the underlying injury has been finally adjudicated.

Second, even if interim fee awards were proper, that would be no reason to conclude that attorneys' fees could be awarded on untimely petitions. The Federal Circuit's initial opinion recognizing the possibility of "interim fees" in a Vaccine Act case rested in part on the court's perception that "[a] special master can often determine at an early stage of the proceedings whether a claim was brought in good faith and with a reasonable basis." *Avera* v. *Secretary of HHS*, 515 F.3d 1343, 1352 (2008). Thus, while the Federal Circuit has held that the Vaccine Act permits some fee awards before the entry of judgment, *Shaw*, 609 F.3d at 1374-1375, the special master must still acquire sufficient familiarity with the underlying facts to determine whether the "good faith" and "reasonable basis" requirements are satisfied. By the same token, the attorneys' fees provision's requirement of "a petition filed under section 300aa-11," 42 U.S.C. 300aa-15(e)(1), makes the availability of a Vaccine Act fee award—interim or otherwise—contingent on the timely submission of a claim. See p. 11, *supra*. Even if interim fee awards under the Vaccine Act were permissible in some circumstances, they could not properly be made without a finding that the petition was timely filed. The Federal Circuit's "interim fee" decisions accordingly provide no support for the proposition that fees may be awarded even after a petition has been determined to be untimely.

e. Finally, the majority below stated that "[r]emedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose." App., *infra*, 8a. On that basis the court concluded that awards of attorneys' fees and costs for un-

timely petitions were appropriate because withholding such awards "could deter victims of vaccine-related injuries from seeking redress." *Ibid.* The general proposition underlying the court of appeals' reasoning is unhelpful in deciding this case because "[n]o legislation pursues its purposes at all costs, and [e]very statute purposes, not only to achieve certain ends, but also to achieve them by particular means." *Freeman* v. *Quicken Loans, Inc.*, 132 S. Ct. 2034, 2044 (2012) (second pair of brackets in original) (internal quotation marks and citations omitted). Here, the relevant provisions of the Vaccine Act obviously limit the availability of a claimant's remedies; the question is in what particular ways are those remedies limited. The statute of limitations bars untimely claims, irrespective of merit. And although the inducement of an award of attorneys' fees and costs was part of Congress's remedial design, such awards are undisputedly available only in proper circumstances, *i.e.*, on a successful petition or an unsuccessful petition filed in good faith with a reasonable basis. See 42 U.S.C. 300aa-15(e)(1). This case simply calls for recognition that timely filing is among the several conditions Congress placed on the availability of an award of attorneys' fees and costs.

### B. The Court Of Appeals' Decision Threatens Significant Adverse Consequences For The Compensation Program

"[C]hallenges brought on limitations grounds will frequently arise in vaccine injury cases." App., *infra*, 11a. The court of appeals' decision can be expected to have two broad and adverse effects on the Compensation Program. Those consequences are sufficiently serious to warrant this Court's intervention.

First, the "shadow trials" described above, pp. 12-16, *supra*, can be expected to consume substantial resources of the special masters, reviewing courts, and others involved in the Compensation Program. Because a Vaccine Act petition may be dismissed as untimely before the special master has acquired substantial familiarity with the underlying facts, the fee proceedings in such cases are likely to be more elaborate and time-consuming than in cases where judgment has been entered on the merits. That is a particularly unwarranted and wasteful allocation of the Compensation Program's resources because the cases affected by the Federal Circuit's holding are by definition cases in which the claimant will not receive compensation. "A request for attorney's fees should not result in a second major litigation." *Hensley*, 461 U.S. at 437. But the Federal Circuit's decision promises exactly that.

Second, the inducement of a fee award to claimants' counsel is likely to increase the number of untimely Vaccine Act petitions. To be sure, the extent of that increase cannot reliably be predicted in advance. The basic purpose of fee-shifting provisions, however, is to increase the incentives for attorneys to provide services in particular categories of cases, thereby enhancing the ability of potential litigants to obtain representation. See, *e.g.*, *Pennsylvania* v. *Delaware Valley Citizens' Council for Clean Air*, 478 U.S. 546, 559-560 (1986). An increase in the number of untimely Vaccine Act petitions would therefore be the natural and expected result of the Federal Circuit's holding that attorneys who file such petitions are eligible for an award of fees.

Because the Program's resources are limited—there is, for example, a statutory cap on the number of special masters, 42 U.S.C. 300aa-12(c)(1)—effort devoted to

collateral matters tends to impede the prompt resolution of meritorious claims for much-needed compensation. By expanding the resources that special masters, reviewing courts, and others must devote to fee litigation and untimely claims, rather than to the merits of timely filed petitions, the court of appeals' decision subverts Congress's effort to establish a compensation system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 131 S. Ct. at 1073; see H.R. Rep. No. 908, 99th Cong., 2d Sess. 3 (1986) (explaining that the Act establishes a "compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity"); *id.* at 17 ("[M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the [Vaccine Act] petitioner can expect judgment," and "without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner"). The court of appeals' decision gravely disserves that purpose and should be corrected.

**CONCLUSION**

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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AUGUST 2012

**APPENDIX A**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

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Apr. 11, 2012

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**ORDER**

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

ON APPLICATION FOR ATTORNEYS FEES AND COSTS

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

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

Opinion for the Court filed by *Circuit Judge* REYNA, in which *Circuit Judges* NEWMAN, LINN, DYK, MOORE, O'MALLEY, and WALLACH join.

Dissenting opinion filed by *Circuit Judge* BRYSON, in which *Chief Judge* RADER and *Circuit Judges* LOURIE, CLEVENGER, GAJARSA, and PROST join.

REYNA, *Circuit Judge*.

Dr. Melissa Cloer sought compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act"), alleging that her Hepatitis B vaccination caused her multiple sclerosis ("MS"). The Chief Special Master dismissed her petition as untimely, and the United States Court of Federal Claims affirmed. Dr. Cloer appealed, and although she did not ultimately prevail on the merits of her Vaccine Act claim, her appeal prompted a change of law in a limited way that potentially opens the door to certain Vaccine Act petitioners who otherwise would have been precluded from seeking redress.

The court must now decide whether Dr. Cloer is eligible to receive an award of reasonable attorneys' fees and costs in connection with her appeal. The Vaccine Act provides for the recovery of attorneys' fees "on a petition filed under section 300aa-11" when "the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa-15(e)(1). We believe that a petitioner who asserts an unsuccessful but non-frivolous limitations argument should be eligible for a determination of whether reasonable attorneys' fees and costs incurred in proceedings related to the petition should be awarded. Therefore, we hold that the court has discretion to re-

mand for a determination of whether Dr. Cloer should be awarded reasonable attorneys' fees and costs.

## I. BACKGROUND

Dr. Cloer was vaccinated for Hepatitis B in 1996 and 1997. Soon thereafter, she developed symptoms of MS. At that time, the medical literature was silent as to any connection between the Hepatitis B vaccination and MS. Several years later, Dr. Cloer learned of such a potential connection for the first time. By then her MS had significantly progressed.

Dr. Cloer filed a petition for compensation under the Vaccine Act. The Chief Special Master dismissed her petition as untimely because it was filed more than 36 months after her first symptom of MS had occurred, and the Court of Federal Claims affirmed. *Cloer v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 141 (2008). Dr. Cloer appealed, and a panel of this court reversed and remanded, ruling that her petition was not time-barred. *Cloer v. Sec'y of Health & Human Servs.*, 603 F.3d 1341 (Fed. Cir. 2010), *vacated*, 399 F. App'x 577 (Fed. Cir. 2010).

Due to the importance of the issues raised by Dr. Cloer, we granted the government's petition for rehearing en banc to determine the applicability of the statute of limitations to Dr. Cloer's case. *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322 (Fed. Cir. 2011) (en banc). In *Cloer*, we held that the Vaccine Act's statute of limitations is not jurisdictional and that some claims brought under the Vaccine Act are subject to equitable tolling. *Id.* at 1344. The court rejected a discovery rule but concluded that Dr. Cloer's claim does not meet those equitable tolling criteria and dismissed her petition as untimely. *Id*. at 1340, 1344-45. Prior to

*Cloer*, courts treated § 300aa-16(a)(2) as jurisdictional, and applications for attorneys' fees related to time-barred petitions were dismissed for lack of jurisdiction. In other words, if a petition was untimely, there was no jurisdiction. *Cloer* rejected that jurisdictional theory.

Dr. Cloer requested an award of reasonable attorneys' fees and costs incurred in her appeal. The government opposed her request on the ground that the Vaccine Act does not permit such an award in connection with a time-barred claim.

## II. DISCUSSION

The Vaccine Act establishes the criteria to be considered in determining whether a petitioner is eligible for attorneys' fees. Section 300aa-15(e) provides:

> (1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—
>
> (A) reasonable attorneys' fees, and
>
> (B) other costs,
>
> *incurred in any proceeding* on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs *incurred in any proceeding* on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(emphasis added). In sum, attorneys' fees are available where the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

This court has not conducted a good faith and reasonable basis analysis of Dr. Cloer's claim; nor did it require the Special Master or Court of Federal Claims to conduct such an analysis. Dr. Cloer asserted a reasonable limitations argument, and absent a determination that her Vaccine Act petition was not brought in good faith or that the claim for which the petition was brought lacked a reasonable basis, she should be eligible to receive an award of reasonable attorneys' fees and costs incurred in proceedings related to her petition.

The statutory language of the Vaccine Act supports our holding. Section 300aa-15(e)(1) provides for the award of reasonable attorneys' fees and costs arising from "a petition filed under section 300aa-11." As § 300aa-11(a)(1) indicates, "*[a] proceeding for compensation* under the [Vaccine] Program for [a] vaccine-related injury or death *shall be initiated* by service upon the Secretary and *the filing of a petition* . . . ." § 300aa-11(a)(1) (emphasis added). The Court of Federal Claims and its special masters have "jurisdiction *over proceedings* to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the [Vaccine] Program . . . ." § 300aa-12(a) (emphasis added). In other words, when a petition is filed, it commences a proceeding over which the Court of Federal Claims has jurisdiction. Unless we conclude that Dr. Cloer's filing was a "petition filed," neither we nor

the Court of Federal Claims had jurisdiction over her appeal.[1]

The plain language of the statute indicates that Congress chose not to tie the right to attorneys' fees to compliance with § 300aa-16. Section 300aa-15(e) does not reference § 300aa-16; rather, it refers to "a petition filed under section 300aa-11." Nor does the plain language of § 300aa-11(a)(1) require that a petition be timely filed in accordance with § 300aa-16. By contrast, § 300aa-11(a)(2)(A), which refers to civil actions brought in state or federal court, does require the filing of a petition "in accordance with section 300aa-16."[2] The absence of an analogous reference to § 300aa-16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with § 300aa-16 as a prerequisite for the recovery of attorneys' fees.

Other statutory provisions support this interpretation. Section 300aa-12(b)(1) states that "[i]n all proceedings brought by the filing of a petition under section 300aa-11(b)," the Secretary shall be named as a respondent and shall participate and be represented in the proceedings. Section 300aa-12(b)(2) requires that within 30 days after receiving service of "any petition filed under section 300aa-11," the Secretary shall publish notice of the petition in the Federal Register. Section

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[1] This interpretation is also consistent with Vaccine Rule 2, which states that "[a] proceeding for compensation under the Vaccine Act is commenced by filing a petition" but does not explicitly require that the petition be filed in compliance with § 300aa-16.

[2] Section 300aa-11(a)(2)(A) provides: "No person may bring a civil action for damages . . . in a State or Federal court for damages arising from a vaccine-related injury or death . . . unless a petition has been filed, in accordance with section 300aa-16 of this title . . . ."

300aa-12(c)(6)(E) obligates the Chief Special Master to report to Congress the number of "petitions filed under section 300aa-11" annually. Section 300aa-13(c) defines "record" as the record established on "a petition filed under section 300aa-11." In referring to "petition[s] filed under section 300aa-11," these provisions refer to all petitions, not just those later determined to have been timely filed. Any requirement that naming the Secretary as a party, publishing notice in the Federal Register, reporting to Congress, and creating the record be held at abeyance until a determination is made as to the timeliness of the petition is unreasonable and would have impractical implications.

Section 300aa-15(e) applies to costs "incurred in any proceeding on such petition," and not solely those fully adjudicated on the merits. Congress made clear that denying interim attorneys' fees under the Vaccine Act is contrary to an underlying purpose of the Vaccine Act. *See Avera v. Sec'y of Health & Human Servs.*, 515 F.3d 1343, 1352 (Fed. Cir. 2008). As we explained in *Avera*:

> [O]ne of the underlying purposes of the Vaccine Act was to ensure that vaccine injury claimants have readily available a competent bar to prosecute their claims. *Denying interim fee awards would clearly make it more difficult for claimants to secure competent counsel because delaying payments decreases the effective value of awards* . . . . Interim fees are particularly appropriate in cases where proceedings are protracted and costly experts must be retained.

*Id*. (emphasis added) (citation omitted); *see also* H.R. Rep. No. 99-908, at 22 (1986) ("the Committee does not intend . . . to limit petitioners' ability to obtain qualified assistance and intends . . . that the court ex-

ercise its discretion to award fees [resulting from] non-prevailing, good faith claims.").

The overarching purpose of the Vaccine Act and the National Childhood Vaccine Injury Compensation Program it created is to award compensation "to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3. Remedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose. *See Atchison, Topeka, & Santa Fe Ry. Co. v. Buell*, 480 U.S. 557, 561-62 (1987). Our interpretation of the statute fulfills congressional intent and the Act's legislative purpose. Congress acknowledged that "[l]awsuits and settlement negotiations can take months and even years to complete. Transaction costs—including attorneys' fees and court payments—are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met." H.R. Rep. No. 99-908, at 6. Congress recognized that having to shoulder attorneys' fees could deter victims of vaccine-related injuries from seeking redress.

Congress did not intend for only prevailing petitioners to receive an award of reasonable attorneys' fees and costs. To the contrary, compensation on a petition should include "an amount to provide for reasonable attorneys' fees and other costs incurred in *proceedings on the petition*. But even where the court does not award compensation on a petition, it may, in its discretion, make such an award for attorneys' fees and costs if it determines that the *action* was brought in good faith and that there was a reasonable basis for the claim for which the action was brought." *Id*. at 21 (emphasis added).

The statutory language requiring a reasonable basis for the claim for which the petition was brought is broad enough to encompass the statute of limitations issue as well as the underlying merits of the claim. It is beyond dispute that Congress intended attorneys' fees to be awarded only in cases brought in good faith and where there was a reasonable basis for the claim underlying the petition, even where the petitioner does not prevail. The good faith and reasonable basis requirements apply to the claim for which the petition was brought; this applies to the entire claim, including timeliness issues. Attorneys' fees should be denied if on remand, it is determined that the petition was not brought in good faith or there was no reasonable basis for the claim for which the petition was brought.

Finally, Dr. Cloer deserves a determination as to whether she is eligible to receive attorneys' fees because her appeal inspired a shift in vaccine jurisprudence. Indeed, the government does not dispute the reasonableness of Dr. Cloer's underlying claim or allege that it was not brought in good faith, which is generally presumed. The confines of the Vaccine Act make clear that a petitioner need not prevail to receive attorneys' fees.

The dissent contends that Dr. Cloer is not entitled to attorneys' fees as a matter of law and creates a rigid rule applicable to requests for attorneys' fees in vaccine cases where the petitioner's claim is rejected solely on limitations grounds. *Cloer* overruled our precedent treating the statute of limitations as jurisdictional and did not endorse the underlying statutory interpretation of such cases. Rather, it eliminated the entire bases for such opinions. Despite this, the dissent would treat Dr. Cloer's petition under a pre-*Cloer* analysis by retroac-

tively eliminating jurisdiction to award attorneys' fees in connection with an unsuccessful statute of limitations argument.

The dissent, primarily in footnote one, argues that § 12 vests the Court of Federal Claims and special masters with jurisdiction to determine whether a petitioner is eligible to file a petition, even if the petition is later deemed untimely. *See* Dis. Op. at 2 n.1. This construction of "petition filed" for purposes of § 300aa-15(e) is inconsistent with the language of the Vaccine Act. Because § 300aa-16(a) states that "no petition may be filed" if it is untimely, the dissent creates a distinction between a "filing a petition" for purposes of § 300aa-11 and a "petition filed" for purposes of § 300aa-15(e) and other statutory provisions. Under this reasoning, an untimely filed petition is a "petition" sufficient to commence proceedings but is not a "petition filed" for purposes of § 300aa-16 and § 300aa-12. Such a distinction between "petitions" and "petitions filed" leads to absurd results, namely that neither this court nor the Court of Federal Claims had jurisdiction over Dr. Cloer's petition.

