Special Masters in the National Vaccine Injury Compensation Program: Placing a Heightened Burden on Vaccine Program Petitioners by Straying from Precedent and Congressional Intent

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Vaccinations are an integral aspect of the success of modern public health initiatives and have greatly improved the quality of life and health of American citizens by preventing the spread of disease. Vaccinations are so important that all fifty states and the District of Columbia require mandatory immunizations for school attendance. Despite the obvious benefits of vaccinations, the risk of adverse reactions exists.


1 H. R. REP. NO. 99-908, at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345 (explaining vaccinations are considered “one of the most . . . effective public health initiatives . . . ever undertaken”). Federal and state immunization programs reduced the number of infections and deaths from polio, measles, mumps, rubella, diphtheria and smallpox. See Erica A. Little, The Role of Special Masters in Off-Table Vaccination Compensation Cases: Assuring Flexibility Over Certainty, 16 FED. CIR. B.J. 355, 355 (2007) (stating “[m]any trumpet childhood immunizations as one of the most successful public health efforts in the United States”).


3 H.R. REP. NO. 99-908. Congress recognized that “[w]hile most of the Nation’s children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured.” Id. at 4. In referencing House Reports, Congress is attributed because: 1) the Federal Circuit, the interpreter of the laws of the Vaccine Program, references Congress when citing to the same House Reports, and 2) Congress adopted the House Report as part of its legislative history when the Vaccine Act was passed. Between 2001 and 2005, over 330,000 Vaccine Adverse Event Reporting System ("VAERS") reports were filed. See Illinois Vaccine Awareness
Congress established the Vaccine Injury Compensation Program to compensate individuals injured from the administration of vaccinations "quickly, easily, and with certainty and generosity." To achieve this goal, instead of bringing suit against vaccine manufacturers, a petitioner must move his case through the Vaccine Program, which allows petitioners compensation without comprehensive tort litigation. The federal Coalition, Vaccine Adverse Event Reporting System: Reports from March 6, 2001 to March 5, 2005, http://www.vaccineawareness.org/VAERS/2001-2005. About 85% of vaccine adverse event reports concern relatively minor events, such as ordinary fevers or redness and swelling at the injection site; the remaining 15% describe serious events such as seizures, high fevers, life threatening illnesses or deaths. Id. Between 2001 and 2005, 1,017 cases were adjudicated in the Vaccine Program and 364 petitioners were compensated. National Vaccine Injury Compensation Program Statistics Report (Jan. 20, 2010), http://www.hrsa.gov/Vaccinecompensation/Docs/StatisticsReport.pdf.


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. See H.R. REP. No. 99-908, at 6-7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347-48. 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 1367, 1368 (Fed. Cir. 2001). Since the establishment of the Vaccine Program, 7,387 cases have been adjudicated; of those, 2,404 petitioners have been compensated for their injuries. National Vaccine Injury Compensation Program, Claims Filed and Compensated or Dismissed by Vaccine (Nov. 3, 2009), http://www.hrsa.gov/Vaccinecompensation/Docs/ClaimsFiledCompenDismiss.pdf.

6 Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994); U.S. Court of Federal Claims, Vaccine Program/Office of Special Masters, http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters (last visited Mar. 31, 2010). All vaccine claims are managed and adjudicated by the congressionally created Office of Special Masters, which currently consists of one chief special master and seven associate special masters who are appointed to serve for four-year terms. Id. The Office of Special Masters is established within the U.S. Court of Federal Claims, which appoints special masters and to which the special masters' decisions are appealed. Id. Decisions may subsequently be appealed to the Federal Circuit Court of Appeals and then to the United States Supreme Court. Id.
statute, 42 U.S.C. §§ 300aa-1–300aa-34, the documented congressional intent for the Program, and the Federal Circuit case law provides the means of interpretation that should prevail in a vaccine claim.

Recently, special masters in the U.S. Court of Federal Claims applied standards in conflict with congressional intent and Federal Circuit case law, acting as a barrier for petitioners to receive compensation. Instead of using the standards set forth in the Vaccine Program, special masters are heightening the burden for petitioners by imposing more standards for causation than required by statute and case law and questioning the credibility of petitioners’ expert witnesses against precedent. The heightened standards in these cases may have severe ramifications, such as an increase in costs due to more appeals, as well as more cases potentially moving out of the Vaccine Program, which increase the number of lawsuits against vaccine manufacturers, in direct opposition to the original purpose of the Vaccine Program.

Part I of this note will examine the established precedent of the Vaccine Program through congressional intent, the federal statute, and case law, as well as outline the process by which cases move through the vaccine program. Because the Vaccine Program is relatively new, case law from the Federal Circuit within the past decade will specifically be explored. Part II will observe recent cases in which special masters have failed to apply these established standards and precedent. Part III will explore the effects of the incorrect application of standards and precedent. Part IV will examine Wilkerson v. Sec'y of Health & Human Servs. Finally, Part V will discuss legal, policy, and


8 See H.R. REP. No. 99-908, at 6-7 (noting Vaccine Program was established to compensate individuals who injured from vaccinations, as well as protect vaccine manufacturers from liability). Before a lawsuit may be filed against a vaccine manufacturer, federal law requires the submission of a claim under the National Vaccine Injury Compensation Program. Christopher J. Rogers, A Primer on the National Vaccine Injury Compensation Program, 21 UTAH B.J. 25, 25 (2008); 42 U.S.C. § 300aa-12 (2006) (stating petitioners who are not compensated within the Program may file traditional tort litigation suit against vaccine manufacturers).

9 593 F.3d 1343 (Fed. Cir. 2010).
consumer concerns with recent actions of the special masters. This section will also survey the potential long-term ramifications of the recent actions of the special masters in certain cases and how they may have a detrimental effect on the Vaccine Program as a whole.

I. Purpose, Reasoning, and Precedent of the National Vaccine Injury Compensation Program

A. Congressional Intent

Two concerns motivated Congress in establishing the Vaccine Program. First, Congress was concerned that tort liability would make production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market. Second, Congress was concerned that the traditional tort system was inadequate to compensate many who were injured by vaccines. Congress's principal findings that required the establishment of the Vaccine Program were as follows:

1) The availability and use of vaccine to prevent childhood diseases is among the Nation's top public health priorities;

2) The 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 vaccine have access to sufficient compensation for their injuries; and

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10 Brice v. Sec'y of Health & Human Servs., 240 F.3d 1367, 1368 (Fed. Cir. 2001). Congress 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. Id. Between 1980 and 1986, individuals brought damages claims totaling $3.5 billion; as a result of liability concerns, many pharmaceutical companies stopped producing and distributing vaccines. Katherine E. Strong, Note, Proving Causation Under the Vaccine Injury Act: A New Approach for A New Day, 75 GEO. WASH. L. REV. 426, 434 (2007) (stating by 1985 only four manufacturers were still producing mandated vaccines).

