2009-5052

United States Court of Appeals

for the

Federal Circuit

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

BRIEF FOR AMICI CURIAE IN SUPPORT OF PETITIONER-APPELLANT IN FAVOR OF AFFIRMANCE

Kevin P. Conway
CONWAY, HOMER & CHIN-CAPLAN, P.C.
16 Shawmut St.
Boston, MA 02116
Phone: (617) 695-1990
Fax: (617) 695-0880

Counsel for Amici Curiae

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COUNSEL PRESS, LLC (202) 783-7288 * (888) 277-3259

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Melissa Cloer v. Secretary of Health and Human Services

No. 2009-5052

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) amici certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Vaccine Injured Petitioners Bar Association (see also Brief of Amici Curiae, Exhibit A)

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

n/a

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

n/a

4. ☐ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Kevin P. Conway

2/18/11
Date

Signature of counsel

Kevin P. Conway
Printed name of counsel

Please Note: All questions must be answered

cc:

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EN BANC BRIEF OF *AMICI CURIAE* IN SUPPORT OF PETITIONER-APPELLANT

I. STATEMENT OF INTEREST OF *AMICI CURIAE*

The fifteen organizations that have signed this amici brief have a strong interest that this case be decided impartially, in accordance with Congressional intent. A full list of the *amici* is attached as Exhibit A. All the undersigned organizations recognize that Congress intended to create an inclusive, generous program to compensate the victims of vaccine injury. Equitable tolling and a

generous "discovery rule" are essential to fulfilling Congress' intent. The *amici* believe it is time for this Court to reevaluate its decision in *Brice v. Sec'y of HHS*,[1] to decide in a way more consistent with Congress' purpose.

Among the *amici* is the Vaccine Injured Petitioners' Bar Association, which advocates for the rights of the vaccine injured. Many of the organizations advocate for the ethical principle of informed consent to vaccination, as every vaccination decision potentially carries the risk of injury or death. Several organizations advocate for the rights of individuals with autism spectrum disorders. Others highlight the risks of mercury in all medicines, including vaccines. The *amici* are united in their view that an interpretation of the 1986 National Childhood Vaccine Injury Act that includes equitable tolling and a "discovery rule" best accords with Congress' intent.

The *amici* file this brief in accordance with Federal Rules of Appellate Procedure, Rule 29(a). This Court noted, "Briefs of amici curiae will be entertained, and any such briefs may be filed without leave of court or the parties consent. . . ." *See* Order of October 25, 2010, page 3.

II. SUMMARY OF THE ARGUMENT

Congress' primary purpose in establishing the Vaccine Program[2] was to promote the nation's health by protecting its current supply of vaccines and by

[1] 240 F.3d 1367, 1368 (Fed. Cir. 2001).

encouraging the development of new vaccines. *See* H.R. Rep. No. 99-908, 99th Cong., 2nd. Sess. (1986). This goal would be furthered, Congress decided, by prohibiting civil lawsuits against vaccine manufacturers for vaccine-related injuries until claimants had first processed their claims through the Vaccine Program. Due to the "no fault," informal and generous nature of the Program, Congress believed that most, if not all, claims for vaccine-related injuries would be resolved in the Program without resort to civil litigation. Congress also provided, however, that a dissatisfied petitioner could reject the Program's ultimate decision and then file a civil lawsuit with certain limitations. *See* §§ 21-23.

The question presented by this case is regarding § 16(a)(2).[3] The legislative history of the Vaccine Act itself is silent as to whether a "discovery rule" or "equitable tolling" is applicable to § 16(a)(2). This is significant, the government argues, because the Vaccine Program is a waiver of sovereign immunity and must be strictly construed. In other words, the government says, unless the statute expressly permits the "discovery rule" and "equitable tolling," they are not

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[2] The Vaccine Act, which established the Vaccine Injury Compensation Program, is located at 42 U.S.C. §§ 300aa-1 *et seq*. For convenience, future references will be to the "Vaccine Act," the "Act" or the "Vaccine Program." Individual sections to the Act will include only the section number.