The dissent also contends that Dr. Cloer is not entitled to attorneys' fees because the Vaccine Act requires an evaluation of the reasonableness of the claim for which the petition was brought, which indicates that Congress did not contemplate awarding attorneys' fees in a case that never reached a merits determination. *See* Dis. Op. at 4. However, as explained above, § 300aa-15(e) explicitly refers to fees "incurred in any proceeding on such petition," including non-frivolous petitions ultimately unsuccessful on limitations grounds. Holding that attorneys' fees are only available where a petition has been subjected to a final adjudication on the merits

is also inconsistent with the recognized practice of awarding interim attorneys' fees, which by definition does not require a final adjudication on the merits.

The dissent claims that "the legislative history of the Vaccine Act is silent as to the reason for the Act's highly unusual attorney fee provision" and goes on to speculate on Congress's motivation for departing from the typical American Rule of fee awards. *See* Dis. Op. at 5 ("It may well be that Congress concluded . . ."); *id*. ("Congress could well have concluded . . ."). Such speculation is unnecessary, however, in light of the remedial nature of the Vaccine Act and Congress's intent to facilitate awards to injured parties.

The dissent advocates adoption of a strict rule that strips discretion from the court and in so doing disregards the Vaccine Act's spirit and purpose. The dissent's interpretation would discourage potential Vaccine Act petitioners from pursuing claims and ignores that potential petitioners will likely be reluctant to bring claims under the Vaccine Act for fear of significant financial risk even when strong arguments exist to challenge the applicability of the statute of limitations.

## III. CONCLUSION

This Order recognizes that issues relating to the award of attorneys' fees in connection with challenges brought on limitations grounds will frequently arise in vaccine injury cases. Under *Cloer*, the Vaccine Act does not incorporate a discovery rule, and the statute of limitations begins to run on "the calendar date of the occurrence of the first medically recognized symptom or manifestation of onset of the [claimed] injury," subject to the doctrine of equitable tolling. *Cloer*, 654 F.3d at 1325, 1340, 1344-45. If a discovery rule were adopted, as Dr.

Cloer now urges in the Supreme Court, the limitations inquiry in vaccine injury cases would then become when the claimant first discovered or should have discovered the potential cause of the disease or injury, rather than when the claimant first experienced symptoms.[3] Under either view, a petitioner may become embroiled in litigation regarding the statute of limitations, and today's order will enable reasonable claims for attorneys' fees arising from that litigation.

A petitioner who asserts an unsuccessful but non-frivolous limitations claim should be eligible for a determination of whether reasonable attorneys' fees and costs incurred in proceedings related to his or her petition should be awarded. Therefore, we remand for a determination as to whether Dr. Cloer's petition was brought in good faith and whether the claim for which her petition was brought had a reasonable basis.

Accordingly,

IT IS ORDERED THAT:

Dr. Cloer's application for reasonable attorneys' fees and costs be remanded to the Court of Federal Claims. The Court of Federal Claims is directed to make a determination consistent with this Order.

FOR THE COURT

Apr. 11, 2012 /s/ JAN HORBALY
Date JAN HORBALY
Clerk

[3] Dr. Cloer filed a petition for certiorari in the United States Supreme Court on December 29, 2011.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

---

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

---

BRYSON, *Circuit Judge*, with whom RADER, *Chief Judge*, and LOURIE, CLEVENGER, GAJARSA, and PROST, *Circuit Judges*, join, dissenting.

The question whether a party who has filed an untimely Vaccine Act petition is entitled to an award of attorneys' fees under section 15(e)(1) of the Act, 42 U.S.C. § 300aa-15(e)(1), presents a difficult statutory construction issue. While there is no clear path to the answer in the plain language or legislative history of the Vaccine Act, I believe that close attention to the text that Congress chose and consideration of the role of the fee-shifting provision both in the Vaccine Act and in the broader context of federal fee-shifting statutes require that we deny the fee request in this case.

1. In *Brice v. Secretary of Health & Human Services*, 358 F.3d 865, 869 (Fed. Cir. 2004), this court held that the attorneys' fees provision of the Vaccine Act

makes fees available only "in connection with a petition filed under section 300aa-11," and that a petition dismissed on grounds of untimeliness is not "a petition filed under section 300aa-11," as required by section 15(e). Similarly, in *Martin v. Secretary of Health & Human Services*, 62 F.3d 1403, 1406 (Fed. Cir. 1995), the court explained that in order for an attorneys' fee award to be permitted under section 15(e)(1), "there must first be a judgment 'on such a petition'—that is, 'on a petition filed under section 300aa-11.'" While this court's en banc decision in *Cloer v. Secretary of Health & Human Services*, 654 F.3d 1322 (Fed. Cir. 2011), overruled *Brice* and *Martin* insofar as they were based on lack of subject matter jurisdiction, *see* 654 F.3d at 1341 & n.9, the en banc court did not disavow the analysis of the statutory structure in those cases, and that analysis is still sound. In substance, as modified by the en banc decision in *Cloer*, *Brice* and *Martin* stand for the following principles: (1) section 16(a) of the Vaccine Act directs that "no petition may be filed for compensation under the Program"—and thus under section 11—after the expiration of the applicable time period, 42 U.S.C. § 300aa-16(a); (2) section 15(e)(1) allows an attorneys' fee award only when a petition is filed under section 11, *id*. § 300aa-15(e)(1); and therefore (3) an attorneys' fee award may be made only if the claimant files a timely petition, either by satisfying the applicable limitations period of section 16 or successfully invoking equitable tolling.[1]

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[1] This interpretation of the statute does not, as the majority opinion suggests, create a jurisdictional impasse. Section 12 of the Act gives the Court of Federal Claims and the special masters jurisdiction "over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation." 42 U.S.C. § 300aa-12(a). That refer-

Besides the reference to a petition filed under section 11, section 15(e)(1) provides for an award of attorneys' fees to an unsuccessful petitioner "if the judgment . . . on such a petition does not award compensation." Although that language, standing alone, could be understood to refer either to a judgment on the merits or to a dismissal for untimeliness, the statutory context indicates that it does not refer to a judgment dismissing the petition for untimeliness. The same language is used in section 21 of the statute, where it clearly refers only to a judgment on the merits. That section provides that if "the judgment did not award compensation," the petitioner is required to file "an election in writing to accept the judgment or to file a civil action for damages for such injury or death." 42 U.S.C. § 300aa-21(a)(2). Because the timely filing of a Vaccine Act petition is a prerequisite to filing a civil tort suit, *see id.* § 300aa-11(a)(2)(A), a claimant who has filed an untimely petition is not eligible to file a civil action for damages. The requirement in section 21 that a petitioner elect whether to file a civil tort suit when "the judgment did not award compensation" therefore does not refer to a claimant whose petition has been denied as untimely. In light of the meaning given to that phrase in section 21, it is fair to infer that the parallel reference in section 15(e)(1) to a "judgment [that] does not award compensa-

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ence gives the Court of Federal Claims and the special masters jurisdiction to determine whether or not the petitioner is eligible under section 16 to file a petition for compensation, even if the petitioner is ultimately determined not to be eligible to file a petition. *See Martin*, 62 F.3d at 1406.

tion" likewise denotes a judgment on the merits, not a dismissal.[2]

Finally, section 16(c) of the Act reinforces the view that the phrase "a petition filed under section 300aa-11" in section 15(e) refers to a timely petition. Section 16(c) provides that if a petition is filed under section 11, state statutes of limitations shall be stayed for any civil action brought for the vaccine-related injury, beginning on the date the petition is filed and ending on the date that an election is made under section 21 to file the civil action. 42 U.S.C. § 300aa-16(c). Because, as noted, such a civil action cannot be filed if the petition was untimely, the reference to "a petition filed under section 300aa-11" in section 16(c) can only mean a petition filed, as section 11 requires, in accordance with section 16, i.e., within the statutory time limits. The same language—"a petition filed under section 300aa-11"—is used as a prerequisite for the payment of attorneys' fees and costs in section 15(e), which is a further textual indication that attorneys' fees and costs are not intended to be paid in cases in which the petition was untimely.

2. Although the legislative history of the Vaccine Act is silent as to the reason for the Act's highly unusual

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[2] The majority finds support for its decision in *Avera v. Secretary of Health & Human Services*, 515 F.3d 1343 (Fed. Cir. 2008), which held that the Vaccine Act permits an award of interim fees to petitioners who are seeking compensation. *Avera*, however, concerned an interim award for a petitioner who had filed a timely petition and therefore was in position to obtain a judgment on the merits, either awarding or denying compensation. Nothing in *Avera* suggests that a fee award, whether interim or otherwise, is appropriate for a claimant who has not filed a timely petition. And nothing in this opinion would prohibit granting interim fees to a petitioner who has filed a timely petition and is seeking a compensation award.

attorney fee provision, the requirement that there be a timely filed petition and a judgment on the merits of the compensation request, as opposed to a dismissal of the petition for untimeliness, makes sense in light of the development and purposes of the Act.

The Vaccine Act evolved from a series of bills that were introduced over a three-year period. All of the bills that featured compensation proceedings contained attorney fee provisions, and all of them, until the very end of the legislative process, required the claimant to be a prevailing party in order to be eligible for a fee award. *See* S. 2117 (Nov. 17, 1983); H.R. 5810 (June 7, 1984); H.R. 1780 (Mar. 27, 1985); S. 827 (Apr. 2, 1985). Several of the early proposals would have allowed claimants to elect to proceed either through the compensation program or by way of a civil tort remedy. The bill that was ultimately enacted, however, required that claimants exhaust their remedies through the Vaccine Act compensation program before filing a tort action. H.R. 5546 (Sept. 18, 1986) (incorporated into S. 1744, which became P.L. 99-660, Title III of which is the Vaccine Act). The proposed exhaustion requirement was controversial and sparked strong opposition from those who did not wish to see any impediments placed in the way of plaintiffs' ability to pursue traditional civil tort remedies. *See Vaccine Injury Compensation: Hearing on H.R. 1780, H.R. 4777, and H.R. 5184 Before the H. Subcomm. on Health and the Env't of the H. Comm. on Energy and Commerce*, 187, 191, 216 (1986) (statements of Jeffrey H. Schwartz, President, Dissatisfied Parents together).

It may well be that Congress concluded that because it was imposing an additional burden on claimants, it

should make fee awards available to claimants who were required to go through the compensation program even though they were not eager to participate in the program and did not ultimately receive compensation. But since claimants who file untimely petitions do not enter the Vaccine Act compensation program and thus do not face the burden of litigating their entitlement to compensation on the merits, Congress could well have concluded that it did not make sense to provide attorneys' fees to those parties in connection with their unsuccessful efforts to avoid the limitations period and gain access to the program.

3. In attempting to discern Congress's purpose in drafting the attorney fee provision at issue in this case, it is important to keep in mind some general principles governing fee-shifting statutes. The background rule applied by American courts is the "American rule," under which each party pays its own fees. *See Alyeska Pipeline Serv. Co. v. Wilderness Soc'y*, 421 U.S. 240, 245 (1975). Some statutes permit or direct a departure from that rule, allowing prevailing parties to obtain an award of attorneys' fees from the losing party under certain circumstances. But it is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees. The Supreme Court put that point succinctly in *Ruckelshaus v. Sierra Club*, 463 U.S. 680, 683-84 (1983), where it noted (emphasis in original):

> Our basic point of reference is the "American Rule," *see Alyeska Pipeline Co. v. Wilderness Society*, 421 U.S. 240, 247 (1975), under which even "the *prevailing* litigant is ordinarily not entitled to collect a reasonable attorneys' fee from the *loser*." It is clear

> that generations of American judges, lawyers, and legislators, with this rule as the point of departure would regard it as "quite inappropriate" to award the "loser" an attorney's fee from the "prevailing litigant."

The Supreme Court in *Ruckelshaus* was able to identify only one federal statute that, as of that time, permitted fee awards to a party whose views were rejected. That statute applied not to litigation, but to the promulgation of rules regarding the regulation of hazardous chemical substances. *Ruckelshaus*, 463 U.S. at 685 n.7, citing 15 U.S.C. § 2605(c)(4)(A).

The statute at issue in this case plainly allows losing parties to obtain a fee award from the prevailing party in some circumstances. But because Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, we should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended. *See Robert C. Herd & Co. v. Krawill Mach. Corp.*, 359 U.S. 297, 304-05 (1959) (a rule of law "in derogation of the common law . . . must be strictly construed"); *In re Crescent City Estates*, 588 F.3d 822, 826 (4th Cir. 2009) ("Because fee-shifting statutes are 'in derogation of the common law,' courts are obligated to construe them strictly.").

That is particularly true in light of the practical effect of requiring the government to pay attorneys' fees to persons who both fail to file a timely petition and then fail in their effort to show that their untimeliness was excused by equitable tolling—which is the only class of persons potentially affected by the resolution of the fee issue before us. Section 15(e)(1) of the Vaccine Act pro-

vides that attorneys' fees can be paid to a petitioner to whom the court does not award compensation "if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa-15(e)(1). As a preliminary matter, it would seem that if Congress had contemplated that claimants making untimely filings should be eligible for attorneys' fees, it would have required both a reasonable basis for the underlying claim and a reasonable basis for the equitable tolling argument; it seems unlikely that Congress would want to compensate claimants who had a reasonable basis for the underlying claim but no reasonable basis to qualify for equitable tolling. More fundamentally, it seems quite implausible that in a case in which the claimant's submission was held to be untimely, Congress would have wanted the special master and the court to conduct a collateral proceeding to determine whether, had the claim been eligible for consideration, it would have had a reasonable chance of success. Yet that is the effect of the court's ruling today.

In a case that has gone to judgment on the merits and the petitioner has lost, it is fairly easy for the special master and the court to determine whether the petitioner's position on the merits was reasonable. In that setting, the special master and the court will have the entire record of the case before them to enable them to make that determination. It is an entirely different matter for the special master to have to conduct a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding. Quite apart from the burden on the special masters and the court, the amount of attorney time (and thus the accumulating fees) that

would be consumed by such a proceeding would likely exceed the fees expended on the typically much simpler question whether equitable tolling is available to the claimant. Again, it seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization, we should be cautious about engrafting one onto the statute. Caution is especially warranted in a case authorizing a monetary award against the government in light of well-settled principles of sovereign immunity. The Supreme Court has held that "[e]xcept to the extent it has waived its immunity, the Government is immune from claims for attorney's fees." *Ruckelshaus*, 463 U.S. at 685-86. And the Court has recently reaffirmed that "a waiver of sovereign immunity must be 'unequivocally expressed' in statutory text"; that "[a]ny ambiguities in the statutory language are to be construed in favor of immunity"; and that "[a]mbiguity exists if there is a plausible interpretation of the statute that would not authorize money damages against the government." *FAA v. Cooper*, No. 10-1024 (U.S. Mar. 28, 2012), slip op. 5.

For these reasons, I respectfully dissent.

**APPENDIX B**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

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Decided: Aug. 5, 2011

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

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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* RADAR, and *Circuit Judges* LOURIE, BRYSON, GAJARSA, PROST, MOORE, and O'MALLEY join.

CLEVENGER, *Circuit Judge*.

This case involves the interpretation and application of the statute of limitations in the National Childhood

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

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 be-

cause "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 complication or effect of her injury was compensable under the program. *Id.*

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[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).

§ 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 it-

self. 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 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

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[2] MS is "a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, parenthesis, 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).

Meyer, an expert in the field of neurology with a specialty in MS. After an MRI examination, Dr. Meyer noted "probable early inactive non-progressive CNS [central nervous system] demyelination/MS," although he explained that her situation did not meet "formal diagnostic criteria for clinically definite MS." *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 argument "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

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 prospec-

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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 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).

tive 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 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 ne-

Further, settled law establishes a firm default rule that a cause of action arises at the same time the statute

gates 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 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).

