No. 11-832

# In the Supreme Court of the United States

MELISSA CLOER, PETITIONER

*v.*

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES

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

## BRIEF FOR THE RESPONDENT IN OPPOSITION

DONALD B. VERRILLI, JR.
*Solicitor General*
*Counsel of Record*
TONY WEST
*Assistant Attorney General*
THOMAS M. BONDY
ANISHA S. DASGUPTA
*Attorneys*
*Department of Justice*
*Washington, D.C. 20530-0001*
*SupremeCtBriefs@usdoj.gov*
*(202) 514-2217*

## QUESTIONS PRESENTED

The National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. 300aa-1 *et seq.*, establishes a program of no-fault compensation for vaccine-related injuries and deaths. The Vaccine Act 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 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). The questions presented are as follows:

1. Whether that 36-month period begins to run on "the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [the] injury" for which compensation is sought, 42 U.S.C. 300aa-16(a)(2), or instead on the date on which a causal link is recognized between the administered vaccine and the injury for which compensation is sought.

2. Whether the limitations period in 42 U.S.C. 300aa-16(a)(2) should have been equitably tolled in petitioner's case for the period during which the medical community did not recognize a causal link between the vaccine she was administered and the injury for which she seeks compensation.

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## OPINIONS BELOW

The en banc opinion of the court of appeals (Pet. App. A98-A165) is reported at 654 F.3d 1322. The opinion of the panel of the court of appeals (Pet. App. A57-A97) is reported at 603 F.3d 1341. The opinion and order of the United States Court of Federal Claims (Pet. App. A26-A56) is reported at 85 Fed. Cl. 141. The decision of the Special Master (Pet. App. A1-A25) is not published but is available at 2008 WL 2275574.

## JURISDICTION

The judgment of the court of appeals was entered on August 5, 2011. On October 20, 2011, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including January 2, 2012. The

petition for a writ of certiorari was filed on December 29, 2011. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

**STATEMENT**

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), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*). The Vaccine Act created the National Vaccine Injury Compensation 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)). 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 as respondent. *Ibid.* A special master of the CFC then issues a decision on the petition. *Ibid.*; see 42 U.S.C. 300aa-11, -12(d) and (e). That decision is subject to deferential review by a judge of the CFC, and in turn by the Federal Circuit. 42 U.S.C. 300aa-12(e)(2)(B) and (f).

The Compensation Program covers categories of vaccines that have been formally recommended for routine administration to children by the Centers for Disease Control and Prevention, 42 U.S.C. 300aa-14(e)(2) and (2)(A). The claimant must show by a preponderance of the evidence that she received a vaccine listed on the Vaccine Injury Table (Table), 42 C.F.R. 100.3, and suffered a corresponding listed injury, or in the case of an injury not listed on the Table, that her injury "was

caused by" a vaccine listed on the Table. 42 U.S.C. 300aa-11(c), -13(a). The claimant need not establish any defect in the vaccine, any fault by the manufacturer, or even the identity of the manufacturer. If medical consensus regarding the link between an injury and a vaccine changes, the Secretary may amend the Table accordingly through notice-and-comment rulemaking on her own motion or upon the petition of "[a]ny person." 42 U.S.C. 300aa-14(c).

The Vaccine Act prescribes time limits for filing a petition for compensation. For a vaccine listed on the Table and administered after October 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). There is one statutory exception to that rule, under which claims based on deaths or injuries from the preceding eight years are revived "[i]f at any time the Vaccine Injury Table is revised" to add a vaccine, such that a previously ineligible individual may obtain compensation, or to add an injury, thereby "significantly increas[ing] the likelihood of obtaining compensation." 42 U.S.C. 300aa-16(b). Under those circumstances, a claimant is excused from the rule that "[o]nly one petition may be filed with respect to each administration of a vaccine," 42 U.S.C. 300aa-11(b)(2), and may "file a petition for such compensation not later than 2 years after the effective date of the revision," 42 U.S.C. 300aa-16(b).

2. a. Petitioner received three doses of the Hepatitis-B vaccine in 1996 and 1997. Pet. App. A100.

In mid-1997, after her final dose, she experienced an "electric shock sensation" in her spine, "known as Lhermitte sign," which has been "long recognized by the medical profession as a common symptom of [multiple sclerosis (MS)]." *Id.* at A107. In 1998, a neurologist noted that petitioner had "'probable early inactive nonprogressive CNS [central nervous system] demyelination/MS,' although he explained that [petitioner's] situation did not meet 'formal diagnostic criteria for clinically definite MS.'" *Ibid.* (first set of brackets in original). Petitioner was definitively diagnosed with MS in 2003. *Id.* at A108.