[3] "[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. . .of such injury." § 16(a)(2).

available to petitioners. However, petitions in the Vaccine Program are not entering lawsuits against the federal government. For this reason, the Vaccine Program is not a waiver of sovereign immunity. Instead, it is a remedial insurance program administered by the Secretary of Health and Human Services. It is not funded by the general treasury, but by a special excise tax on vaccines, which directly funds the Vaccine Trust Fund. Indeed, in light of the Act's clearly stated goals of an ***inclusive*** Vaccine Program, one intended to divert injured persons away from civil litigation, both a "discovery rule" and "equitable tolling" must be available to petitioners. Any other interpretation, leaving civil litigation as the sole available remedy,[4] would undoubtedly frustrate Congressional intent.

[4] In *Brice v. Sec'y of HHS,* the Federal Circuit observed, "We need not decide in this case whether a petitioner who fails to file a timely petition under the Program may still pursue traditional tort remedies." 240 F.3d at 1368. However, the answer to this question is both relevant and important. Certainly, vaccine manufacturers may argue that untimely filings by children and adults in the Program cut off traditional state tort remedies. Indeed, one of the purposes of the Vaccine Act is to shield vaccine manufacturers from lawsuits. However, most states toll statutes of limitations for minors and for brain-damaged individuals. It is inconceivable that Congress would have intended such a sweeping preemption of the rights of children and mentally handicapped persons without a single word in the statute. The Vaccine Act expressly states that, except as otherwise provided, "State law shall apply to a civil action brought for a vaccine-related injury or death." § 22(a). The Vaccine Act does not provide that untimely petitioners in the Program forfeit all rights to civil litigation. Indeed, such an interpretation is incongruous with Congressional intent, will be firmly rejected by state courts, and, should be rejected by this Court.

In *Brice*, Judge Newman stated that the majority's patent refusal to permit equitable tolling with respect to § 16(a)(2) no matter how worthy the petitioner or how compelling the petition was "neither a necessary interpretation of the Vaccine Act, nor a tolerable one." *Brice*, 240 F.3d at 1374 (dissenting opinion). Surely, Judge Newman will agree, the "discovery rule" should also be available to petitioners, as it "opens the door to a petitioner upon whom the door should not be shut." *Id*. Any other interpretation of the statute serves only to undermine Congressional intent.

Finally, in the view of *amici*, the circumstances of this particular case support an equitable tolling of § 16(a)(2). Dr. Melissa Cloer ("Dr. Cloer") exercised due diligence in presenting her claim once she became aware of the cause of her injury.

III. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Background[5]

Dr. Cloer was asymptomatic when she received two hepatitis B ("hep B") vaccines in 1996. After each vaccine, she experienced numbness and tingling. She received the third hep B in April of 1997. Approximately one month later, Dr.

[5] The following facts are taken from the panel's majority opinion. *See Cloer v. Sec'y of HHS*, 603 F.3d 1341, 1343-1344 (Fed. Cir. 2010).

Cloer had an electric shock-like sensation known as Lhermitte sign,[6] which can be associated with multiple sclerosis ("MS"), but is not diagnostic of MS. Several months later, in October of 1997, she lost sensation in both her left hand and left arm. The symptoms resolved. Only after Dr. Cloer had additional symptoms and testing in 1998, did a medical record relate the differential diagnosis of "probable early inactive non-progressive CNS [central nervous system] demyelination/MS." On November 26, 2003, she was given a provisional diagnosis of MS. In May of 2004, a physician, in retrospect, noted that Dr. Cloer first began to have symptoms of MS in 1997. Dr. Cloer first became aware of an association between the hep B vaccine and MS when she read the September 2004 issue of *Neurology*. On October 11, 2004, she filed a VAERS report noting that she had experienced numbness and tingling after the first two hep B vaccinations.

B. Procedural Background

On September 16, 2005, Dr. Cloer filed a petition in the Vaccine Program. The Respondent-Appellee moved to dismiss her claim as untimely as it was not within the 36-month limitation period provided by § 16(a)(2). In response, she filed an affidavit from a treating neurologist, Dr. Michael Andrew Meyer, who stated that he believed, in retrospect, Melissa had suffered the first symptom of her

[6] Lhermitte sign: "[S]udden electric-like shocks extending down the spine on flexing the head." STEDMAN'S ELECTRONIC MEDICAL DICTIONARY (Lippincott Williams & Wilkens, 27th ed. CD-ROM, 2000).