11 Brice, 240 F.3d at 1368. Upon enacting the Vaccine Act, Congress recognized that "[w]hile most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured." H.R. REP. NO. 99-908, at 4.
3) Private or non-governmental activities have proven inadequate in achieving either of these goals.\textsuperscript{12}

Thus, the Vaccine Program was established for two purposes: (1) to protect the Nation's vaccine supply and encourage the developments of new and safer vaccines,\textsuperscript{13} and (2) to compensate persons injured by vaccines.\textsuperscript{14}

Congress stated two overriding concerns that led to the development of this legislation: (1) the inadequacy of the current approach to compensating those injured by vaccines, and (2) the instability and unpredictability of the vaccine market.\textsuperscript{15} Congress hoped the Vaccine Program would reduce the number of lawsuits against vaccine manufacturers, while simultaneously promoting the "development of new and improved vaccines."\textsuperscript{16} Congress stated that awards "can be made to vaccine injured persons quickly, easily, and with certainty and generosity."\textsuperscript{17}

B. The Process

All vaccine claims are managed and adjudicated by the congressionally created Office of Special Masters, which currently consists of one Chief Special Master and seven Associate Special Masters who are appointed by the U.S. Court of Federal Claims to serve for four-year terms.\textsuperscript{18} The U.S. Court of Federal Claims hears appeals from the special masters' decisions.\textsuperscript{19} Special masters make the initial decision for compensation


\textsuperscript{13} Since the Vaccine Program was established in 1988, the following vaccines have been developed and added to the Vaccine Table: hepatitis B vaccine ("hep B"), \textit{haemophilus influenzae} type b vaccine ("Hib"), varicella vaccine, rotavirus vaccine, pneumococcal conjugate vaccines, hepatitis A vaccine, the adult "flu" vaccine, meningococcal vaccine, and the human papillomavirus vaccine. See 42 U.S.C. § 300aa-14 (2006).

\textsuperscript{14} See Brice, 240 F.3d at 1368; H.R. REP. NO. 99-908, at 5 (1986).

\textsuperscript{15} H.R. REP. NO. 99-908, at 7 (1986).

\textsuperscript{16} H.R. REP. NO. 99-908, at 4. Congress also hoped the Vaccine Program would help create "a new system for compensating individuals who have been injured by immunizations routinely administered." \textit{Id.} at 3.


\textsuperscript{19} \textit{Id.} Special masters actively and frequently interact with the parties (generally counsel representing petitioner and a Department of Justice attorney representing Secretary of Health and Human Services). \textit{Id.}
under the Program. After appealing special masters' decisions to the U.S. Court of Federal Claims, decisions may be subsequently appealed to the Federal Circuit Court of Appeals and then to the Supreme Court.

Under the Vaccine Act, when reviewing a decision of a special master on a motion for review, the Court of Federal Claims has jurisdiction to "undertake a review of the record of the proceedings." The court may take any of the following actions: (1) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision, (2) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and issue its own findings of fact and conclusions of law, or (3) remand the petition to the special master for further action in accordance with the court's direction. The Vaccine Act requires the Court of Federal Claims to analyze conclusions of law made by a special master to determine whether they are in accordance with law and may set aside factual findings by a special master if they find them to be arbitrary or capricious or if a special master has abused his or her discretion in making such findings. Prior to 1989, the appellate courts in the Vaccine Program had the option of either "adopt[ing] the findings of the special master as [their] own judgment, or mak[ing] a de novo determination of any matter and issu[ing] judgment accordingly." Congress amended the statute in 1989, eliminating the ability of U.S. Court of Federal Claims to conduct a de novo review of the special master's decision.

20 Conway, Homer and Chin-Caplan, P.C., Vaccine Program: The Process, www.ccandh.com/vl.asp, (last visited on Mar. 31, 2010). Compensation that may be awarded for a vaccine-related injury include: reasonable compensation for past and future medical care, custodial care and rehabilitation costs, a $250,000 cap for actual and projected pain and suffering and emotional distress, lost earnings, and reasonable attorneys' fees and costs. Id.
23 42 U.S.C. § 300aa-12(e)(2).
24 See 42 U.S.C. § 300aa-12(e). The Federal Circuit has commented that "reversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inference and articulated a rational basis for the decision." Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (explaining arbitrary and capricious standard of review is difficult for appellant to satisfy).
25 Keiser, supra note 2, at 23 (italics added).
26 See Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6601(h), 103 Stat. 2106, 2289 (codified at 42 U.S.C. § 300aa-12(e) (2006)). The statutory standard of review applicable to the factual findings of a special master in a Vaccine Act case require the Court of Federal Claims to uphold a special master's findings unless the court concludes that those findings are arbitrary and capricious. See 42 U.S.C. § 300aa-12(e)(2)(B); Saunders v. Sec'y of Health & Human Servs., 25 F.3d 1031, 1033 (Fed. Cir. 1994); Munn v. Sec'y of Health & Human
C. Case and Statutory Law

A petitioner must meet several requirements before bringing a case under the National Childhood Vaccine Injury Act of 1986. The requirements set forth in 42 U.S.C. § 300aa-11, are that a petitioner must: (1) receive the vaccine in the United States,27 (2) be injured from a vaccine listed on the Vaccine Injury Table,28 (3) not previously collected an award or settlement for such vaccine-related injuries,29 and (4) either suffered residual effects of injury for more than six months, died from the administration of the vaccine, or required inpatient hospitalization and surgical intervention.30 If these requirements are met, a successful petition in the Vaccine Program can be brought in two ways.31 First, a petitioner may bring a claim if they sustained an injury set forth in a statutorily set Vaccine Injury Table32 with the initial listed symptom occurring within the time period defined in the table.33 A vaccine is the presumed cause of an injury if the petitioner establishes that his or her table injury occurred within the time period set forth in the table.34 However, because of the narrowly defined injuries set forth on the Vaccine Injury Table, proving a table injury is difficult.35 As a result, most petitioners in the Vaccine Program bring a petition under the second option, commonly called off-table cases, encompassing injuries not listed on

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28 See 42 U.S.C. § 300aa-11(1)(A); see also 42 U.S.C. § 300aa-14 (2006). The Vaccine Injury Table groups the vaccines by antigen and outlines the injuries for each of the groups of vaccines, as well as the time frame in which the symptoms appear. Id.
33 See 42 U.S.C. § 300aa-11(c)(1)(C)(i) (2006). A petitioner may have “sustained, or had significantly aggravated any ... injury ... set forth in the Vaccine Injury table ... and the first symptom ... of the ... injury ... occurred within the time period [defined in the table] after vaccine administration.” Id.
34 See Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (2005) (describing statutory prescription for causation if injury is included as table injury).
35 See U.S. Department of Health and Human Services, Vaccine Table, available at http://www.hrsa.gov/vaccinecompensation/table.htm (last visited Mar. 31, 2010). For example, if a petitioner experienced anaphylactic shock zero to four hours after the administration of a tetanus toxoid-containing vaccine (such as DTaP, Tdap, Td, etc.), causation is presumed. Id. See generally 42 U.S.C. § 300aa-14 (2006). For example, seizures are not sufficient to satisfy the definition of encephalopathy under § 14, a petitioner must also demonstrate several other symptoms. Id.
the Vaccine Injury Table.36

Off-table cases must be proven by a preponderance of the evidence.37 To establish by preponderant evidence that a vaccine caused an off-table injury, the vaccine must be the “but for” cause of the petitioner’s injury and a substantial factor in bringing about that injury.38 In this regard, the Federal Circuit ruled that the vaccine may be only one of several concurrent causes of the injury.39 It need not be the sole cause or even the predominant cause; rather, it need only be a “substantial factor.”40 In order to be eligible for compensation, a petitioner must file his or her petition with the court within three years from the onset of symptoms.41 The Federal Circuit held that the first symptom or manifestation of onset is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.42

Althen v. Sec’y of Health & Human Servs. states that a petitioner will prevail in an off-table case upon establishing that: “(1) a medical theory causally connect[s] the vaccination and the injury; (2) a logical sequence of cause and effect show[s] that the

