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Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know before Rushing out of Vaccine Court

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Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know before Rushing out of Vaccine Court

Abstract

This Comment sheds light on the “opt-out” provision of the Vaccine Act. It namely discusses the effect of short-form petitions and their impact on subsequent civil action, by examining consequences flowing from the Omnibus Autism Proceeding. In short, it argues that the Vaccine Court erred with its decision to permit short-form petitions by overlooking that procedure’s long-term implications on vaccine plaintiffs. In addition, this Comment lays out a scenario to illustrate the potential pitfalls of a hasty exit from the OAP and offers some guidance to plaintiffs to avoid this outcome. The final part of this Comment offers some ideas for improving the Vaccine Act to ensure that such an anomaly does not occur in the future.

Keywords

Autism, Vaccine court, Omnibus Autism Proceeding, Vaccine plaintiffs

**MERCURY RISING:
THE OMNIBUS AUTISM PROCEEDING AND
WHAT FAMILIES SHOULD KNOW BEFORE
RUSHING OUT OF VACCINE COURT**

GORDON SHEMIN*

TABLE OF CONTENTS

| | |
|---|-----|
| Introduction..... | 460 |
| I. Background | 467 |
| A. A Short History of Vaccines: Past, Present, and Future ... | 467 |
| B. Sore Spots: Side Effects, Lawsuits, and Falling National Stockpiles | 468 |
| C. The National Childhood Vaccine Injury Compensation Act | 470 |
| 1. Jurisdiction and preemption of state law..... | 471 |
| 2. Filing a claim | 472 |
| 3. The required “supporting documentation” | 473 |
| 4. The time-frame for adjudicating Vaccine Act claims .. | 474 |
| 5. Proving causation: Table vs. off-table claims | 474 |
| 6. Compensation and Vaccine Act funding | 476 |
| 7. Judgments and appeals..... | 477 |
| D. The Vaccine-Autism Controversy..... | 478 |
| E. The Vaccine-Autism Controversy and the Vaccine Court | 482 |
| II. The Early Stages of the Omnibus Autism Proceeding | 484 |
| A. The Vaccine Court Concludes it has Jurisdiction over Thimerosal..... | 484 |
| B. The Decision to Utilize Short-Form Petitions | 486 |

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| | |
|---|-----|
| C. The Decision Not to Issue “Decisions” | 489 |
| III. Potential Problems in the Aftermath of the Omnibus Autism Proceeding | 491 |
| A. The Plaintiffs Never Filed a “Petition” Under Section 11 of the Vaccine Act | 494 |
| B. The Plaintiffs Have Not Filed a Petition “in Accordance with” Section 16 of the Vaccine Act | 497 |
| C. A Constitutional Challenge to the Omnibus Autism Proceeding is Unlikely to Succeed | 499 |
| D. Plaintiffs May Be Prevented from Re-entering Vaccine Court | 502 |
| IV. Some Recommendations | 508 |
| A. Attach a “No Omnibus” Provision to Section 12 of the Vaccine Act | 509 |
| B. Amend Section 11 of the Act to Prohibit the Use of Short-Form Petitions | 511 |
| C. Increase the Number of Special Masters..... | 512 |
| Conclusion | 513 |

INTRODUCTION

On the morning of June 11, 2007, the wheelchair carrying twelve-year-old Michelle Cedillo was pushed into the front of a courtroom of the U.S. Court of Federal Claims in Washington, D.C.¹ Michelle, whose health began deteriorating seven days after receiving a measles-mumps-rubella (MMR) vaccination and who currently suffers from autism,² wore hearing protection and hit herself repeatedly before being wheeled out of the courtroom.³ A short time later, opening statements began in the long-awaited case of *Cedillo v. Secretary of Health & Human Services*.⁴

The *Cedillo* case is the first autism test case⁵ to go to an evidentiary hearing in the “Vaccine Court,” a tribunal of special masters situated within the Court of Federal Claims.⁶ In brief, the test cases are the

1. Gardiner Harris, *Opening Statements in Case on Autism and Vaccinations*, N.Y. TIMES, June 12, 2007, at A21.

2. Shankar Vedantam, *Fight Over Vaccine-Autism Link Hits Court*, WASH. POST, June 10, 2007, at A6. In addition to autism, Michelle Cedillo suffers from seizures, arthritis, gastro-intestinal issues, and is nearly blind. *Id.* Michelle’s mother recalled that the “profound downward change in Michelle’s health began seven days following the MMR [measles, mumps, and rubella vaccine].” Tony Mauro, *Vaccine Test Case Reaches Federal Court*, LEGAL TIMES, June 4, 2007, at 10.

3. Harris, *supra* note 1.

4. No. 98-916V, 2007 WL 1577972 (Fed. Cl. May 10, 2007).

5. For a description of the Omnibus Autism Proceeding and the test case framework, see *infra* Part I.E.

6. *Cedillo* is taking place under the auspices of the National Childhood Vaccine Injury Compensation Act. 42 U.S.C. §§ 300aa-10 to -34 (2006). Section 12 of the Act established the Office of Special Masters within the Court of Federal Claims. *Id.*

first part of a larger Omnibus Autism Proceeding (OAP)⁷ created by the Vaccine Court in July, 2002, to determine whether the administration of certain vaccines, and in particular vaccines containing the mercury-based preservative thimerosal,⁸ cause or contribute to autism.⁹ After almost five years of arguments pertaining to jurisdiction, discovery, procedure, and expert testimony,¹⁰ the panel of three special masters was finally ready to listen to the evidence and decide whether the vaccinations in question caused or significantly aggravated Michelle's condition.¹¹

§ 300aa-12(c). Media accounts often refer to the Office of Special Masters as the "Vaccine Court." *E.g.*, Mauro, *supra* note 2. This Comment uses the term "Vaccine Court" to refer to the Office of Special Masters and the phrase "Vaccine Act" or "Act" to refer to the National Childhood Vaccine Injury Compensation Act. For a fuller description on the statutory structure of the Vaccine Act, see *infra* Part I.C.

7. See Autism General Order #1, *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder v. Sec'y of Health & Human Servs., Autism Master File (Fed. Cl. July 3, 2002), 2002 WL 31696785, available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf> (setting out the reasoning for conducting the OAP). As part of the OAP framework, the Vaccine Court created an Autism Docket, which contains a complete list of the various legal filings, updates, court orders, and rulings. United States Court of Federal Claims, Docket of Omnibus Autism Proceeding, <http://www.uscfc.uscourts.gov/node/2718> (last visited Oct. 1, 2008). All the filings on the Autism Docket have the same case caption, "*In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder" [hereinafter *Omnibus Autism Proceeding*]. For a fuller discussion on the background of the vaccine-autism controversy and creation of the OAP, see *infra* Part I.D–E.

8. Thimerosal is an organic compound that is approximately fifty percent mercury by weight and has been used since the 1930s as a preservative in some vaccines. U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, <http://www.fda.gov/CBER/vaccine/thimerosal.htm> (last visited Sept. 27, 2008). Food and Drug Administration ("FDA") regulations require that preservatives be used in multidose vials of vaccines, except live viral vaccines, to prevent bacterial and fungal contamination which can lead to serious illness and death in recipients. See *Leroy v. Sec'y of Health & Human Servs.*, No. 02-392V, 2002 WL 31730680, at *8 (Fed. Cl. Oct. 11, 2002) (summarizing the history and uses of thimerosal); see also *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 293 (E.D. Pa. 2007) ("In childhood vaccines, thimerosal has been used to 'deter microbial and fungal growth, thereby maintaining safety, purity and potency of vaccines' both during and after the manufacturing process."). Thimerosal has been largely removed from vaccines. *Infra* note 105.

9. For a brief discussion on the scientific and medical literature surrounding the vaccine-autism controversy, see *infra* Part I.D. Although it highlights some scientific and medical articles, this Comment does not attempt to analyze the relevant literature or reach a conclusion regarding the studies concerning the safety of vaccines. Instead, this Comment is focused on exploring some of the legal decisions made early in the course of the OAP and examining how those decisions could become problematic for certain plaintiffs in the aftermath of decisions in *Cedillo* and the rest of the test cases.

10. For a discussion and analysis of some of the legal challenges encountered during the OAP, see *infra* Part II.

11. The Vaccine Act utilizes different standards of proof than traditional tort litigation. *Infra* Part I.C.5

The potential implications of the OAP are vast.¹² At stake in the outcome of the litigation is not only whether Cedillo's claim and approximately 4900 other pending autism claimants will receive compensation and medical care, but also the future of the National Childhood Vaccine Injury Compensation Program and perhaps public confidence in the safety and effectiveness of vaccines.¹³

Whatever the outcome in the test cases, some things are already clear. For instance, while *Cedillo* and the autism litigation have received a considerable share of attention,¹⁴ the test cases are unlikely to be the end of the legal fight over vaccines and autism.¹⁵ In fact, even after the completion of the *Cedillo* hearing, the OAP framework still calls for additional hearings exploring the possible vaccine-autism link.¹⁶ Moreover, because the test case hearings did not conclude until July 2008, a decision from the Vaccine Court

12. See Mauro, *supra* note 2 (highlighting some potential implications of the test cases); see also Roy Richard Grinker, Op-Ed., *Science on Trial*, WALL ST. J., June 30, 2007, at A6 ("The anti-vaccine movement may be evidence that public confidence in science is eroding, which means that public health is at risk too.")

13. See Mauro, *supra* note 2 (noting the "dramatic public health consequences" of the litigation); see also Gardiner Harris, *Measles Cases Grow in Number, and Officials Blame Parents' Fears of Autism*, N.Y. TIMES, Aug. 22, 2008, at A16 (reporting on the rising number of parents who refuse to vaccinate their children over fears that vaccines cause autism).