In 2005, eight years after the Lhermitte sign, petitioner filed a claim for compensation under the Vaccine Act. Pet. App. A109. The Hepatitis-B vaccine is listed on the Table, but the Table did not then (and does not now) list MS as an injury associated with the vaccine, nor has the medical community at large ever recognized a causal link between the Hepatitis-B vaccine and MS. *Id.* at A75-A76. The special master dismissed petitioner's claim as untimely because it was filed more than 36 months after her first symptom of MS in 1997. *Id.* at A25. The CFC affirmed. *Id.* at A56.

3. A divided panel of the court of appeals reversed. Pet. App. A57-A97. The majority noted that Section 300aa-16(a)(2) speaks of the "first symptom or manifestation of onset or of the significant aggravation of" a "vaccine-related injury." *Id.* at A66. In the panel majority's view, an injury is not a "vaccine-related injury" unless—and thus a symptom or manifestation of the injury does not trigger the running of the limitations period until—"the medical community at large objectively recognizes a link between the vaccine and the injury." *Id.* at A66-A67. Accordingly, the panel majority held

that "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?" *Id.* at A67. On the record here, the panel majority determined that such recognition first occurred, if at all, "at the earliest" in September 2004. *Id.* at A73.

Judge Clevenger dissented. Pet. App. A75-A97. He concluded that the Vaccine Act's text and structure, as well as the court of appeals' precedents, distinguished between medical recognition that a symptom was connected to an injury and medical recognition that an injury was caused by a vaccine. "[T]he statute of limitations in the Vaccine Program begins to run upon the first symptom or manifestation of a claimed vaccine injury, where the 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." *Id.* at A96-A97.

4. The court of appeals granted the government's petition for rehearing en banc and affirmed the judgment of the CFC dismissing petitioner's claim as untimely. Pet. App. A98-A147, A166-A169. In rehearing the case, the court ordered the parties to submit supplemental briefs addressing whether the court should read into the Vaccine Act a discovery rule like that used in medical malpractice cases, whether the court should overrule circuit precedent holding that the Vaccine Act's limitations periods were not subject to equitable tolling, and whether the circumstances of this case would support equitable tolling if tolling is not barred. *Id.* at A168.

a. "Consistent with the plain meaning of the statute," the en banc court held "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." Pet. App. A101.

The court rejected petitioner's contention 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," Pet. App. A113, explaining that petitioner's interpretation was inconsistent with Congress's use of the term "vaccine-related injury" in other provisions of the Vaccine Act, *id.* at A114-A119. The court pointed out that, for example, "only '*[a] person who has sustained a vaccine-related injury . . .* may * * * file a petition for compensation,'" and thus under petitioner's view, "the key element of the petition for compensation[—]the vaccine-related injury[—]does not arise until the requisite medical consensus exists," yet that result would leave "[petitioner], like the great majority of non-Table injury petitioners, [without] standing to file a petition until the requisite medical consensus arises." *Id.* at A118-A119 (first set of brackets in original).

The court added that petitioner's proposed approach would be an unwarranted departure from the "firm default rule that a cause of action arises at the same time the statute of limitations begins to run on the cause." Pet. App. A120 (citing *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 545 U.S. 409, 418 (2005)). The court also pointed out that petitioner's theory both was in tension with the

Vaccine Act's provision for revival of claims upon revision of the Table, and would produce the odd result that petitioner "would enjoy a more generous statute of limitations than Congress provided for Table Injury petitioners, for whom causation is presumed." *Id.* at A122.

b. The en banc court also declined petitioner's invitation to apply a medical-malpractice-like discovery rule that would trigger the Vaccine Act's time limits, not at the "occurrence of the first symptom or manifestation of onset" of injury, 42 U.S.C. 300aa-16(a)(2), but rather only once "the claimant has knowledge or reason to know the cause of her injury," Pet. App. A126. The court found no textual warrant for the discovery rule petitioner proposed; to the contrary, it reasoned, "the clearly dominant language in the statute of limitations is 'the date of occurrence of the first symptom or manifestation of onset.'" *Id.* at A130.