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 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

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

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the Vaccine Act statute of limitations. We address that questions in part VI.A below.

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 question 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 perceptions 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 addressed 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

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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.

> 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). 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 ac-

crual 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]

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

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

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 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 Vaccine 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*

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).

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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).

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. C*o., 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 treats 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*,

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

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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 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.

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.

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

[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 admin-

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 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*

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istered in 1986 and the state court suit was brought on November 15, 1989. *Martin*, 62 F.3d at 1404.

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 post conviction 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 stat-

utes 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 dili-

gently 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]

Accordingly, the judgment below is

AFFIRMED.

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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.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

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

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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]

I

It is well established in both state and federal law that a discovery rule should be presumed for limitations

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

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

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[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 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 exis-

("[L]ower federal 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 structure of the Act confirm that Congress adopted the prevailing discovery rule approach.

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tence 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).

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 required 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

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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.

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 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

[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).

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 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

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

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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 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*,

limitations 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 a*dditional* 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

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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).

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 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 ex-

[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.

[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.

ists. 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 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.

**APPENDIX C**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

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Oct. 25, 2010

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**ORDER**

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

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

PER CURIAM.

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[*] Judge Clevenger participated only in the decision on panel rehearing.

Respondent-Appellee filed a combined petition for panel rehearing and rehearing en banc. The panel requested a response from Petitioner-Appellant.

The petition for rehearing was considered by the panel that heard the appeal,[**] and thereafter the petition for rehearing en banc and the response were referred to the circuit judges who are authorized to request a poll on whether to rehear the appeal en banc. A poll was requested, taken, and the court has decided that the appeal warrants en banc consideration.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition of Respondent-Appellee for panel rehearing is denied.

(2) The petition of Respondent-Appellee for rehearing en banc is granted.

(3) The court's May 6, 2010 opinion is vacated, and the appeal is reinstated.

(4) The parties are requested to file new briefs addressing the following three 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?

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[**] Chief Judge Michel, who was on the original merits panel, retired on May 31, 2010 and did not participate in the decision on rehearing.

(b) Should *Brice v. Secretary of Health and 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?

(5) This appeal will be heard en banc on the basis of the originally filed briefs and additional briefing ordered herein. The court will determine whether oral argument is appropriate after reviewing the briefs. An original and thirty copies of all originally filed briefs shall be filed within 20 days from the date of filing of this order. An original and thirty copies of new en banc briefs shall be filed, and two copies of each en banc brief shall be served on opposing counsel. Respondent-Appellee's en banc brief is due within 45 days from the date of this order. Petitioner-Appellant's en banc response brief is due within 40 days of service of Respondent-Appellee's new en banc brief, and Respondent-Appellee's reply brief, if any, is due within 15 days of service of Petitioner-Appellant's response brief. Briefs shall adhere to the type-volume limitations set forth in Federal Rule of Appellate Procedure 32 and Federal Circuit Rule 32.

(6) Briefs of amici curiae will be entertained, and any such briefs may be filed without leave of court or the parties' consent but otherwise must comply with Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29.

(7) If needed, oral argument will be held at a time and date to be announced later.

FOR THE COURT

Oct. 25, 2010
Date

/s/ JAN HORBALY
JAN HORBALY
Clerk

cc: Mari C. Bush, Esq.
Anisha S. Dasgupta, Esq.

**APPENDIX D**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

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Decided: May 6, 2010

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**OPINION**

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

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

Opinion for the court filed by *Chief Judge* MICHEL. Dissenting opinion filed by *Circuit Judge* CLEVENGER.

MICHEL, *Chief Judge*.

Petitioner-appellant Melissa Cloer, M.D., appeals the decision of the United States Court of Federal Claims.

*Cloer v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 141 (Fed. Cl. 2008). The decision affirmed the Chief Special Master's report, which denied Dr. Cloer's petition for compensation under the Vaccine Injury Compensation Program ("Vaccine Program") established by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act"), because it was time-barred. *See Cloer v. Sec'y of Dep't of Health & Human Servs.*, No. 05-1002V (Fed. Cl. May 15, 2008).

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

## I. BACKGROUND

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

About a month after her final vaccination, Dr. Cloer began to experience an electric-like shock sensation in her spine. Medical professionals call this sensation a

Lhermitte sign, a common symptom of MS. In September and October 1997, petitioner also lost sensation in her left arm and left hand. Dr. Cloer consulted with her primary care physician, Dr. Pereira, who prescribed Motrin. The symptoms resolved over a short period of time.

When Dr. Cloer experienced additional problems in 1998, she returned to Dr. Pereira. Dr. Cloer underwent further testing, including a magnetic resonance imaging (MRI) scan on May 12, 1998. The MRI scan indicated that possible diagnoses for Dr. Cloer included MS, lyme disease, acute disseminating encephalomyelitis, or other demyelinating processes. A May 15, 1998 medical record specifically noted, "Probable early inactive non-progressive CNS [central nervous system] demylination/MS. . . ."

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

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

the fall of 2003 when she beg[a]n to have manifestations of the full blown disease."

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

On September 16, 2005, Dr. Cloer filed a claim for compensation under the Vaccine Act, alleging that her Hep-B vaccinations caused or significantly aggravated her latent MS condition. On December 1, 2005, respondent-appellee Health and Human Services ("HHS") moved to dismiss the petition because it was filed after the expiration of the statutorily prescribed limitations period.

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

Dr. Meyer did not believe, or even consider, that Dr. Cloer had suffered a vaccine injury when he evaluated her in 1998. Dr. Meyer did not become aware of the association between MS and Hep-B immunization until he was contacted by Dr. Cloer's counsel in late 2005. Dr. Meyer testified that a member of the medical community at large would not have recognized or believed Dr.

Cloer had a vaccine injury as of 1999. Having reviewed Dr. Cloer's prior medical records, Dr. Meyer found no indication of a link between her MS and the Hep-B immunizations before 2004. Dr. Meyer's testimony was not rebutted by any expert.

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

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

## II. DISCUSSION

### A.

Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1277 (Fed. Cir. 2005). We review legal determinations of the Court of Federal Claims *de novo*. *Althen*, 418 F.3d at 1278. To the extent that the Court of Federal Claims adopts factual findings made by the special master, we accord them the same deference as the Court of Federal Claims and review them under the arbitrary and capricious standard as provided in the

statute. *Munn v. Sec'y of the Dep't of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). While we owe no deference to either the special master or the trial court on questions of law, *Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1106 (Fed. Cir. 1996), we review factual findings for clear error, *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1523 (Fed. Cir. 1991).

B.

Congress established the Vaccine Act to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa-1. As part of the Vaccine Act, the Vaccine Program permits claimants to petition to receive compensation for vaccine-related injuries. *See* § 300aa-100(a). The Vaccine Injury Table lists vaccines that are covered under the Vaccine Act. *See* §§ 300aa-11(c)(1)(C)(ii), 300aa-14. The Vaccine Injury Table also lists injuries that may arise from these vaccines, which are referred to as Table injuries. § 300aa-14. Other injuries, including MS, are not listed in the Vaccine Injury Table and referred to as non-Table injuries. § 300aa-11(c)(1)(C)(ii).

The Vaccine Act sets forth a statute of limitations:

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

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

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

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

where she was diagnosed with having a grandmal seizure. *Id.* at 1355.

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

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

> In the case of . . . a vaccine set forth in the Vaccine Injury Table which is administered after October 1,

> 1988, if a *vaccine-related injury* occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of *such injury*.

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

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

ute of limitations may start running later for certain non-Table injuries does not "eviscerate" the statue of limitations.

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

supporting documentation, demonstrating that the person who suffered such injury . . . sustained, or had significantly aggravated, any illness, disability, injury or condition . . . which was *caused* by a Vaccine referred to in subparagraph (A). . . . " 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (emphasis added). This difference in language is not inadvertent since in the statutory provisions relating to Table injuries, the right to bring suit depends on satisfying the "first symptom or manifestation" standard within the time period set forth in the Table.[1] Thus, for Table cases, which do not require causation, the "first symptom or manifestation" language is used in both the statute of limitations and proof of injury subsections. In contrast, for non-Table cases, the "first symptom or manifestation" language is only used in the statute of limitation subsection and the "cause[s]" language applies to the proof of injury subsection. This deliberate choice of different language shows that the time one can bring suit for a non-Table injury (and prevail)[2] is not the same as the time the limitations period begins. *See Dodd*, 454 U.S. at 361.

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

[2] § 300aa-11(c)(1) provides the requirements for a Vaccine Act petition. § 300aa-13(a)(1) states that compensation shall be awarded if the special master or court finds on the record as a whole that the petitioner has demonstrated by a preponderance of the evidence the matters required by § 300aa-11(c)(1). Thus, § 300aa-11(c)(1) lists the requirements for a successful petition at trial.

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

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

necessarily constitutes a merits-based inquiry that should not preclude the filing of a claim.

Our decision does not conflict with *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367 (Fed. Cir. 2001), because our holding is based upon the proper interpretation of § 300aa-16(a)(2). We do not need to equitably toll the limitations period to save Cloer's complaint because § 300aa-16(a)(2) permits her claim since the limitations period, properly interpreted, never began. In addition, while Brice noted that Congress had intended that Vaccine Act claims be resolved "as expeditiously as possible," this statement was in the broader context of replacing a traditional tort system that "was inadequate to compensate many who were injured by vaccines." *See id.* at 1368-69. As this court stated in *Brice*, "Congress noted that opportunities of those injured by vaccines to seek redress under the traditional tort system were 'limited, time-consuming, [and] expensive,' and that for the injured, 'mounting expenses must be met.'" *Id.* at 1368 (quoting H.R. Rep. No. 99-908, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347). Congress intended that awards under the Vaccine Act be made "quickly, easily, and with certainty and generosity." *Id.* at 1368-69 (quoting H.R. Rep. No. 99-908, at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6344). Thus, generosity and reliability to petitioners were as much emphases of Congress as speed. The dissenting opinion, however, would not resolve Vaccine Act petitions generously or with certainty, given that one who is injured would be expected to predict whether there would be a medical linkage between a symptom and a vaccine by a pioneering expert within the next three years. Nor does it encourage expeditious resolution of the claims because a perfectly diligent person would still not know to file a claim any earlier than when

the medical community recognizes a link. Thus, Congress could not have intended to prevent petitioners in such a situation from filing claims.

The dissenting opinion also argues that the majority opinion is inconsistent with *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353 (Fed. Cir. 2007). However, as discussed above, *Markovich* is factually distinguishable from the instant case and thus compelled a different result. In *Markovich*, there was no dispute that the petitioner suffered from seizures as a result of the administration of the vaccine. *Id.* at 1356. The first symptom that Ashlyn experienced, a rapid eye blinking episode, was not normal childhood behavior and would have at the very least raised the suspicions of medical professionals. *See id.* at 1360. The central dispute was whether the statute of limitations should be objective or subjective. *See id.* at 1356-57. The Markoviches argued that the standard should be subjective, based solely on the view of a particular parent. *Id.* at 1356. The government argued that the standard should be objective, based on the recognized standards of the medical community. *Id.* at 1357. We held that the standard necessarily focused on the recognized standards of the medical community and apply that same holding to the facts here.

Finally, the dissent points out that in *Wilkerson*, we stated that "[w]e do not read *Markovich* as requiring in each case a showing of the date on which the medical profession at large has such a recognition." Dissenting op. 9 (quoting *(Wilkerson v. Sec'y of Dep't of HHS*, 2010 WL 292661, at *3 (Fed. Cir. Jan. 27, 2001)). Consistent with *Wilkerson*, we do not suggest that general medical community recognition of a link is required in every case

in order for the statute of limitations to begin running. Where a claimant has received a medical opinion or medical knowledge that symptoms suggest a possible link between the vaccine and the injury, such notice will also suffice to trigger the statute of limitations.

When Dr. Cloer first experienced symptoms in 1997, the medical community at large did not recognize a link between MS and her vaccine. Dr. Meyer, a recognized expert in neurology, testified that he was unfamiliar with any causal link between MS and a vaccine. HHS's own brief also notes that "the medical community at large does not accept a causal association between the hepatitis B vaccine and multiple sclerosis." Appellant's Br. at 16 n.4. In addition, the Vaccine Injury Table does not list MS as a vaccine-related injury. *See* §§ 300aa-11(c)(1)(C)(ii), 300aa-14.

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

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

## CONCLUSION

For the reasons provided above, the judgment of the Court of Federal Claims is

*REVERSED AND REMANDED*

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

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

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CLEVENGER, *Circuit Judge*, dissenting.

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

causal association between the hepatitis B vaccine and MS.[1]

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

For petitioners suffering from non-Table injuries who fail to bring suit within three years of onset, the majority provides the best possible solution, especially with

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

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

regard to diseases that initially present with mild symptoms, such as MS. Under the majority's solution, the person suffering need not worry about the three-year statute of limitations in the Vaccine Act, unless there is consensus in the medical profession that the administered vaccine causes the adverse condition being experienced.[3] As there is no present medical consensus regarding almost all alleged non-Table injuries, injured persons can generally pick the time when they wish to bring their cases. For them, as for Dr. Cloer, the majority proposes that there is no applicable statute of limitations in the Vaccine Act.

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

I

Dr. Melissa Cloer received her third and final hepatitis B vaccination on April 3, 1997. Before that time, she had no significant medical issues and enjoyed generally good health. About a month after her final vaccination, she began to experience numbness in her left forearm and hand. She also began to experience what she described as an "electric shock sensation" with "electric like sensations going down the center of her back to both feet with forward head flexion." This sensation is known as Lhermitte sign, long recognized by the medical profession as a common symptom of MS. *See Dor-*

[3] This is the "general" rule created by the majority. The majority's exception to its general rule is discussed in Part VI, *infra*.

*land's Illustrated Medical Dictionary* 1700 (30th ed. 2003).[4]

In 1998, about a year after her final vaccination, Dr. Cloer sought treatment from Dr. Michael Andrew Meyer, an expert in the field of neurology with a specialty in MS. After an MRI examination, Dr. Meyer noted "probable early inactive non-progressive CNS [central nervous system] demyelination/MS," although he explained that her situation did not meet "formal diagnostic criteria for clinically definite MS." Even so, because the MRI revealed lesions on the white matter of her central nervous system, Dr. Meyer concluded that Dr. Cloer could have MS, Singular Sclerosis, Lyme Disease, and acute disseminating encephalomyelitis, along with other demyelinating processes. Before the Special Master, Dr. Meyer testified that "I think that the first MS related symptom was the [Lhermitte] phenomenon that she had in 1997."

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

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

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

Before the Chief Special Master, and then the Court of Federal Claims, Dr. Cloer did not challenge the uncontroverted evidence that she had suffered symptoms of MS, and likely the manifestation of onset of MS, recognizable as such by the medical profession, more than three years before the filing of her petition, thus time-barring her petition. Her primary argument to the Chief Special Master was that the statute of limitations should not begin to run until she received a "clinically definite" diagnosis of MS in 2003.

Relying on precedent of this court, the Chief Special Master rejected Dr. Cloer's theory and held that the statute of limitations begins to run on the occurrence of the first symptom or manifestation of onset of the injury which the petitioner alleges has resulted from the vaccination. The Chief Special Master discussed at length our decision in *Markovich v. Secretary of Health and*

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

*Human Services*, 477 F.3d 1353 (Fed. Cir. 2007), quoting that "the terms of the Vaccine Act demonstrate that Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." *Cloer v. Sec'y of Health & Human Servs.*, 2008 WL 2275574, *5 (Fed. Cl. Sp. Mstr. May 15, 2008). The Chief Special Master expressly dismissed Dr. Cloer's argument that a "clinically definite" diagnosis is required by *Markovich*:

> Petitioner misreads *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 (emphasis in original).

Just as before the Chief Special Master, Dr. Cloer focused her argument at the Court of Federal Claims on her failure to receive a "clinically definite" diagnosis of MS until 2003. In addition, Dr. Cloer argued to the court that "because the first set of symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a 'vaccine injury.'"

