No. 11-832

IN THE

Supreme Court of the United States

MELISSA CLOER, M.D.,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

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

MOTION FOR LEAVE TO FILE BRIEF OUT OF TIME AND BRIEF OF *AMICI CURIAE* NATIONAL VACCINE INFORMATION CENTER, VACCINE INJURED PETITIONERS BAR ASSOCIATION, AND OTHER ORGANIZATIONS IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* OUT OF TIME

The National Vaccine Information Center, the Vaccine Injured Petitioners Bar Association, The George Washington University Vaccine Injury Clinic, the Office of Medical and Scientific Justice, and the Canary Party respectfully move for leave to file the attached brief as *amici curiae* out of time. Both Respondent's counsel, the Solicitor General, and Petitioner's counsel, have consented to the filing of this *amici* brief by February 23, 2012.

Amici are groups who have been involved in the National Vaccine Injury Compensation Program for many years, including the Vaccine Injured Petitioners Bar Association, and a number of organizations advocating for the interests of children and families. *Amici* urge the Court to grant the petition for a writ of certiorari in this case because of its great importance to the continued operation of the National Vaccine Injury Compensation Program. This case has exceptional importance for three principle reasons: First, the issue in this case, involving the interpretation and application of the statute of limitations in the National Childhood Vaccine Injury Act, is a very important, commonly recurring issue that has affected and will continue to affect a great many petitioners in the Vaccine Injury Compensation Program. Second, the *en banc* decision by the United States Court of Appeals for the Federal Circuit conflicts with this Court's prior precedents concerning implied discovery rules in other similar statute of limitations provisions. Finally, the decision contradicts the Congressional intent of the statute of insuring a forum to litigate vaccine injury claims in the United States Court of Federal Claims instead of

other state and federal courts. If certiorari were granted in this case, *amici* intend to file a brief addressing these important questions.

Respectfully submitted,

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QUESTIONS PRESENTED

The National Childhood Vaccine Injury Act of 1986 had two principal policy goals: to ensure the "availability and use of vaccines to prevent childhood diseases" as well as to insure "access to sufficient compensation for [vaccine-related] injuries," H.R. Rep. No. 908 at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6346. The Vaccine Act largely freed manufacturers from fear of liability, and provided claimants with what was intended to be an expeditious and hospitable forum to litigate their claims. The *en banc* decision by the United States Court of Appeals for the Federal Circuit in *Cloer,* interpreting the Act's statute of limitations provision, threatens to undermine the ability of many potential petitioners to file claims for compensation in this program instead of in other state and federal courts. The questions presented are:

1. Should the Vaccine Act's statue of limitations provision, 42 U.S.C. § 300aa-16, be construed to run against a petitioner only after there is an objective basis for knowing that a vaccine-related injury has occurred?

2. Is the Vaccine Act's statute of limitations subject to equitable tolling where a claimant is aware of a symptom of a possible injury, but there is no basis for the medical community to know that the injury incurred was related to the vaccination that the claimant had received?

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are groups who have been involved in the National Vaccine Injury Compensation Program for many years, and a number of organizations for children and families. *Amici* seek to have this Court grant the petition for a writ of certiorari in this case because of its great importance to the continued operation of the National Vaccine Injury Compensation Program.[1]

Amicus curiae the National Vaccine Information Center ("NVIC"), founded in 1982 by parents whose children were injured or died following DPT vaccinations, is widely recognized as the oldest, largest, and most effective non-profit national organization advocating for the institution of vaccine safety and informed consent protections in U.S. health programs. NVIC has assisted thousands of individuals who have suffered serious health problems, hospitalizations, injuries and deaths following vaccinations. It promotes scientific research to evaluate vaccine safety and defends the ethical principle of informed consent for medical interventions, including vaccination, which carry a risk of injury or death.