37 See 42 U.S.C. § 300aa-13(a)(1)(A) (2006); Althen, 418 F.3d at 1274 (“The purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a filed bereft of complete and direct proof [as to] how vaccine affect the human body”); Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991) (“The standard of proof required by the Act is simple preponderance of evidence; not scientific certainty . . . . [I]t is not plaintiff’s burden to disprove every possible ground of causation suggested by defendant nor must the findings of the court meet the standards of the laboratorian”).
38 See Shyface, 165 F.3d at 1352 (discussing necessity of adequate causation).
39 See id. Further, a petitioner may be compensated if the vaccine was shown to have significantly aggravated an underlying condition. See 42 U.S.C. § 300aa-33(4) (2006). The term “significant aggravation” means any change for the worse in a preexisting condition that results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health. Id.
40 Shyface, 165 F.3d at 1352-53. A petitioner need not eliminate all possible alternative causes of injury, however, as a practical matter, proof of a “logical sequence of cause and effect” will eliminate potential likely alternatives. Id. at 1353. See also Walther v. Sec’y of Health & Human Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007).
41 42 U.S.C. § 300aa-16(a)(2) (2006) (stating “if a vaccine injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation . . . for such injury after the expiration of [thirty-six] months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury”). If the petitioner is deceased, the statute of limitations is twenty-four months from the date of the vaccination. Id.
vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between [the] vaccination and the injury." 43 Each element of this three-prong Althen test can be satisfied by circumstantial evidence consisting of medical records or a medical opinion. 44 Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. 45

A petitioner is not required to satisfy any element of the three-prong Althen test with scientific certainty. 46 Rather, a petitioner need only demonstrate with circumstantial evidence the existence of causation between the vaccine and the injury. 47 In this regard, a differential diagnosis of a treating physician sufficiently meets the reliability standard set forth in Daubert v. Merrell Dow Pharm., Inc. 48 and may be used as indirect evidence of causation. 49 In light of the Act's purpose, scientific and objective confirmation of the biologic mechanism by which the vaccine caused the injury with additional medical documentation to establish a theory of causation to fulfill the first Althen prong is unnecessary. 50 Requiring scientific certainty to prove the biologic mechanism would thwart the purpose of the Act by requiring "sequence[s] hitherto

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43 Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005) [hereinafter "Althen test"]). The Althen test was established in response to other tests created and applied by special masters heightening the petitioner's evidentiary burden. See generally id.

44 See id. at 1278 (explaining logical sequence of cause and effect can be supported by "reputable medical or scientific explanation" or "evidence in the form of . . . expert medical testimony").

45 See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (holding "[w]e see no reason why evidence used to satisfy one of the Althen . . . prongs cannot overlap to satisfy another prong").

46 See Althen, 418 F.3d at 1280.

47 See id.


49 See Kelley v. Sec'y of Health & Human Services, 68 Fed. Cl. 84, 90 n.7 (Fed. Cir. 1994). The Federal Circuit also stated:

The assessment of whether a proffered theory of causation is "reputable" can involve assessment of the relevant scientific data. Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard.


50 See Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 87-88 (Fed. Cl. 2005) (quoting Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278-81 (Fed. Cir. 2005)) (emphasizing requiring proof of biological mechanisms of causation would be inconsistent with purpose and nature of Vaccine Program). Further, "determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994).
unproven in medicine” and surpass the preponderance standard demanded by Congress.

When reviewing the record to determine if the Althen test is met, a special master must consider the opinions of treating physicians. In this regard, the treating physician offers a medical opinion that is quite probative in establishing a logical sequence of cause and effect. The Federal Circuit noted that physicians are in the best position to determine causation; their opinions are presumed to meet a sufficient level of reliability and are thus favored in vaccine cases. To remove all doubt, the Federal Circuit reaffirmed the probative value of the opinions of treating physicians in satisfying this prong in Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., stating that “treating physicians are likely in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.” The opinions of treating physicians contained in medical records can be sufficient to demonstrate a logical sequence of cause and effect between the vaccine and the injury. For example, the court noted that a treating physician may rely on the close temporal proximity between a vaccine and an injury in concluding that there is a logical sequence of cause and effect between a vaccine and injury.

Finally, in proving a prima facie case, a petitioner need not eliminate all possible alternate causes of injury. As a practical matter, however, proof of a “logical sequence

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51 Althen v. Sec'y of Health and Human Servs. 418 F.3d 1274, 1280 (Fed. Cir. 2005). “The standard of proof required by the [Vaccine] Act is simple preponderance of evidence; not scientific certainty . . . . [I]t is not plaintiff's burden to disprove every possible ground of causation suggested by defendant nor must the findings of the court meet the standards of the laboratorian.” Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991) (citations and internal quotation marks omitted).
52 See Bunting, 931 F.2d at 873. The Federal Circuit consistently recognized the uncertainty of the science relating to vaccine injuries stating, “to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” Knudsen, 35 F.3d at 549.
54 See id.
55 See id.
56 Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009) (quoting Capizzano, 440 F.3d at 1326). Further, the Federal Circuit held that conclusive proof is unnecessary and not congruent with the law, stating that the special master had “imposed upon [petitioners] an elevated evidentiary burden requiring them to submit conclusive proof in the medical literature” to show a vaccine caused an injury. See id. at 1375.
57 See id. at 1376.
58 See id.
59 See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999). In all
of cause and effect" will eliminate potential alternatives. In any event, once a petitioner has made a prima facie case, the burden of proof shifts, and the government must prove that the "injury... described in the petition is due to factors unrelated to the.. vaccine." In such a case, the government must not merely prove the existence of an alternative cause but that such an alternative actually caused the injury. A special master should weigh the evidence contained in the "record as a whole." The Federal Circuit held where the evidence is found in equipoise, the court should enter judgment in favor of the petitioner.

II. Examples of Special Masters' Incorrect Application of Precedents and Standards

Instead of using the standards set forth in the Vaccine Program, special masters heightened the burden for petitioners by: (1) imposing more standards of causation than required by statute and case law, and (2) questioning the credibility of petitioners' expert witnesses in certain cases in opposition to established precedent.

vaccine injuries, genetic susceptibility plays a role. See id. Frequently, non-vaccine environmental factors also contribute to the injury. See id. When concurrent forces cause a single harm, the Federal Circuit has held the burden is on the government to show that the alternative cause is so predominant that the vaccine is insignificant; it must eliminate the vaccine as a substantial contributing factor. See id. Once a petitioner has made a prima facie case, the burden of proof shifts and the government must prove that an alternative cause exists and that it actually caused the injury. See Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994).

Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007).

See id.


See Knudsen, 35 F.3d at 549. Further, as the Federal Circuit pointed out in Walther, "the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm." 485 F.3d 1146, 1151 (Fed. Cir. 2007).

See Knudsen, 35 F.3d at 550 (suggesting if evidence establishes equally plausible etiologies for injury then petitioner should prevail).

The standards and initiatives as established supra, Congressional intent, 42 U.S.C. §§ 300aa-1–300aa-34, and the decisions from the U.S. Federal Court of Claims and the U.S. Federal Circuit.

This section will explore several recent cases where special masters' decisions have been either appealed by petitioners for incorrectly applying standards or have already been deemed arbitrary and capricious and overturned by the appellate courts.68

A. Imposing More Standards for Causation than Required by Case Law and Statute

The three-prong test from Althen resulted from a special master's decision to impose a five-prong test for petitioners to meet in order to receive compensation in the Program.69 The five-prong test required that petitioner provide proof of: "(1) medical plausibility, (2) confirmation of medical plausibility from the medical community and literature, (3) an injury recognized by the medical plausibility evidence and literature, (4) a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and (5) the elimination of other causes."70 The special master determined that because the petitioner did not provide peer-reviewed literature, she did not qualify for compensation.71 Upon review, the Federal Circuit determined that the application of the five-prong test was contrary to law, stating that both prongs two and three of the test "contravene the plain language of the statute."72 The Federal Circuit held that requiring medical literature "impermissibly"73 raised petitioner's burden and was in direct conflict with the statute's allowance of medical opinion as proof.74 Finally, the Federal Circuit noted that the role of the special master is "not to craft a new legal standard."75

2008).