14. There have been a lot of stories concerning the *Cedillo* case and autism in the mainstream media. For instance, both Oprah Winfrey and Larry King devoted entire episodes of their television programs to discussing autism. *Larry King Live* (CNN television broadcast Feb. 28, 2008); *Oprah Winfrey Show* (ABC television broadcast Sept. 17, 2007). Also, the legal drama *Eli Stone* premiered with an episode depicting a trial where a jury awards a mother \$5.2 million in damages after it is revealed the CEO of a healthcare company kept his daughter from receiving a vaccine containing mercury. *Eli Stone: Pilot Episode* (ABC television broadcast Jan. 31, 2008). On April 2, 2008, the United Nations marked the first World Autism Awareness Day. Press Release, United Nations General Assembly, Secretary-General Hails Courage of Children, Families Confronting Autism (Apr. 2, 2008), available at <http://www.un.org/apps/news/story.asp?NewsID=26177&Cr=child&Cr1=health>.

15. See Autism Update-January 19, 2007 at 5-8, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Jan. 19, 2007), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism%20Update%201%2019%2007.pdf> (discussing the plans for two additional test cases). Moreover, a decision in *Cedillo* is not expected until sometime in the fall of 2008, and a decision on the merits in the thimerosal only test case is not likely until 2009. See *infra* note 17 (noting that the hearings are not supposed to conclude until September 2008 and that post-hearing motions will likely delay a final decision until 2009); see also Grinker, *supra* note 12 ("We should not expect too much out of this trial, or the next eight.")

16. See Autism Update-March 14, 2007 at 4-6, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Mar. 14, 2007) available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism%20Update%203%2014%2007.pdf> (explaining that the additional theories to be heard by the court are (1) whether thimerosal alone causes autism and (2) whether the Measles-Mumps-Rubella vaccine alone causes autism).

regarding causation in the final test case is unlikely to be issued until well into 2009.¹⁷

In addition, the legal fight over vaccines and autism will go on long after the OAP because the decisions reached by the special masters are likely to be appealed.¹⁸ Indeed, the test case proceedings call upon the special masters to consider thousands of pages of medical documents, epidemiological studies, and expert scientific and medical testimony.¹⁹ Thus, there will surely be several legal avenues to challenge the special masters' factual findings on matters such as witness and expert credibility and legal conclusions with respect to causation.²⁰ Under the terms of the Vaccine Act,²¹ the Court of

17. The hearings on the remaining general causation theories were originally scheduled to conclude by September 30, 2008. Autism Update-January 17, 2008 at 2, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Jan. 17, 2008), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/update%201%2017%2008.pdf>. However, in September 2008, the Vaccine Court, acting on requests from the government and petitioners, announced it was no longer necessary to hold hearings in the third test case theory because that theory was not distinct at all from theories one and two. Autism Update-September 29, 2008 at 3, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Sept. 29, 2008), available at http://www.uscfc.uscourts.gov/sites/default/files/autism/autism_update_9_29_08.pdf; see also *infra* note 127 (describing the three original test case theories). Taking into account the time to submit post-hearing briefs and further time for the special masters to evaluate the relevant evidence, it seems a decision regarding the second theory would not be issued until 2009.

18. Indeed, the decision of one special master is not binding on any other special master. See, e.g., *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998) ("Special Masters are neither bound by their own decisions nor by cases from the Court of Federal Claims"); see also Notice Regarding Reassignment at 1, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Jan. 11, 2007) available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/1%2011%2007.pdf> ("For the [Office of Special Masters] to finally resolve not only petitioners' proposed test cases, but also the remaining over 4700 cases, will require rulings from the Court of Appeals for the Federal Circuit.") (emphasis added).

19. See Autism Update-May 25, 2007 at 2, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. May 25, 2007), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism%20Update%20Untitled.pdf> (noting that the government provided petitioners approximately 218,000 pages of material during discovery). In addition, the government made several federal agency officials available for depositions. Ruling Concerning Petitioners' "Second Motion to Compel" at 4, *Omnibus Autism Proceeding*, Autism Master File, (Fed. Cl. May 25, 2007), 2007 WL 1983780, at *3, available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Ruling%20Untitled.pdf>. Furthermore, at the *Cedillo* hearing, the Vaccine Court heard testimony from eighteen different expert witnesses. List of Expert Witnesses at 1-2, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. June 12, 2007) available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/List%20of%20Expert%20Witnesses.pdf>.

20. To make matters slightly more complicated, the Federal Rules of Evidence do not apply in Vaccine Act cases. See *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 21 Cl. Ct. 634, 647 (1990) ("There is nothing in the Vaccine Rules or the Vaccine Act to indicate that the Special Master is bound by formal evidentiary rules that govern the consideration of evidence in federal trial courts."); Order Denying Motions for Exclusion of Expert Testimony at 2, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. May 29, 2007), available at <http://www.uscfc.uscourts.gov/sites/>

Federal Claims and the U.S. Court of Appeals for the Federal Circuit have jurisdiction over appeals of the decisions of the special masters.²²

In addition to the possible appeals within the Court of Federal Claims, the Vaccine Act allows claimants to reject decisions reached by the special masters and take their claims outside the Vaccine Court and into state civil court systems.²³ Thus, if the special masters ultimately find against the Cedillos, it seems possible some plaintiffs might prefer to opt out of Vaccine Court and proceed to civil court, where they would have the benefit of obtaining discovery documents from vaccine manufacturers denied to them in the OAP and be eligible for jury trials and greater damages awards.²⁴

Whatever the outcome in *Cedillo* and the remainder of the test cases, it seems one loser in the autism litigation could be the National Childhood Vaccine Injury Compensation Program. As this Comment documents, despite the best efforts of the special masters, deciding to conduct the OAP may actually result in the procedural anomaly of completely barring some families from filing vaccine-related lawsuits in state or federal court.²⁵ In fact, because of two decisions made early in the course of the OAP—one holding that thimerosal claims fall under the jurisdiction of the Vaccine Court,²⁶ and the other permitting the filing of special “short-form petitions” in the OAP²⁷—

default/files/autism/Order%20Denying%20Untitled.pdf (indicating the special master has discretion to exclude scientific expert testimony after hearing it, not before). For a discussion of the relevant standards and burden of proof in Vaccine Act claims, see *infra* Part I.C.5.

21. 42 U.S.C. §§ 300aa-10 to -34 (2006).

22. See 42 U.S.C. § 300aa-12(e), (f) (providing for judicial review of special master decisions in the Court of Federal Claims and Court of Appeals for the Federal Circuit).

23. See *id.* § 300aa-21 (providing the various mechanisms for vaccine claimants to leave Vaccine Court). For a fuller consideration of how the withdrawal provisions may work in the specific context of the OAP, see *infra* Part III.

24. Indeed, Special Master Hastings largely denied plaintiffs’ discovery requests from the vaccine manufacturers. See Ruling Concerning Petitioners’ “Second Motion to Compel,” *supra* note 19, at 1, 2007 WL 1983780, at*1 (denying request by petitioners to obtain discovery documents from vaccine manufacturers); Ruling Concerning Motion for Discovery from Merck Re MMR Vaccine at 1, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. July 16, 2004), 2004 WL 1660351, at *1, available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Ruling%20Concerning%20Motion%20For%20Discovery%20From%20Merck%20Re%20MMR%20Vaccine.pdf> (same).

25. Indeed, the Vaccine Act preempts other state and federal litigation unless a plaintiff has first gone through the Vaccine Court. 42 U.S.C. § 300aa-11(a)(2) (2006). Further, this same provision of the Act imposes specific requirements that must be met before a plaintiff may file a lawsuit in state or federal court. *Id.*

26. *Leroy v. Sec’y of Health & Human Servs.*, No. 02-392V, 2002 WL 31730680 (Fed. Cl. Oct. 11, 2002).

27. *Stewart ex rel. Stewart v. Sec’y of Health & Human Servs.*, No. 02-819V, 2002 WL 31965743 (Fed. Cl. Dec. 30, 2002).

there is at least one scenario where an unsuspecting plaintiff, after waiting years in Vaccine Court, could elect to “opt out” of Vaccine Court but end up being barred from bringing a lawsuit in state or federal court because of unmet Vaccine Act requirements.²⁸ Furthermore, that same plaintiff may even be barred from *returning* to Vaccine Court because of the Vaccine Act’s statute of limitations and the provision governing the filing of multiple petitions, potentially leaving him without any cause of action for a vaccine-related injury.²⁹

So far, the long-term impacts of permitting short-form petitions, and the procedural anomaly that could result, have generally stayed beneath the radar. Indeed, because the many lawyers, scientists, and parents following the progress of the OAP are likely focused on the medical, scientific, and technical issues involved in the test cases, it seems easy to overlook the procedural dictates in section 11(a) of the Vaccine Act, the provision that must be satisfied before commencing a civil action in state or federal court against a vaccine manufacturer. Moreover, because there has not yet been a decision reached in any test case, and therefore no flood of claimants opting out of the OAP,³⁰ it does not appear that a state court or federal district court has considered the effect of how a short-form petition might impact a subsequent civil action.

This Comment sheds light on this dimension of the Vaccine Act by examining some consequences that may flow in the aftermath of the OAP. In short, this Comment argues that the Vaccine Court erred with its decision to permit short-form petitions by overlooking that procedure’s long-term implications on vaccine plaintiffs. In addition, this Comment lays out a scenario to illustrate the potential pitfalls of a hasty exit from the OAP and offers some guidance to plaintiffs to

28. See *infra* Part III.A–B (explaining that certain procedural requirements of the Vaccine Act may bar a plaintiff from bringing a valid claim in state court). The unmet requirements, as set forth in section 11(a) of the Vaccine Act, are that the plaintiffs have never filed a proper “petition” and further that the petition was never filed “in accordance with” section 16 of the Act. 42 U.S.C. § 300aa-11(a).

29. See *infra* Part III.D (applying certain procedural requirements of the Vaccine Act to a hypothetical situation to demonstrate how a plaintiff who filed a short-form petition may ultimately be left without a forum to bring a Vaccine Act cause of action).

30. This is not to say that no petitioners have ever left the OAP. To the contrary, Special Master Hastings noted that some petitioners have left the OAP. *E.g.*, Autism Update-June 23, 2004 at 1 n.2, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. June 23, 2004), available at <http://www.usfc.uscourts.gov/sites/default/files/autism/6%2023%2004%20Autism%20Update.pdf> (indicating that some cases have been voluntarily dismissed or withdrawn by the petitioners). Still, the number of petitioners leaving the program is relatively small and does not number in the hundreds or thousands.

avoid this outcome. The final part of this Comment offers some ideas for improving the Vaccine Act to ensure that such an anomaly does not occur in the future.