MS in 1997, but the medical community at large *would not have recognized that she had a vaccine injury. He stated that he was unaware of an association between the hep B vaccine and MS until so informed by Melissa's counsel in 2005.*

In 2007, a special master dismissed her claim, determining that the first symptom of her MS was in 1997, when she experienced the Lhermitte sign. *See Cloer v. Sec'y of HHS*, No. 05-1002V, 2008 WL 2275574 (USCFC Spec. Mstr. May 2008). The Court of Federal Claims affirmed. *See Cloer v. Sec'y of HHS*, 85 Fed.Cl. 141 (USCFC 2008). The Federal Circuit, however, reversed, holding that the limitations period does not begin to run until the "medical community at large objectively recognizes a link between the vaccine and the injury." *Cloer*, 603 F.3d at 1346. A dissenting opinion argued that the Court's previous decisions in *Brice v. Sec'y of HHS*, 240 F.3d 1367 (Fed. Cir. 2001), *Markovich v, Sec'y of HHS*, 477 F.3d 1353 (Fed. Cir. 2007), and *Wilkerson v. Sec'y of HHS*, 593 F.3d 1343 (Fed. Cir. 2010), make it clear that the limitation period begins to run at the time of the first symptom or manifestation of onset of the injury, regardless of whether the petitioner or the medical community at large is aware of a potential link between the injury and a vaccine. *Cloer*, 603 F.3d at 1352-1353.

On October 10, 2010, at the request of the Respondent-Appellee, the Court decided that this appeal warrants *en banc* consideration. The parties were requested to file briefs addressing 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?

(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?

Order of October 25, 2010, pages 2-3. The Court also stated that briefs of *amici curiae* would be entertained. *Id*. at 3.

IV. STANDARD OF REVIEW

This Court reviews the decisions below to determine if they were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[7] The Court applies a *de novo* standard, owing no deference either to the special master or the trial court on questions of law.[8]

[7] § 12(e)(2)(B).

[8] *Whitecotton v. Sec'y of HHS*, 81 F.3d 1099, 1106 (Fed. Cir. 1996).

V. ARGUMENT

A. The "Discovery Rule" Should Apply to § 16(a)(2) of the Vaccine Act

i. The Supreme Court's Decisions in *United States v. Kubrick*[9] and *TRW Inc. v. Andrews*[10] Support this Proposition

The "discovery rule" should apply to § 16(a)(2) of the Vaccine Act. The Supreme Court decisions cited by this Court in its order granting the Respondent-Appellee's petition for rehearing *en banc* provide strong support for this proposition. *In United States v. Kubrick*, Kubrick, a veteran, suffered hearing loss after the administration of the antibiotic neomycin. The injury occurred in 1968. In January of 1969, Kubrick was advised that the neomycin caused the hearing loss. In June of 1971, he learned that the drug was negligently administered. Thereafter, in 1972, he filed a claim for medical malpractice pursuant to the Federal Torts Claims Act ("FTCA"). The Supreme Court found that the presentment of Kubrick's claim was untimely. In this regard, the Court noted, 28 U.S.C. § 2401(b) bars claims not presented "within two years after such claim accrues." *Kubrick*, 444 U.S. at 113. In Kubrick's case, the Court held, the claim accrued in January of 1969, when he learned that the neomycin had caused his hearing loss. In so ruling, the Court stated that:

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[9] 444 U.S. 111 (1979).

[10] 534 U.S. 19 (2001).

> [P]laintiff[s] such as Kubrick, armed with the facts about the harm done to him, can protect himself by seeking advice in the medical and legal community. To excuse him from promptly doing so by postponing the accrual of his claim would undermine the purpose of the limitations statute, which is to require the reasonably diligent presentation of tort claims against the Government.

Kubrick, 444 U.S. at 123.

It is noteworthy, however, and relevant to Dr. Cloer, that the Court distinguished Kubrick's case from one where the nature of the injury or its cause is not known.

> We are 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. That he has been injured in fact 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.

Id. at 122.

In this case, Dr. Cloer first became aware of an association between the hep B vaccine and her MS in September of 2004. On September 16, 2005, she filed a petition in the Vaccine Program, well within the three years provided by § 16(a)(2). Dr. Cloer did not file an FTCA claim. She filed a claim in the Vaccine Program. However, the Supreme Court's reasoning in *Kubrick* can surely be extended to support the proposition that, for purposes of § 16(a)(2), a claim does not accrue until, at a minimum, the cause of the injury is discovered.