70 Althen, 418 F.3d at 1279 (outlining five-prong test the special master employed).
72 Id. at 1281. See also 42 U.S.C. § 300aa-12(a)(1) (2006) (stating petitioner must prove causation in fact by "preponderance of the evidence," substantiated by medical records or medical opinion).
73 Althen, 418 F.3d at 1280.
74 See id.; see also 42 U.S.C. § 300aa-13(a)(1).
75 Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005) (explaining role of special master is to "assist the courts by judging the merits of individual claims on a case by case basis"). See also 42 U.S.C. § 300aa-13(a)(1).
Despite the Federal Circuit’s explanation that special masters are not to construct new legal standards, in Capizzano v. Sec’y of Health & Human Servs., the special master created a new “disjunctive” four-prong test for petitioners to meet in order to receive compensation for vaccine-related injuries. This new test required that in order to show the second prong of the Althen test, a logical sequence of cause and effect between the injury and the vaccination, a petitioner must show one of the following: (1) epidemiologic studies, (2) rechallenge, (3) the presence of pathological markers or genetic disposition, or (4) general acceptance in the scientific or medical community. The Federal Circuit determined that the special master’s approach was “inconsistent with allowing ‘the use of circumstantial evidence envisioned by the preponderance standard.’” Because the petitioner’s treating physicians repeatedly associated the petitioner’s injury with the vaccine, the Federal Circuit determined that the petitioner fulfilled the requirement of a logical sequence of cause and effect as outlined by 42 U.S.C. § 300aa-13(a)(1).

In Andreu v. Sec’y of Health & Human Servs., the Federal Circuit again found that a special master imposed higher standards for causation on the petitioner than required by statute and case law, stating:

In Althen . . . we expressly rejected the [five-prong] test, concluding that requiring “objective confirmation” in the medical literature prevents

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77 Id.
78 When two or more administrations of a vaccine to the same person are followed by the same adverse event, positive rechallenge is said to occur. M. Miles Braun, Vaccine Adverse Event Reporting System (VAERS): Usefulness and Limitations, INSTITUTE FOR VACCINE SAFETY, http://www.vaccinesafety.edu/VAERS.htm (last visited Mar. 31, 2010). Positive rechallenge represents stronger evidence than temporal association of a since adverse event. Id.
79 See Capizzano, 440 F.3d at 1325.
80 Id. The Federal Circuit went on to state that the new requirements impermissibly raised the claimant’s burden under the Vaccine Act, and hindered the system created by Congress, “in which close calls regarding causation are resolved in favor of injured claimants.” Id. at 1325-26.
81 See Capizzano, 440 F.3d at 1325-26 (stating “medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury”) (quoting Althen v. Sec’y of Health and Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005))); see also 42 U.S.C. § 300aa-13(a)(1) (“The special master or court may not make . . . a finding [of causation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion”).
"the use of circumstantial evidence . . . and negates the system created by Congress" . . . . Here, however, the special master resurrected the defunct [five-prong] test in an effort to discredit [petitioner's medical expert]'s theory of causation.82

In Andreu, the Federal Circuit held that the special master erred in requiring proof of confirmation of medical plausibility from the medical community and literature in order to establish causation of the vaccine to the petitioner's injury.83

B. Incorrect Credibility Determination Of Petitioners' Expert Witnesses

Special masters also recently questioned the credibility of petitioners' expert witnesses against established precedent discussed hereinafter; as such, their rulings have been deemed arbitrary and capricious and were overturned by the appellate courts.84 In Rotoli, five petitioners alleged that the hepatitis B vaccine caused them to suffer autoimmune hepatitis.85 The special master for these five petitioners determined that the petitioners' expert immunologist, who testified on behalf of all five petitioners, was neither credible nor truthful when he testified that vaccine caused these injuries, and dismissed all five petitions.86 On appeal, the Court of Federal Claims determined that

82 Andreu ex. rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009) (concluding requiring "objective confirmation" in medical literature prevents "the use of circumstantial evidence . . . and negate[s] the system created by Congress through the Vaccine Act" (citing Althen, 418 F.3d at 1280)).
83 See Andreu, 569 F.3d at 1379.
85 Rotoli, 89 Fed. Cl. at 76-77. The petitioners alleged that the hepatitis B vaccine, which they each received in three doses in the 1990s, caused them to suffer autoimmune hepatitis and associated injuries. Id.
In these five cases, the special master’s analysis of the petitioners’ evidence of causation ran afoul of the Federal Circuit’s standards regarding credibility determinations. The Court of Federal Claims found that the special master erroneously founded the rejection of the petitioners’ theory of causation on an assessment of the petitioners’ expert’s “poor” credibility. The special master’s discussion of petitioners’ expert’s credibility “permeated” his analysis of the petitioners’ claims. References to the credibility of petitioners’ expert also pervaded the special master’s analyses of the medical theory proposed by all five petitioners and of the specific evidence of causation in each of the five cases. By couching his rejection of petitioners’ expert’s testimony in terms of credibility, the special master expected his analysis to be “virtually not reviewable on appeal.”

and threatened to deny the fees of the petitioners’ expert and their attorneys. Id. He also advised the petitioners to accept his decisions as final and warned the petitioners and their attorneys that special masters’ decisions with respect to findings of credibility were “virtually unreviewable” by higher courts. Id. 

87 Rotoi, 89 Fed. Cl. at 80, No. 99-644V, 2009 WL 2868840, at *5 (2009). The court issued a single, consolidated Opinion and Order for all five cases because of the substantial overlap of the legal and factual issues in each. Id. at 77, 2009 WL 2868840, at *1.


89 See Rotoi, No. 99-644V, 2008 WL 4483739, at *7 (noting expert’s retreat from proposed theory is “poor mark on his credibility as an expert”). While considerable deference must be accorded to the credibility determinations of special masters this does not mean that a special master can “cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review.” Andru ex rel. Andru v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1992). See also Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1373-74 (Fed. Cir. 2000) (noting when a highly qualified expert presents a biologically plausible theory linking an injury to a vaccine, the issue should not be one of credibility).

90 Id.

91 See id. The special master included a nine-page section (a substantial portion of the total length of his decision) entitled “Additional Comments Regarding [Petitioners’ Expert]” in which he questioned not only “[Petitioners’ expert’s] persuasiveness but also his truthfulness” as a result of various weaknesses in the evidence underlying [petitioner’s expert’s] claims and [petitioner’s expert’s] “demeanor.” See, e.g., Rotoi, No. 99-644V, 2008 WL 4483739 at *22-30. “[T]he evidence from each case solely supports a finding that [petitioner’s expert] lacks credibility.” Id. at *29.

92 See Rotoi v. Sec’y of Health & Human Servs., 89 Fed. Cl. 71, 81 (Fed. Cl. 2009). In reviewing the evidence, including the medical literature, the special master did not follow precedent and establish simply whether petitioner’s expert’s medical theory of causation was supported by the weight of that evidence. Instead, he went so far as to conclude that the “questions about the basis for [petitioner’s expert’s] statements . . . have led to a question about [petitioner’s expert’s] veracity.” See, e.g., Rotoi, No. 99-644V, 2008 WL 4483739, at *30.