The Court of Federal Claims rejected Dr. Cloer's theory that a "vaccine-related injury" cannot arise until the time when a causal link is shown between the claimed injury and the administration of a vaccine. Initially, the court noted that Dr. Cloer's statutory argument was essentially the same as her main argument requiring a

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

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

II

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

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

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

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

In *Markovich v. Secretary of Health and Human Services*, 477 F.3d 1353 (Fed. Cir. 2007), the plaintiff argued that eye blinking episodes were not enough to trigger the statute of limitations because "the eye blinking symptom could not reasonably alert the Markoviches that anything was wrong." 477 F.3d at 1357. Rejecting the argument that "the standard for statute of limitations purposes should be a subjective one, focusing on the particular view of a specific parent," *id.* at 1356, the

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

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

did not matter that the eye blinking was not recognized as being causally linked to administration of a vaccine. *Id.* It only mattered that the eye blinking episodes were "connected to the injury of seizure disorder within ample time to have filed a timely claim." *Id.* at 1359. The court found the petition time-barred under section 300aa-16(a)(2). *Id.*

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

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

*Id.* at 1345-46. Notwithstanding *Wilkerson*, the majority wants to interpret the same statement in *Markovich*

as holding that *Markovich* requires a contemporaneous recognition in the medical community of a link between the vaccine and the injury. To do so, the court simply ignores the holding in *Wilkerson* that "the Act's time for filing runs from 'the date of the occurrence of the first symptom or manifestation of onset,' not the date of its recognition." *Id.* at 1346.

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

III

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

ing but plausible constructions are possible, "we should adopt the construction that starts the time limit running when the cause of action [] accrues." *Id.*

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

## IV

Under the Vaccine Act, there are two types of petitions, both of which are defined in the section of the Act titled "Petitions for Compensation." *See* 42 U.S.C. § 300aa-11. A person sustaining any "vaccine-related injury" must allege in their petition that they received a vaccine set forth in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-11(c). For harms already recognized by the medical community, the Vaccine Act identifies the injuries commonly associated with each vaccine in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14. If the alleged injury is listed in the Vaccine Injury Table then the petitioner can file a Table petition; otherwise the petitioner must file a non-Table petition.

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

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

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

The Act contains a single statute of limitations for all persons suffering a "vaccine-related injury," regardless of whether they file Table or non-Table petitions. *See* 42 U.S.C. § 300aa-16(a)(2). The limitations statute applies "if a vaccine-related injury occurred as a result of the administration of [a] vaccine." *Id.* The phrase "occurred as a result of" necessarily refers to causation; presumptive causation in the instance of a Table Injury and alleged causation in non-Table petitions. In either instance, the petition must be filed within three years of "the date of the occurrence of the first symptom or man-

ifestation of onset" of the claimed vaccine-related injury. *Id.*

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

V

In light of the clear and binding precedent and the text of the Vaccine Act, the reader is surely asking how Dr. Cloer could possibly prevail. The answer lies in two steps taken by the majority. First the majority proposes: "Dr. Cloer interprets *Markovich* to mean that the medical community at large needs to recognize a link between the injury and the vaccine for the statute of limitations to begin running. We generally agree." *See* Maj. Op. at 6. As our recent decision in *Wilkerson* confirms, the majority and Dr. Cloer misread *Markovich*. As explained above, *Markovich* holds that the statute of limitations cannot run from just any symptom or manifestation; the triggering symptom or manifestation has to be one that the medical community at large recog-

nizes as a sign of the claimed injury. *Markovich* does not help the majority because, under our precedent, the statute of limitations begins to run before the medical profession at large concludes that the vaccine has caused the injury claimed; the lack of consensus exists in nearly every non-Table case ever brought before this court. In short, under our precedent, specifically *Brice*, *Markovich*, and *Wilkerson*, Dr. Cloer cannot prevail.

Second, the majority is forced to confront the general rule that a statute of limitations begins to run at the same time the cause of action arises because the term "vaccine-related injury" appears throughout the Vaccine Act. It appears in the provisions creating the cause of action and specifying the statute of limitations. A petitioner cannot file a petition seeking relief under the Act unless a "vaccine-related injury" has occurred, *see* 42 U.S.C. § 300aa-11(a)(1), and the statute of limitations begins to run three years after "the date of the occurrence of the first symptom or manifestation of onset . . . of such [vaccine-related] injury." *See* 42 U.S.C. § 300aa-16(a)(2). Because the majority defines a "vaccine-related injury" for purposes of the statute of limitations to mean "an injury that is causally connected by medical consensus to the vaccine in question," it necessarily understands that it can be criticized for erecting a bar that prevents petitioners (including Dr. Cloer) from filing causation-in-fact Vaccine Act petitions until such a time as there is consensus in the medical profession that the vaccine has caused the injury claimed. This would be so because if there is no "vaccine-related injury" without medical consensus on causation for statute of limitations purposes, *see* 42 U.S.C. § 300aa-16(a)(2), there can also be no "vaccine-related injury" for a cause

of action until the medical consensus is formed, *see* 42 U.S.C. § 300aa-11(a)(1).

The majority, however, appreciates the effect of the general rule, which would bar the public from filing non-Table petitions until after a medical consensus states that a vaccine causes a particular injury. To avoid the general rule, the majority separates the time of accrual of non-Table causes of action from the time on which the statute of limitations begins to run for such cases. In short, the majority dictates that the general rule which links accrual with initiation of the statute of limitations applies for Table Injury petitions, but does not apply to non-Table petitions. As a practical matter, there no longer will be any statute of limitations for non-Table petitions, as they by definition allege injuries that the Secretary has not added to the Vaccine Injury Table due to a lack of consensus on causation. As a legal mater, this ignores the plain language of the statute that creates a single cause of action for both Table and non-Table petitions. *See* 42 U.S.C. § 300aa-11(a)(1).

The majority seeks to justify its bifurcation by pointing out that, for Table petitions, the requirements include pleading the occurrence of a first symptom or manifestation of a defined vaccine injury within the Table-specified time, and the Vaccine Act statute of limitations uses the same language to trigger the running of the three-year period for bringing Vaccine Program claims. The majority then points out that the requirements for non-Table petitions, though arising under the same cause of action, do not mention "first symptom or manifestation" and instead require a petitioner to plead that the vaccine caused the claimed injury. This "deliberate choice" of different language for the contents of

Table and non-Table petitions, according to the majority, proves beyond question that Congress intended to produce the "odd result" that for non-Table petitioners the cause of action can arise before the statute of limitations begins to run, and that, in fact, there may not even be a statute of limitations for most non-Table cases as the alleged injuries may never be objectively recognized as caused by the vaccine.

Notably, there is no evidence whatsoever in the legislative history of the Act that Congress made a "deliberate choice" of different language in the petition requirements in order to reject the normal rule that a cause of action arises at the same time the statute of limitations begins to run. The difference in language is required because the Vaccine Injury Table only contains injuries that the medical community has concluded are likely to be caused by certain vaccines. Thus, petitioners alleging a Table Injury must comply with the requirements of the Vaccine Injury Table, and the statute of limitations runs from the defined time of the relevant symptom or manifestation listed in the Table. *See* 42 U.S.C. § 300aa-14. For non-Table injuries, there are no such medically agreed-upon symptoms or manifestations that appear within a defined timeframe after administration of the vaccine. Because Congress provided a single limitations period to run for all vaccine cases from the date of the first symptom or manifestation, *see* 42 U.S.C. § 300aa-16(a)(2), Congress left it to petitioners alleging non-Table injuries to prove when their first symptom or manifestation of onset occurred. Our case law has defined that date to require that the symptom or manifestation of onset be recognized by the medical profession as a symptom or manifestation of the injury claimed.

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

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

## VI

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

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

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

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

Enough said. I need not belabor the wrongness of the majority's bewildering exception test for starting the statute of limitation on non-Table petitioners. I might add, as a possible explanatory note to the readers, that Ms. Cloer did not present the majority's exception theory below, nor in the briefs or at oral argument here. Ms. Cloer argued only that the statute should not begin to run until the medical community arrived at a consensus causally linking the hepatitis B vaccine to MS. The illogic of her position and the chaos it would cause for bringing non-Table cases are evident, given the rule that a cause of action accrues and the statute of limitations begins to run at the same time. The majority overcomes Dr. Cloer's flawed argument first by refusing to follow

*Brice*, *Markovich* and *Wilkerson* and by misapplying *Dodd*, and finally by trying to limit the damage done by its general rule by hiving onto it a subjective condition.

VII

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

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

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

by the medical profession. Under the correct test, Dr. Cloer's petition is time-barred.

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

**APPENDIX E**

UNITED STATES COURT OF FEDERAL CLAIMS

No. 05-1002 V

MELISSA CLOER, M.D., PETITIONER

*v.*

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

Filed Under Seal: Nov. 25, 2008

**OPINION AND ORDER**

BLOCK, Judge.

## I. INTRODUCTION

The case before the court is a review of the Chief Special Master Golkiewicz's decision dismissing petitioner's claim for compensation under the National Vaccine Injury Compensation Program ("the Program" or "the Vaccine Act"),[1] 42 U.S.C. §§ 300aa-10 to -34. *Cloer v. Sec'y of the Dep't of Health & Human Servs.* ("*Cloer I*"), 2008 WL 2275574 (Sp. Mstr. Fed. Cl. May 15, 2008). The

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act").

issue in this case surrounds the proper interpretation of the Vaccine Act's limitations period. Section 300aa-16(a)(2) of Title 42 bars all petitions seeking compensation for any vaccine injury from an on-Table vaccine "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." The issue facing this court is whether the limitations period commences according to a subjective test of when a petitioner discovered the existence of the disease or malady, or according to the more restrictive objective test of when the earlier of the first particular symptom of a vaccine injury occurred or the onset of that injury manifested.

The petitioner, Dr. Melissa Cloer, had received a series of three Hepatitis B ("Hep-B") *vaccinations* starting in fall of 1996, after which, in 1997, she began to experience neurological symptoms indicating a demyelinating[2] disease. *Cloer I* at *1-*3. Following a May 1998 MRI revealing lesions on the white matter of her central nervous system, Dr. Cloer received differential diagnoses that included Multiple Sclerosis,[3] Singular Sclerosis,

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[2] "Myelin is a collection of lipid fats and proteins that sheaths the long extensions of nerve cells (neurons) called axons. Myelin considerably increases the speed that nerve signals (impulses) move down the axons." Multiple Sclerosis Encylopaedia, *Myelin*, http://www.mult-sclerosis.org/myelin.html. Thus, a demyelinating disease is one in which lesions appear in the myelin sheaths surrounding the axons.

[3] See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1669 (30th ed.2003) (observing that the etiology-also known as "causation"—of MS is unknown). MS is:

> a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of

Lyme Disease, and acute disseminating encephalomyelitis, along with other demyelinating processes. *Id.* Over the next several years, Dr. Cloer suffered other episodic symptoms consistent with a demyelinating disease. *See id.* at *2-*4. On November 26, 2003, Dr. Cloer received a "provisional" diagnosis of MS by her treating neurologist, Dr. Wood. *Id.* at *2.

But it was not until September 16, 2005, that Dr. Cloer filed a petition pursuant to the Program, alleging that she "had sustained and/or significantly aggravated Multiple Sclerosis as a result of receiving Hep-B immunizations in 1996 and 1997." *Id.* at *1. After receiving evidence, holding a hearing, and receiving post-hearing briefs from both parties, Chief Special Master Golkiewicz dismissed Dr. Cloer's petition because she failed to file within three years of the first symptom or manifestation of onset of her claimed vaccine injury, which occurred in 1997. *Id.* at *8-*10. Accordingly, the Chief Special Master applied the more restrictive construction of the Vaccine Act's limitations period. *Id.* at *4-*9. The Chief Special Master rejected petitioner's contention that the more lenient subjective view of the limitations period should control. *Id.* at *8-*9. Petitioner had argued that because it was not until November, 2003, that Dr. Cloer received even a provisional diagnosis of MS, not only would it be wholly unfair to apply the more restrictive objective limitations period, it would also vio-

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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*. Four types are recognized, based on the course of the disease: relapsing remitting, secondary progressive, primary progressive, and progressive relapsing.

late Fifth Amendment constitutional precepts of equal protection and due process. *See id.* at *9 n.10.

On June 16, 2008, petitioner filed in this court a Motion for Review of the Chief Special Master's decision. Pet.'s Mem. 34. Thus, petitioner asks this court to reverse the Chief Special Master's May 15, 2008 decision dismissing her petition based on the restrictive view of the Program's three-year statute of limitations. Pet.'s Mem. 1. Upon review, for the reasons stated below, the court holds that the Chief Special Master applied the correct legal standard in determining that Dr. Cloer's petition was untimely. Furthermore, as also explained below, the court rejects petitioner's constitutional arguments.

## II. BACKGROUND[4]

### A. Dr. Cloer's Medical History

Dr. Cloer was born on January 22, 1968. Prior to exhibiting symptoms of a demyelinating disease, Dr. Cloer had no significant medical issues and enjoyed generally good health. She began the series of Hep-B vaccinations on September 3, 1996, and received the second vaccination on November 11, 1996. Thereafter, Dr. Cloer reported that after these two vaccinations, she experienced some numbness and tingling. Dr. Cloer received her third and final Hep-B vaccination on April 3, 1997.

About a month after her final vaccination, Dr. Cloer began to experience numbness in her left forearm and hand. Dr. Cloer also began to experience what she des-

[4] The facts, drawn from the pleadings and the Chief Special Master's decision in *Cloer I*, are undisputed, although, as the Chief Special Master characterized it, "the significance of the facts is the consequence of the dispute." *Cloer I* at *3.

cribed 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, a common symptom of MS.[5]

Concerned about these symptoms, Dr. Cloer went to her family physician, who prescribed Motrin. This initial set of symptoms mostly disappeared over the next few months. In 1998, about a year after receiving her final vaccination, Dr. Cloer sought treatment from Dr. Michael Andrew Meyer, an expert in the field of neurology with a specialty in MS. Dr. Meyer ordered an MRI, and based on the results indicating white matter lesion, concluded that Dr. Cloer could have MS, lyme disease, acute disseminating encephalomyelitis, or other demyelinating processes. Dr. Meyer noted "[p]robable early inactive non-progressive CNS [central nervous system] demyelination/MS," even though he had not yet *diagnosed* Dr. Cloer with MS. Dr. Meyer later recalled that during the period he treated Dr. Cloer, "[t]here had been no manifestation of onset of clinically definite multiple sclerosis." *Id.* at *3 (quoting Dr. Meyer's affidavit (emphasis added)). Dr. Meyer explained in his affidavit to the Chief Special Master that Dr. Cloer did not meet "*formal diagnostic criteria* for *clinically definite* MS" because Dr. Cloer's "singular demyelinating change

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[5] Also known as Lhermitte's sign or Lhermitte's phenomenon. Lhermitte sign is defined as:

> the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; *seen mainly in multiple sclerosis* but also in compression and other disorders of the cervical cord.
>
> DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1700 (30th ed. 2003) (emphasis added).

could have remained a clinically isolated event with no sequela." *Id.* (quoting Dr. Meyer's affidavit (emphases added)).

On May 6, 1999, Dr. Cloer received a neurological examination from Dr. Ted Colapinto. Dr. Colapinto noted Dr. Cloer's medical history, described above, and recorded her complaints of numbness in her face, arms, and legs, and her difficulty in walking. Dr. Colapinto noted that Dr. Cloer's symptoms likely represented a demyelinating disease. During a follow-up visit on June 3, 1999, Dr. Colapinto observed improvement in Dr. Cloer's lower extremities, though she still had weakness and numbness in her right leg. At this time, Dr. Colapinto again expressed his concern that Dr. Cloer had a demyelinating disease.

Dr. Kevin Wood, who evaluated Dr. Cloer on November 26, 2003, recorded that Dr. Cloer believed that her symptoms began in 1997. Discussing the patient history, Dr. Wood noted that Dr. Cloer also had episodes of variable weakness and numbness of her legs, and an episode of numbness of her right face. Dr. Wood's notes also record that Dr. Cloer's 1998 MRI was reportedly suspicious for demyelinating areas, though her spinal cord MRIs were unremarkable. After examining Dr. Cloer's medical history and 1998 MRIs, Dr. Wood gave her a "provisional diagnosis" of MS. Dr. James P. Metcalf, who evaluated Dr. Cloer for Social Security Disability in 2004, observed that she began to show symptoms consistent with MS in 1997; though these symptoms waxed and waned until fall of 2003, when Dr. Cloer began to manifest "full blown" MS. *Id.* at *2.