Amicus curiae the Vaccine Injured Petitioners Bar Association ("Petitioners Bar"), is a voluntary bar association composed of attorneys who represent

1. Pursuant to Sup. Ct. R. 37.2(a), *amici curiae* note that counsel of record for all parties received timely notice of the *amici's* intent to file this brief. Pursuant to Sup. Ct. R. 37.6, *amici* note that no part of this brief was authored by counsel for any party. *Amici* also note that no party or counsel made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or entity other than *amici* or their members made such a monetary contribution. This brief is filed with the consent of all parties.

petitioners in the National vaccine Injury Compensation Program. Members of Petitioners Bar have assisted the families of children and adults who have suffered adverse reactions to vaccinations since the inception of the Vaccine Program. The organization and its members have a professional responsibility to ensure that the families of the vaccine-injured receive justice as Congress intended —swiftly, and with generosity and certainty.

To that end, members of the Petitioners Bar have testified before Congress on numerous occasions concerning vaccine injuries and the compensation program. It is in the performance of their professional duties that the attorneys in the Petitioners Bar have seen, and continue to see, many injured individuals who have a potential vaccine injury claims, but who cannot bring them because they are bared by the statue of limitations as interpreted by the *en banc* court in *Cloer*.

Amici curiae The George Washington University Law School Vaccine Injury Clinic ("Vaccine Injury Clinic") represents the families of young children and adults in the Vaccine Compensation Program. Through the efforts of its Student-Attorneys and faculty, the Vaccine Injury Clinic has obtained compensation for children with severe mental and physical disabilities and has prevailed in appeals to the United States Court of Appeals for the Federal Circuit on significant vaccine issues. The Vaccine Injury Clinic has also advocated before the Department of Health and Human Services for modifications in the Vaccine Act.

Amicus curiae Office of Medical and Scientific Justice is a 501(C)(3) non-profit organization based in Los Angeles that investigates cases related to medical and scientific corruption, including instances involving vaccines.

Amicus curiae Canary Party is a movement created to stand up for the victims of medical injury, environmental toxins and industrial foods by restoring balance to our free and civil society, and empowering consumers to make health and nutrition decisions that promote wellness.

SUMMARY OF ARGUMENT

Amici urge this Court to grant review in this case for three principal reasons. First, the issue in this case, involving the interpretation and application of the statute of limitations in the National Childhood Vaccine Injury Act, is a very important, commonly recurring issue that has affected and will continue to affect a great many petitioners in the Vaccine Injury Compensation Program. Second, the *en banc* decision by the United States Court of Appeals for the Federal Circuit conflicts with this Court's prior precedents concerning implied discovery rules in similar statute of limitations provisions. Finally, the decision contradicts the Congressional intent of the statute of ensuring a forum to litigate vaccine injury claims in the United States Court of Federal Claims instead of other state and federal courts.

ARGUMENT

I. The Interpretation and Application of the Vaccine Act's Statute of Limitations is a Very Important and Recurring Issue That Affects a Substantial Number of Petitioners in the Vaccine Injury Compensation Program

One of the most important and widely recurring problems faced by petitioners in the Vaccine Injury Compensation Program ("VICP") is the time barring

of otherwise strong claims.[2] Representing a variety of interested groups, including the Vaccine Injured Petitioners Bar Association, this brief confirms that a substantial number of otherwise qualified petitioners either have their claims dismissed from the VICP without ever reaching the merits or never even file their claims in the program, because of an inability to meet the statute of limitations. Unless this Court intervenes and determines the proper interpretation and application of the statute of limitations, including when it can properly be tolled, many petitioners will have no remedy for their vaccine-related injuries.

Vaccine-related injuries are relatively rare. Of the millions of vaccinations administered in the United States, a minute fraction gives rise to a claim in the VICP. Consequently, few people, even physicians, are knowledgeable about the science involving the types of injuries that vaccines may cause. When these injuries do occur, the potential petitioners often fail to recognize that the injury could be related to the vaccination. Furthermore, many of the injuries suffered by potential petitioners are not readily diagnosable, and are often not diagnosed until after the statute of limitations period has run. The following are a few of the many cases that the members of the Petitioner's Bar have encountered that illustrate the nature of this very serious problem.