Nor, the court concluded, was the statute "susceptible to an implied discovery rule." Pet. App. A130. It explained that the express statutory trigger—"the date of the occurrence of the first symptom or manifestation of onset," 42 U.S.C. 300aa-16(a)(2)—"goes a long way to showing that Congress 'conveyed its refusal to adopt a discovery rule.'" Pet. App. A133 (quoting *TRW* v. *Andrews*, 534 U.S. 19, 27 (2001)). This conclusion was confirmed by the absence of any statutory reference to the Vaccine Act claimant's knowledge. *Id.* at A134. More broadly, the court pointed out that the "complicated inquiry about whether [a] petitioner knew or reasonably should have known of a causal connection" would be "antithetical to the simple, symptom-keyed test expressly required by the Vaccine Act's text" and to the "Vaccine Act's structure as a simplified no-fault administrative scheme." *Id.* at A135-A136.

c. With respect to equitable tolling, the en banc court accepted petitioner's contention that the Vaccine Act does not foreclose equitable tolling, and overruled the contrary holding in *Brice* v. *Secretary of HHS*, 240 F.3d 1367 (Fed. Cir.), cert. denied, 534 U.S. 1040 (2001). Pet. App. A137-A147. The court acknowledged the government's argument that strict time limits and certain narrowly drawn statutory tolling exceptions in the Vaccine Act suggested an intent to foreclose open-ended equitable tolling, *id.* at A140-A141, but it concluded that those were not materially different from the sort of time limits and exceptions that this Court, in examining the Antiterrorism and Effective Death Penalty Act's habeas corpus limitations provisions in *Holland* v. *Florida*, 130 S. Ct. 2549 (2010), had found insufficient to overcome the presumption in favor of equitable tolling. Pet. App. A142-A143.

The court of appeals nonetheless declined to hold "equitable tolling [appropriate] in [petitioner's] case, and presumably in other future cases with similar facts," inasmuch as it would become "a substitute for the discovery rule." Pet. App. A145-A146. Focusing on traditional circumstances warranting equitable tolling, the court explained that petitioner "has put no argument before this court that, for example, she has been the victim of a fraud, or of duress," and it rejected her contention that applying the Act's time limits "is *ipso facto* unfair because it threatens to deprive her of her claim" as "not, in [the court's] view, the sort of circumstance that might merit equitable tolling." *Id.* at A146. The court elsewhere pointed out that, in practice, the pleading requirements of the Vaccine Act "have not been insurmountable" by other petitioners "alleging MS caused by the Hep-B vaccine"; "at least 14 of those petitioners

have been successful," and "[m]any of the successful petitioners filed their petitions in 1999." *Id.* at A119 n.4.

c. Judge Dyk, joined by three other judges, dissented from the majority's rejection of a medical-malpractice-like discovery rule. Pet. App. A148-A165. The dissenting judges believed such a rule was justified by the Vaccine Act's "remedial nature," *id.* at A159, analogizing the Vaccine Act to the medical malpractice remedies that it "is similar to, and replaces," *id.* at A150. The dissent acknowledged that a discovery rule would create two sets of time limits: one limitations period applying to claims based on injuries identified on the Table, and another "more generous limitations period" for claims based on injuries not identified on the Table. *Id.* at A164 n.10. The dissent would have accepted "the different treatment of the statute of limitations for Table and non-Table injuries," *ibid.*, observing that the record here, for example, showed that petitioner did not "suspect a connection between [MS] and the Hepatitis B vaccine before 2004," *id.* at A165, even though "there is no dispute that the first symptom or manifestation of injury occurred in May 1997," *ibid.*

**ARGUMENT**

The court of appeals correctly held that petitioner filed her claim outside of the time limits provided by the Vaccine Act and that equitable tolling was unavailable to her, even accepting her characterization of her factual circumstances. The court's decision does not conflict with any decision of this Court or of any other court of appeals. Further review is unwarranted.

1. Petitioner's Vaccine Act claim seeks compensation for her MS based on Hepatitis-B immunizations she received in 1996 and 1997. Pet. App. A106-A109. Sec-

tion 300aa-16(a)(2) 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 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." There is no dispute that "the first symptom or manifestation of onset or of the significant aggravation" of petitioner's MS was the Lhermitte sign in mid-1997. *Id.* at A107. Petitioner's claim was not filed until 2005 (*id.* A109), so absent a basis for suspending the running of the limitations period, her claim is barred as untimely.