This Comment proceeds as follows. Part I begins with a general discussion of vaccine use in the United States and describes the historical circumstances that led to the creation of the Vaccine Act. After highlighting the statutory framework of the Vaccine Act, Part I describes the origins of the vaccine-autism controversy and the creation of the OAP.

Part II analyzes three decisions made in the early stages of the OAP. The first portion looks at the Vaccine Court's assertion of jurisdiction over thimerosal claims. The second portion considers and criticizes the decision to allow short-form petitions to be filed. The third portion looks at the special master's attempt to stop the potential flood of opt-out lawsuits in civil court by declining to issue decisions.

Part III uses a hypothetical scenario to illustrate how the decisions of the special masters, combined with statutory language of section 11(a) of the Vaccine Act, could work to bar some plaintiffs from filing a vaccine lawsuit in civil court. In particular, this Part shows that a plaintiff who leaves the OAP can expect a vaccine manufacturer to challenge his civil claim on at least two specific grounds, namely that a short-form petition is not technically a petition under section 11(c) of the Vaccine Act and further that the short-form petition was not filed in accordance with section 16 of the Vaccine Act. This Part further demonstrates why due process and equal protection challenges to the Vaccine Act are unlikely to be successful. Finally, this Part shows that if a plaintiff is sent back to the Vaccine Court, recent Supreme Court jurisprudence and the provisions of the Vaccine Act may even bar the claim there as well.

Part IV proposes some recommendations for improving the Vaccine Act that draw on lessons learned from the OAP. Specifically, Part IV proposes amending section 12 of the Vaccine Act to include a "no omnibus" provision and amending section 11 to prohibit short form petitions. Lastly, this Part proposes amending the Vaccine Act to increase the number of special masters.

I. BACKGROUND

A. *A Short History of Vaccines: Past, Present, and Future*

Vaccines are one of the triumphs of modern medicine.³¹ Diseases such as smallpox, polio, diphtheria, tuberculosis, pertussis, measles, mumps, and rubella that severely disabled people and claimed many lives during the nineteenth and early twentieth centuries have been eliminated or dramatically reduced because of the development of vaccines.³² At present, death rates from diseases preventable with vaccinations are at all-time lows in the United States.³³

Congress has long recognized the importance of vaccines and passed some of the first vaccine-related legislation at the beginning of the nineteenth century.³⁴ The Supreme Court also recognized the importance of vaccines, holding in 1905 that states have authority under their police powers to require mandatory vaccinations.³⁵

31. See generally Matthew Herper & Robert Langreth, *Fear Factor*, FORBES, Sept. 27, 2007, http://www.forbes.com/sciencessandmedicine/2007/09/26/vaccines-thimerosal-autism-biz-sci-cx_mh_rl_0927vaccines.html (“[E]very year the shots administered to children prevent 14 million infections, prevent 33,000 deaths and save society \$40 billion in direct and indirect medical costs.”); The Vaccine Education Center at The Children’s Hospital of Philadelphia, <http://www.chop.edu/consumer/jsp/division/generic.jsp?id=75697> (last visited Oct. 4, 2008) (listing some of the successes of vaccines).

32. Herper & Langreth, *supra* note 31. For a fuller discussion regarding the history and benefits of vaccinations, see Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 362–82 (2004).

33. Donald G. McNeil, Jr., *Sharp Drop Seen in Deaths From Ills Fought by Vaccine*, N.Y. TIMES, Nov. 14, 2007, at A18. Statistics confirm that the incidence of certain diseases is way down. For example, at present there are about 150 cases of measles reported annually in the United States, compared to 763,094 cases of measles reported in 1958 alone. Press Release, Centers for Disease Control, Morbidity and Mortality Weekly Report, Measles, (May 1, 2008), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm57e501a1.htm>. But see Harris, *supra* note 13 (noting the relationship between the rising number of measles infections in the first seven months of 2008 and the growing number of parents who refuse to vaccinate their children).

34. PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 876–77 (3d ed. 2007). The federal legislation, passed in 1813, was aimed to encourage vaccination and combat impure vaccines by giving the President authority to appoint a Vaccine Agent to “preserve the genuine vaccine matter.” *Id.* at 876 (quoting 2 Stat. 806 (1813)). Congress later repealed the legislation, though, on the idea that it was “better to commit the subject altogether to the local authorities.” *Id.* at 877 (quoting 3 Stat. 677 (1822)).

35. See *Jacobson v. Massachusetts*, 197 U.S. 11, 38–39 (1905) (recognizing the power to require vaccinations is an appropriate exercise of the state’s police powers); see also *Zucht v. King*, 260 U.S. 174, 176 (1922) (citing *Jacobson* for the proposition that it is “settled that it is within the police power of a state to provide for compulsory vaccination”); see also Note, *Toward a Twenty-First Century: Jacobson v. Massachusetts*, 121 HARV. L. REV. 1820, 1821 (2008) (observing the reasoning and logic in *Jacobson* “pervade vaccine law decisions to this day”).

Today all fifty states as well as the District of Columbia mandate childhood immunizations.³⁶

In terms of vaccine production, the vaccine industry is presently experiencing a “renaissance.”³⁷ Development is ongoing for several brand new vaccines such as malaria and avian flu,³⁸ and Wall Street estimates profits from the global vaccine business will grow by eighteen percent a year and reach thirty billion dollars annually by 2011.³⁹

B. Sore Spots: Side Effects, Lawsuits, and Falling National Stockpiles

Despite the many successes of vaccines, they are not without controversy. After administration of a vaccine some recipients inevitably suffer mild to severe side effects.⁴⁰ Further, because the government recommends children receive eleven different vaccines, with some such as the Hepatitis B vaccine requiring three separate doses,⁴¹ there is a greater chance of experiencing an adverse reaction.⁴² Though only a small percentage of recipients experience

36. See Calandrillo, *supra* note 32, at 383 (noting that every state requires a person to present evidence of receiving a vaccination for diphtheria, measles, rubella, and polio prior to entering public school). However, in order to balance public health and safety with individual rights and liberties, state legislatures have been increasing the amount of allowable exemptions to vaccine laws. *Id.*; see also James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 863 tbl.1 (2001) (surveying court decisions concerning vaccination law and policy).

37. See Robert Langreth, *Booster Shot*, FORBES, Nov. 12, 2007, at 78 (declaring “[a] new golden age of vaccines is at hand”). Currently, development is under way for vaccines to fight against illnesses such as malaria, meningitis, and avian flu. *Id.*; see also Kendra Marr, *Novavax Moves Closer to Licensing Bird Flu Vaccine*, WASH. POST, Aug. 27, 2008, at D4 (reporting on the efforts of large national biotech companies to develop a bird flu vaccine).

38. See Langreth, *supra* note 37 (citing government support and public-private partnerships as factors enabling the development of vaccines for pandemic influenzas and diseases concentrated in poor countries).

39. *Id.*

40. See Centers for Disease Control and Prevention, Vaccine Safety and Adverse Events, <http://www.cdc.gov/vaccines/vac-gen/safety/default.htm> (last visited Oct. 4, 2008) (providing links to information about vaccine side effects such as fainting after vaccination and other medical concerns about which parents should be aware).

41. According to the 2008 guidelines, the Centers for Disease Control and Prevention (CDC) recommends that children receive doses of eleven different vaccines by the age of six. These vaccines are the Hepatitis B, Rotavirus, Diphtheria-Tetanus-Pertussis, Haemophilus influenza type b, Pneumococcal, Polio, Influenza, Measles-Mumps-Rubella, Varicella, Hepatitis A, and Meningococcal. Centers for Disease Control, Recommended Immunization Schedules for Persons Aged 0–18 Years, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5701a8.htm?s_cid=mm5701a8_e (last visited Oct. 4, 2008).

42. Randall B. Keiser, *Déjà Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986*, 47 FOOD & DRUG L.J. 15, 15–16 (1992). The nature of the side effects varies from redness and swelling at the injection site, to more systemic reactions such as convulsions, very high fevers, or even death. *Id.* at 16.

a side effect, the risk of a reaction is nearly impossible to avoid,⁴³ and the severity of the reaction is nearly impossible to predict.⁴⁴

As awareness of vaccine side effects entered the public consciousness,⁴⁵ many families of injured vaccine recipients sought legal relief through the civil tort system.⁴⁶ In fact, between 1980 and 1986 individuals brought damages claims of over three billion dollars against vaccine manufacturers.⁴⁷ Although some claims were successful, many claims went uncompensated due to the difficult nature of vaccine litigation in the civil tort system.⁴⁸

43. See H.R. REP. NO. 99-908, at 5 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 (“There is today no ‘perfect’ or reaction-free childhood vaccine on the market.”); Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 313–14 (1999) (listing various types of adverse reactions to immunizations). For example, although the Centers for Disease Control lists long-term seizures and permanent brain damage as severe reactions associated with the DTaP vaccine, the agency notes that these are so rare it is hard to tell whether they are even caused by the vaccine. Centers for Disease Control and Prevention, Information on Vaccine Adverse Reactions, <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm> (last visited Oct. 4, 2008).

44. H.R. REP. NO. 99-908, at 4; *see also* Mary Beth Neraas, Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 150 (1988) (noting the very small percentage of vaccine recipients who suffer a side effect).

45. There were several items that helped raise public awareness regarding the risks of immunizations. In 1982, the television documentary “DTP Vaccine Roulette” received an Emmy nomination for its depiction of those who suffered neurological injuries following DTP vaccinations. Breen, *supra* note 43, at 315. In addition, mandatory swine flu vaccinations in the 1970s stirred fears of developing Guillian Barre Syndrome. Kathy Koch, *Vaccine Controversies: Are Today’s Vaccines Safe Enough?*, 10 CONG. Q. RESEARCHER 641, 645 (2000). Further, the depiction of side effects linked to vaccines continues in modern times. *E.g.*, *Eli Stone: Pilot Episode* (ABC television broadcast Jan. 31, 2008) (suggesting a relationship between vaccines and autism); *see also* *The Simpsons: The Computer Wore Menace Shoes* (FOX television broadcast Dec. 3, 2000) (presenting an episode where Homer is taken to a mysterious island after reporting that the flu vaccine is actually a form of mind control meant to stimulate commerce during the holiday shopping season).