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2. The Vaccine Act's statute of limitations permits injured claimants or their representatives to file a petition for compensation within three years from the onset of the injury or two years from the time of death. 42 U.S.C. § 300aa-16(a).

A. Petitioners Whose Conditions Are Correctly Diagnosed Only After the Statute of Limitations Has Run

There have been multiple cases in which a petitioner's condition has been initially misdiagnosed, or a diagnosis could not be made by the treating doctor, and only much later, after the statute of limitations has expired, was a correct diagnosis made. Under the rule adopted by the *en banc* Court of Appeals in this case, these individuals are unable to seek compensation for their vaccine-related injuries.

One example of this problem is the situation faced by J.H.[3], who like many Americans of modest means, was without health insurance when he received hepatitis B vaccinations on March 17 and April 25, 2006. After each injection he experienced various symptoms, but his treating physicians could not make a diagnosis. Because J.H. was uninsured, he was unable to obtain Magnetic Resonance Imaging (an "MRI") for three years. Subsequently, an MRI was taken, and it showed evidence that J.H. was suffering from a demyelinating disease, very likely multiple sclerosis ("MS"). MS has been linked to vaccinations in the past and claims for this debilitating, degenerative disease are routinely filed in the VICP. Because J.H. could not bring such a claim without a diagnosis, and because obtaining the diagnosis took longer than three years, J. H.'s claim is barred by the statute of limitations, as interpreted in the *en banc*

3. J.H. approached a member of the Petitioner's Bar and has given permission to share his story. We refer to him as J.H. for privacy purposes.

decision in *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1346 (2011) (en banc), and the program will never reach the merits of J. H.'s case.

Because situations like J. H.'s are commonplace, a goal of the VICP—to maintain an accessible and efficient forum for individuals found to be injured by vaccines - is often unmet.

B. Petitioners Who Are Misinformed That Their Injuries Could Not be the Result of a Vaccination

It also sometimes happens that a medical provider to tell a patient that the vaccination the patient received did not induce the patient's injury, when in fact the vaccination could have triggered the patient's aliment. In *Hebern v. Sec'y of Health & Human Servs.*, 81 F. App'x 333 (Fed. Cir. 2003), Sarah Hebern ("Sarah") became paralyzed after receiving the polio vaccination in 1990. 81 F. App'x 333, 334 (Fed. Cir. 2003). Because Sarah's paralysis occurred 30 days after the receipt of vaccination, her doctors' concluded the vaccination did not induce paralysis. *Id.* In 2000, however, "Sarah's doctors agree[d] that her paralysis was caused by polio that she contracted through contact with another child following the other child's vaccination," warranting a potential claim in the VICP. *Id*. The Heberns filed a petition for relief in vaccine court in 2001, however, their claim was barred because the statute of limitations had tolled. At the onset of her injury, Petitioner had no reason to suspect that her paralysis was caused by a polio vaccination because medical professionals told her that the vaccine did not induce the injury.

C. Petitioners Who Are Unaware That Their Injuries Could be the Result of Their Vaccinations

A.C.[4] suffered from a seizure disorder allegedly traceable to a DPaT vaccination she received when she was one and a half years old. A.C.'s mother, F.C., like many parents of children injured by vaccinations, did not suspect that the injection her child received could have been the cause of her daughter's seizures. Furthermore, F.C., like many parents, was unaware of the existence of the VICP. F.C. began making inquiries before the statute of limitations tolled; however, F.C. did not file a petition within the three years statute of limitation period, and now is unable to seek compensation under the *Cloer en banc* decision.