**B. *Cloer I***

Dr. Cloer filed her petition for compensation for a vaccine injury on September 16, 2005. Chief Special Master Golkiewicz received multiple pleadings and affidavits concerning whether Dr. Cloer's petition was timely under the Program. *Cloer I* at *1. Chief Special Master Golkiewicz also held a telephonic hearing to elicit testimony from Dr. Meyer, after which both parties filed additional post-hearing briefs. *Id.* In evaluating Dr. Cloer's petition for compensation for a vaccine injury under the Program, the Chief Special Master provided an extensive discussion of Dr. Cloer's medical history and the affidavits of her physicians.

Dr. Cloer's argument made to the Chief Special Master is as follows: although Dr. Cloer experienced Lhermitte sign, a symptom of MS, in 1997, and each doctor who saw Dr. Cloer for her demyelinating disease traced its first symptoms back to her Lhermitte sign in 1997, Dr. Cloer did not receive a *clinically definite diagnosis* of MS prior to 2003 and neither she nor her physicians were aware of a potential link between MS and vaccinations until after 2003. *Cloer I* at *1-*7. To be sure, Dr. Cloer argued that, based on the knowledge available at that time to the medical community, a diagnosis of MS due to a vaccine injury must be predicated on a manifestation of MS that lasted for at least six months. *Id.* at *9-*10. Thus, Dr. Cloer argues that she could not have petitioned for compensation because no member of the medical community at large would have linked her demyelinating disease problems to the Hep-B vaccinations until after 2003, and as such, her petition was timely. In essence, Dr. Cloer was asking the Chief Special Master to apply the more lenient subjective stat-

ute of limitations period of *Setnes v. United States*, 57 Fed. Cl. 175, 181 (2003) (holding that limitations period begins to run only when subtle symptoms of injury become clearly apparent and the onset of the manifestation of the disease can be diagnosed by a "treating physician").

In rejecting Dr. Cloer's argument, the Chief Special Master relied on the Federal Circuit opinion in *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353 (2007), in applying the restrictive view of the limitation's period of the Vaccine Act. The Chief Special Master observed that in *Markovich*, the Federal Circuit interpreted the Vaccine Act's limitations period to commence on the date the first symptom or manifestation of onset occurs, even though that indication may well be "before many petitioners would be able to recognize with reasonable certainty the nature of the injury." *Id.* at 1357 (quoting *Markovich*). The Chief Special Master also noted that this view is supported by the Federal Circuit's recognition of the disjunctive test in § 16(a)(2) that emphasized the distinction between a symptom and a manifestation of onset.[6] *Id.*

[6] The court stressed that the words "symptom" and "manifestation of onset" are in the disjunctive as used in the Act and that the words have different meanings. Thus, symptom "may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury," whereas a manifestation of onset "is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." Accordingly, the court found that the Act's statutory standard of first symptom or manifestation of onset could include subtle symptoms that a petitioner would recognize "only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury" and would be "recognizable to the medical profession at large but not neces-

In reviewing Dr. Cloer's medical history and the affidavits of her doctors, the Chief Special Master concluded, based on the affidavits of Dr. Cloer and her doctors, that the first manifestation of MS was the Lhermitte sign-the "electric shock sensation" that she experienced in 1997. *Id*. at *6-*8. Moreover, The Chief Special Master observed that even Dr. Meyer, Dr. Cloer's expert and the neurologist who treated Dr. Cloer in 1998, considered in retrospect that the first Lhermitte sign was her first symptom of MS. *Id.* at *9.

Accordingly, based on § 16(a)(2) of the Vaccine Act as informed by *Markovich*, the Chief Special Master interpreted the statute of limitations to trigger on the first symptom or manifestation of onset of MS in 1997, rather than adopt the more lenient view of the limitations period endorsed in *Setnes*—when the petitioner received her definitive diagnosis of the disease in 2003. *Id*. The Chief Special Master ultimately concluded that Dr. Cloer's petition, filed in 2005, was well outside the statute of limitations, which ended in 2000. *Id*. at *7-*8. Thus, Chief Special Master Golkiewicz dismissed Dr. Cloer's petition as barred by the Vaccine Act's three-year statute of limitations.

Finally, as to the constitutional arguments, the Chief Special Master noted in passing that petitioner had raised certain constitutional objections, which respondent vigorously opposed. *See Cloer I* at *9 n.10. Nevertheless, the Chief Special Master rejected these contentions without much comment because they were "not well-developed" and because similar or the same provisions were "analyzed and found to pass constitutional

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sarily to the parent." *Cloer I* at *5 (quoting *Markovich*) (internal citations omitted).

scrutiny" in *Leuz v. Secretary of HHS*, 63 Fed. Cl. 602 (2005). *Id.*

## III. DISCUSSION

Section 12(e)(1) of the Vaccine Act establishes this court's jurisdiction to review decisions of a Special Master upon a properly filed motion for review. 42 U.S.C. § 300aa-12(e)(1); *see also* Vaccine Rule 23; *Phillips v. Sec'y of the Dep't of Health & Human Servs.*, 988 F.2d 111, 112 (Fed. Cir. 1993). This court may embark on one of three courses of action when reviewing a special master's decision in a vaccine case. *Rupert v. Sec'y of Dep't of Health & Human Servs.*, 55 Fed. Cl. 293, 297 (2003). This court may:

> (A) uphold the findings of fact and conclusions of law of the Special Master and sustain the Special Master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the Special Master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the Special Master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(A)-(C); *see also* Vaccine Rules 27, 36(b).

This court, moreover, should apply a different standard depending on what aspect of the Special Master's decision is under review.

> These standards vary in application as well as in degree of deference. Each standard applies to a differ-

> ent aspect of the judgment. Fact findings are reviewed by [the Federal Circuit], as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard.

*Saunders v. Sec'y of Dep't of Health & Human Servs.*, 25 F.3d 1031, 1034 (Fed. Cir. 1994) (*quoting Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10); *see also Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1277 (Fed. Cir. 2005) ("Under the Vaccine Act, the [United States] Court of Federal Claims reviews the special master's decision to determine if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (internal quotations omitted)). The practical effect of this structure is to give the Special Master's determinations decisional effect, and to place this court in the role of a reviewing court. *Munn*, 970 F.2d at 869.

Clearly, the "not in accordance with law" standard is applicable in the case at bar because the primary dispute-interpretation and application of the appropriate limitations period-is a pure legal issue. *See Hines v. Sec'y Dep't of Health & Human Servs.*, 940 F.2d 1518, 1527 (Fed. Cir. 1991). And so are the constitutional claims attacking the Vaccine Act's limitation period. *See Leuz*, 63 Fed. Cl. at 607-12; *Blackmon v. American Home Prods.*, 328 F. Supp. 2d 647, 655-57 (S.D. Tex. 2004). Moreover, the petitioner also asserts an ancillary claim predicated on the arbitrary and capricious standard.

The court's inquiry in this regard must focus on whether the Chief Special Master examined the "relevant data" and articulated a "'satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *See Hines*, 940 F.2d at 1527 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983) (applying a similar standard of review for agency rulemaking under the Administrative Procedure Act)); *see also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S. Ct. 814, 28 L. Ed. 2d 136 (1971) (The "arbitrary and capricious" determination involves a "consideration of the relevant factors and whether there has been a clear error of judgment."). The scope of review under this standard is highly deferential and precludes this court from substituting its own judgment for that of the Special Master. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43, 103 S. Ct. 2856 (*citing Bowman Transp. Inc. v. Arkansas-Best Freight System*, 419 U.S. at 286, 95 S. Ct. 438, 42 L. Ed. 2d 447 (1973)).

To be sure, this court must even "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Id.* (internal citations omitted); *Hines*, 940 F.2d at 1527 ("If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate."). Furthermore, the Act makes clear that this court "is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges v. Sec'y of the Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). Indeed,

"[t]his is a standard well understood to be the most deferential possible." *Munn*, 970 F.2d at 870. Thus, the petitioner has a difficult row to hoe.

**A. Was *Cloer I* "in accordance with law?"**

With these standards in mind, the court turns to the two legal issues proffered by petitioner, the proper construction of the 36-month limitations period found in 42 U.S.C. § 300aa-16(a)(2), and the constitutionality of that section. Preliminarily, it should be noted that the statute of limitations issue goes to the heart of the jurisdiction of this court. This is so because the limitations period in the Vaccine Act "'is a condition on the waiver of sovereign immunity by the United States,' and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.'" *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (quoting *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000)). Consequently, absent such congressional consent, this court lacks jurisdiction to grant relief. *See, e.g., United States v. Testan*, 424 U.S. 392, 399, 96 S. Ct. 948, 47 L. Ed. 2d 114 (1976); *United States v. Sherwood*, 312 U.S. 584, 61 S. Ct. 767, 85 L. Ed. 1058 (1941). It is also beyond doubt that waiver of sovereign immunity must be strictly construed. *See United States v. Mitchell*, 445 U.S. 535, 538, 100 S. Ct. 1349, 63 L. Ed. 2d 607 (1980); *Markovich*, 477 F.3d at 1360 (observing that the Vaccine Act's limitation period must be "strictly and narrowly construed because it is a condition on the waiver of sovereign immunity by the United States"). Thus, it is critical for this court to construe the relevant statute of limitations properly.

Accordingly, the issue presented to this court is whether the Chief Special Master correctly construed the limitations period of 42 U.S.C. § 300aa-16(a)(2). It is worth repeating that, by its terms, it bars all petitions seeking compensation for any vaccine injury from an on-Table vaccine "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." The Hepatitis-B vaccine, the alleged culprit in this case, is indeed an "on-Table" vaccine. 42 U.S.C. § 300aa-14.[7] Section 300aa-16(a)(2) was therefore the proper limitations period to apply in this case. There are several cases that address this provision and clarify its construction, although one is contrary to the other two.

The first piece of the puzzle is *Brice*, where the Federal Circuit held that equitable tolling does not apply to the Vaccine Act's statute of limitations, 42 U.S.C. § 300aa-16(a)(2). 240 F.3d at 1372-74. In so holding, the Federal Circuit noted that this statute of limitations "begins to run upon the first symptom or manifestation of the onset of injury, *even if the petitioner reasonably would not have known at that time that the vaccine had caused an injury*." *Id.* at 1373 (emphasis added). The *Brice* court apparently rejected the view (enunciated, as explained above, by petitioner in this court) that the limitations period begins only when a sufferer has reason to believe the vaccine caused the injury. To be sure, in explaining why this restrictive construction of the limitations provision buttressed the belief that the doctrine

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[7] *See* HRSA-National Vaccine Injury Compensation Program, *http://www.hrsa.gov/Vaccinecompensation/table.htm* (listing "VIII. Hepatitis B antigen-containing vaccines" on the Table).

of equitable tolling does not apply to § 300aa-16(a)(2), the court observed that it would be "quite odd for Congress to allow a limitations period to run in cases in which a petitioner has no reason to know that a vaccine recipient has suffered an injury, but to provide for equitable tolling when a petitioner is aware that a vaccine has caused an injury but has delayed in filing suit." *Id.* The issue of how strict is *Brice*'s restrictive view of the Vaccine Act's limitations period was addressed by the Court of Federal Claims in *Setnes v. United States*, 57 Fed. Cl. 175 (2003).

In reviewing a claim alleging that the vaccine recipient suffered the injury of an autism spectrum disorder, the Court of Federal Claims in *Setnes* took a broad view of the Vaccine Act's statute of limitations. (It is thus the odd-man out in this set of cases.) The Setneses had argued that the 36-month statute of limitations should date from July 16, 1999, when AJ's pediatrician, for the first time, found that AJ was not meeting "*medically appropriate* development guidelines." *Id.* at 179 (emphasis in original). Specifically, the Setneses maintained that because of its unique nature, "there can be no 'manifestation of onset' [for autism spectrum disorder] until such time as the medical and psychological professionals verify through reliable medical and psychological means that a constellation of behaviors presented in a specific child meet [its] criteria." *Id.* In response, the government, taking the more restrictive view, asserted that the plain language of the statute of limitations triggers only on "the occurrence of the first symptom" of the vaccine injury. *See id.* at 180.

In rejecting the government's restrictive view of the limitations period, the court concluded, based on expert

evidence, that "the beginning stage of autism cannot be reduced to a single, identifiable symptom . . . . [m]any of the initial symptoms are subtle and can easily be confused with typical childhood behavior." *Id.* The *Setnes* court determined that autism was a special case, "as distinguished from other medical conditions," because "there is no clear start to the injury." *Id.* Moreover, the court interpreted the "first symptom" and the "manifestation of onset" in the statute of limitations to have different meanings, rejecting the government's contention that the "onset" was determined by the first symptom. *See id.* Significantly, the court construed the limitations provision's term "manifestation of onset" to mean that the resulting disease must be "manifest," i.e., evident at the time, to trigger the statute of limitations. *Id.* at 180 (citing BLACK'S LAW DICTIONARY 867 (5th ed. 1979)). Thus, to the court, for diseases that develop "insidiously over time" in which the initial symptoms are not readily connected to any injury or disorder, the limitations period begins to run only when the manifestation of onset of a particular recognizable injury becomes evident. *See id.* The *Setnes* court concluded that because the special master improperly relied upon retrospective observations as to symptoms rather than contemporaneous medical conclusions as to the manifestation of the specific disease, the special master's decision was reversed and remanded. *Id.* at 180-81.

However, the validity of *Setnes* was made doubtful by the Federal Circuit in *Markovich*. Relying on *Setnes*, the Markoviches urged the Federal Circuit to interpret the Vaccine Act's statute of limitations to embody the more lenient subjective standard commencing only when the petitioner knew that an injury or symptom had occurred. *Markovich*, 477 F.3d at 1356. In affirming the

Court of Federal Claims, the Federal Circuit emphasized that the Vaccine Act's statute of limitations is disjunctive, and thus is triggered by *the earlier* of the first symptom of a vaccine injury or the manifestation of its onset. *See id.* at 1357-58. The court further distinguished between a "symptom" and "a manifestation of onset," giving semantic effect to the statute of limitations' syntactic distinction. *Id.* at 1358. The court explained that:

> [a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury. A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury.

*Id.* Significantly, the *Markovich* court criticized the *Setnes* rationale as problematic because it "effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was appreciable evidence shoring a symptom *and* manifestation of the injury," in contrast to the clearly disjunctive language in the text. *Id.* (emphasis in original). The Federal Circuit also criticized *Setnes* for suggesting that a "subtle symptom or manifestation of the onset of the injury . . . that would be recognizable to the medical profession at large but not to the parent, would not be sufficient to trigger" the statute of limitations. *Id.* Instead, the Federal Circuit cited *Brice* for support, emphasizing that the Federal Circuit has consistently interpreted the Vaccine Act's statute of limitations to be triggered even on "subtle symptoms or manifestations of onset of the injury." *Id.*

Turning to the case at bar, what is fatal to petitioner's cause is that despite protests to the contrary, petitioner relies for support almost exclusively on *Setnes*. Thus, petitioner contends that her petition was timely within the statute of limitations because she only received a "clinically definite" diagnosis of MS in 2003, less than 36 months before filing her petition for compensation in 2005. Pet.'s Mem. 2, 15-21. Petitioner focuses on the medical criteria for *diagnosing* MS and the practical difficulties in doing so given the vagaries of the disease (which is a good application of the holding in *Setnes*), yet astonishingly claims that it is *Markovich* and § 300aa-16(a)(2) that requires that a doctor definitively connect the first symptom to a particular disease before the statute of limitations begins to run. *See, e.g.*, Pet.'s Mem. 3 (referring to "diagnosis or manifestation of onset of *Multiple Sclerosis*" (emphasis added)), 4 & n.2 (discussing criteria for diagnosing MS and how petitioner did not meet these diagnostic criteria), 8-9 (discussing Dr. Meyer's affidavit that he could not diagnose petitioner with clinically definite MS in 1998). According to petitioner, because she did not receive a definitive diagnosis of MS until 2003, and there was no reason for the medical community to suspect a vaccine link to MS until 2004, she could not have had a symptom or manifested the onset of MS as judged by the medical community at large. *Id.* at 11-14. In other words, petitioner is arguing for this court to apply the holding of *Setnes*, which is of questionable validity and not binding upon this court, rather than the valid binding precedent of *Markovich*.