46. *E.g.*, *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1264, 1269 (5th Cir. 1974) (affirming a \$200,000 jury verdict against manufacturer of oral polio vaccine); *Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318 (Kan. 1986) (reversing a jury verdict of ten million dollars in damages against a vaccine manufacturer, including eight million dollars of punitive damages, awarded to a family in a vaccine injury case). Injured vaccine recipients sought relief under a variety of legal theories including negligent manufacture or administration of vaccines, inadequate warnings from the manufacturer, and failure to provide alternatives. *See* Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL’Y & L. 59, 60 (1999) (citing cases).

47. *See* Ridgway, *supra* note 46, at 61 (“[T]he potential for liability appeared to be unlimited.”); *see also* 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) (noting the unpredictability of lawsuits against vaccine manufacturers and concern of limitless liability for vaccine manufacturers and administrators).

48. *See* Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons From the Vaccine Act*, 44 AM. U. L. REV. 1853, 1859–60 (1995) (explaining that vaccine litigation is difficult in the civil court system because of the

The increase in vaccine litigation threatened to reduce the vaccine supply in the United States by crippling the vaccine manufacturing industry.⁴⁹ Indeed, as legal costs and the inability to obtain product liability insurance made producing vaccines unprofitable, vaccine manufacturers left the market and national vaccine supply began to fall to low levels.⁵⁰ Thus, in 1986, in response to the shortage of available vaccines, the potential decline in the number of immunized children, and the pleas of the uncompensated victims of vaccine injuries, Congress enacted the National Childhood Vaccine Injury Compensation Act.⁵¹

C. *The National Childhood Vaccine Injury Compensation Act*

As stated by Congress, the twofold purpose of the Vaccine Act was to offer fair compensation to persons injured by vaccinations and to ensure the continued supply of vaccines by shielding vaccine manufacturers from civil liability.⁵² The Act has two parts. The first part of the legislation establishes the National Vaccine Program whereby federal officials coordinate vaccine safety and research to ensure the overall effectiveness of the nationwide immunization

inability to raise design defect claims, the difficulty in establishing proximate cause, and the length of time it takes to litigate claims).

49. See *Hunt v. United States*, 636 F.2d 580, 589–93 (D.C. Cir. 1980) (discussing the mandatory swine flu vaccinations and noting that the “four manufacturers of the [swine flu vaccine] found their insurers unwilling to accept the risk of claims by persons alleging injury from the vaccination, and the manufacturers would not proceed without insurance protection”).

50. See Neraas, *supra* note 44, at 151–52 (noting that many pharmaceutical companies withdrew from the vaccine business between the 1960s and 1980s due to concerns over liability). Indeed, during a portion of the vaccine supply crisis in the 1980s there was only one manufacturer of the oral polio vaccine, one manufacturer of the MMR vaccine, and two manufacturers of the DTP vaccine. *Id.* at 151 n.16. During this same time six vaccine manufacturers ceased production of vaccines, and the stockpiles of vaccines fell below levels recommended by the CDC. Cantor, *supra* note 48, at 1858–59.

51. 42 U.S.C. §§ 300aa-10 to -34 (2006). For a fuller discussion of the vaccine supply crisis and the creation of the Vaccine Act, see Ridgway, *supra* note 46, at 60–62.

52. See H.R. REP. NO. 99-908, at 7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6346 (declaring that the Act will establish a system for vaccine injury compensation that is fair, simple, and easy to administer and will lead to more stability in the childhood vaccine market); see also *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2–3 (1st Cir. 1994) (noting that the Act creates a remedial system that tries to deliver compensation to victims more quickly while also reducing insurance and litigation costs for manufacturers); *McGowan v. Sec’y of Health & Human Servs.*, 31 Fed. Cl. 734, 738 (1994) (emphasizing that two central reasons for creating the Vaccine Act were liability protection for vaccine manufacturers and easier compensation for injured children).

program.⁵³ The second part creates the National Childhood Vaccine Injury Compensation Program.⁵⁴ This part spells out the terms by which a person who has suffered a vaccine-related injury may seek and obtain compensation.⁵⁵

In order to fully appreciate the specific context of the OAP, the extent to which its framework differs from the structure of the Vaccine Act, and the impact it may have on future civil litigation outside the confines of the Vaccine Court, it is first necessary to understand the legal regime set out by the Vaccine Act for adjudicating claims. The discussion below provides a Vaccine Act primer and describes the jurisdictional components of the Act, the process for filing a claim, the petition for compensation and discovery, the timeframe for adjudicating claims, the standards for determining compensation under the Act, the scope of damages available, and the right to appeal a Vaccine Act decision.⁵⁶

1. *Jurisdiction and preemption of state law*

There are a few threshold requirements that Vaccine Act petitioners must meet before being eligible to proceed in Vaccine Court. For instance, a petitioner must be prepared to show that he “received a vaccine set forth in the Vaccine Injury Table”⁵⁷ and also that he received the vaccine “in the United States or in its trust territories.”⁵⁸ In addition, with respect to the nature of the injury, the petitioner (or his representative) must demonstrate that either he “suffered the residual effects or complications” from the injury for more than six months, “died from the administration of the vaccine,” or his injury resulted in “hospitalization and surgical intervention.”⁵⁹ Further, the Act includes a statute of limitations provision that states that claims brought under the Vaccine Act must be filed within thirty-six months of “the date of the occurrence of the first symptom or

53. 42 U.S.C. § 300aa-1. For a discussion about this aspect of the Vaccine Act, see Phillip K. Russell, *Development of Vaccines to Meet Public Health Needs: Incentives and Obstacles*, 7 RISK 239, 250 (1996).

54. 42 U.S.C. § 300aa-10 to -34.

55. See *infra* Part I.C (detailing the parameters of the Vaccine Act).

56. For another overview of the legal regime set out by the Vaccine Act, including a more comprehensive discussion regarding attorneys’ fees, amendments to the Vaccine Injury Table, and the congressional goals behind the legislation, see Strong, *supra* note 47, at 436–44.

57. 42 U.S.C. § 300aa-11(c)(1)(A); *infra* Part I.C.4.

58. 42 U.S.C. § 300aa-11(c)(1)(B)(I).

59. *Id.* § 300aa-11(c)(1)(D)(i).

manifestation of onset or of the significant aggravation of such injury.”⁶⁰

In addition, the Vaccine Act prohibits state law claims against vaccine manufacturers for “vaccine-related”⁶¹ injuries unless a petitioner has exhausted his remedies under the Vaccine Act.⁶² If a petitioner proceeds to civil court, the Act provides additional protections for vaccine manufacturers named as defendants by making several modifications to state tort law.⁶³

2. *Filing a claim*

If a person believes he has suffered a vaccine-related injury, that person or his legal representative may bring a Vaccine Act claim by filing a petition in the United States Court of Federal Claims and serving a copy upon the Secretary of Health and Human Services.⁶⁴

60. *Id.* § 300aa-16(a)(2). However, if the claim is alleging death from the administration of the vaccine, the estate must file the action within twenty-four months of death, and within forty-eight months of the onset of the original symptoms leading to death. *Id.* § 300aa-16(a)(3). Filing an untimely petition can be fatal to a vaccine claim because equitable tolling is not available to Vaccine Act petitioners who file petitions beyond the statutory deadline. *See Brice v. Sec’y of Health & Human Servs.*, 240 F.3d 1367, 1374 (Fed. Cir. 2001) (“We determine . . . that equitable tolling is inconsistent with the existing statutory scheme.”).

61. “Vaccine-related” is defined as an “illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table.” 42 U.S.C. § 300aa-33(5).

62. *See id.* § 300aa-11(a)(2)(A) (“No person may bring a civil action for damages in an amount greater than \$1,000 . . . against a vaccine administrator or a manufacturer in a State or Federal court for damages arising from a vaccine-related injury . . . unless a petition has been filed, in accordance with section 300aa-16 of this title . . .” and the United States Court of Federal Claims has issued a judgment under section 12 and the petitioner rejects the judgment under section 21(a)); *see also id.* § 300aa-21(b) (providing that a petitioner may withdraw from the Vaccine Program if the Vaccine Court moves too slowly). If a vaccinee misinterprets or ignores the jurisdiction of the Vaccine Program and files a civil action in federal or state court, under section 11(a)(2)(B) of the Vaccine Act, that court must dismiss the claim until the vaccinee exhausts his or her remedies under the Vaccine Program. *See id.* § 300aa-11(a)(2)(B) (instructing the receiving court to dismiss the petition); *see also* *Laughter v. Aventis Pasteur, Inc.*, 291 F. Supp. 2d 406, 411 (M.D.N.C. 2003) (“If a petitioner has not exhausted his or her remedies in this fashion, then pursuant to [section eleven] he or she is not allowed to bring a civil action related to the claimed vaccine-related injuries in state or federal court.”). For more discussion on the relationship between the OAP program, and the requirements of section 11(a) of the Vaccine Act, and future state civil claims, *see infra* Part III.

63. For instance, section 22(b)(1) of the Act forbids the award of compensation for injuries that flow from “unavoidable [] side effects” of vaccines, section 22(c) frees the manufacturer from liability for not providing direct warnings to an injured person, and section 22(b)(2) imposes a presumption that the manufacturer complied with FDA requirements regarding proper directions and warnings. 42 U.S.C. § 300aa-22; *see also* *Shafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (summarizing the Vaccine Act’s impacts on state tort law); Cantor, *supra* note 48, at 1863–64 (considering the Vaccine Act’s ban on direct failure to warn claims).