In *TRW Inc. v. Andrews*, the plaintiff, Adelaide Andrews, was a victim of identity theft. At the request of the thief, TRW provided Andrews' credit report to various businesses, on four occasions, July 25, 1994, September 27, 1994, October 28, 1994, and January 3, 1995. Andrews did not learn of TRW's actions until May 31, 1995. Seventeen (17) months later, she filed a claim under the Fair Credit Reporting Act ("FCRA").[11] She alleged she had suffered damages because TRW had improperly disclosed her credit report. She argued that the limitations period provided by 15 U.S.C. § 1681(p) ("two years from the date on which liability arises") should not begin to run until she had discovered TRW's actions. The Court held that her complaint was untimely, because the limitations period prescribed by § 1681(p) specifically provided an exception as to when the "discovery rule" was applicable and that Andrews did not fall within that exception. *TRW Inc. v. Andrews*, 534 U.S. at 28. However, again relevant to Dr. Cloer's petition, the Supreme Court recognized that:

> [L]ower federal courts 'generally apply a discovery accrual rule when a statute is silent on the issue.' *Rotella,* 528 U.S. at 555, 120 S.Ct. 1075; *see also Klehr v. A.O. SmithCorp.,* 521 U.S. 179, 191, 117 S.Ct. 1984, 138 L.Ed.2d 373 (1997) (citing *Connors v. Hallmark & Son Coal Co.,* 935 F.2d 336, 342 (C.A.D.C. 1991), for the proposition that 'federal courts generally apply [a] discovery accrual rule when [the] statute does not call for a different rule').

[11] 15 U.S.C. § 1681 *et seq*.

TRW Inc. v. Andrews, 534 U.S. at 27. The Supreme Court also noted that it had applied the discovery rule in cases of fraud (*Holmberg v. Armbrecht*, 327 U.S. 392 (1946)) and in cases involving "latent disease and medical malpractice, 'where the cry for [such a] rule is loudest,' *Rotella v. Wood,* 528 U.S. 549, 555. . . ." *TRW Inc. v. Andrews*, 534 U.S. at 27. The Court observed, "The FCRA does not govern an area of the law that cries out for application of a discovery rule. . . ." *Id*. at 28. However, the Vaccine Act clearly covers such an area of law and does cry out for application of the discovery rule. Issues relating to latent disease and vaccine-causation are routine in the Vaccine Program. As this Court has noted:

> While this case involves the possible link between TT vaccination and central nervous system injury, a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.

Althen v. Sec'y of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

The Supreme Court's reasoning in *U.S. v. Kubrick* and *TRW Inc. v. Andrews* should be adopted by this Court to apply the "discovery rule" to § 16(a)(2). Clearly, such an interpretation would further Congressional intent.

ii. The Statutory Scheme of the Vaccine Act Supports this Proposition

The Vaccine Program was established for two purposes: (1) to protect the nation's existing vaccine supply and encourage the development of new and safer vaccines; and (2) to compensate persons injured by vaccines. *See* H.R. Rep. No.

99-908. The first goal would be accomplished, Congress believed, by reducing the liability risks of vaccine manufacturers. An interpretation of § 16(a)(2) that permits application of the "discovery rule" is consistent with these goals.

In this regard, it is worth repeating Congress' "principal findings" that required the establishment of the Vaccine Program. They are:

> 1. [t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities;
>
> 2. [t]he Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries; and
>
> 3. [p]rivate or non-governmental activities have proven inadequate in achieving either of these goals. . . .

H.R. Rep. No. 99-908 at 5.

Thus, Congress stated, "two overriding concerns have led to the development of this legislation:

> (a) the inadequacy – from both the perspective of vaccine-injured persons as well as vaccine manufacturers – of the current approach to compensating those who have been damaged by a vaccine; and
>
> (b) the instability and unpredictability of the childhood vaccine market. . . ."

Id. at 7.

To remedy these concerns, the Vaccine Program was established. Congress hoped the Vaccine Program would lessen the number of lawsuits against manufacturers. In so doing, it hoped the Vaccine Program would promote the "development of both new and improved vaccines. . . ." *Id*. at 4. It also hoped it would help to create "a new system for compensating individuals who have been injured by vaccines routinely administered." *Id*. at 3. Such awards, Congress intended, "can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908 at 3.

Since 1988, the Program has been in effect. Many new vaccines have been developed and are now available.[12] In addition, hundreds of petitioners have received compensation without resorting to civil litigation. An interpretation of § 16(a)(2) that permits application of the "discovery rule" is consistent with Congressional intent to make the Vaccine Program inclusive. An interpretation that the rule is inapplicable would leave affected petitioners with only one remedy—civil litigation. As this is precisely what Congress sought to prevent, such an interpretation is intolerable.