Similarly, this court must reject petitioner's contention that the Chief Special Master's dismissal was legally erroneous because he relied on an idiosyncratic

definition of a "vaccine injury." This argument dresses the *Setnes* wolf in sheep's attire. Once again, petitioner argues that a "vaccine injury," the *sine qua non* for recovery under the Vaccine Act, by definition, cannot be based on the first occurrence of a symptom but is instead contingent on a physician's ultimate diagnosis of a disease based on a particular set of symptoms. Pet.'s Mem. 15-16. In other words, because the first set of symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a "vaccine injury." According to the petitioner, the clock should begin to run only when it was known that the vaccine caused the complained-of specific injury. Nevertheless, all of this is contrary to *Markovich*, which held that the limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming. 477 F.3d at 1358-59. Logical or not, unfair or not, this is what Congress intended. *Id.* at 1358 ("the terms of the Vaccine Act demonstrate that 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" (emphasis added)); *Brice*, 240 F.3d at 1368-69, 1372-73. Indeed, the Chief Special Master, applying *Markovich*, correctly observed that "[t]he Federal Circuit was very clear that diagnosis is not the test for the purposes of the statute of limitations." *Cloer I* at *8.

Another of petitioner's objections is based on based on 42 U.S.C. § 300aa-11(c)(1)(D)(i). This provision requires that a petition under the Vaccine Act contain an affidavit or other supporting material that a petitioner has "suffered the residual effects or complications of

such illness, disability, injury, or condition for more than six months after the administration of the vaccine." Characterizing this language as a tolling provision, petitioner argues that the Chief Special Master erred in dismissing her petition because the limitations period could not begin to run until her injury persisted for six months, which did not occur until 2003-04 (which would thus make her claim timely). Pet.'s Mem. 22-23. The assertion that this requirement has any relation to the Vaccine Act's 36-month statute of limitations has no support in case law, the text of the statute of limitations, or the text of this six-month requirement. Section 300aa-11(c) merely contains the requirements for a petitioner to commence an action before the vaccine special master, one of which is a declaration that petitioner suffered from effects or complications six months after the administration of the vaccine. 42 U.S.C. § 300aa-11(c)(1)(D)(i). Therefore, this language is a condition precedent to the filing of the petition, not a limitations period cutting off the availability of an action.

Although also labeled as an arbitrary and capricious, abuse of discretion argument, petitioner's final "in accordance with law" question raises constitutional arguments. Pet.'s Mem. 30-33. These arguments, arising out of the Fifth Amendment's Due Process Clause, U.S. CONST. amend. V, are twofold: (1) that the Chief Special Master's construction of the Vaccine Act's limitations period impermissibly, in violation of equal protection precepts, discriminates against those victims of vaccines who, like Dr. Cloer, suffer from injuries that cannot be diagnosed within the Act's 36-month limitations period; and (2) that this construction denies petitioner her due process rights. Similar arguments have been addressed

by various courts. And each of these courts have uniformly rejected those arguments.

For instance, in *Leuz*, the parents of a boy who died following a vaccination raised arguments similar to those made by Dr. Cloer in the case at bar, although a different limitations period provision of the Vaccine Act was involved. 63 Fed. Cl. at 604. At issue was 42 U.S.C. § 300aa-16(a)(3), which requires that claims alleging death due to a vaccination be filed within 24 months of the death. The *Leuz* petitioners contrasted this with the non-death injuries, for which § 16(a)(2) (the provision at controversy in our case) provides for a 36-month limitations period following the injury. *Id.* The petitioners did not dispute that they filed their petition 33 months after their son's death, but instead contended that the Act violated their rights to equal protection and due process because the limitations period for death injuries was shorter than the 36-month limitations period for all other injuries under the Vaccine Act. *Id.* at 605.

The court rejected their constitutional arguments. Opining that rational basis review applied because the petitioners' Vaccine Act equal protection discrimination claims[8] did not implicate any fundamental right, the court concluded that the differing limitations period passed constitutional muster so long as it was reasonably related to a permissible government goal. *See id.* (citing *Black v. Sec'y of Health & Human Servs.*, 93

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[8] "Although," as the court explained, "the Fifth Amendment contains no equal protection clause," it forbids discrimination that is "'so unjustifiable as to be violative of due process.'" *Id.* at 608 (quoting *Schneider v. Rusk*, 377 U.S. 163, 168, 84 S. Ct. 1187, 12 L. Ed. 2d 218 (1964) (quoting *Bolling v. Sharpe*, 347 U.S. 497, 499, 74 S. Ct. 693, 98 L. Ed. 884 (1954))).

F.3d 781, 787 (1996)). The court noted that "Congress is not obligated to extend the coverage of the Vaccine Act cases to all person [sic] suffering a vaccine-related injury." *Id.* (citing *Black*, 93 F.3d at 788; *Califano v. Boles*, 443 U.S. 282, 296, 99 S. Ct. 2767, 61 L. Ed. 2d 541 (1979)). Contrary to petitioners' claim that it was irrational, the court found logical reasons, and thus a rational basis, for the distinction—while in a non-death case, symptoms continue to evolve, and may need more time to diagnose, the events surrounding a death are static, and preclude the injury from worsening, changing, abating, or evolving. *See id.* at 608-09.

Nor did the limitations period run afoul, according to the court, of either substantive or procedural due process. Thus, the court determined that the limitations period did not violate substantive due process because it neither shocked the conscience nor interfered with any right implicit in the concept of ordered liberty. *Id.* at 609-10 (citing *United States v. Salerno*, 481 U.S. 739, 746, 107 S. Ct. 2095, 95 L. Ed. 2d 697 (1987) (quoting *Rochin v. California*, 342 U.S. 165, 172, 72 S. Ct. 205, 96 L. Ed. 183 (1952))). Rather, the court noted that the 24-month period is "rationally related to the Act's dual purposes of settling claims quickly and easily, without collateral litigation, and protecting manufacturers from uncertain tort liability." *Id.* at 610. In sum, the court concluded that "the petitioners have not persuasively argued that the statute of limitations has operated in any manner contrary to its legislative purpose." *Id.* Similarly, the court concluded that the limitations period did not violate procedural due process. *Id.* at 610-11. Because petitioners had no vested right in any claim for damages until there is a final judgment, they had only a "unilateral expectation" that does not rise to a level of

entitlement. *Id.* (citing *Board of Regents v. Roth*, 408 U.S. 564, 577, 92 S. Ct. 2701, 33 L. Ed. 2d 548 (1972); *Hammond v. United States*, 786 F.2d 8, 12 (1st Cir. 1986)). Moreover, the court, in applying the balancing test under *Mathews v. Eldridge*, 424 U.S. 319, 335, 96 S. Ct. 893, 47 L. Ed. 2d 18 (1976),[9] concluded that tolling the limitations period as petitioners requested would come at a great societal cost by harming public health and thus would be inconsistent with the Act's overall statutory scheme. *See id.* at 611-12.

An even more apropos case is *Blackmon*. In facing equal protection and due process constitutional challenges to § 16(a)(2)'s 36-month limitations period—the same limitations period in controversy here—the court faced an argument similar to that made by Dr. Cloer: the Vaccine Act's limitations period unconstitutionally discriminated against those with latent, slow-developing vaccine injuries that cannot be fully diagnosed until the 36-month period has run. *Blackmon*, 328 F. Supp. 2d at 655. While emphasizing that the limitations period did impose a hardship on some people, because the statute of limitations was only subject to rational basis review, the 36-month limitations period bore a clear and logical connection to a "repose" purpose of the Vaccine Act in protecting vaccine manufacturers from open-ended lawsuits in order to maintain the supply of vaccines. *Id.*

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[9] These factors include: "(1) the strength of the private interests that would be affected by the official action; (2) the 'risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards,' and (3) 'the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.'" *Leuz*, 63 Fed. Cl. at 611 (quoting *Mathews*, 424 U.S. at 335, 96 S. Ct. 893).

(citing *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994)).

The plaintiffs' other Fifth Amendment argument (again, much like Dr. Cloer's) asserted that the Act's statute of limitations, expiring before the plaintiffs knew or could have known of their children's vaccine injuries, violated the constitutional guarantee of due process. *See id.* at 655-56. In rejecting petitioners' assertions, the court observed the well-settled rule that "[t]he Due Process Clause does not entitle every litigant to a hearing on the merits in every case," and emphasized that statutes of limitations are themselves common and unremarkable means to avoid stale claims and provide an end-date to potential litigation. *See id.* at 656. The court noted that plaintiffs failed their burden to prove that the Vaccine Act's limitations period was "wholly arbitrary." *Id.* (citing *Montagino v. Canale*, 792 F.2d 554, 557 (5th Cir. 1986)). Indeed, to the court, "[t]he mere fact that certain victims fail to discover and file their claims before the limitations period expires, while regrettable, does not render the limitation unreasonable." *Id.* at 656-57 (quoting *Ciccarelli v. Carey Canadian Mines Ltd.*, 757 F.2d 548, 555 (3d Cir. 1985) ("Because statutory periods are in some sense arbitrary, the period to initiate suit occasionally expires before a claimant has sustained any injury . . . or before the claimant knows he has sustained an injury . . . .")). Instead, the limitations period was constitutional because "it is reasonably calculated to serve a permissible legislative goal." *Id.*

The equal protection and due process arguments proffered by petitioner in the case at bar must be rejected for the reason the virtually-same arguments were

rejected by the *Leuz* and *Blackmon* courts—there can be no question that applying the Vaccine Act's limitation period is rationally related to the dual legitimate legislative purposes undergirding the Vaccine Act: (1) the settling of claims quickly and easily,[10] and (2) the protecting of manufacturers from uncertain liability making "production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market." *Brice*, 240 F.3d at 1368. And because petitioner also lacks a vested property interest in her claim, it is difficult to see a Fifth Amendment due process violation.

**B. Was *Cloer I* an Abuse of Discretion or Arbitrary and Capricious?**

Turning to this set of objections, petitioner contends that it was an abuse of discretion or arbitrary and capricious of the Chief Special Master not to account for the "insidious[ ]" development of MS and the difficulties in diagnosing it, especially as MS was not listed as an injury for any vaccine on the Table. Pet.'s Mem. 23-24. In other words, petitioner maintains that an exception should have been made to the restrictive view of the limitations period because petitioner did not and could not receive a definitive diagnosis for her particular demyelinating disease until 2003. *See, e.g.*, Pet.'s Mem. 21, 24. Yet this is another *Setnes* argument that petitioner tries to dress up in new garb. At its heart it is a matter of the

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[10] *See* H.R. REP. NO. 99-908, at 17, *reprinted in* 1986 U.S.C.C.A.N. at 6358 ("[M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.").

interpretation of the limitations period provision, which is a pure legal issue, not one of whether the Chief Special Master's marshaling of the evidence was unreasonable or arbitrary.

Nevertheless, even using the arbitrary and capricious rubric, and contrary to petitioner's contention, the Chief Special Master did not abuse his discretion, nor act arbitrarily or capriciously, in refusing to carve out an atextual exception for petitioner's particular claimed injury. The record would not allow it. To be sure, as far back as 1998, plaintiff's own expert, Dr. Meyer, considered MS to be a possible cause of Dr. Cloer's symptoms. *Cloer I* at *1 ("May 15, 1998 record of UM-Columbia noted '[p]robable early inactive non- progressive CNS [central nervous system] demyelination/MS'"). In retrospect, Dr. Meyer similarly concluded that the first sign of MS was the Lhermitte Sign that Dr. Cloer experienced in 1997. *Id.* at *4. It is this Lhermitte sign, which was then indicative of MS and remains so today, that was the "first symptom" (or perhaps even a "manifestation of onset") of what is by definition a vaccine injury under the Act. *See Brice*, 240 F.3d at 1373 (observing that for the purpose of the Vaccine Act's limitations period the first symptom of a vaccine injury may predate the final diagnosis of a disease). That Dr. Cloer was finally able, in 2003, to definitively attach a particular name to the symptoms that she had on and off for six years does not and cannot mean that she did not suffer a vaccine injury until 2003. The statute of limitations does not provide "first clinically *definitive symptom* or manifestation of onset of a medical syndrome;" rather, it is sparked by the "first symptom or manifestation of onset of a vaccine injury." *See* 42 U.S.C. § 300aa-16(a)(2).

Furthermore, there is other evidence in the record that supports the Chief Special Master's conclusion that the first symptoms of MS occurred prior to 2003. In May 1999, Dr. Colapinto traced the beginning of petitioner's neurological symptoms, which "likely represent demyelinating disease," back to the numbness in Dr. Cloer's left arm and hand that accompanied her Lhermitte sign. *Id.* at *1. Similarly, Dr. Wood, in 2003, and Dr. Metcalf, in 2004, both trace petitioner's first symptoms back to her neurological problems of 1997. *See id.* at *2.

Similarly, petitioner's other "arbitrary and capricious" arguments are really "not in accordance with law" objections. Nor are they persuasive. For instance, the petitioner asserts that by rejecting the application of *Setnes* to the instant facts, *Cloer I* is not only not in accordance with law, but also is an abuse of discretion or arbitrary and capricious. Pet.'s Mem. 24-25. The Chief Special Master concluded, and this court agrees, that *Setnes* does not apply to the instant facts, *Cloer I* at *4-*5, and that even if it did, as stated above, *Setnes* is contrary to *Markovich*, which, unlike *Setnes*, is binding upon this court. Petitioner likewise contends that the Chief Special Master's decision to deny compensation is arbitrary and capricious because it violates the remedial purpose of the Vaccine Act, which is demonstrated by its generous provisions and because it is less adversarial than a product liability lawsuit. Pet.'s Mem. 25-28. But of course, it is the duty of the Chief Special Master here to enforce the Vaccine Act's specific limitations provision, the meaning of which is the best exemplar of congressional intent. *See Nixon v. United States*, 506 U.S. 224, 232, 113 S. Ct. 732, 122 L. Ed. 2d 1 (1993) (observ-

ing "the well-established rule that the plain language of the enacted text is the best indicator of intent").

Yet another "arbitrary and capricious" objection by petitioner is that the Chief Special Master ignored her proffered "unrebutted expert testimony" supporting her position. Pet.'s Mem. 29-30. This objection is also vague and not well-developed. Petitioner failed to detail which "unrebutted" testimony the Chief Special Master ignored. In fact, there is no evidence that Chief Special Master Golkiewicz ignored or failed to weigh testimony on *any medical issue* in the case. Yet there remains one other proffered argument that falls into the "vague and not well-developed" category. In asserting yet another *Setnes* argument, petitioner argues that because she did not find out until 2005 that the Hep-B vaccinations to which she traces her MS contained Thimerosal, the court must liberally construe the Vaccine Act's 36-month statute of limitations to begin to run on the diagnosis of the disease rather than trigger on its first symptom or the manifestation of its onset.[11] Pet.'s Mem. 33-34. Petitioner further claims that *Cloer I* fails to address recent concerns on Thimerosal and the potential bearing of this new information on the accrual of her claims under the Vaccine Program. Pet.'s Mem. 34. Besides the fact that there is no evidence that petitioner raised this issue before the Chief Special Master, neither the potential effects of Thimerosal nor its inclusion in the Hep-B vaccine have any bearing on whether petitioner sought com-

[11] Thimerosal is a compound that had been added to vaccines as a preservative and is the subject of a number of claims alleging that it causes vaccine injuries, most notably but not exclusively autism spectrum disorder. *See generally* Thimerosal in Vaccines, http://www.fda.gov/CBER/vaccine/thimerosal.htm. An examination of the effects of Thimerosal is beyond the scope of this opinion.

pensation within three years of the first symptom or manifestation of the onset of her demyelinating disease.

To be sure, this court has an enormous amount of sympathy for petitioner's predicament—MS is not easy to diagnose, its etiology remains largely unknown, and its manifestation and symptoms are episodic, waxing and waning, disappearing and recurring. *See* note 3, *supra*. That petitioner may be without relief for her MS gives this court no small measure of discomfort. But, as the Federal Circuit noted in *Brice*, weighing the pros and cons of a particular statutory scheme is a problem for Congress to address. 240 F.3d at 1373. The 36-month limitations period of the Vaccine Act is neither unlawful nor unconstitutional. Nor was the Chief Special Master's decision arbitrary, capricious, or an abuse of discretion.

## IV. CONCLUSION

For the foregoing reasons, the court **AFFIRMS** the Special Master's decision. The court, accordingly, dismisses the petition with prejudice.