64. 42 U.S.C. § 300aa-11(a)(1). Under the terms of the Vaccine Act, the Secretary of Health and Human Services is to “undertake reasonable efforts to

Only one petition may be filed with respect to administration of each vaccine.⁶⁵ After filing, the petition is directed to the Chief Special Master who may either keep the petition for himself or assign it to another special master.⁶⁶ The special master assigned to the claim will determine whether compensation is appropriate.⁶⁷ The Secretary of Health and Human Services, who is the respondent in Vaccine Act cases, is represented in Vaccine Court by attorneys from the United States Department of Justice.⁶⁸

3. *The required “supporting documentation”*

As discussed above, a Vaccine Act claim is initiated by filing a petition for compensation in the Court of Federal Claims.⁶⁹ The petition for compensation must be accompanied by specific documents and the requirements governing petitions are more elaborate than the pleading requirements utilized in federal court.⁷⁰ For example, according to section 11(c) of the Vaccine Act, a petition for compensation “shall contain . . . an affidavit, and supporting documentation.”⁷¹ Section 11(c) further specifies that the supporting documentation “shall” include:

maternal prenatal and delivery records, newborn hospital records (including all physicians’ and nurses’ notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records . . . (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results⁷²

inform the public of the availability of the Program.” *Id.* § 300aa-10(c). For a discussion regarding why the contents of the petition are so important, and the potential consequence of not adhering to the requirements of section 11(c) of the Act, see *infra* Part III.

65. 42 U.S.C. § 300aa-11(b)(2).

66. *See id.* § 300aa-11(a)(1) (instructing the clerk of the court to forward the petition to the chief special master).

67. *See id.* § 300aa-12(d)(3) (indicating that the special master’s decision must include findings of fact and conclusions of law).

68. *Id.* § 300aa-12(b)(1).

69. *Id.* § 300aa-11(a)(1).

70. For instance, under the Federal Rules of Civil Procedure, a pleading for relief need only make a short and plain statement of jurisdiction, a short and plain statement of the claim, and a demand for the relief sought. FED. R. CIV. P. 8(a).

71. 42 U.S.C. § 300aa-11(c)(1).

72. *Id.* § 300aa-11(c)(2). The Act also allows the petition for compensation to include “other available relevant medical records relating to the person who suffered such injury.” *Id.* § 300aa-11(d).

If any records are unavailable, the Act instructs the petitioner to provide “an identification of any records of the type described . . . which are unavailable to the petitioner and the reasons for their unavailability.”⁷³

In addition, if additional records are needed, the Vaccine Act allows for some discovery. Specifically, section 12(d)(3) gives the special master authority to “require the testimony of any person and the production of any documents as may be reasonable and necessary.”⁷⁴ The Act specifically states that “[t]here may be no discovery in a proceeding on a petition other than the discovery required by the special master.”⁷⁵ Special masters, however, are hesitant to order far-reaching discovery consisting of documents other than medical records.⁷⁶

4. *The time-frame for adjudicating Vaccine Act claims*

The Vaccine Act sets forth a schedule that envisions a streamlined period for adjudicating claims. For example, under section 12(g), the special master assigned to the petition is required to render a decision “as expeditiously as practicable but not later than 240 days” from the date the petition was filed.⁷⁷ If the 240 day period is not met, the Act provides that the special master may suspend proceedings, but the total aggregate period for suspension cannot exceed 180 days.⁷⁸ The Act therefore envisions a maximum time-frame of 420 days to adjudicate a claim. However, a petitioner may elect to remain in Vaccine Court beyond the 420 day time period.⁷⁹

5. *Proving causation: Table vs. off-table claims*

The Vaccine Act sets out two separate avenues for a petitioner to be compensated. First, a petitioner can bring a claim under the Vaccine

73. *Id.* § 300aa-11(c)(3).

74. *Id.* § 300aa-12(d)(3)(B)(iii).

75. *Id.* § 300aa-12(d)(3)(B).

76. *See* Ruling Concerning Motion for Discovery From Merck Re MMR Vaccine, *supra* note 24, at 6–10, 2004 WL 1660351, at *7–9 (discussing the scope of discovery in Vaccine Act proceedings and noting there is “extremely little case law relating to discovery questions during the 15-year history of the Vaccine Act”).

77. 42 U.S.C. § 300aa-12(d)(3)(A)(ii).

78. *Id.* § 300aa-12(d)(3)(C). If the special master has not made a decision by the end of the 240 day period, the Act allows petitioners to choose whether to remain in the Program or withdraw the petition. *Id.* §§ 300aa-12(g), 21(b).

79. In the event no decision is made in the 420 day period, section 12(g) of the Act instructs the special master to “notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa-21(b) of the title or the petitioner may choose under section 300aa-21(b) of this title to have the petition remain before the special master.” *Id.* § 300aa-12(g).

Injury Table,⁸⁰ which lists the vaccines covered by the Vaccine Act, the injuries associated with each vaccine, and the time requirements by which the first symptoms or manifestations of the injuries must arise.⁸¹ Under this theory, if the petitioner establishes that he received a covered vaccine, sustained one of the injuries listed in the Vaccine Injury Table, and the first manifestation of the injury occurred within the time-frame provided in the Table, he is entitled to a rebuttable presumption that the vaccine caused the injury.⁸²

If the claim does not fall under the Vaccine Table, a petitioner may try his claim via the second compensation avenue by bringing an “off-table” claim.⁸³ Under this theory, also referred to as a causation-in-

80. *See id.* § 300aa-14(a) (providing the original Vaccine Injury Table); 42 C.F.R. § 100.3(a) (2007) (providing the current Vaccine Injury Table after revisions through notice and comment rulemaking). An online version of the Vaccine Injury Table is available at <http://www.hrsa.gov/vaccinecompensation/table.htm>. The statute gives the Secretary of Health and Human Services authority to amend the Table through administrative rulemaking as additional scientific evidence becomes available. 42 U.S.C. § 300aa-14(c); *see also* *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1305 (Fed. Cir. 1999) (holding the Secretary’s authority to modify the injuries and symptoms included in the Table does not violate the Presentment Clause of the Constitution). The Vaccine Injury Table has been amended several times since the creation of the program. For example, in April, 2007, the human papillomavirus vaccine was added to the Table, though the Table has not yet listed recognized adverse events or a recognized timetable for this vaccine. *See* National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19,937 (Apr. 20, 2007) (“[T]he Secretary announces that meningococcal (conjugate and polysaccharide) and human papillomavirus (HPV) vaccines are covered vaccines under the National Vaccine Injury Compensation Program This Notice serves to include meningococcal and HPV vaccines as covered vaccines under Category XIV (new vaccines) of the Vaccine Injury Table”).

81. 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a) (2007). For instance, one recognized side effect of the Rubella virus containing vaccine is chronic arthritis which is said to manifest in 7–42 days. 42 C.F.R. § 100.3(a).

82. *See Gruber v. Sec’y of Health & Human Servs.*, 61 Fed. Cl. 674, 678 (2004) (discussing the mechanics of proving causation using the Vaccine Injury Table). For example, if a petitioner demonstrated he received the MMR vaccine and experienced an encephalopathy within 5–15 days after administration of the vaccine, he would be entitled to a presumption of causation because he meets the criteria set forth in the Vaccine Injury Table for that vaccine. 42 C.F.R. § 100.3(a); National Vaccine Injury Compensation Program, Vaccine Injury Table, <http://www.hrsa.gov/vaccinecompensation/table.htm> (last visited Oct. 4, 2008). However, even if a petitioner makes this showing, the government may rebut the presumption by making an affirmative showing by the preponderance of the evidence that the injury in question is due to factors unrelated to the administration of the vaccine. *See Gruber*, 61 Fed. Cl. at 678 (“[A] ‘factor unrelated’ does not include ‘any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.’”) (citation omitted); *see also* 42 U.S.C. § 300aa-13(a)(1)(B) (“[T]hat there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.”).

83. *See Andreu ex rel. Andreu v. Sec’y of Dep’t of Health & Human Servs.*, No. 98-817V, 2007 WL 2706157, at *2 (Fed. Cl. Aug. 29, 2007) (describing statutory basis for the off-table causation in fact claims).

fact claim, the petitioner may prevail if he proves by a preponderance of the evidence that the vaccine actually caused his injury.⁸⁴ There is no presumption of causation under this theory and recovery via the off-table avenue is more difficult to establish than the on-table method.⁸⁵ Indeed, the Court of Appeals for the Federal Circuit remarked that under the off-table theory the “heavy lifting must be done by the petitioner” and added further that the lifting “is heavy indeed.”⁸⁶ Furthermore, the government assumes a more adversarial position when defending off-table claims.⁸⁷ Because autism is not listed as an injury on the Vaccine Injury Table, claims alleging autism must proceed via the off-table theory.⁸⁸

6. *Compensation and Vaccine Act funding*

Section 15 of the Vaccine Act spells out the compensation available to a plaintiff.⁸⁹ Under that provision, recovery for a vaccine injury includes medical expenses, lost wages, costs of future medical care,

84. 42 U.S.C. § 300aa-13(a)(1); *see also* *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1276 (Fed. Cir. 2005) (declaring that petitioner met the statutory burden of establishing causation by a preponderance of the evidence). According to the U.S. Court of Appeals for the Federal Circuit, in order to prevail on a causation-in-fact claim, a petitioner must show by a preponderance of evidence that the vaccination caused their injury by establishing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. *Id.* at 1278. One special master describes the preponderance of the evidence standard as “fifty percent and a feather.” *E.g.*, *Banks v. Sec’y of Health & Human Servs.*, No. 02-738V, 2007 WL 2296047, at *2 (Fed. Cl. July 20, 2007) (affording particular weight to medical records in determining whether a preponderance of the evidence was met).

85. *See Grant v. Sec’y of Dep’t of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (“The Act relaxes proof of causation for injuries satisfying the Table . . . but does not relax proof of causation for causation in fact for non-Table Injuries.”).

86. *Hodges v. Sec’y of Dep’t of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993).