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[12] Since the Vaccine Program was established, the following vaccines have been developed and added to the Vaccine Table: hep B vaccine, *haemophilus influenzae* type B vaccine, varicella vaccine, rotavirus vaccine, pneumococcal conjugate vaccines, hepatitis A vaccine, trivalent influenza vaccine, meningococcal vaccine, and human papillomavirus vaccine. *See* § 14.

iii. The Remedial Nature of the Vaccine Program Supports this Proposition

The Vaccine Act is a "super-statute,"[13] remedial in nature, one that must be broadly construed to achieve Congressional goals.[14] In this regard, Congress intended that the Vaccine Program supplement the civil tort system for vaccine injuries. Congress intended that the Vaccine Program be *more generous*, not more parsimonious, than the civil tort system. Congress intended that vaccine cases resolve **in** the Program, rather than in a civil tort action against a vaccine

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[13] A super-statute is one that "seeks to establish a new normative or institutional framework for state policy." Eskridge, Jr., W. N., Ferejohn, J., *Super-statutes,* 50 DUKE L.J. 1215, 1216 (1996). Such statutes "stick in the public culture" and have "a broad effect on the law." *Id.* at 1216. They are enacted "only after lengthy normative debate about a vexing social or economic problem." *Id*. As such, "super-statutes should be construed liberally. . .[and] in light of the statutory purpose and principle. . . ." *Id*. at 1247. An example of a super-statute that, like the Vaccine Act, intends to protect the public health is the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 (1994) (as amended). The Supreme Court ruled this statute must be given "a liberal construction consistent with [its] overriding purpose to protect the public health." *United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

[14] It is axiomatic that remedial statutes are broadly construed to ensure Congressional intent is satisfied. *See A.H. Phillips, Inc. v. Walling*, 324 U.S. 490, 493 (1945) (For a court to do otherwise, would "abuse the interpretive process and. . . frustrate the announced will of the people"); *Cosmopolitan Shipping Co., Inc. v. McAllister*, 337 U.S. 783, 790 (1949) (The Jones Act, 'as welfare legislation. . .is entitled to a liberal construction to accomplish its beneficent purposes"); *Atchison, Topeka and Santa Fe Railway Company v. Buell*, 480 U.S. 557, 562 (1987) (Federal Employer's Liability Act "is a broad remedial statute, and [we] have adopted a 'standard of liberal construction in order to accomplish [Congress'] objects.' *Urie v. Thompson*, 337 U.S. 163, 180 (1949)").

manufacturer.[15] For these reasons, application of the "discovery rule" to § 16(a)(2) is appropriate. It will permit more cases to be filed in the Program. It will lessen the number of civil lawsuits.

The Respondent-Appellee argues that the language of § 16(a)(2) does not explicitly provide a discovery rule, and, as a waiver of sovereign immunity, the Act must be strictly construed. Indeed, three Federal Circuit decisions have referred to the "sovereign immunity" doctrine in a Vaccine Program decision. *See Brice v. Sec'y of HHS, Martin v. Sec'y of HHS*, 62 F.3d 1403 (Fed. Cir. 1995), and *Schumacher v. Sec'y of HHS*, 2 F.3d 1128 (Fed. Cir. 1993). However, these decisions do not address the doctrine on the merits. In actuality, all three cases involved the issue of subject matter jurisdiction. In this regard, a Supreme Court decision has referred to "such unrefined dispositions as 'drive-by jurisdictional rulings' that should be accorded 'no precedential effect'. . . ." *Arbaugh v. Y & H Corp*., 546 U.S. 500, 511 (2006). In *United States v. Shaw*, the Supreme Court held that once Congress has given authority (*i.e*. waived immunity and established jurisdiction), this authority must be "liberally construed." 309 U.S. 495, 501 (1940). Also, in *Block v. Neal*, the Court stated, "[T]he exemption of the sovereign

[15] Although vaccine-injured persons are legally required to initially file their claims in the Program (§ 11(a)(2)), they may withdraw from the Program after specified time periods (§ 21(b)) or may reject the Vaccine Program judgment and elect to file a civil action. § 21(a).

from suit involves hardship enough where consent has been withheld. We are not to add to its rigor by refinement of construction where consent has been announced." 460 U.S. 289, 298 (1983) (quoting Justice Cardozo in *Anderson v. Hayes Const., Co*. 243 N.Y. 140, 147 (1926)); *see also United States v. Aetna Casualty & Surety Co.*, 338 U.S. 366, 383 (1949), and *In re Town & Country Home Nursing Services, Inc.*, 963 F.2d 1146, 1151 (9th Cir. 1991) ("It is well established that when the federal government waives its immunity, the scope of the waiver is construed to achieve its remedial purpose").