93 See, e.g., Rotoi, No. 99-644V, 2008 WL 4483739, at *4 (noting a “decision about the persuasiveness of an expert is virtually not reviewable on appeal” (citing Bradley v. Sec’y of
The U.S. Court of Federal Claims found that the special master violated precedent set forth in *Andreu v. Sec'y of Health & Human Servs.* and erroneously used his assessment of petitioners' expert's credibility as a basis for rejecting the expert's testimony regarding causation. Moreover, the court found that the pervasiveness of the comments regarding to the expert's credibility throughout the special master's decisions made it impossible to review the special master's evaluation of the evidence separately from his erroneous credibility determination. Accordingly, the U.S. Court of Federal Claims found that the special master framed his rejection of the petitioners' theory of causation "under the rubric of a 'credibility' determination," which constituted a legal error, resulting in the court setting aside the special master's findings.

Similarly, in *Campbell v. Sec'y of Health & Human Servs.*, the special master denied relief to the petitioner based on a credibility determination. In *Campbell*, the special master based his decision to deny the petitioner compensation in substantial part on his finding that respondent's expert was more credible than petitioner's expert. Because there was no genuine issue with regard to petitioner's expert's candor or truthfulness, the special master ran afoul of the Federal Circuit's standards regarding the use of credibility determinations.

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95 See *Rotoli*, 89 Fed. Cl. at 81-82.
96 See id. at 82 (noting "the special master's error has tainted his entire causation analysis").
97 See id. (citing *Andreu*, 569 F.3d at 1379).
98 See 42 U.S.C. § 300aa-12(e)(2)(B) (2006). The court discarded the special masters decisions, re-examined the evidence, and issued new findings in each case. See generally *Rotoli*, 89 Fed. Cl. 71. The court found that three petitioners were entitled to compensation and that two petitioners were not. *Id.*
100 The special master denied relief to the petitioner on the grounds that she "has not established that the theories offered by her expert [to explain how the influenza vaccine could cause the onset of rheumatoid arthritis] are reliable," and "even if her expert's theories were reliable, she experienced signs and symptoms of rheumatoid arthritis within the time predicted by her expert." *Campbell v. Sec'y of Health & Human Servs.*, No. 07-465V, 2009 WL 2252550, at *1 (Fed. Cl. Spec. Mstr. July 7, 2009).
101 See *Campbell* 90 Fed. Cl. at 382 (stating "[b]ecause there was no genuine issue with regard to [petitioner's expert's] candor or truthfulness, the special master ran afoul of the Federal Circuit's standards regarding the use of credibility determinations").
102 In *Andreu*, the Federal Circuit held that "[w]hile considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." *Andreu ex. rel. Andreu v. Sec'y of Health & Human*
As in *Andreu* and *Rotoli*, the special master in *Campbell* “cloth[ed] much of his rejection of petitioner’s theory of causation ‘under the rubric of a ‘credibility’ determination’ regarding . . . petitioner’s expert witness.”\(^\text{103}\) Similar to the result in *Rotoli*, petitioner’s expert in this case was a “highly qualified expert witness whose extensive credentials [were] not in dispute.”\(^\text{104}\) At the conclusion of the expert opinion evaluation, the special master cited the petitioner’s expert’s credibility as a primary reason for finding that the petitioner had not established a proximate temporal relationship between her vaccination and her injury under the third prong of *Althen*.\(^\text{105}\) Like in *Rotoli*, the special master expected his analysis of whether petitioner had established causation in fact to be “virtually not reviewable on appeal”\(^\text{106}\) because in this case he couched his rejection of petitioner’s claim in terms of credibility.\(^\text{107}\) Despite the special master’s attempt to insulate his decision from review by the “incantation of magic words,”\(^\text{108}\) the U.S. Court of Federal Claims found that he erroneously relied on an assessment of petitioner’s expert’s credibility as a basis for rejecting petitioner’s expert’s testimony.\(^\text{109}\) Further, the special master’s error tainted his entire analysis of whether petitioner established causation in fact.\(^\text{110}\)

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\(^{103}\) See *Rotoli* v. Sec’y of Health & Human Servs., 89 Fed. Cl. 71, 81 (Fed. Cl. 2009) (citing *Andreu*, 569 F.3d at 1379).

\(^{104}\) See *Rotoli*, 89 Fed. Cl. at 81 (emphasis in original). “[W]here a highly qualified expert . . . presents a biologically plausible theory of causation in a vaccine case, the issue is not one of credibility.” See *id.* (citing *Andreu*, 569 F.3d at 1379).

\(^{105}\) Specifically, the special master stated that “[the factors that contributed] to the finding that [respondent’s expert] was more persuasive than [petitioner’s expert] . . . underlie the analysis of the three factors from *Althen* [that follows].” *Id.* at 83.

\(^{106}\) *Rotoli*, 89 Fed. Cl. at 82.

\(^{107}\) *Id.* at 81. “A decision about the persuasiveness of a witness is virtually not reviewable on appeal.” *Id.* (upholding a special master’s credibility determination regarding a non-expert witness (citing *Bradley* v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993))).

\(^{108}\) See *Campbell* v. Sec’y of Health & Human Servs., 90 Fed. Cl. 369, 384 (Fed. Cl. 2009).

\(^{109}\) See *id.* As stated supra, an evaluation of the credibility of an expert witness should be reserved for “assess[ing] the candor of a fact witness” and petitioner’s expert’s candor is not in dispute. *Andreu ex. rel. Andreu* v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009).

\(^{110}\) See *Campbell*, 90 Fed. Cl. at 384.

Not only did the special master expressly base his finding that [petitioner] did not establish a proximate temporal relationship primarily on his evaluation of [petitioner’s expert’s] credibility, see Entitlement Decision at *11, but, by the special master’s own averment, his evaluation of the experts pervaded his
In accord with Andreu and 42 U.S.C. § 300aa-12(e)(2)(B), the court finds that the special master improperly framed his rejection of [petitioner's] claim 'under the rubric of a ‘credibility’ determination' and thereby sets aside the special master's findings as legal error.”

III. The Effects of the Incorrect Application of Standards and Precedent

Special masters recently drifted from using established precedent and documented congressional intent, heightening the burden on petitioners in the Vaccine Program. If this trend continues, the ramifications will extend beyond simply making compensation in the Vaccine Program more difficult and could jeopardize the very foundation of the Vaccine Program itself. The above-mentioned cases may have deeper ramifications, for example, an increase in costly appeals. This section will discuss concerns regarding the effect on the appellate process, as the appellate courts have overturned several cases decided by special masters. This section will also address a competing policy concern.

A. Effect on the Appellate Process

One of the goals of the Vaccine Program as stated by Congress in its establishment was to compensate petitioners injured by enumerated vaccines. analysis of the remaining factors under Althen.

Id. at 384 (citing Andreu, 569 F.3d at 1379 (citation omitted); Rotoli, 89 Fed.Cl. at 81-82). The special master's ruling was vacated and remanded. Campbell, 90 Fed. Cl. at 388.

See Rotoli v. Sec'y of Health and Human Servs., 89 Fed.Cl. 71, 82 (Fed. Cl. 2009) (noting special master's decisions in these cases were “arbitrary and capricious”).

See Brice v. Sec'y of Health & Human Servs., 240 F.3d 1367, 1367 (Fed. Cir. 2001). If the courts are pushing petitioners out of programs by denying compensation based on a narrow determination of what “manifestation of onset” means, petitioners may then move into tort litigation to be compensated, defeating the purpose of the Vaccine Program. See H.R. REP. NO. 100-391(I) (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1 (noting Congressional intent is to leave state law unaffected); see also 42 U.S.C. § 300aa-22 of the Vaccine Act (explaining state law applies to civil action brought for vaccine-related injury or death).