87. *See Stevens v. Sec’y of Dep’t of Health & Human Servs.*, No. 99-594V, 2001 WL 387418, at *8 (Fed. Cl. Mar. 30, 2001) (observing that each off-table case “proceeds as a traditionally litigated case—that is, full blown litigation”); *Matthews v. Sec’y of Dep’t of Health & Human Servs.*, 18 Cl. Ct. 514, 534 (1989) (indicating the government as taking a “fully adversarial” position in challenging the petitioner’s claim); *Strong*, *supra* note 47, at 446–47 (commenting on the adversarial nature of off-table claims and noting that a common criticism of the Vaccine Act voiced by petitioners’ attorneys and special masters is that the government attorneys were “over-litigating” off-table claims). *But see Knudsen v. Sec’y of Dep’t of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994) (“The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims.”).

88. *See Analla v. Sec’y of Health & Human Servs.*, 70 Fed. Cl. 552, 556 (2006) (noting petitioners who cannot show a table claim must bring claims under the off-table theory); *see also* 42 C.F.R. § 100.3(a) (2007) (providing injuries currently covered under the Vaccine Act).

89. 42 U.S.C. § 300aa-15 (2006).

and a maximum of \$250,000 in pain and suffering.⁹⁰ The Vaccine Act does not allow for punitive damages,⁹¹ and in cases involving death, damages are specifically set at \$250,000.⁹² Compensation to successful claimants is paid from the Vaccine Injury Compensation Trust Fund, which is overseen by the Treasury Department and funded by a seventy-five cent tax levied on each dose of vaccine covered by the Act.⁹³

7. *Judgments and appeals*

After a program decision has been made and judgment has been entered, the petitioner has ninety days to file an election with the Vaccine Court choosing to accept or reject the judgment.⁹⁴ If a petitioner accepts, he will be barred from subsequently initiating a civil lawsuit “against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered.”⁹⁵ Government data indicates very few Vaccine Act petitioners choose to reject a favorable Vaccine Act judgment and file a civil action.⁹⁶

The Act also provides for the right to appeal within the Court of Federal Claims. For instance, after a special master issues a decision,

90. *Id.* Unreimbursed medical expenses include past and future expenses for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, special equipment, related travel expenses, and facilities determined to be reasonably necessary. *Id.* § 300aa-15(a)(1)(B)(iii). According to government statistics, since fiscal year 1990 there have been 954 awards paid out of the Vaccine Court amounting to over \$809 million. NATIONAL VACCINE INJURY COMPENSATION PROGRAM, U.S. DEP’T OF HEALTH & HUMAN SERVS., STATISTICS REPORT (2008), available at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.

91. 42 U.S.C. § 300aa-15(d)(1).

92. *Id.* § 300aa-15(a)(2).

93. See 26 U.S.C. § 9510 (2006) (establishing a Vaccine Injury Compensation Trust Fund in the Treasury of the United States); *id.* § 4131 (imposing a tax of seventy-five cents per dose of vaccine). As of January 2007, there was approximately \$2.5 billion in the trust fund. See National Vaccine Injury Compensation Program, http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm (last visited Oct. 4, 2008) (describing how the trust fund operates).

94. See 42 U.S.C. § 300aa-21(a) (providing for the election or rejection of judgments made by the Court of Federal Claims).

95. See *id.* (“If a person elects to receive compensation under a judgment of the court . . . such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered.”).

96. Indeed, according to statistics maintained by the Department of Health and Human Services for claimants who reject a judgment awarding compensation, zero percent of Vaccine Program claimants elected to reject their judgment in 2004 and 2005 while only 1.5% elected to do so in 2003. DIVISION OF VACCINE INQUIRY COMPENSATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., STRATEGIC PLAN FOR NATIONAL VACCINE INJURY COMPENSATION PROGRAM (2006), available at http://www.hrsa.gov/vaccinecompensation/strategic_plan.htm.

either the petitioner or the government may move for review in the United States Court of Federal Claims.⁹⁷ Decisions from the Court of Federal Claims may be appealed to the United States Court of Appeals for the Federal Circuit.⁹⁸

D. *The Vaccine-Autism Controversy*

The rise of the incidence of autism⁹⁹ is one of the most serious public health issues in recent years.¹⁰⁰ The prevalence of the condition has increased markedly, with current statistics suggesting that roughly one child out of every 150 has autism or an autistic-like disorder, compared to earlier estimates placing the rate at four or five children out of every 10,000.¹⁰¹ The etiology of autism remains a mystery and science has not yet been able to determine a cause.¹⁰²

97. 42 U.S.C. § 300aa-12(e). As a reviewing body, the Court of Federal Claims reviews findings of fact under the arbitrary and capricious standard; legal questions under the not in accordance with law standard; and discretionary rulings under the abuse of discretion standard. See *Dixon v. Sec'y of Dep't of Health & Human Servs.*, 61 Fed. Cl. 1, 8 (2004) (discussing the standard of review utilized by the Court of Federal Claims and Federal Circuit); see also *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1323 (Fed. Cir. 2006) (“[W]e apply the same standard of review that the Court of Federal Claims applied to the special master’s decision.”).

98. 42 U.S.C. § 300aa-12(f). The parties have sixty days from the judgment of the Court of Federal Claims to file an appeal in the Court of Appeals for the Federal Circuit. *Id.*

99. Autism is one of a group of disorders known as autism spectrum disorders (“ASDs”). ASDs are developmental disabilities that cause substantial impairments in social interaction and communication and the presence of unusual behaviors and interests. See generally Centers for Disease Control and Prevention, Autism Information Center, <http://www.cdc.gov/autism> (last visited Oct. 4, 2008) (providing information about autism including material about symptoms, screening, and treatment). For some statistics concerning the rise of autism, see *infra* note 101.

100. A report by the Harvard School of Public Health found that it costs society about \$3.2 million to care for an autistic person over her lifetime, and caring for all people with autism costs about \$35 billion. See Press Release, Harvard School of Public Health, Autism Has High Costs to U.S. Society (Apr. 26, 2006), available at <http://www.hsph.harvard.edu/news/press-releases/2006-releases/press04252006.html> (showing the cost was broken down into two components, direct medical costs (such as physician services, therapies and medication) that amounted to more than \$29,000 per person per year and indirect costs (such as special education and child care) that amounted to anywhere between \$38,000 to \$43,000 per person per year). In recent years, a number of organizations have been founded with the purpose of raising awareness about autism and devoting resources towards finding a cure. *E.g.*, Autism Speaks, <http://www.autismspeaks.org> (last visited Oct. 4, 2008). The specific fear that vaccines are linked with autism has made some parents hesitant to vaccinate their children, making them more vulnerable to the diseases vaccines are designed to prevent. See Harris, *supra* note 13 (reporting that many anti-vaccine advocates “will take measles over autism”).

101. Compare Benedict Carey, *Study Puts Rate of Autism at 1 in 150 U.S. Children*, N.Y. TIMES, Feb. 9, 2007, at A12 (reporting on data from a 2007 CDC study concluding 1 in 150 children will develop an ASD by the age of eight), with Centers for Disease Control, Autism Information Center, http://www.cdc.gov/ncbddd/autism/faq_prevalence.htm (last visited Sept. 20, 2008) (“For decades, autism was believed to occur in 4 to 5 per 10,000 children.”). It has also been suggested that a

The belief that vaccines were linked to the increase in the incidence of autism gained prominence due to several events over the past ten years. First, a scientific study published in the United Kingdom suggested there is a link between autism and MMR vaccine.¹⁰³ The study received a lot of attention in the United States, appearing in television stories and drawing strong reactions from members of Congress.¹⁰⁴ And second, shortly after the United Kingdom study was published, the various federal public health agencies recommended that the preservative thimerosal be phased out of vaccines.¹⁰⁵ Other events, such as legislation on Capitol Hill, news coverage in the mass media, and the publication of additional scientific studies helped spur the vaccine-autism debate as well.¹⁰⁶

change in diagnostic criteria accounts for some of this increase. See Paul T. Shattuck & Maureen Durkin, Op-Ed., *A Spectrum of Disputes*, N.Y. TIMES, June 11, 2007, at A19 (comparing the criteria used to diagnose autism in 1943 with the current diagnostic guidelines).

102. See Centers for Disease Control, Autism Information Center, <http://www.cdc.gov/ncbddd/autism/overview.htm#causes> (last visited Sept. 20, 2008) (“[W]e still don’t know a lot about the causes of [autistic spectrum disorders].”). There are a number of suggestions as to what causes autism, with everything from television to PCBs being suspected. See, e.g., Erica Goode, *Autism Cases Up; Cause is Unclear*, N.Y. TIMES, Jan. 26, 2004, at A1 (listing environmental factors such as prescription drugs, PCB’s, and food additives that have been named as potential causes of autism); Gregg Easterbrook, *In Search of the Cause of Autism, How About Television?*, SLATE, Sept. 5, 2006, <http://www.slate.com/id/2149002/> (speculating that increased television watching in the 1980s may be responsible for the rise in autism).

103. See A.J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637, 637 (1998) (attributing gastrointestinal disease and developmental regression in a group of previously normal children to environmental factors).

104. Philip J. Hilts, *House Panel Asks for Study of a Vaccine*, N.Y. TIMES, Apr. 7, 2000, at A20. Speaking on the possible link between autism and vaccines, Congressman Dan Burton, then chairman of the House Government Reform and Oversight Committee, said that “[w]e owe it to our children and grandchildren to insure we’re being diligent in looking for causes of autism. We can’t stick our heads in the sand and ignore the possibility.” *Id.*; see also *60 Minutes: MMR Vaccine* (CBS television broadcast Nov. 12, 2000).

105. In 1999, the Federal Public Health Service Agencies, “the American Academy of Pediatrics, and [the] vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure.” Centers for Disease Control and Prevention, *Vaccine Safety*, <http://www.cdc.gov/vaccinesafety/concerns/thimerosal.htm> (last visited Oct. 4, 2008). With the exception of some influenza vaccines, thimerosal was removed from vaccines by 2001, and is no longer used as a preservative in the manufacturing process. *Id.*

106. For example, in 2003, members of Congress attached a last minute provision to a Homeland Security bill designed to shield thimerosal manufacturers from liability. Susan Warner, *New Vaccine Clause Angers Parents of Autistic; Amendment Buried in Homeland Security Law Restricts Right to Sue Makers of Drug Preservative*, WASH. POST, Dec. 9, 2002, at A3; see also Bartholomew C. Wacek, *Taking Sides in the Vaccine/Autism Legal Battle*, 8 DEPAUL J. HEALTH CARE L. 305, 308–09 (2004) (providing references to scientific studies supporting a causal relationship between childhood vaccines and

While some of the evidence supporting a link has been criticized, and the qualifications of some experts called into question,¹⁰⁷ the perception that vaccines are responsible in some way for causing autism remains very much alive.¹⁰⁸ Indeed, during the 2008 Presidential campaign, both John McCain and Barack Obama made statements suggesting there is a link.¹⁰⁹ And, in March 2008, it became public that the Secretary of Health and Human Services conceded that vaccines may have aggravated an underlying mitochondrial disorder in a young girl, which ultimately led to a

autism); Herper & Langreth, *supra* note 31 (referencing instances of vaccine-autism stories depicted in the mainstream media).