Indeed, nowhere does Congress suggest that the Vaccine Program is a waiver of sovereign immunity. Instead, Congress said, "the new Federal Compensation Program **substitutes a Federal insurance system** for the existing State-law tort and private insurance system, as applied to vaccine manufacturers" (emphasis added). *See* Joint Committee on Taxation, *Issues Arising in the Determination of an Appropriate Funding Source for the National Vaccine Injury Compensation Program* (JCS-4-87), March 5, 1987, page 2. This "**Federal insurance system**," Congress stated, would "likely. . .eliminate the perceived threat to compliance with the immunization program by lessening pressure for price increases by providing greater certainty of compensation for injuries (e.g. through specified amounts and lower standards of proof necessary for recovery)

. . . ." *Id*. at 3 (emphasis added). When considering various options for funding the Vaccine Program, Congress considered whether such funding should come from the general treasury or from a special excise tax on vaccines. Thus, Congress stated, "[T]he choice between an excise tax on vaccines and the use of general revenues to fund the compensation program depends, in part, on the degree to which the Federal Government should subsidize the **cost of this insurance**." *Id*. at 17.[16] It is also noteworthy that Congress clearly distinguished a petition in the Vaccine Program from a lawsuit against the federal government. Thus the Vaccine Act states, petitions for compensation must be served upon the Secretary of Health and Human Services. § 11(a)(1). The Vaccine Program is then "to be administered by the Secretary. . . ." § 10(a). The Vaccine Act, then, is not a waiver of sovereign immunity to be strictly construed. It is legislation that established an insurance program, a remedial Program. The statute must be broadly construed to achieve the goals of Congress.

[16] As the Court is aware, Congress ultimately decided that the Vaccine Program would **not** be funded by the general treasury. Instead, Congress decided, "A tax is to be imposed on the sale of. . .vaccines. . . .The taxes are set to generate sufficient annual income for the Fund to cover all costs of compensation. . . .The taxes are set at different rates among vaccines to reflect the currently accepted views regarding relative reactogenicty of vaccines." H.R. Rep. No. 908, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6375. As of today, the Vaccine Trust Fund contains approximately $3.1 billion. *See* http://www.treasurydirect.gov/govt/reports/tfmp/vaccomp/vaccomp.htm.

The Vaccine Program is a remedy. To discourage civil litigation, Congress established a ***generous*** alternative. As this Court has noted, "In sum, Congress was concerned with the instability and unpredictability in the childhood vaccine market. . . .To deal with these problems, Congress established a 'no-fault' compensation program under which awards were to be made to vaccine injured persons 'quickly' and with 'generosity'." *Capizzano v. Sec'y of HHS,* 440 F.3d 1317, 1327, n.7 (Fed. Cir. 2006); *see also Knudsen by Knudsen v. Sec'y of HHS,* 35 F.3d 543, 549 (Fed. Cir. 1994) (holding that "the Vaccine Act established a federal compensation program under which awards are to be made to vaccine-injured persons quickly, easily, and with certainty and generosity"). There is nothing generous about strictly enforcing the time limitations of § 16(a)(2). For this reason, this Court must enforce Congress' explicit instructions for the Program to be generous. It must rule that the discovery rule is applicable with respect to § 16(a)(2).

Another super-statute, the FTCA,[17] like the Vaccine Act, was enacted after "years of congressional consideration and was drawn with numerous substantive limitations and administrative safeguards." *Indian Towing Company v. United States*, 350 U.S. 61 (1955). The FTCA was an explicit and direct waiver of sovereign immunity. However, as Justice Frankfurter recognized:

[17] 28 U.S.C. § 1346(b).

> The broad and just purpose which the statute was designed to effect was to compensate the victims of negligence in the conduct of government activities in circumstances like unto those in which a private person would be liable. . . .Of course, when dealing with a statute subjecting the Government to liability for potentially large sums of money, this Court must not promote profligacy by careless construction. **Neither should it as a self-constituted guardian of the Treasury import immunity back into a statute designed to limit it.**

Id. at 68-69 (emphasis added).