These are just a few examples of the many cases that attorneys with the Petitioner's Bar Association have seen. The statue of limitations is a common concern to the attorneys in this program because they often speak to potential petitioners who cannot file because the statute of limitations has expired under the *Cloer* majority's interpretation. This is a constant and re-occurring problem facing many persons who seek compensation in the Vaccine Injury Compensation Program. This is a very serious problem in the Vaccine Injury Compensation Program, and it should be addressed now by this Court.

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4. A.C. and F.C. approached a member of the Petitioner's Bar. We refer to them as A.C. and F.C. to maintain their privacy.

II. The Decision Reached by the *En Banc* Court of Appeals Conflicts With This Court's Precedents Regarding When Courts Should Imply a Discovery Rule in Analogous Federal Statutes of Limitations.

This Court's precedents show that a discovery rule should be implied into the Vaccine Act. Federal courts, this Court has said, "generally apply a discovery accrual rule when a statute is silent on the issue." *TRW Inc. v. Andrews*, 534 U.S. 19, 27 (2001) (quoting *Rotella v. Wood*, 528 U.S. 549, 555 (2000)). And while the Court noted in *TRW* that it had not explicitly adopted an automatic requirement for a discovery rule in all such situations, 534 U.S. at 27, it noted that it has, at the very least, "recognized a prevailing discovery rule . . . 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). *See also Holmberg v. Armbrecht*, 327 U.S. 392, 397 (recognizing a discovery rule where a plaintiff is injured by fraud).

The reasoning of *United States v. Kubrick*, 444 U.S. 111 (1979), which dealt with a medical malpractice claim brought under the Federal Tort Claims Act, helps to explain to which cases courts should apply a discovery rule. There, the Court said it was "unconvinced that for statute of limitations purposes a plaintiff's ignorance of his legal rights and his ignorance of the fact of his injury *or its cause* should receive identical treatment." *Id.* at 122 (emphasis added). In other words, the Court distinguished between a plaintiff who knows all the facts relating to her injury, but not the legal implications of those facts, and one who does not and cannot know the cause of her injury. *See id.*; *Rotella*, 528 U.S. at 556 ("A person suffering from inadequate treatment is thus responsible for determining

within the limitations period then running whether the inadequacy was malpractice."). The plaintiff in *Kubrick* knew both the nature of his injury and who had caused it, and thus "armed with the facts about the harm done to him, [could] protect himself by seeking advice in the medical and legal community," a step that would have quickly informed him of his doctors' negligence. *Kubrick*, 444 U.S. at 123. Therefore, the discovery rule should only toll the statute for plaintiffs who, through no fault of their own, cannot know some fact essential to their claim.

The dissenting opinion in the Court of Appeals noted that "the Vaccine Act is similar to, and replaces, a medical malpractice or similar remedy," a position that the majority did not dispute. *Cloer*, *supra*, 654 F.3d at 1346 (Dyk, J., dissenting). *See also Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1073-74 (2011) (noting that the remedies provided to claimants under the Vaccine Act are a "*quid pro quo* for . . . significant tort-liability protections for vaccine manufacturers"). Thus, even if the discovery rule is applied only to cases involving malpractice and latent injuries, it should apply to the Vaccine Act.

Dr. Cloer's case illustrates the logic of and necessity for such a rule: While she began to experience symptoms linked to the substance of her injury, Multiple Sclerosis, as early as 1997, she had no knowledge of the cause of that injury, the Hepatitis B vaccination, until 2004. *Cloer*, 654 F.3d at 1327-28. Unlike the plaintiff in *Kubrick* who knew the cause of his injury but not his potential remedy, Dr. Cloer had no cognizance of the cause of her injury despite numerous medical consultations and her own medical background. *Id.*