2. Petitioner principally argues (Pet. 5-20) that Section 300aa-16(a)(2) incorporates (expressly or by implication) a medical-malpractice-like discovery rule under which the Act's time limits do not start to run until a claimant "knows, or reasonably should know (based upon professional consultation), 'the cause of his injury,'" Pet. 15—that is, until she or a reasonable person in her position (or perhaps the medical profession at large) would have been aware of a link (or the possibility of a link) between the injury and the vaccine. The court of appeals correctly rejected petitioner's invitation to substitute such a timing rule for the one actually articulated in the statute.

a. As the court of appeals recognized, the discovery rule petitioner proposes would contradict the Vaccine Act's explicit trigger of "the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [the] injury." 42 U.S.C. 300aa-16(a)(1)-(3). As this Court explained in a closely related context, "[t]here cannot be two first symptoms or onsets of the same injury." *Shalala* v. *Whitecotton*,

514 U.S. 268, 274 (1995). When that symptom or onset occurs, the statute of limitations begins to run, irrespective of what else the claimant or the medical community may or may not have recognized. Engrafting a discovery rule onto that scheme would effectively supersede the statute's own clear rule about when the limitations period begins to run.

The facts of petitioner's case illustrate the incompatibility of her proposed rule with this basic feature of the Vaccine Act's statute of limitations. Petitioner concedes that the event signaling the onset of her MS occurred in 1997, when she "began to experience a temporary electric-like shock sensation in her spine" (a Lhermitte sign), which is a common and recognizable symptom of MS. Pet. 2, 4. Yet even though this was the "occurrence of the first symptom or manifestation of onset" of petitioner's claimed injury, 42 U.S.C. 300aa-16(a)(2), it would be irrelevant under her proposed rule, which would instead focus (with no textual warrant) on the date on which it was "reasonabl[e]" (Pet. 8) for petitioner or her doctors, or the medical community at large, to suspect that her MS was caused by a vaccine.

Moreover, the rule petitioner advocates would be inconsistent with the Vaccine Act's special provision reviving certain claims upon the subsequent amendment of the Table to add an injury based on the recognition of an association between a vaccine and the injury. See p. 3, *supra*. In particular, Congress provided that, in the specific circumstance of a Table revision, a claimant may "file a petition for * * * compensation not later than 2 years after the effective date of the revision" if the vaccine-related injury or death "occurred [not] more than 8 years before the date of the revision of the table." 42 U.S.C. 300aa-16(b). This exception is carefully

crafted to provide relief when the link between a vaccine and an injury is recognized by the scientific community—and formally confirmed by the Secretary through a Table amendment—after the Vaccine Act's general limitations period has run for specific petitioners. That special provision affords those petitioners who would benefit from the revised Table a new opportunity to seek compensation. The discovery rule petitioner proposes would make this carefully calibrated exception superfluous by suspending the general limitations period in the very sort of cases the revival provision is designed to address.

Those two features of the Vaccine Act's statute of limitations—an explicit date on which the limitations period begins to run based on the objective circumstances of the first symptom or manifestation of the injury, coupled with a calibrated exception—closely resemble the features of the statute of limitations at issue in *TRW* v. *Andrews*, 534 U.S. 19, 22-23 (2001), that led this Court to reject a discovery rule there. *TRW* concerned the Fair Credit Reporting Act, under which the "two-year statute of limitations runs from 'the date on which the liability arises,' subject to a single exception for cases involving a defendant's willful misrepresentation of material information." *Id.* at 28 (quoting 15 U.S.C. 1681p). The Court noted that "incorporating a general discovery rule" into that provision "would not merely supplement the explicit exception contrary to Congress' apparent intent; it would in practical effect render that exception entirely superfluous in all but the most unusual circumstances." *Id*. at 29. The result would be that "a rule nowhere contained in the text * * * would do the bulk of that provision's work, while a proviso accounting for more than half of that text

would lie dormant in all but the most unlikely situations." *Id.* at 31. The Court thus refused to hold "that Congress, when it inserted a carefully worded exception to the main rule" on the running of the limitations period, "intended simultaneously to create a general discovery rule that would render that exception superfluous." *Id.* at 33. That reasoning applies equally here.

Petitioner's proposed discovery rule apparently would also substitute subjective considerations for the objective standard selected by Congress; at a minimum, it would require a significantly more complicated inquiry into the state of medical knowledge than the symptom-focused trigger specified in the Vaccine Act. Either way, it would significantly complicate the threshold question of timeliness in a way Congress did not intend in constructing 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 *Whitecotton*, 514 U.S. at 269).