Indeed, the Supreme Court recently stated, "The sovereign immunity canon is just that – a canon of construction. It is a tool for interpreting the law, and we have never held that it displaces the other traditional tools of statutory construction." *Richlin Security Service Company v. Michael Chertoff, Sec'y of Homeland Security*, 553 U.S. 571, 589 (2008).

In another case, addressing attempts to narrowly construe provisions of the Federal Employers' Liability Act ("FELA"), the Supreme Court stated, to limit FELA's scope "would be contradictory to the wording, the remedial and humanitarian purpose, and the constant and established course of liberal construction of the Act followed by this Court*." Urie v. Thompson,* 337 U.S. 163, 181, 182 (1949).

The Vaccine Act also has a "remedial and humanitarian purpose." Its provisions must be broadly construed to implement the goals of Congress. Application of the discovery rule to § 16(a)(2) is consistent with these goals.

B. Equitable Tolling Should be Permitted with Respect to § 16(a)(2)

In *Brice*, the majority ruled that equitable tolling of § 16(a)(2) is not available in the Vaccine Program. This decision should be overruled to permit equitable tolling. Once again, an examination of Congressional intent clearly favors such action. In *Brice*, Judge Dyke aptly described the concerns Congress addressed, stating:

> In establishing the Vaccine Program, two concerns motivated Congress. First, it was concerned that tort liability would make production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market . . . .Congress thus included in the Act certain federal modifications of state tort law, including limits on punitive damage awards and a rule that a vaccine manufacturer shall not be held liable in post-Act cases if an injury resulted from unavoidable side effects provided the vaccine was properly prepared and accompanied by proper directions and warnings. *See* 42 U.S.C. §§ 300aa-22(b)(1), 300aa-23(d). Second, Congress was concerned that the traditional tort system was inadequate to compensate many who were injured by vaccines.

240 F.3d at 1368.

It is indisputable, then, that Congress took strong measures to ensure that claims be resolved in the Program, not in civil courts. It took measures to ensure that vaccine-injured persons were generously compensated in the Program. In other words, Congress intended that the Program be *inclusive* — not *exclusive*. Clearly, permitting equitable tolling to be applied to § 16(a)(2) is consistent with Congressional intent.

In *Brice*, this Court examined the Supreme Court's ruling in *United States v. Brockamp*, 519 U.S. 347 (1997). In *Brockamp*, the plaintiff requested equitable tolling for an untimely request for a federal tax refund. The Court found equitable tolling was not available and listed five (5) criteria for courts to use when determining if equitable tolling applies in a given case: 1) The statute's detail; 2) The statute's technical language; 3) The statute's multiple iterations of the limitations period in procedural and substantive form; 4) The statute's explicit inclusion of exceptions; and, 5) The statute's underlying subject matter. *Id*. at 352. The *Brice* Court held that factors 2, 3, and 5 favored equitable tolling but that factors 1 and 4 were "decisive." *Brice*, 240 F.3d at 1373. The Court found the Vaccine Act to be a detailed statutory scheme with "strict deadlines." The Court also found an exception to § 16(a)(2) in § 11(a)(2)(B), which states that a petitioner who inadvertently files a civil action within three years, must dismiss it and then has one year in which to file a claim in the Vaccine Program.

In her dissent, Judge Newman stated that the majority's decision "was neither a necessary interpretation of the Vaccine Act nor a tolerable one." *Brice*, 240 F.3d at 1374. In support of her argument, Judge Newman first noted that *Brockamp* emphasized that the tax refund provision was an exception to the general rule that equitable tolling is applicable to statutes of limitations. In *Brockamp*, the Court noted that 90 million refund applications are filed each year

and also noted the "unusually emphatic form" of the limitations period. *Brockamp*, 519 U.S. at 350. The Court stated, "tax law, after all, is not normally characterized by case-specific exceptions reflecting individualized equities." *Id*. at 352; *see also Irwin v. Dept of Veteran's Affairs,* 498 U.S. 89, 95 (1990) (stating it is a rebuttable presumption that equitable tolling is available in suits against the government as it is between private parties when Congress has not otherwise provided); *Burnett v. New York Central Railroad Co.*, 380 U.S. 424, 427 (1965) (holding that equitable tolling was available because FELA is a "humane and remedial Act").