107. Recently, Andrew Wakefield, the primary author behind the 1998 study, was charged with professional misconduct for his role in the study. See Karen McVeigh, *Doctor in MMR Row Defends Stance at Disciplinary Hearing*, GUARDIAN (London), Mar. 28, 2008, at 12 available at <http://www.guardian.co.uk/society/2008/mar/28/health.children> ("It is alleged Wakefield accepted £50,000 for research to support parents' attempts to fight for compensation."). Furthermore, several years after it was published, ten of the thirteen authors of the Wakefield study issued a retraction. Glenn Frankel, *Charismatic Doctor at Vortex of Vaccine Dispute*, WASH. POST, July 11, 2004, at A1. Moreover, the expertise of Dr. Mark Geier, a geneticist and author of some studies in support of a vaccine-autism link, has also been called into question. See *Redfoot v. B.F. Ascher & Co.*, No. 05-2045PJH, 2007 WL 1593239, at *10 (N.D. Cal. June 1, 2007) ("Dr. Geier is not qualified as a pediatrician, a neurologist, a toxicologist, or an epidemiologist."); *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 476 (M.D.N.C. 2006) (ruling Dr. Geier was not qualified to testify as an expert witness); *Schrum v. Sec'y of Dep't of Health & Human Servs.*, No. 04-210V, 2007 WL 1772056, at *4 (Fed. Cl. May 31, 2007) (noting that Dr. Geier's "credentials and methodology" have been questioned in many cases in which he gave expert testimony).

108. Robert Kennedy Jr., in particular, has been vocal in voicing his belief that there is a government cover-up regarding vaccines and autism. For example, in 2005, he referred to the studies indicating no link between vaccines and autism as "junk science," decried the existence of secret government meetings about the safety of vaccines, and further added that "the same regulatory bureaucrats that green-lighted thimerosal originally are now trying to cover their tracks." *Morning Joe: A Coverup For a Cause of Autism?* (MSNBC television broadcast June 22, 2005), available at <http://www.msnbc.msn.com/id/8243264/>; see also Robert Kennedy Jr., *Deadly Immunity*, ROLLING STONE, June 20, 2005, available at http://www.rollingstone.com/politics/story/7395411/deadly_immunity/ (arguing that there is a government cover-up regarding vaccines and autism). There were other developments in 2005 as well. For instance, Tim Russert devoted a portion of his television show to discussing the issue of autism and vaccines, see *Meet the Press* (NBC television broadcast Aug. 7, 2005), and author David Kirby published a book exploring the relationship between vaccines and autism. See generally DAVID KIRBY, EVIDENCE OF HARM (2005).

109. Specifically, John McCain stated that there is "strong evidence" that autism has to do "with a preservative in vaccines." See Benedict Carey, *Into the Fray Over the Cause of Autism*, N.Y. TIMES, Mar. 4, 2008, at A18; *id.* (observing that Mr. McCain's statement "marked his entry into one of the most politicized scientific issues in a generation"). Also, at a rally the day before the Pennsylvania primary, Barack Obama said "[w]e've seen just a skyrocketing autism rate. Some people are suspicious that it's connected to the vaccines. This person included." David Kirby, *Obama Climbs On The Vaccine Research Bandwagon*, HUFFINGTON POST, Apr. 22, 2008, http://www.huffingtonpost.com/david-kirby/obama-climbs-on-the-vacci_b_97969.html.

diagnosis of autism.¹¹⁰ The impact of this concession, however, is not yet clear because the case was decided under a settlement agreement and not in a Vaccine Court decision, and the government still maintains that vaccines do not cause autism.¹¹¹

On the other side of the debate, there is plenty of scientific and epidemiological evidence indicating there is no relationship between vaccines and autism.¹¹² For example, an exhaustive report by the Institute of Medicine published in 2004 recommended rejecting a causal relationship between vaccines and autism.¹¹³ In addition, numerous other peer-reviewed scientific and epidemiological studies have concluded there is no such link.¹¹⁴ Moreover, some evidence shows that even after 2001, when thimerosal was removed from most vaccines, autism rates continued to rise.¹¹⁵ Finally, scientists

110. See Gardiner Harris, *Deal in an Autism Case Fuels Debate on Vaccine*, N.Y. TIMES, Mar. 8, 2008, at A9 (noting the government conceded vaccines may have hurt the child and has agreed to pay her family for her care); Alison Young, *First Autism-Vaccine Link: How Hannah Made History*, ATLANTA J. CONST., Mar. 6, 2008, at A1 (noting the government concession was that vaccines aggravated a rare underlying metabolic condition, that in turn resulted in a brain disorder with features of autism spectrum disorder).

111. See Autism Update-March 27, 2008 at 5, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Mar. 27, 2008), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism%20Update%203%2027%2008.pdf> (noting the inaccurate media descriptions on the conceded case and emphasizing the Vaccine Court has not issued any ruling, decision, or opinion on it); see also Young, *supra* note 110 (observing the language in the settlement agreement “does not establish a clear-cut vaccine-autism link” and further that “government officials continue to maintain that vaccines don’t cause autism”).

112. See, e.g., Eric Fombonne et al., *Pervasive Developmental Disorders in Montreal, Quebec, Canada. Prevalence and Links with Immunizations*, 118 PEDIATRICS e139, e140 (2006) (finding that “thimerosal exposure was unrelated to the increasing trend in the prevalence of pervasive development disorder”).

113. See generally IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 1 (2004) (surveying published and unpublished scientific and epidemiological literature and concluding that “the body of epidemiological evidence” favors rejection of both a causal relationship between the MMR vaccine and autism and between thimerosal-containing vaccines and autism).

114. E.g., Anders Hviid et al., *Association Between Thimerosal-Containing Vaccine and Autism*, 290 J. AM. MED. ASS’N 1763, 1763 (2003) (finding the risk of autism did not differ significantly between children vaccinated with thimerosal-containing vaccines and children vaccinated with thimerosal-free vaccines); Kreesten Meldgaard Madsen et al., *A Population-Based Study of Measles, Mumps, and Rubella Vaccination and Autism*, 347 NEW ENG. J. MED. 1477, 1477 (2002) (studying children born in Denmark between 1991 and 1998 and finding no association between the age at the time of vaccination, the time since vaccination, the date of vaccination, and the development of autism).

115. See *Study Finds Vaccine Preservative is Not Linked to Risks of Autism*, N.Y. TIMES, Jan. 8, 2008, at A18 (reporting on a study by California public health officials finding the autism rate in children rose continuously in the period from 1995 to 2007); see also Posting of Sanjay Gupta to Paging Dr. Gupta Blog, <http://www.cnn.com/HEALTH/blogs/paging.dr.gupta/2008/01/investigating-roots-of-autism.html> (Jan. 9, 2008, 10:53 EST) (“From 2004 to 2007, when exposure to thimerosal dropped significantly for 3-to 5-year-olds, the autism rates continued to go up . . .”).

attempting to replicate the original design of the United Kingdom study recently concluded there is strong evidence against a link between autism and the MMR vaccine.¹¹⁶

E. The Vaccine-Autism Controversy and the Vaccine Court

As the vaccine-autism debate gained traction in the public discourse, the Vaccine Court saw a rise in claims alleging that vaccines were responsible for autism.¹¹⁷ In fact, in the six-month period before the creation of the OAP over 300 cases were filed alleging a thimerosal-autism link.¹¹⁸ In July 2002, the Vaccine Court issued General Order #1 and announced it was adopting a special procedure—the OAP—to handle the rising number of autism claims that had been filed or were expected to be filed.¹¹⁹ Special Master George Hastings was selected to oversee the process.¹²⁰

The framework of the OAP differs in some respects from the statutory framework of the Vaccine Act described above. For instance, instead of adjudicating autism claims on a case-by-case basis, the OAP created a two-part procedure for conducting the inquiry into the causation issue. According to the Vaccine Court, the first part of the OAP would not evaluate the petition and supporting documentation in individual cases but instead “inquire into the *general causation issues* involved in these cases—*i.e.*, whether the vaccinations in question can cause autism and/or similar disorders,

116. Mady Hornig et al., *Lack of Association Between Measles Virus Vaccine and Autism with Enteropathy: A Case Control Study*, 3 PLOS ONE e3140 (2008), available at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0003140>.

117. See Autism General Order #1, *supra* note 7, at 1, 2002 WL 31696785, at *1 (noting “the influx of Program claims and the potential for many more such claims”). In addition, numerous civil lawsuits against vaccine manufacturers, alleging that thimerosal causes autism, were being filed in courts across the United States. *Id.* In general, the courts that received these cases dismissed them as a matter of law saying that such claims belonged in the Vaccine Court which had initial jurisdiction over the claims because injuries sustained from “thimerosal” were vaccine related under section 11(a) of the Vaccine Act. *E.g.*, Owens *ex rel.* Schafer v. Am. Home Prods. Corp., 203 F. Supp. 2d 748, 756 (S.D. Tex. 2002) (granting vaccine manufacturer’s motion to dismiss and recommending the plaintiffs proceed to the Vaccine Court).

118. Autism General Order #1, *supra* note 7, at 1, 2002 WL 31696785, at *1.

119. *Id.* The Chief Special Master added:

It is in the interests of all that the [Vaccine Court] aggressively, but fairly, manage this docket to ensure a timely presentation and resolution of the difficult medical and legal issues raised in these cases The court is confident that this procedure, coupled with the cooperative efforts and quality advocacy of counsel, will provide the necessary information for resolving these cases, within a reasonable time frame.