This case illustrates the difficulty petitioner's rule would create. Under a straightforward application of the clear statutory text, in accordance with the decision of the en banc court of appeals, there is no significant dispute that contemporaneous medical records reveal that petitioner's first symptom of MS occurred in 1997. By contrast, applying petitioner's rule would be difficult. Petitioner says she "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*." Pet. App. A61. Yet, as the Vaccine Safety Committee of the Institute of Medicine noted in a 1994 report commissioned by the Secretary of Health and Human Services at Congress' direction (see National Childhood Vaccine Injury Act of 1986, Pub. L.

No. 99-660, § 313(a), 100 Stat. 3781-3782), medical studies were exploring the potential connection between the Hepatitis-B vaccine and MS as early as 1992, and at least one such study expressly noted "a possible mechanism" underlying such a connection. Vaccine Safety Comm., Inst. of Med., *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* 220 (1994); see also *id.* at 222 (concluding that "[t]he evidence is inadequate to accept or reject a causal relation between hepatitis B vaccine and * * * multiple sclerosis," but noting that "[a] number of * * * prospective studies are under way, and they should be pursued for the occurrence of demyelinating diseases following receipt of hepatitis B vaccine").

b. Petitioner's arguments in favor of her discovery rule are unpersuasive. She contends that the Vaccine Act's reference to "a vaccine-related injury [that] occurred as a result of the administration of such vaccine," 42 U.S.C. 300aa-16(a)(2), must be read to suspend the running of the Act's time limits until "a claimant must reasonably know that a symptom has some causal connection to the administration of a vaccine." Pet. 12. In particular, petitioner proposes to read the statutory term "vaccine-related injury" to require that the alleged injury be recognized by "the medical profession at large" as related to the vaccine before it can be deemed a "vaccine-related injury." Pet. 15.

But as the court of appeals explained (Pet. App. A118), the Vaccine Act's usage elsewhere of the phrase "vaccine-related injury" is inconsistent with petitioner's interpretation. The Vaccine Act uses that term in creating a cause of action for petitioners, 42 U.S.C. 300aa-11(a)(1), in setting out the period for filing a claim, 42 U.S.C. 300aa-16(a)(2), and in specifying the

circumstances in which a person may sue a vaccine manufacturer "for damages arising from a vaccine-related injury or death," 42 U.S.C. 300aa-22. Applying petitioner's proposed construction of "vaccine-related injury" in those provisions would create puzzling and untoward results. For example, it would require medical recognition of a vaccine-injury link before a claimant could even file a claim—an approach demonstrably at odds with the Vaccine Act's framework for deciding "off-Table" claims.

c. Petitioner suggests "it would be strange indeed for Congress to have required those seeking compensation for non-Table vaccine injuries to prove 'cause in fact' on the one hand, while also requiring a petitioner to bring a Vaccine Act claim when neither the claimant nor the medical community at large recognizes the causal connection between a particular injury and a vaccine, on the other hand." Pet. 13. But far from "strange," that is in keeping with this Court's rejection of proposed discovery rules under which the time for filing a claim would not run until a plaintiff discovers all elements of her claim; in those cases, the Court has explained that statutory limitations periods *ordinarily* begin to run before a plaintiff has complete knowledge of every element of her cause of action. *E.g.*, *Rotella* v. *Wood*, 528 U.S. 549, 555-556 (2000); *United States* v. *Kubrick*, 444 U.S. 111, 118, 125 (1979); cf. *Peak* v. *United States*, 353 U.S. 43, 51 (1957) ("[I]t has been the consistent opinion of this Court that limitations, particularly against the United States, may not be tolled, without statutory authorization, merely because a plaintiff might not be in a position to carry the burden of proof within the statutory period.").