**IT IS SO ORDERED**.

**APPENDIX F**

UNITED STATES COURT OF FEDERAL CLAIMS

No. 05-1002V

MELISSA CLOER, M.D., PETITIONER

*v.*

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENT

May 15, 2008

***DECISION***[1]

GOLKIEWICZ, Chief Special Master.

On September 16, 2005, petitioner, Melissa Cloer, M.D. (Dr. Cloer), filed a Petition pursuant to the Nat-

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" decision will be available to the public. *Id.*

ional Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that she "had sustained and/or significantly aggravated Multiple Sclerosis[3] (MS) as a result of receiving Hep-B immunizations in 1996 and 1997."[4] Petition (Pet.) at 1. On December 1, 2005, respondent filed a Motion to Dismiss alleging the Petition was filed outside the statutorily prescribed limitations period. Respondent's Motion to Dismiss (hereinafter R Motion to Dismiss) at 1. Multiple pleadings and affidavits were subsequently submitted by the parties addressing the issue of whether the above-captioned

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[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 *et seq*. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

[3] Multiple Sclerosis (MS) is defined as: a disease in which there are foci of demyelination of various sizes throughout the white matter of 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. Four types are recognized, based on the course of the disease: *relapsing remitting, secondary progressive, primary progressive,* and *progressive relapsing*. The etiology is unknown. Dorland's Illustrated Medical Dictionary 1669 (30th ed 2003).

[4] The undersigned notes that while petitioner alleged in her petition she "had sustained and/or significantly aggravated Multiple Sclerosis (MS) as a result of receiving Hep-B immunizations in 1996 and 1997," petitioner did not produce any evidence distinguishing between "sustained" and "aggravated" for purposes of determining whether the Petition was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." § 16(a)(2).

case was timely filed. Ultimately, a telephonic Hearing was convened to elicit testimony from petitioner's treating physician, Dr. Michael Andrew Meyer. Petitioner and respondent subsequently filed post-Hearing briefs. The issue is ripe for resolution.

**Issue**

The sole issue presented at this stage in the proceedings is whether Dr. Cloer's Petition for compensation for her *multiple sclerosis* injury was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." § 16(a)(2).[5] For the reasons set forth below the undersigned must dismiss this petition as untimely filed.

**Facts**

The facts presented in this matter are uncontested, although the significance of the facts is the centerpiece of the dispute. Dr. Cloer was born on January 22, 1968. Pet. at 1. Prior to Dr. Cloer's MS injury she had no significant medical issues and enjoyed good health. *Id.* at 2. Dr. Cloer received a series of three Hep-B vaccinations on September 3, 1996, November 11, 1996, and April 3, 1997. *Id.* The following excerpt from respon-

[5] The undersigned requested the parties to address the applicability of the Act's distinct time period for filing a claim based upon a revision to the Vaccine Injury Table. *See* § 16(b). Respondent raised the issue in Respondent's Reply to Petitioner's Opposition to the Motion to Dismiss at 6-7. Petitioner argued that § 16(b) was inapplicable. Petitioner's Response to Respondent's Argument Regarding the Applicability of § 16(b). Thereafter, respondent's counsel indicated to the undersigned in a joint status conference with petitioner's counsel on May 15, 2006 that respondent agreed with petitioner's position. Given the resolution of this case, it is unnecessary to discuss the § 16(b) issue.

dent's post-Hearing brief fairly and accurately summarizes petitioner's pertinent medical records following her three Hep-B vaccinations.

1. April 28, 1998 records of UM–Columbia reveal that one year earlier petitioner complained of an "electric-like shock sensation going down [the] center of [her] back into both feet," and, in September and October 1997, petitioner lost sensation in her left arm and left hand. Petitioner's Exhibit ("Pet. Exh.") 12 at 12;

2. May 12, 1998 magnetic resonance imaging (MRI) scan; possible diagnoses included "multiple sclerosis, lyme[ ] disease, ADEM [acute disseminating encephalomyelitis], or other demyelinating processes." Pet. Exh. 12 at 16;

3. May 15, 1998 record of UM–Columbia noted "[p]robable early inactive non-progressive CNS [central nervous system] demyelination/MS. . . ." Pet. Exh. 12 at 17;

4. June 23, 1998 electromyography (EMG) to evaluate "numbness and tingling in the L ulnar nerve distribution." Pet. Exh. 12 at 22;

5. May 6, 1999 neurological examination by Ted Colapinto, M.D. Pet. Ex. 12 at 36. Dr. Colapinto noted petitioner's history "beg[an] approximately two years ago when she had the onset of neurological symptoms in her left hand. She complain[ed] that her left hand felt numb . . . this lasted approximately two months, but gradually resolved mostly." *Id.* Dr. Colapinto recorded petitioner's complaints of numbness in her face, arms, and legs, and noted that she had difficulty walking. *Id.* He felt that peti-

tioner's neurological symptoms "likely represent demyelinating disease." *Id.*;

6. June 3, 1999 follow-up visit to Dr. Colapinto noted "a lot of improvement in the symptoms in the lower extremities, but still notice[d] some feelings of proximal weakness in the right leg, as well as some numbness of the anterior aspect of the right thigh." Pet. Exh. 12 at 41. Dr. Colapinto expressed continuing concern that petitioner had a demyelinating disease. *Id.*;

7. November 26, 2003 record of Dr. Wood detailing petitioner's medical history:

> [Melissa] actually believes that she has had problems dating from 1997 when she was in Missouri. She had episodes of variable weakness and numbness of her legs, at one time numbness of her right face. She had an MRI of the brain in 1997 which reportedly was suspicious for demyelinating areas and also had spinal cord MRIs reportedly unremarkable . . . She had actually been recommended for treatment for MS, but did not take any. Pet. Exh. 13 at 17.[6]

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[6] The undersigned notes that Dr. Johnson, who evaluated Dr. Cloer in August of 2002 for symptoms consistent with retrobulbar neuritis, submitted an affidavit in this case stating "[t]o the extent Dr. Wood's note indicates that Dr. Cloer was recommended for treatment for MS, but did not take any, that would not apply to my care and treatment of Dr. Cloer." Pet. Exh. 21 at 2. Dr. Johnson also disputes a notation in Dr. Wood's November 26, 2003 record indicating Dr. Cloer was urged to get treatment for retrobulbar neuritis in the fall of 2002. Dr. Johnson states Dr. Cloer had "symptoms in the left eye when I consulted with her. I did not urge any treatment." *Id.* The undersigned finds it

Respondent's Reply to Petitioner's Post-Hearing Brief (hereinafter R. Post-Hearing Reply) at 3-4.

Dr. Cloer was given a "provisional" diagnosis of MS on November 26, 2003 by her treating neurologist Dr. Wood subsequent to his obtaining Dr. Cloer's medical history and results of an MRI examination. Pet. Exh. 13 at 16–19.

Dr. Cloer applied for and was awarded Social Security Disability in 2004. Pet. Exh. 14 at 1–2. As part of that process Dr. Cloer was evaluated by Dr. James P. Metcalf on June 17, 2004. *Id.* at 3. Dr. Metcalf noted Dr. Cloer reported she "first begin [sic] to have some symptoms consistent with MS in 1997," however, her "symptoms waxed and waned until the fall of 2003 when she begin [sic] to have manifestations of the full blown disease." *Id.*

Dr. Cloer reported to the Vaccine Adverse Event Reporting System (VAERS) on October 11, 2004, that she experienced numbness and tingling after her first two Hep–B vaccinations. Pet. Exh. 19 at 2. Dr. Cloer stated these symptoms were followed by "Lhermitte's"[7] approximately one month after her third vaccination. *Id.*

**AFFIDAVITS OF MELISSA L. CLOER, MD**

Dr. Cloer, petitioner, submitted a sworn affidavit as part of the Petition in this case. The critical portion relevant to the issue at hand states as follows:

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is not necessary to determine whether or not Dr. Johnson recommended Dr. Cloer receive MS treatment in 2002 to resolve the issue presented in the instant case.

[7] Lhermitte's phenomenon is discussed at n.8, infra at p. 7.

> 12. In late 2003, I was diagnosed with multiple sclerosis. While I had experienced some isolated symptoms prior to that time, it wasn't until November 2003 that probable multiple sclerosis was diagnosed.
>
> 13. For instance, in 1997 I had an electric shock sensation in my spine and numbness in my left forearms and hand. My family physician, Dr. Susan Pereira, prescribed Motrin and the symptoms resolved over a short period of time. An MRI done on May 12, 1998 included differential diagnoses of MS, Lymes Disease, ADEM or other demyelinating processes. Dr. Meyer, the neurologist, described my problem as a "probable early inactive non-progressive" condition.

Pet. Exh. 2 at 3. As the legal issue of whether her Petition was filed timely developed, petitioner thereafter filed a second affidavit. Pet. Exh. 26. The affidavit provides in relevant part as follows:

> 4. I have been asked to address when any of the signs, the first occurrence of the first symptom or manifestation of onset of my Multiple Sclerosis (MS) lasted six months or more.
>
> 5. It was not until late 2003 or early 2004 that any signs, the first symptoms or manifestation of onset of my Multiple Sclerosis persisted for six months or more.

*Id.*

**AFFIDAVITS FROM DR. MICHAEL MEYER**

Dr. Meyer is a neurologist who treated petitioner in 1998, about one year following her immunizations. Dr. Meyer's first affidavit was filed on February 16, 2007. Pet. Exh. 20. In relevant part, Dr. Meyer stated that at

the time he examined Dr. Cloer, "she had the manifestations of onset of what can be termed 'singular sclerosis' . . . [and] she had what appeared to be early inactive non-progressive CNS demyelinating disease." *Id.* He also stated that:

> 10. At the time I evaluated Dr. Cloer in 1998, she had not yet been formally diagnosed with the clinical syndrome complex of multiple sclerosis (MS).
>
> 11. There had been no manifestation for the onset of clinically definite multiple sclerosis during the time period I evaluated Dr. Cloer.

*Id.* Following a number of status conferences between the undersigned and counsel discussing the statute of limitations issue, petitioner filed a second affidavit from Dr. Meyer. Pet. Exh. 23. In that affidavit, Dr. Meyer expanded on and explained statements he made in his earlier affidavit. *Id.* Relevant to the issue at hand, Dr. Meyer maintained that when he evaluated Dr. Cloer in 1998, she did not meet "formal diagnostic criteria for clinically definite MS." *Id.* He explained that at that time in 1998, Dr. Cloer's "singular demyelinating change could have remained a clinically isolated event with no sequela." *Id.*

Following the Court of Appeals for the Federal Circuit's decision in *Markovich v. Secretary of HHS*, 477 F.3d 1353 (Fed. Cir. 2007), which addressed the appropriate legal interpretation of the Act's statute of limitations, Dr. Meyer issued a third affidavit. Pet. Exh. 25. In this affidavit, Dr. Meyer repeats the medical points made in his two prior affidavits. In addition, having been provided by counsel a copy of the *Markovich* opinion, Dr. Meyer attempts to interpret and apply *Marko-*

*vich* to the medical facts of Dr. Cloer's case. Obviously, it is not Dr. Meyer's role as a medical expert to interpret the law, and his efforts were not helpful.

After reviewing Dr. Meyer's three affidavits and discussing them with counsel, it was clear that Dr. Meyer's testimony was necessary to understand several points, including what he meant by "she had the manifestations of onset of what can be termed 'singular sclerosis'" in 1998, Pet. Exh. 20, and "[t]here had been no manifestation for the onset of clinically definite multiple sclerosis during the time period I evaluated Dr. Cloer." *Id.* A Hearing was conducted to take Dr. Meyer's testimony.

***DR. MEYER'S TESTIMONY***

Michael Andrew Meyer, M.D., testified without objection as an expert in the field of neurology with a speciality in MS. Hearing Transcript (hereinafter "Tr. at __") at 9. Dr. Meyer testified consistently with his affidavits. He was extremely knowledgeable about the medical issues involved and, having reviewed the medical records, was well-prepared to discuss the case. The undersigned found Dr. Meyer to be a very credible witness. However, at times Dr. Meyer's testimony appeared contradictory and confusing. But this was not the fault of Dr. Meyer, and was not interpreted in any way to detract from his credibility. The confusing testimony was the direct result of questions from petitioner's counsel designed to finesse the facts of this case into the legal standard crafted by the Federal Circuit in *Markovich*. Dr. Meyer struggled at times with his answers to these questions, answers the undersigned found unhelpful. Dr. Meyer's testimony regarding the medical issues was clear and convincing. These issues will be discussed later.

During his testimony, Dr. Meyer summarized petitioner's medical history beginning when he first evaluated petitioner on April 28, 1998 at the University of Missouri Medical Clinic. Tr. at 11; Pet. Exh. 12 at 12. Dr. Meyer testified that his notes from his initial evaluation with Dr. Cloer indicate she complained of experiencing one year ago, in 1997, "electric like sensations going down the center of her back to both feet with forward head flexion"[8] for several months. Tr. at 12; Pet. Exh. 12 at 12. Dr. Cloer also reported to Dr. Meyer that she experienced "decreased sensation at the left posterior shoulder area and back" in 1997. *Id.* Dr. Meyer explained based upon the history taken, as well as his physical examination of Dr. Cloer, he ordered an MRI scan "to rule out MS." *Id.* at 12-13. Dr. Meyer testified that in 1998 "he did not think she [Dr. Cloer] had definite MS at that time." Tr. at 15, 34. However, Dr. Meyer testified that in retrospect petitioner's experience of Lhermitte's sign in 1997 was the **first symptom** of Dr. Cloer's MS. *Id.* at 49-50, 52, 54-55.

***LEGAL STANDARD***

Pursuant to the Vaccine Act petitioners may be compensated for injuries caused by certain vaccines. 42 U.S.C. §§ 300aa-10 to -34. However, the Vaccine Act provides statutory deadlines for filing program petitions

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[8] Dr. Meyer testified at the Hearing that this "sensation" experienced by Dr. Cloer is Lhermitte's phenomenon. Tr. at 34–35. Lhermitte's sign is defined as "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord." Dorland's Illustrated Medical Dictionary 1700 (30th ed 2003).

at § 300aa-16. In relevant part, the Vaccine Act provides:

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

§ 300aa-16(a)(2) (emphasis added). The Vaccine Act is a waiver of the United States' sovereign immunity and accordingly "must be strictly and narrowly construed." *Markovich v. Secretary of HHS,* 477 F.3d 1353, 1356 (Fed. Cir. 2007). The Federal Circuit has instructed "courts should be careful not to interpret a waiver in a manner that would extend the waiver in a manner beyond that which Congress intend." *Markovich*, 477 F.3d at 1360, citing *Brice v. Secretary of HHS*, 240 F.3d 1367, 1370 (Fed. Cir. 2001). The Circuit's decision in *Markovich* directly addressed the question of "what standard should be applied in determining the date of 'the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury,'" *Markovich*, 477 F.3d at 1356, by holding "'the first symptom or manifestation of onset,' for purposes of § 300aa16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Id.* at 1360.[9] Accordingly, petitioners have 36 months from

[9] Although not directly stated, the *Markovich* decision appears to have found that *Setnes v. Secretary of HHS*, 57 Fed. Cl. 175 (2003) was incorrectly decided. In *Setnes*, the Court of Federal Claims determined

the first recognizable sign of their alleged vaccine injury to file their claim.