Without full consideration of the precedents above, the *Cloer* majority concluded that a discovery rule could not be read into the Vaccine Act's statute of limitations based on an impermissible broadening of this Court's opinion in *TRW*. *See Cloer*, 654 F.3d at 1337-40. In *TRW*, this Court explained that while certain legal contexts warranted a discovery rule, Congress could "convey its refusal to adopt a discovery rule" either explicitly or "by implication from the structure or text of the particular statute." 534 U.S. at 27-28. In that case, the Court reasoned that the Fair Credit Reporting Act ("FCRA") did not incorporate a general discovery rule for two reasons: First, the FCRA, a statute dealing with banking and consumer privacy, did not "govern an area of the law that cries out for application of a discovery rule." *Id.* at 23, 28; *see also id.* at 27 (quoting *Rotella*, 528 U.S. at 555) (recognizing medical malpractice and latent injuries as cases "where the cry for [such a] rule is loudest"). Second, the FCRA already included a limited discovery rule, which allowed a plaintiff to bring an action within two years of discovering the willful misrepresentation of information required to bring a claim under the Act. *Id.* This limited discovery rule showed that Congress, through the structure and text of the FCRA, intended to "implicitly exclude[] a general discovery rule by explicitly including a more limited one." *Id.* at 28. Thus, where a statute concerns a subject that cries out for a discovery rule and does not directly address the subject, such as by including a limited discovery rule, courts should imply one into the statute.

Although the majority in *Cloer* cited *TRW* as precedent for its holding, *see Cloer*, 654 F.3d at 1338, 1340, it impermissibly veered from the case when interpreting the Vaccine Act. To begin, the majority failed to consider the threshold question of whether cases brought under

the Vaccine Act "cr[y] out for application of a discovery rule." *See TRW*, 534 U.S. at 28; *Cloer*, 654 F.3d at 1337-38. As noted above, the Vaccine Act serves as the effective equivalent of a malpractice remedy, *Cloer*, 654 F.3d at 1346 (Dyk, J., dissenting), and the Court has said that plaintiffs seeking such a remedy should benefit from this kind of rule, *see TRW*, 534 U.S. at 27. Instead, the *Cloer* majority skipped to step two of the analysis and asked whether Congress "conveyed its refusal to permit an implied discovery rule" with the structure or text of the Vaccine Act. 654 F.3d at 1338. Further, in finding that Congress did convey such an intention, the majority misapplied *TRW*.

In *TRW*, Congress wrote one "single exception" into the FCRA's statute of limitations which "address[ed] the precise question" of whether Congress intended to imply a discovery rule. 534 U.S. at 27-28. The *Cloer* majority failed to point to a similarly telling provision in the Vaccine Act; instead, the majority focused on the Act's statute of limitations, which contains no discovery rule of any sort, and on Congress' general motives in creating the Vaccine Program. *See Cloer*, 654 F.3d at 1338-40. The majority thereby shifted the inquiry away from whether the structure or text of the statute *itself* led to preclusion of a discovery rule, a significant departure from this Court's precedent in *TRW*. *See Cloer*, 654 F.3d at 1339-40; *TRW*, 534 U.S. at 28-33.

Together with the majority's failure to consider whether the Vaccine Act "crie[d] out for application of a discovery rule," *see TRW*, 534 U.S. at 28; *Cloer*, 654 F.3d at 1337-40, its misapplication of *TRW* represents a significant conflict with this Court's precedent and warrants review.

III. The *En Banc* Decision Contradicts the Congressional Intent Behind the Vaccine Act

The Federal Circuit's *en banc* decision in *Cloer* also directly contradicts the Congressional intent behind the Vaccine Act. Congress intended to "ensure that all children who are injured by vaccines *have access* to sufficient compensation for their injuries." H.R. Rep. No. 908 at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6346 (emphasis added). However, the current state of the law directly contradicts Congress's intent; many claimants who are unable to seek redress in state court after this Court's decision in *Bruesewitz v. Wyeth*, 131 S. Ct. at 1073, are now also barred from seeking redress through the Vaccine Injury Compensation Program under *Cloer,* leaving children and adults who have suffered a vaccine-related injury *without access* to an effective forum in which to seek redress for their injuries.