Petitioner's amici (Br. at 5-7) offer examples of what they contend are sympathetic but time-barred Vaccine Act claimants. But the fact that "[t]he result in individual cases may be harsh" is no aid in construing the limitations provision at issue here, because "that may be true in [the] case of any statute of limitations." *Scaife Co.* v. *Commissioner*, 314 U.S. 459, 463 (1941). In all events, any objection to the time bars in amici's examples would reflect a quarrel with one or another feature of the Vaccine Act's limitations framework *not* at issue here. In particular, a person who cannot "bring * * * a claim without a diagnosis" (Amici Br. 5) may be barred because the limitations period runs not from actual diagnosis but instead from the "first symptom or manifestation of onset," 42 U.S.C. 300aa-16(a)(2), that would be "objectively recognizable * * * by the medical profession at large," *Markovich* v. *Secretary of HHS*, 477 F.3d 1353, 1360 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007). And a person who subjectively does not believe she has suffered an injury caused by a vaccine because she was "misinformed" (Amici Br. 6) or "unaware" (*id.* at 7) may be barred because the limitations period depends not on the "subjective * * * particular view of a specific parent [or claimant]," but instead on "an objective standard that focuses on the recognized standards of the medical profession at large," which "treats petitioners equally, without regard to their individual degree of medical awareness." *Wilkerson* v. *Secretary of HHS*, 593 F.3d 1343, 1344-1345 (Fed. Cir. 2010) (quoting *Markovich*, 477 F.3d at 1356, 1360). Thus, while it might be that the rule petitioner urges here would adventitiously extend the limitations period in some of the examples amici offer, those examples make no case for disregarding the

text and structure of the Vaccine Act or for review by this Court of the limitations issue petitioner raises.

d. The court of appeals' decision regarding the inappropriateness of a discovery rule in the Vaccine Act context is consistent with this Court's teachings on the interpretation of statutes of limitations. The result here is different from the result in *Kubrick* (see Pet. 8-11, 14-15) in the sense that *Kubrick* recognized a discovery rule in the context of the statute at issue there. But that difference reflects only the different statutory texts and contexts, and as explained above, pp. 12-13, *supra*, the court of appeals' decision is particularly well-supported by this Court's more recent decision in *TRW*.

3. Petitioner also argues (Pet. 20-21) that although the court of appeals was correct to hold that equitable tolling is available under the Vaccine Act, it erred in rejecting equitable tolling on the facts here. Although the government disagrees with the court of appeals' decision to recognize the possibility of equitable tolling under the Vaccine Act, this case presents only the narrow and fact-bound question whether petitioner herself (or someone similarly situated) is entitled to equitable tolling. The court of appeals correctly concluded she is not.

"Generally, a litigant seeking equitable tolling bears the burden of establishing two elements: (1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way." *Pace* v. *DiGuglielmo*, 544 U.S. 408, 418 (2005). Petitioner argues that equitable tolling is appropriate because "[she], a member of the medical community at large, was unaware of" any connection between MS and a vaccine "until she did her own research in 2004," that "[her] awareness as a physician should have been factored into

the * * * analysis," and that she faced the extraordinary circumstance that "the medical community at large" would not have recognized a connection between Hepatitis B and multiple sclerosis "until 2004 or later." Pet. 21.

Petitioner's plea for equitable tolling fails both elements articulated in *Pace*. As for diligence, petitioner does not suggest that information about the possibility of a link between MS and the Hepatitis-B vaccine was unavailable "until she did her own research in 2004," Pet. 21. To the contrary, medical studies were exploring the possibility of such a connection as early as 1992, and the details of such studies were readily available in an official report prepared pursuant to Congress's direction in the Vaccine Act itself. See pp. 13-14, *supra.* Moreover, as the court of appeals pointed out, there have been other petitioners "alleging MS caused by the Hep-B vaccine"; "at least 14 of those petitioners have been successful"; and "[m]any of the successful petitioners filed their petitions in 1999," when a claim by petitioner would have been timely even without equitable tolling. Pet. App. A119 n.4.

Nor would it be an "extraordinary circumstance," *Pace*, 544 U.S. at 418, if (as petitioner claims, see Pet. 20-21) there were no awareness of a possible connection between MS and the Hepatitis-B vaccine among petitioner's consulting physicians or in the medical community at large. Rather, the Vaccine Act is structured to provide procedures for a claimant in precisely those circumstances to obtain compensation for an injury outside the parameters of the Table—*i.e.*, an injury that is *not* recognized as associated with the vaccine in question—by showing that her injury "was caused by" the covered vaccine. 42 U.S.C. 300aa-11(c)(1)(C)(ii). Peti-

tioner's situation was thus the ordinary sort contemplated by the Vaccine Act.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

DONALD B. VERRILLI, JR.
*Solicitor General*
TONY WEST
*Assistant Attorney General*
THOMAS M. BONDY
ANISHA S. DASGUPTA
*Attorneys*

MARCH 2012