In her dissent in *Brice,* Judge Newman observed:

> [The petitioner's] vaccine-related injury was not diagnosed or accepted by the physicians who initially treated him. . . .Almost three years elapsed before his injury was diagnosed and its cause established. Although it is conceded that the first seizure occurred a few days after the MMR vaccine, thus starting the running of the period of limitations, late diagnosis of causation is relevant to equitable tolling. The misdiagnoses and absence of critical information that left the Brices uninformed until almost the end of the limitations period are factors to be considered. . . .When viewed objectively and with humanity, and taking note of the generosity of administration required in the Vaccine Act itself, equitable tolling is surely warranted in this case.

240 F.3d at 1378.

Judge Newman also emphasized "the judicial obligation. . .to examine 'whether Congressional purpose is effectuated. . . .'" *Brice*, 240 F.3d at 1375 (citing *Burnett*, 380 U.S. 424). In Judge Newman's view, the majority failed to discharge this obligation. In *Cloer,* this Court has another chance to effectuate

Congressional purpose and determine that equitable tolling should be available in the Vaccine Program.

i. The Circumstances of Dr. Cloer's Case Support Equitable Tolling

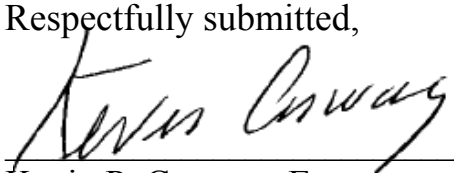
The circumstances of this case support equitable tolling of the statute of limitations. Prior to September of 2004, science had made no causal connection between the hep B vaccine and MS. Once Dr. Cloer was made aware of a potential link, she exercised due diligence in investigating, researching, and filing a claim in the Vaccine Program. In light of the nature of the science, the remedial and generous nature of the Program, equitable tolling is warranted in this case.

VI. CONCLUSION

This Court should implement Congressional intent by ruling, *en banc*, that the "discovery rule" and "equitable tolling" apply in the Vaccine Program. The Court should also rule, as a matter of law, that Dr. Cloer's petition was timely filed and remand the case for an assessment of its merits.

DATED: February 22, 2011

Respectfully submitted,



Kevin P. Conway, Esq.
Counsel of Record for *Amici Curiae*
Conway, Homer & Chin-Caplan, P.C.
16 Shawmut St.
Boston, MA 02116
Phone: (617) 695-1990
Fax: (617) 695-0880

EXHIBIT A

The Vaccine Injured Petitioners' Bar Association

Elizabeth Birth Center for Autism Law and Advocacy (EBCALA) (www.ebcala.org)

Age of Autism (www.ageofautism.com)

AutismOne (www.autismone.org)

Autism File USA (www.autismfile.com)

Autism Trust USA (www.theautismtrust.com)

Center for Personal Rights (www.centerforpersonalrights.org)

The Coalition for Safe Minds (www.safeminds.org)

Generation Rescue (www.generationrescue.org)

International Medical Council on Vaccination (http://www.vaccinationcouncil.org)

Maryland Coalition for Vaccine Choice (http.mdvaccinechoice.wordpress.com)

National Autism Association (www.nationalautismassociation.org)

Schafer Autism Report (www.sarnet.org)

Talk About Curing Autism (www.talkaboutcuringautism.org)

Think Twice Global Vaccine Institute (www.thinktwice.com)

United States Court of Appeals
for the Federal Circuit

No. 2009-5052

----------)

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

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

----------)

DECLARATION OF AUTHORITY PURSUANT TO 28 U.S.C. § 1746 AND FEDERAL CIRCUIT RULE 47.3(d)

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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February 22, 2011

Robyn Cocho

CERTIFICATE OF SERVICE

United States Court of Appeals
for the Federal Circuit
No. 2009-5052

---)

MELISSA CLOER, M.D.,
Petitioner-Appellant,
v.
SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

---)

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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Anisha S. Dasgupta
Tony West
Thomas Bondy
Attorneys, Appellate Staff
Civil Division, Room 7533
Department of Justice
950 Pennsylvania NW
Washington DC 20530-0001
(202) 514-5328

MARI C. BUSH
KAYE AND BUSH, LLC
2300 15th Street
Suite 200
Denver, CO 80202
(303) 477-8787

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Counsel for Record for
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