See Rotoli v. Sec'y of Health & Human Servs., 89 Fed. Cl. 71, 82 (Fed. Cl. 2009) (holding special masters' credibility determination decisions to be arbitrary and capricious); see also Campbell v. Sec'y of Health & Human Servs., 90 Fed. Cl. 369, 383 (Fed. Cl. 2009) (holding special master cloaked applications of an erroneous legal standard by stating it was a credibility determination).

See Brice v. Sec'y of Health & Human Servs., 240 F.3d 1367, 1368 (Fed. Cir. 2001). The Federal Circuit Court observed in establishing the Vaccine program. See id. Two specific concerns motivated Congress, one being that Congress was concerned that the traditional tort
Congress established the Vaccine Injury Compensation Program to compensate individuals "quickly, easily and with . . . generosity." Many petitioners who meet the three-prong test set forth in *Althen v. Sec'y of Health & Human Servs.* and should be compensated are either not getting compensated or their compensation is being postponed. Beyond the negative effect of postponing the compensation of petitioners, failing to compensate petitioners who meet the requirements of *Althen* will have the effect of increasing the length of time for each case through the appeals process. This will lead to an increased cost for the government and the Vaccine Program because attorneys' fees and costs, such as expert witness fees, are awarded by the government as established by the Vaccine Act. This costs the government and the vaccine fund more money. If a petitioner who satisfies the three-prong test from *Althen v. Sec'y of Health & Human Servs.* is awarded compensation at the Special Master level, instead of having to appeal his case to the Court of Federal Claims or the Federal Circuit to be compensated, attorneys' fees would be much less. It is likely an underlying reason that Congress intended for petitioners to be awarded quickly because the Vaccine Program awards attorneys' fees and costs, which, if the process is not expedited, have the possibility to grow exponentially higher than if the petitioner was awarded.

system was inadequate to compensate many who were injured by vaccines. *See id.*


117. *See Althen v. Sec'y of Health and Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (outlining three-prong test). Petitioners must satisfy by a preponderance of evidence the following: "(1) a medical theory causally connect[s] the vaccination and the injury; (2) a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.*

118. *See supra* note 68.

119. *See U.S. Court of Federal Claims, supra* note 6. The Office of Special Masters is established within the U.S. Court of Federal Claims which appoints special masters and to which the special masters' decisions are appealed. *Id.* Decisions may be subsequently appealed to the Federal Circuit Court of Appeals, and then to the Supreme Court. *Id.*

120. *See 42 U.S.C § 300aa-15(e) (2006)* (outlining attorneys' fees and costs). "In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall award as part of such compensation an amount to cover reasonable attorneys' fees, and other costs incurred in any proceeding on such petition." *Id.* Attorneys for petitioners work to establish a case with expert testimony and medical records must wait to be paid; long delays in compensation may cause petitioners to have trouble finding an attorney willing to represent them in a vaccine case. Lisa J. Steel, *National Childhood Vaccine Injury Compensation Program: Is This The Best We Can Do For Our Children?*, 63 GEO. WASH. L. REV. 144, 164-65 (1994).

121. The VICP, funded by a $0.75 tax on each vaccination given, is a no fault system designed to compensate the injured while protecting healthcare providers and vaccine manufacturers from lawsuits. Lawyers.com, *National Injury Compensation Program*, http://personal-injury.lawyers.com/National-Vaccine-Injury-Compensation-Program.html (last visited Mar. 31, 2010).
compensation at the special master level.

B. Competing Policy Concern

Without question, vaccines are an important part of a modern society because they contribute to a healthy and disease free environment. In several congressional hearings since the establishment of the Vaccine Program, Congressman Henry Waxman, a primary architect of the Program, continually articulated the importance of vaccines and stated his concern at the prospect of public outcry regarding the risks of adverse reaction from vaccines. Congressman Waxman stated "today, we are becoming complacent about our success against infectious diseases. Unlike our parents and grandparents, we aren't terrorized every year by paralytic polio and whooping cough epidemics. This makes it easier to forget the value of vaccines and to focus on their potential risks." Congressman Waxman also re-emphasized one of the primary purposes of the Program is to compensate individuals who are entitled to compensation, and if a person is injured after a vaccination and there exists no connection between the


> Vaccines have saved more lives than any other medical intervention in history.
> Thanks to universal immunization, the United States has made tremendous progress against polio, diphtheria, whooping cough, and other diseases.
> Without vaccination, American children would be vulnerable to catastrophic epidemics.


124 Id. Congressman Waxman later emphasized:

> I don't want this country to become lax in the area of vaccinating our kids because I don't want these diseases to come back and I don't want people looking at a hearing like this and thinking "Oh, my gosh. More people are hurt than helped . . . when the child is immunized."

injury and the vaccine, these are not the individuals that should be compensated under the Program.\footnote{Congressman Waxman stated:}

Chief Special Master Gary Golkiewicz commented on Congressman Waxman's policy statements at a meeting of the Advisory Commission on Childhood Vaccines.\footnote{Transcript, Advisory Commission on Childhood Vaccines Meeting, March 6-7, 2008, U.S. Department of Health and Human Services, National Vaccine Injury Compensation Program, available at http://www.hrsa.gov/vaccinecompensation/GolkiewiczTranscript.htm (last visited Mar. 31, 2010).} Chief Special Master Golkiewicz outlined Congressman Waxman's statements as two competing policy objectives: (1) a stated purpose of the Program—promoting receipt and production of vaccines by protecting manufacturers from liability and compensating individuals who have sustained a vaccine-related injury, and (2) "protecting the integrity of vaccines . . . that vaccine does not cause every injury that follows immunization."\footnote{See id.} Chief Special Master Golkiewicz stated that there is a tension between these two policy objectives, which significantly affects the outcomes of cases in the vaccine program.\footnote{See id.}

As demonstrated previously, several Federal Circuit opinions overturned some decisions of special masters and compensated individuals who were not compensated at the special master level.\footnote{See id.} Chief Special Master Golkiewicz explained that recent Federal Circuit decisions set a standard that leans more toward providing for compensation, which reduces the pool of potential cases against vaccine manufacturers.

\footnote{See e.g., Rotoli, 89 Fed. Cl. 71; Andreu, 569 F.3d 1367; Capizzano, 440 F.3d 1317; Althen, 418 F.3d 1274.}
in congruence with the policy objective demonstrated by the purpose of the Vaccine Program. Chief Special Master Golkiewicz then explained that proponents of the competing policy concern of protecting the integrity of vaccines would likely believe that recent Federal Circuit opinions compensating individuals were incorrectly decided.

IV. Wilkerson v. Sec'y of Health & Human Servs.: First Symptom or Manifestation of Onset

A case must be filed within thirty-six months from the first symptom or manifestation of onset to be timely filed in the Vaccine Program. Wilkerson v. Sec'y of Health & Human Servs., a case regarding the issue of what constitutes the first symptom or manifestation of onset, was appealed to the Federal Circuit after the special master dismissed the case as untimely, and the Court of Federal Claims denied the petitioner's motion for review. The Federal Circuit upheld the special master's decision to deny the petition based on timeliness. In this case, the petitioner alleged that several


132 Wilkerson, 593 F.3d 1343 (Fed. Cir. 2010).


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.

Id.