Prior to the Vaccine Act, the science establishing an association between vaccinations and subsequent injuries was shaky and unknown to the general population. But as the science improved and people became more aware that vaccines pose a risk of subsequent injury, civil litigation seeking redress for those injuries in state court increased substantially through the early 1980s. *Bruesewitz v. Wyeth*, 131 S. Ct. 1068, 1073 (2011); *see also* H.R. Rep. No. 908 at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 ("[Injured] children . . . and their families have resorted in greater numbers to the tort system for some form of financial relief."). As litigation increased, however, vaccine manufacturers perceived a financial threat from a continuing flood of litigation. *Bruesewitz*, 131 S. Ct. at 1073 ("[The threat of litigation] destabilized the market,

forcing two of the three domestic manufacturers [of the DPT vaccine] to withdraw."). Additionally, claimants who suffered a vaccine-related injury and sought redress in state court were subject to a system that Congress identified as "limited, time-consuming, expensive, and often unanswered." H.R. Rep. No. 908 at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344.

Congress had two separate policy goals in the Vaccine Act—to ensure the "availability and use of vaccines to prevent childhood diseases" as well as to insure "access to sufficient compensation for [vaccine-related] injuries," H.R. Rep. No. 908 at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6346. The Vaccine Act largely freed manufacturers from fear of liability, and provided claimants with an expeditious and hospitable forum to litigate their claims. *Cloer, supra*, 654 F.3d 1322 at 1325.

The structure of the Vaccine Act initially achieved both of Congress's goals: vaccine manufacturers have remained in production, and individuals who have suffered from vaccine-related injuries have been able to turn to the Vaccine Injury Compensation Program to seek redress. However, the Federal Circuit's recent decision in *Cloer*, together with this Court's recent decision in *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011), have largely eliminated access to compensation for individuals who have suffered vaccine-related injuries.

In *Cloer*, the majority opinion held that the Vaccine Act does not contain either an explicit or an implicit discovery rule. 654 F.3d at 1337. Under this holding, an injured claimant or representative who fails to file a claim within the Act's statute of limitations is time-barred

from filing a claim in the Vaccine Injury Compensation Program. *See id.* In light of this Court's recent decision in *Bruesewitz*, which held that the Vaccine Act preempts all design-defect claims brought by injured claimants against vaccine manufacturers, *Bruesewitz*, 131 S. Ct. at 1082, the Federal Circuit's decision in *Cloer* effectively leaves many otherwise-qualified litigants *without an effective forum* in which to file a vaccine injury claim.

The law as it currently stands is in clear contradiction of the congressional intent behind the Vaccine Act. As indicated above, Congress's goal was to assist both the vaccine manufacturers and the injured parties. But after *Bruesewitz* and *Cloer*, vaccine manufacturers now enjoy near-immunity from civil action liability, while claimants "who have been gravely injured" lack an effective forum in which to seek redress. H.R. Rep. No. 908 at 5 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6346. Allowing *Cloer* to stand would deny many children access to the Vaccine Injury Compensation Program and would contradict Congress's intent to "ensure that all children who are injured by vaccines *have access* to sufficient compensation for their injuries." H.R. Rep. No. 908 at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6346 (emphasis added). Congress intended to increase the availability of compensation by reducing the hurdles presented in state court, rather than decrease the number of individuals eligible to file a claim. H.R. Rep. No. 908 at 10 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6354 ("Many vaccine-injured persons are presently without legal remedy under current tort law. The Committee anticipates that many of these persons will be compensated for their injuries under the compensation system.").

The Federal Circuit's *en banc* decision in *Cloer* is inconsistent with this Congressional intent. It is important for this Court to grant review in this case to insure that the Congressional intent in providing a widely-available Vaccine Injury Compensation Program remedy for individuals who have been injured by vaccinations is effectuated.

CONCLUSION

For the reasons stated above, and those stated in the petition, the writ of certiorari should be granted, and the judgment reversed.

Respectfully submitted,

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