The Circuit explained in *Markovich* 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." *Id.* at 1358. The Circuit elaborated that by choosing to "start the running of the statute of limitations period on the date the first symptom or manifestation of the onset occurs, Congress chose to start the running of the statute before many petitioners would be able to recognize with reasonable certainty, the nature of the injury." *Id.* The Court noted that the Act has "consistently been interpreted" to include "subtle" symptoms or manifestations of onset as triggers of the Act's statute of limitations. *Id.* The Court stressed that the words "symptom" and "manifestation of onset" are in the disjunctive as used in the Act and that the words have different

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that "[w]here there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptom.'" *Setnes*, 57 Fed. Cl. at 179. The *Setnes* court stated that because the symptoms of autism develop "insidiously over time" and the child's behavior cannot readily be connected to an injury or disorder, the court's inquiry into the onset of the autistic condition is not limited to a determination of when the first symptom or manifestation of the condition occurred, but rather is informed by the child's subsequent medical or psychological evaluations of when the "manifestation of onset" occurred. *Id.* at 181. The Federal Circuit found a "significant problem with the rationale of *Setnes*" in that *Setnes* "effectively" required evidence of a "symptom *and* manifestation" whereas the Act requires either a symptom or manifestation of onset, whichever occurs first, to trigger the statute of limitations. *Markovich*, 477 F.3d at 1358.

meanings. *Id.* at 1357. Thus, **symptom** "may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury," whereas a **manifestation of onset** "is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." *Id.* Accordingly, the Court found that the Act's statutory standard of first symptom or manifestation of onset could include subtle symptoms that a petitioner would recognize "only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury" and would be "recognizable to the medical profession at large but not necessarily to the parent." *Id.* at 1358, 1360 (citing *Goetz v. Secretary of HHS*, 45 Fed. Cl. 340, 342 (1999)). Thus, the Circuit in interpreting the Act's statute of limitations, rejected applying a "subjective standard that focuses on the parent's view" of the timing of onset in favor of an "objective standard that focuses on the recognized standards of the medical profession at large." *Id.* at 1360.

***Discussion***

The undersigned notes that the complexity of the issues presented in this case evolved with the development of the case law. The initial arguments and discussions took place within the context of the *Setnes* ruling, which unquestionably presented much reasonable room for disagreement and debate. However, with the issuance of the Circuit's decision in *Markovich*, the standard for resolving issues under the Act's statute of limitations has crystalized and the room for debate narrowed greatly. In light of *Markovich*, the issues presented in this case are now relatively straightforward.

After considering the entire record and the parties' respective arguments, this case must be dismissed as untimely. It is clear from the medical records, petitioner's affidavits, as well as Dr. Meyer's affidavits and testimony that the first symptom of the onset of Dr. Cloer's MS was in 1997. Since the Petition was filed eight years later, the Petition was untimely. *See* § 16(a)(2).

Dr. Meyer conceded several times at the August 30, 2003 hearing that in **retrospect** the first symptom of Dr. Cloer's MS was the Lhermitte's sign which Dr. Cloer experienced in 1997.

> THE COURT: [Y]ou said back in 1998 [petitioner] had a singular sclerosis. Looking back at this case now from today's vantage point is that singular sclerosis part of what was ultimately diagnosed as multiple sclerosis?
>
> DR. MEYER: Retrospectively I think that there was a relation, and I think that it's probably linked in some way. You know, we're talking about a disease that's not uncommon, and prospectively the symptoms could have represented many different things. The [Lhermitte's] phenomenon that she does talk about or had talked about does raise some concern about MS specific type symptoms.
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> Tr. at 49.
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> THE COURT: [F]rom today with the totality of this record was that singular sclerosis part what was ultimately diagnosed as multiple sclerosis?
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> DR. MEYER: I can't say definitely. I say that there's a likelihood that there's a relationship, that

there's probably a link. A more yes than no, but I can't say definitely.

THE COURT: Okay. So I interpret that to mean on a probability scale that you would say it was more probably than not related?

DR. MEYER: Yes. More probably yes than no.

Tr. at 49–50.

THE COURT: [L]ooking back at this retrospectively with this record you have in front of you, on a probability scale what's the first evidence of her multiple sclerosis?

WITNESS: I think that the first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997 where she would have the electric shock like sensation going down her back when she would bring her head forward.

Tr. at 52.

In response to questioning, Dr. Meyer agreed that petitioner had a demyelinating disease in 1998. Tr. at 37. However, she did not have the requisite number of lesions to have clinically definite multiple sclerosis. *Id.* Eventually, petitioner's symptoms progressed to where it became multiple sclerosis. Tr. at 41. Dr. Meyer stated that although it is difficult and individual cases vary, a retrospective linking of past symptoms to a current diagnosis of multiple sclerosis can "find the connection often." Tr. at 39.

Dr. Meyer's retrospective testimony is consistent with the medical records in noting a demyelinating disease in Dr. Cloer in 1998. The contemporaneous medical

records are replete with references to demyelinating symptoms and to possible MS. *See* Pet. Exh. 12 at 17 (Dr. Meyer's 5/15/98 progress notes states "[p]robable early inactive non-progressive cns [central nervous system] demyelination/ms . . . "); *Id.* at 16 (5/12/98 MRI notes a clinical history of "DYMILANATING [sic] MS" (emphasis in original) and states under "IMPRESSION" "Multiple Sclerosis, Lymes Disease, ADEM, or other Demyelinating Processes"); *Id.* at 37 (Noting a two-year history of onset of neurological symptoms, Dr. Colapinto's posits in a May 6, 1999 letter 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."). Also, later records date the onset of Dr. Cloer's MS to the events of 1997. *See* Pet. Exh. 13 at 17 (Dr. Wood's 11/26/03 history noting that Dr. Cloer "had an MRI of the brain in 1997 which reportedly was suspicious for demyelinating areas . . . "); Pet. Exh. 14 at 3 (Dr. Metcalf's 6/17/04 examination of Dr. Cloer wherein he notes that Dr. Cloer "states she first began to have some symptoms consistent with MS in 1997.") (emphasis added); Pet Exh. 13 at 35 (Dr. Wood, providing medical information for a student financial aid application for Dr. Cloer in February of 2005, states "MRI proven Multiple Sclerosis of brain and spinal cord, 8 yrs duration," i.e., MS began in 1997).

In addition, petitioner's first affidavit acknowledged that in 1997, she experienced an "electric shock sensation" in her spine. Pet. Exh. 2 at 2. Petitioner also filed a VAERS report in 2004 stating that she suffered Lhermitte's approximately a month following her immunization. Pet. Exh. 19 at 2. Dr. Meyer testified that the shock-like sensation experienced by petitioner was

Lhermitte's phenomenon, tr. at 34-35, and that the "first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997." *Id.* at 52.

Dr. Cloer's onset of MS also can be traced through the testimony of Dr. Meyer. Dr. Meyer first evaluated Dr. Cloer in 1998 and stated that Dr. Cloer had "demyelinating disease" at that time, but that "she did not yet have the requisite lesions in multiple areas of her central nervous system to qualify as clinically definite multiple sclerosis." Tr. at 37. Dr. Meyer explained that there is often a significant delay between the initial symptoms of MS and a definitive diagnosis of MS. Based upon the study of patient histories it is known that "patients who wind up with a definitive diagnosis of MS when they are looked [at] retrospectively there can be a great delay . . . a gap of many years." Tr. at 38. Dr. Meyer stated that the initial symptoms may progress, may wax and wan, or may never return. Tr. at 40, 43. It is a "fickle" disease. Tr. at 43. However, regarding Dr. Cloer, he stated:

> From what I know about what happened, what transpired over the years, that things did change, and in 2002 and 2003 she had progressed, changed.

Tr. at 40-41. In Dr. Cloer's case, Dr. Meyer testified her condition "became multiple sclerosis." Tr. at 41. Thus, Dr. Meyer agreed, it can be apparent retrospectively that symptoms which are part of the "same demyelinating process" may "culminate in a diagnosis of *multiple sclerosis* many years later." Tr. at 39. Dr. Meyer elaborated "retrospectively you can look back in this pool of patients and find the connection often," tr. at 39, and in Dr. Cloer's case the "**first sign to a clinician retrospectively was the [Lhermitte's] phenomenon back**

**in 1997**." Tr. at 55 (emphasis added); *see id.* at 49, 50, and 52.

The Act provides a window of three years from "the first symptom or manifestation of onset" to file a vaccine-related claim. § 16(a)(2). The Federal Circuit provided recently in *Markovich* the precedential interpretation of that section of the Act. Dr. Meyer testified that the first symptom of Dr. Cloer's MS occurred in 1997. The contemporaneous medical records support Dr. Meyer's testimony. Petitioner's contemporaneous histories given to treating doctors support the finding of the first symptom of her MS occurring in 1997. Lastly, petitioner's affidavit and statements on her VAERS reports state that the first symptom occurred in 1997. Accordingly, the undesigned finds that the overwhelming evidence supports a finding that the first symptom of Dr. Cloer's MS occurred in 1997. Thus, petitioner had three years, or until the year 2000, to file her vaccine injury claim. § 16(a)(2). Petitioner filed her claim on September 16, 2005. Clearly, petitioner filed her Petition beyond the Act's three-year statute of limitations. Accordingly, respondent's Motion to Dismiss is hereby granted.

Petitioner argues that the Vaccine Act's statute of limitations should not begin to run in the instant case until November of 2003 or thereafter based primarily upon the following: petitioner was not diagnosed with MS until 2003, neither petitioner nor her medical care providers were aware of a potential link between *vaccinations* and MS until after 2003, and MS poses diagnostic challenges. Thus, petitioner argues:

> The medical community at large would not have authoritatively associated her condition, injury or prob-

> lems to MS until 2003. It wasn't until after the November 2003 diagnosis of MS, based on accepted criteria, that Dr. Cloer became aware of the potential link to her earlier *immunizations*. There is no indication that other members of the "medical community at large" would have so linked her problems to the *vaccinations* until 2003 or thereafter.
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> Petitioner's Post-Hearing Brief at 9.

Even assuming each of these arguments to be factually correct, these arguments fail, because petitioner misunderstands or chooses to ignore the standard enunciated by the Federal Circuit in *Markovich* and the plain language of the statute.

Throughout petitioner's briefs and even in questions posed to Dr. Meyer, petitioner raises the argument that there was no diagnosis of multiple sclerosis until November 2003. *See* Petitioner's Amended Brief in Opposition to Respondent's Motion to Dismiss (hereinafter P. Amended Brief in Opposition) filed February 17, 2006 at 3; *see also* Tr. at 26-27. Petitioner argues the statute of limitations should begin to run in 2003 at the earliest, relying upon Dr. Meyer's testimony that prior to petitioner's 2003 MRI, the medical community at-large would not have diagnosed Dr. Cloer with MS. Tr. at 27, 47, 55. Closely related to the argument of when the diagnosis was made is petitioner's contention that the "manifestation of onset" of Dr. Cloer's MS was in 2003. Petitioner's Post-Hearing Brief at 6; Tr. at 27-28. As discussed, *see supra* at pp. 7-8, the commencement of the Vaccine Act begins upon the *first symptom or manifestation* of the alleged vaccine related injury. The Federal Circuit interpreted that statutory language in the disjunctive, and recognized the "dissimilar meaning of

the words "symptom" and "manifestation of onset." *Markovich*, 477 F.3d at 1357. Dr. Meyer testified, and the medical records support, that the first symptom of petitioner's MS occurred in 1997. Having found the first symptom of Dr. Cloer's MS occurred in 1997, for purposes of the disjunctive standard of § 16(a)(2), it is thus irrelevant when the manifestation of onset occurred. Likewise, also irrelevant are petitioner's continued arguments regarding when the diagnosis of MS occurred. The Federal Circuit was very clear that diagnosis is not the test for purposes of the statute of limitations. *See id.* ("For example, in this case, the eye-blinking episode was a symptom of a seizure disorder without any diagnosis. . . . "); *see also id.* at 1358 ("[A] petitioner typically will recognize that a particular symptom constitutes the first symptom or manifestation of the onset of a certain injury only with the benefit of hindsight, **after** a doctor makes a definitive diagnosis of the injury.") (emphasis added).

A second argument that permeates petitioner's briefs and questions is that petitioner was not diagnosed with a **vaccine injury** before 2004. Petitioner's Post-Hearing Brief at 6; Tr. at 14, 20, 23, 26, and 28. Petitioner misreads *Markovich*. The Court's holding was that for purposes of § 300aa16(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. In this case, the first "sign" of petitioner's MS, the alleged vaccine injury in this case, recognized by Dr. Meyer, a representative of the medical profession, tr. at 8, was the Lhermitte's phenomenon that occurred in 1997. Tr. at 52. Dr. Meyer's position is corroborated by both the

medical records and petitioner's affidavit. Accordingly, the first symptom for triggering the statute of limitations was the Lhermitte's phenomenon Dr. Cloer experienced in 1997.

Petitioner further argues the statute of limitations period should begin to run in 2003, because prior to this time petitioner did not suffer "the residual effects or complications of such illness, disability, injury or condition for more than six months," as required by § 11(c)(1)(D)(I) and thus could not have filed a valid petition. The undersigned agrees with respondent,

> whether or not a petitioner has shown that an injury has persisted for more than six months has no bearing on whether the petition was filed within 36 months of the first symptom or manifestation of onset of that injury. Section 11(c)(1)(D)(I) does not extend the filing date of a petition until a time when a petitioner's alleged vaccine-related injury persists for at least six months.
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> R. Post-Hearing Reply at 5.[10]

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[10] The undersigned notes petitioner raised a number of constitutional arguments in her filings in opposition to Respondent' Motion to Dismiss. Specifically, petitioner argues that the Vaccine Act's Statute of Limitations violates the Due Process or the Equal Protection Clause of the U.S. Constitution's Fifth Amendment. P. Amended Brief in Opposition at 17-23. Respondent strongly opposed petitioner's constitutional arguments. Respondent's Reply to Petitioner's Opposition to Respondent's Motion to Dismiss at 9-14. Petitioner's arguments were not well-developed. In any event, the undersigned finds it unnecessary to engage in a lengthy analysis since the criteria for eligibility has been analyzed and found to pass constitutional scrutiny. *Leuz. v. Secretary of HHS*, 63 Fed. Cl. 602 (2005).

Petitioner argues lastly that the statute of limitations should be tolled in the instant case as "there was no reason to suspect that Dr. Cloer's symptoms were in fact symptoms of MS" and as distinguishable from the *Brice* case as "there was neither a subjective nor an objective basis for drawing such a connection until some three years before the filing of Dr. Cloer's petition." P. Amended Brief in Opposition at 15. The undersigned disagrees. Upon taking petitioner's medical history and reviewing her MRI in 1998, Dr. Meyer did suspect MS as a potential diagnosis of petitioner's injury. In fact petitioner's medical records are replete with indications that her injury was potentially connected to MS in 1997 and 1998. *See supra* at pp. 2-4, and 10. Further, the Federal Circuit has found that "the statute of limitations [in the Vaccine Act] begins to run upon the first symptom or manifestation of onset of injury, even if the petitioner reasonably would not have known at that time that the vaccine caused an injury." *Brice v. Secretary of HHS*, 240 F.3d 1367, 1373 (Fed. Cir. 2001). In *Markovich*, the Circuit reaffirmed its' holding in *Brice* that "equitable tolling is not available for claims arising under § 300-16(a)(2)." *Markovich*, 477 F.3d at 1358.

For the reasons stated above and based upon the undersigned's review of the record as a whole, the undersigned finds that a preponderance of the evidence does not support that the Petition was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury" as required by the Vaccine Act. Petitioner's claim is dismissed. The Clerk shall enter judgment accordingly.

**IT IS SO ORDERED.**

## APPENDIX G

1. 42 U.S.C. 300aa-11provides in pertinent part:

**Petitions for compensation**

**(a) General rule**

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa-12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and—

* * * * *

2. 42 U.S.C. 300aa-12 provides in pertinent part:

**Court jurisdiction**

**(a) General rule**

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

**(b) Parties**

(1) In all proceedings brought by the filing of a petition under section 300aa-11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa-11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title.

**(c) United States Court of Federal Claims special masters**

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters.
* * *

* * * * *

(6) The chief special master shall be responsible for the following:

* * * * *

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa-11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

* * * * *

3. 42 U.S.C. 300aa-13 provides in pertinent part:

**Determination of eligibility and compensation**

* * * * *

**(c) "Record" defined**

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa-11 of this title

4. 42 U.S.C. 300aa-15 provides in pertinent part:

**Compensation**

* * * * *

**(e) Attorneys' fees**

(1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reason-

able basis for the claim for which the petition was brought.

* * * * *

**(f) Payment of compensation**

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa-21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) of this section shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa-12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa-21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

* * * * *

5. 42 U.S.C. 300aa-16 provides in pertinent part:

**Limitations of actions**

**(a) General rule**

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 manifestation of onset or of the significant aggravation of such injury, and

* * * * *

6. 42 U.S.C. 300aa-21 provides in pertinent part:

**Authority to bring actions**

**(a) Election**

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa-12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11 of this title shall file with the clerk of the United States Court of Federal Claims—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

* * * * *