135 See Wilkerson v. Sec'y of Health & Human Servs., 593 F.3d 1343 (Fed. Cir. 2010).
mercury-containing vaccines caused him to suffer mercury toxicity and attention deficit hyperactive disorder ("ADHD"). Both parties submitted a physician's expert report addressing the date of onset of petitioner's ADHD symptoms; both medical experts agreed that, more probably than not, petitioner's symptoms first appeared on or before November 3, 2001.137

The court denied the petitioner compensation because the petitioner filed on February 17, 2005, more than thirty-six months from the first symptom of petitioner's injury on November 3, 2001.138 Petitioner argued that petitioner's injury, ADHD, is a condition that requires a manifestation of onset event to trigger the statute of limitations and that its first symptom is not sufficient.139 The Federal Circuit, following Markovich v. Sec'y of Health & Human Servs.,140 held that first symptom or manifestation of onset of injury means that either a symptom or a manifestation of onset can trigger the running of the statute, whichever is first.141 Markovich stated that the manifestation of onset is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.

136 See id. Petitioner received his first vaccination on his day of birth (May 30, 1997) and, by September 1998, received multiple vaccinations. Id. By the end of 1999, petitioner began misbehaving. Id. At preschool, in 2001, petitioner had difficulty playing well with other children, disturbed class, and hurt classmates. By 2003, a physician treating [petitioner] suspected that he may have ADHD and referred him to a clinic for testing. Wilkerson, 593 F.3d at 1343-44. A licensed clinical social worker concluded that he "clearly" met the diagnostic criteria for the disorder. Id. at 1343. A pediatrician corroborated this diagnosis in January 2004. Id.

137 See Wilkerson, 593 F.3d at 1344.

138 See id. The special master, Court of Federal Claims, and the Federal Circuit determined that the phrase "manifestation of onset" refers to when the onset manifested itself retrospectively to the current medical community. Id.

139 See id. at 1345 (noting petitioner argued, while symptoms began by 2001, injury was not recognizable to contemporaneous medical community until later). See generally Setnes ex rel. Setnes v. U.S., 57 Fed. Cl. 175 (Fed. Cl. 2003). Addressing 42 U.S.C. § 300aa-16(a)(2) (2006), the Court of Federal Claims has held:

A statute is to be construed in a manner that gives meaning and effect to all its terms . . . . Under respondents interpretation, there would be no discernable difference between "first symptom" and "manifestation of onset." The statute, as respondent asks the court to read it, would require that the petition be filed within 36 months of the "occurrence of the first symptom or manifestation of [the first symptom]." Such a construction renders "manifestation of onset" meaningless and leads to a nonsensical result.

Id. at 180 (citations omitted).

140 Markovich, 477 F.3d at 1360 (Fed. Cir. 2007) (holding "first symptom or 'manifestation of onset,' for the purposes of § 300aa-16(a)(2) is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large").

141 See Wilkerson v. Sec'y of Health & Human Servs., 593 F.3d 1343, 1345 (Fed. Cir. 2010) (quoting Markovich, 477 F.3d at 1360).
profession at large.\textsuperscript{142}

The Department of Justice (representing the Secretary of Health and Human Services), began to review the medical records of 5,000 autistic petitioners presently participating in the Vaccine Program’s OMNIBUS Autism Proceeding based on the narrow construct\textsuperscript{143} of the first symptom or manifestation of onset from Wilkerson and Markovich.\textsuperscript{144} This review resulted in motions to dismiss the claims of autism petitioners.\textsuperscript{145}

V. Conclusion

A. Effect on Vaccine Program

Decisions of special masters that are incongruent with congressional intent or Federal Circuit precedent may also have a detrimental effect on the Vaccine Program as a whole. By working against the Program’s established legislative purpose of compensating individuals “quickly, easily, and with certainty and generosity,”\textsuperscript{146} special

\textsuperscript{142} See Markovich, 477 F.3d at 1460 (explaining use of the words “first” and “or” require statute of limitations commence with whichever event occurs first).

\textsuperscript{143} See Markovich, 477 F.3d at 1360.

The Vaccine Act’s statute of limitations must be strictly and narrowly construed because it is “a condition on the waiver of sovereign immunity by the United States, and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.”

\textit{Id.}

\textsuperscript{144} See Wilkerson v. Sec’y of Health & Human Servs., 593 F.3d 1343 (Fed. Cir. 2010); Markovich v. Sec’y of Health & Human Servs., 477 F.3d 1353 (Fed. Cir. 2007).

\textsuperscript{145} These cases will have “timeliness” hearings to elicit fact witness testimony, expert testimony, or both. See Brief of Petitioner-Appellant at n.14, Wilkerson v. Sec’y of Health & Human Servs., No. 2009-5090, 2009 WL 2610095 (Fed. Cir. Aug. 3, 2009) (listing following cases: Small v. Sec’y of Health & Human Servs., No. 02-1616V; Killiam v. Sec’y of Health & Human Servs., No. 02-1735V; Manco v. Sec’y of Health & Human Servs., No. 02-1961V; Chistoffer v. Sec’y of Health & Human Servs., 03-398V; Hunter v. Sec’y of Health & Human Servs., No. 07-717V; Wagner v. Sec’y of Health & Human Servs., No. 03-378V; Sherman v. Sec’y of Health & Human Servs., No. 07-289V; Hokkanen v. Sec’y of Health & Human Servs., No. 03-1753; Nuttal v. Sec’y of Health & Human Servs., No. 07-810V). Prior to Markovich, the U.S. Court of Federal Claims issued a decision in \textit{Setnes}, 57 Fed. Cl. 175. In \textit{Setnes}, the court ruled that the words “manifestation of onset” have distinct meaning. \textit{Id.} In that case, the court recognized that some illnesses, like autism, have an insidious onset, and for the purposes of the statute of limitations, the manifestation of onset is when the illness becomes “evident.” \textit{Id.} at 180.

masters rendered decisions in certain cases that are inconsistent with the stated congressional intent. By dismissing Federal Circuit precedent, establishing higher burdens for petitioners, and narrowly interpreting the Act, special masters are making decisions in certain cases that conflict with the purpose of the Vaccine Program.

There are also potential economic concerns for the Program when special masters deny deserving petitioners compensation in certain cases. By denying requisite compensation at the special master level, the special masters are effectively costing the Vaccine Program more money in attorneys' fees and costs, as well as the cost of the appellate process.

B. Effect on Petitioners

Consumers injured from vaccines have a statutory right to be compensated for their losses. By denying compensation for claims that satisfy the three-prong Althen test, petitioners continue to wait for compensation to take care of medical bills, lifestyle changes (such as necessary physical, occupational, and speech therapy), or expenses related to death injuries. Petitioners are waiting longer to be compensated, if at all, and experience a longer, more stressful, and litigious process than the legislatively directed "quick" and "generous" process.

147 The Vaccine Injury Compensation Program benefits consumers, parties injured from vaccines, as well as the vaccine companies, as it was established in an effort to stabilize U.S. vaccine supplies while also preserving vaccine companies' assets for research into safer vaccines. Lawyers.com, supra note 121. See also Brice, 240 F.3d at 1368.

148 See Shyface, 165 F.3d at 1351 (quoting H.R. REP. NO. 99-908 (1986)). The Federal Circuit Court observed that Congress established the vaccine program to encourage vaccine companies to remain in the market and to adequately compensate many who were injured from vaccines. Brice, 240 F.3d at 1368.


150 See, e.g., Rotoli v. Sec'y of Health & Human Servs., 89 Fed. Cl. 71, 82 (Fed. Cl. 2009) (holding special master's decisions to be "arbitrary and capricious"); Campbell v. Sec'y of Health & Human Servs., 90 Fed. Cl. 369, 384 (Fed. Cl. 2009) (holding special master cloaked applications of erroneous legal standard by stating it was a credibility determination). Petitioners in these cases were forced to wait for the Federal Circuit decision's appeal process to obtain compensation for their injuries, despite Congressional intent that compensation be quick. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999) (quoting H.R. REP. NO. 99-908, at 3).
Further, many of the petitioners were mandated to receive these vaccines, such as childhood vaccines before entering school or vaccines before employment at certain facilities, or have voluntarily received vaccines in an attempt to protect themselves and others from the spread of disease, an action that Congressman Waxman iterates as paramount to public health. When individuals are injured from a vaccine, the federal statute outlines that they should be promptly and adequately compensated for their injuries.\textsuperscript{151} Also, many of these petitioners are parents of children who either continue to experience severe problems or who have died from vaccine complications.\textsuperscript{152} Denying compensation and forcing petitioners to continue in the appeals process for compensation subjects these individuals and their families to more adversity and litigation than necessary, certainly more than the Vaccine Program intended.\textsuperscript{153}

Finally, because petitioners' attorneys' fees and costs are awarded through the Vaccine Program, postponing compensation could also lead to an inability for firms representing these petitioners to stay in business.\textsuperscript{154} Unlike many other law firms, those that handle cases in the Vaccine Program do not secure a retainer prior to working on the case and must themselves pay the necessary expenses for the collection of medical records or filing fees because fees are generally awarded post-litigation, with the exception of interim fees.\textsuperscript{155}

\textsuperscript{151}See 42 U.S.C. §§ 300aa-1–300aa-34 (2006) (establishing National Injury Compensation Program, where petitioners are granted compensation for injury resulting from administration of vaccines covered under the Act). The Federal Circuit Court observed that "Congress established the [vaccine program] . . . to provide compensation for vaccine-related injuries and death." \textit{Brice}, 240 F.3d at 1368.


\textsuperscript{153}See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999) (confirming Congress established Vaccine Injury Compensation Program to compensate individuals "quickly, easily, and with certainty and generosity").

\textsuperscript{154}See 42 U.S.C § 300aa-15(e) (2006) (outlining attorneys' fees and costs). "In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall award as part of such compensation an amount to cover reasonable attorneys' fees, and other costs incurred in any proceeding on such petition." \textit{Id}.

\textsuperscript{155}See 42 U.S.C § 300aa-15(e) (stating "[i]n awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall award as part of such compensation an amount to cover reasonable attorneys' fees . . . "); Christopher J. Rodgers, \textit{A Primer on the National Vaccine Injury Compensation Program}, 21 UTAH B. J. 25, 27 (2008) (noting discovery is completed before petition is filed with court requiring petitioner's attorneys to obtain and submit complete medical records of injured party by time petition is filed).
C. Public Health Concern

If petitioners cannot seek legal remedy in the Program, they may be able to bring a tort claim against vaccine manufacturers because statutes of limitation are tolled for minors at the state level. Congress established the Vaccine Program to make awards to "vaccine-injured persons quickly, easily and with certainty and generosity." The primary goal of the Act was to limit lawsuits against vaccine manufacturers and Congress believed this would best be accomplished by directing potential lawsuits into a generous forum: the Vaccine Program.

If courts continue to narrowly interpret first symptom or manifestation of onset, it may have the effect of pushing petitioners out of the Vaccine Program, giving petitioners the opportunity to sue vaccine companies. This could pose a risk to consumers, as it did prior to the establishment of the Vaccine Program.

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156 See Brice v. Sec'y of Health & Human Servs., 240 F.3d 1367, 1372-74 (Fed. Cir. 2001) (discussing limitation period). The Federal Circuit observed, "[w]e 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." Id. at 1368. However, this determination is both relevant and important; all fifty states toll statutes of limitations for minors and for brain-damaged individuals. See John H. Derrick, Tolling of Statute of Limitations, on Account of Minority of Injured Child, as Applicable to Parent's or Guardian's Right of Action Arising Out of Same Injury, 49 A.L.R.4th 216, § 2 (1986). Congress noted "[i]t is not the Committee's intention to preclude court actions under applicable law. The Committee's intent . . . is to leave otherwise applicable law unaffected, except as expressly altered by the Act." H.R. REP. No. 100-391(I) (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1. Further, the Vaccine Act does not provide that untimely petitioners in the Program forfeit all rights to civil litigation, as it expressly states that unless otherwise provided, "[s]tate law shall apply to a civil action brought for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a).


The Vaccine Injury Compensation Program was designed to replace the state law civil tort system with a simple, fair and expeditious means for compensating vaccine injured persons. The Program was established to make awards to "vaccine-injured persons quickly, easily and with certainty and generosity." H.R. REP. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6344. The intent to be generous is demonstrated in Congress' recognition and acceptance of the fact that persons might be compensated under the act for illnesses that are not vaccine related. H.R. REP. No. 908 at 18, reprinted in 1986 U.S.C.C.A.N. at 6359.

Id. at 770-71.


159 See 42 U.S.C. § 300aa-22(a) (asserting state law shall apply to civil action brought for vaccine-related injury or death); see also Derrick, supra note 156 (explaining statutes of limitations are tolled for minors at state level).
manufacturers were faced with tort litigation from persons injured by vaccines. If vaccine manufacturers again have suits brought against them, their incentives to make vaccines and to create new vaccines would be hindered, which could lead to a vaccine shortage. The Vaccine Program was established in an effort to protect vaccine manufacturers, in turn, protecting the nation's vaccine supply and the health of the American public from infectious disease. If petitioners are pushed out of the Program and bring suit against vaccine manufacturers, vaccine supplies and public health may once again be jeopardized.

Undoubtedly, vaccines play an important role in modern society; their benefits are ample, and their positive effects are widespread. The introduction and extensive use of vaccines has resulted in a dramatic decline in the United States in the morbidity, disability, and mortality rates caused by a variety of infectious diseases, including diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B virus, small pox and varicella. Prevalent use of vaccines in the United States eliminated or nearly eliminated infectious diseases that were once terrifying household names. However, vaccines can have detrimental effects, as "a small but significant number [of vaccinated persons] have been gravely injured." The federal government has addressed this with the establishment of the no-fault program to compensate petitioners who have been injured from vaccinations: The National Vaccine Injury Compensation Program.

In establishing the Vaccine Program, Congress outlined the purpose and reasoning, and early cases paved the way for precedent that compensated those who had been injured from vaccinations. Special masters recently strayed from established

160 See National Injury Compensation Program, supra note 121 (noting prior to the Vaccine Program the rising number of lawsuits filed against healthcare providers and vaccine manufacturers based on injuries and deaths attributed to vaccines caused a number of vaccine manufacturers to discontinue manufacturing vaccines).

161 See National Injury Compensation Program, supra note 121. Congress responded by passing the National Childhood Vaccine Injury Act of 1986, aimed at stabilizing U.S. vaccine supplies while also preserving vaccine companies' assets for research into safer vaccines. Id.


164 H.R. REP. No. 99-908, at 4 (1986). Between 2001 and 2005, over 330,000 VAERS reports were filed. See Vaccine Adverse Event Reporting System: Reports from March 6, 2001 to March 5, 2005, http://www.vaccineawareness.org/VAERS/2001-2005 (last visited Mar. 31, 2010). About 85% of vaccine adverse event reports concern relatively minor events, such as ordinary fevers or redness and swelling at the injection site; the remaining 15% describe serious events such as seizures, high fevers, life threatening illnesses or deaths. Id.
purpose and precedent and heightened the burden on petitioners, making it more difficult to be compensated for an injury caused from a vaccine. These effects have the propensity not only to further injure legitimate petitioners but also to undermine the Vaccine Program itself.