Id.

120. *Id.* at *3.

and if so in what circumstances.”¹²¹ In the second part of the OAP, the conclusions reached in the general causation inquiry will be applied to the individual cases.¹²² With respect to scheduling, the Vaccine Court departed from the 240/420 day time-period set out in section 12(g) of the Vaccine Act and instead laid out a two-year timeline to conduct the OAP which envisioned a discovery period,¹²³ an evidentiary hearing, and decision on the general causation issue to be handed down in the summer of 2004.¹²⁴

As it turned out, the OAP did not meet the schedule set out in General Order #1.¹²⁵ Indeed, much time after the creation of the OAP was devoted to sorting out procedural issues and conducting discovery.¹²⁶ Moreover, by the time the *Cedillo* hearing began in June 2007, the Vaccine Court had split the general causation inquiry into three separate theories,¹²⁷ and two additional special masters had been appointed to help with the general causation inquiry.¹²⁸ As of

121. *Id.*

122. *Id.*

123. The original schedule called for a 410-day period to conduct discovery. *Id.* at app. E.

124. *Id.* at *4. The court declared it expected that “the parties will act promptly and vigorously to *adhere* to this schedule, if not move more quickly.” *Id.* at *5. The Court further added that “the OSM and the presiding special master will strictly manage these proceedings in an effort to resolve the causation issues in less than the allotted two-year time period.” *Id.*

125. See Ruling Concerning Issue of Time at 3, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Aug. 11, 2005), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Ruling%20Concerning%20Issue%20of%20Time.pdf> (noting that the actual course of the OAP had “quite obviously” deviated from the initial schedule and stating that the discovery process has taken much longer than initially expected).

126. The discovery process was completed in early 2007, well over three years beyond the original timeline. See Autism Update-March 14, 2007, *supra* note 16, at 2 (“[W]e are very pleased to report that the production process was *completed* on February 12, 2007.”) (emphasis in original).

127. See *id.* at 5 (dividing evidence into three different theories “(1) that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism . . . (2) that MMR vaccines alone can cause autism, and (3) that thimerosal-containing vaccines alone can cause autism”). The three theories that will be heard are whether (1) MMR vaccines and thimerosal-containing vaccines can combine to cause autism; (2) that MMR vaccines alone can cause autism; and (3) that thimerosal containing vaccines alone can cause autism. *Id.* In September 2008, however, the Vaccine Court announced it was no longer necessary to hold hearings in third theory because it was not distinct in any way from the first two theories. Autism Update-September 29, 2008, *supra* note 17, at 3.

128. See Notice Regarding Reassignment, *supra* note 18, at 2 (explaining that with three special masters deciding the test cases all pertinent medical and legal issues will be thoroughly examined). There, Special Master Hastings wrote that:

To ensure that the Federal Circuit has the broadest perspective and clearest understanding of the issues presented to the special masters . . . the undersigned has decided, after much thought and discussion with the other special masters, to assign two additional special masters to hear and decide the issues presented in the test cases.

November 14, 2008, no decision had been issued in *Cedillo* or any other test case.

II. THE EARLY STAGES OF THE OMNIBUS AUTISM PROCEEDING

As highlighted above, the framework of the OAP represented a departure from how the Vaccine Court is generally structured to handle claims.¹²⁹ In fact, in the months following the creation of the OAP, the Vaccine Court faced challenges to the legality of the OAP and issued three decisions upholding its authority to process claims in this fashion. Namely, the Vaccine Court affirmed its jurisdiction over thimerosal claims, upheld the validity of “short-form petitions,” and modified its practice regarding issuing “decisions” to dissuade claimants from leaving Vaccine Court. While these decisions may have made practical sense in the short-term, they lay the foundation for problems that may arise in the aftermath of the OAP.

A. *The Vaccine Court Concludes it has Jurisdiction over Thimerosal*

One of the first decisions reached after the creation of the OAP was in *Leroy v. Secretary of Health & Human Services*.¹³⁰ The issue there was whether injuries resulting from thimerosal were “vaccine-related” and therefore whether such injuries properly belonged in the Vaccine Court.¹³¹ As discussed above, the Vaccine Court has jurisdiction only over those claims that allege a “vaccine-related” injury. The Vaccine Act defines the term “vaccine-related,” and that definition specifically excludes injuries resulting from an “adulterant or contaminant intentionally added” to a vaccine.¹³² In *Leroy*, Chief Special Master Golkiewicz¹³³ concluded that injuries from thimerosal were “vaccine-related,” and that the “thimerosal preservative in

Id. at 2.

129. See *supra* Part I.C (describing the statutory framework of the Vaccine Act).

130. No. 02-392, 2002 WL 31730680 (Fed. Cl. Oct. 11, 2002).

131. *Id.* at *1. In *Leroy*, the claimant argued that injuries caused specifically by thimerosal were not “vaccine-related” injuries and therefore could be brought initially in state or district courts. *Id.*

132. See 42 U.S.C. § 300aa-11(a)(1) (2006) (describing who may bring a suit and the procedures those plaintiffs must follow). The Vaccine Act states the term “vaccine related” does not include “an illness, injury, condition or death associated with an adulterant or contaminant intentionally added to such a vaccine.” *Id.* § 300aa-33(5).

133. The petition in *Leroy* was filed on April 24, 2002, about two months before the creation of the OAP, and assigned to Chief Special Master Golkiewicz. *Leroy*, 2002 WL 31730680, at *1. Special Master Hastings subsequently added the decision in *Leroy* to the autism master file. Ruling by the Chief Special Master in *Leroy v. Secretary of HHS* at 1, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Nov. 22, 2002), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Leroy%201.pdf>.

vaccines is not an ‘adulterant’ or ‘contaminant’ under [section] 33(5) of the Vaccine Act.”¹³⁴ Therefore, injuries resulting from thimerosal properly fell within the Vaccine Court’s jurisdiction.¹³⁵

The reasoning in *Leroy* is justified on a number of different grounds. The Chief Special Master grounded his ruling in common definitions of relevant statutory language,¹³⁶ congressionally stated Vaccine Act goals,¹³⁷ relevant scientific evidence,¹³⁸ and case law.¹³⁹ In particular, the Chief Special Master emphasized how thimerosal is actually the “antithesis” of an adulterant or contaminant because thimerosal is actually used to preserve vaccines in order to prevent against adulteration or contamination.¹⁴⁰ Further, the Chief Special Master showed that the ordinary meaning of “vaccine” would include preservatives because a vaccine is generally defined as a “suspension” or “preparation” composed of both micro-organisms and additional ingredients.¹⁴¹ Interestingly, shortly after *Leroy* was issued, Congress

134. *See Leroy*, 2002 WL 31730680, at *17 (declaring that “any injury or death arising from the thimerosal component is encompassed within the statutory definition”).

135. *See id.* (stating the petitioners are “obligated to either submit to this court’s jurisdiction for 240 days . . . or until a judgment is rendered, whichever occurs first”). The court further added that “petitioners alleging an injury or death from the thimerosal preservative in vaccines are statutorily obligated to file their claim against a manufacturer or administrator of the vaccine in the Court of Federal Claims, *in the first instance.*” *Id.*

136. *See id.* at *5 (“Applying accepted canons of statutory interpretation and following a review of common dictionary definitions of the terms ‘adulterant’ and ‘contaminant’, the court finds that a preservative is not an intentionally added ingredient of the vaccine meant to make impure, inferior, or contaminated the vaccine end product.”)

137. *See id.* at *10 (noting pending Vaccine Act legislation in Congress). The Chief Special Master added that Congress, not the Vaccine Court, has the power to exclude the thimerosal preservative from the scope of the Vaccine Act. *Id.*

138. *See id.* at *12 (relying on evidence from the FDA and the Institute of Medicine to conclude “pertinent evidence from the scientific community tends to refute petitioners’ claims that thimerosal is a separate entity of a vaccine or that it is an ‘adulterant’ or ‘contaminant’ within the meaning of the Vaccine Act”). Indeed, FDA regulations treat preservatives as a constituent part of vaccines, not as adulterants. *Id.*; see 21 C.F.R. § 610.15 (2007) (stating that “[p]roducts in multiple dose containers shall contain a preservative”).

139. *E.g.*, *Liu v. Aventis Pasteur, Inc.*, 219 F. Supp. 2d 762, 766 (W.D. Tex. 2002) (“[I]t appears every federal court to have ruled on the issue has held injuries resulting from thimerosal contained in vaccines are vaccine-related under the meaning of the Vaccine Act.”); *Owens ex rel. Schafer v. Am. Home Prods. Corp.*, 203 F. Supp. 2d 748, 755 (S.D. Tex. 2002) (opining that because the alleged injuries were linked to a vaccine ingredient, the injuries are necessarily vaccine-related). Both these opinions were cited in *Leroy* to buttress the argument that thimerosal is neither an adulterant nor a contaminant. 2002 WL 31730680, at *6.

140. *Leroy*, 2002 WL 31730680, at *7 (arguing that thimerosal actually prevents corruption of the vaccines and that vaccines “sold in multiple-dose vials indeed must” contain a preservative such as thimerosal) (citation omitted).

141. *See id.* at *8–9 (citing dictionaries to show how the ordinary usage of the term vaccine “strongly implies the inclusion of bacterium and additional ingredients”).

amended section 33 of the Vaccine Act, the section containing the definitions, to make sure thimerosal injuries were covered under the Act by narrowing the definition of “adulterant” or “contaminant,” and broadening the definition of “vaccine manufacturer” to include institutions that manufacture a component or ingredient of any vaccine.¹⁴² The amendments, however, were short-lived and repealed a few months later.¹⁴³ Legislative maneuvering aside, the main result of *Leroy* was that every potential claimant wanting to bring a thimerosal-vaccine claim was now obligated to go to the Vaccine Court instead of federal district court or state court.¹⁴⁴ Thus, because so many thimerosal claims were looming in the background, the Vaccine Court had to consider the administrative effect of the potential influx of thousands of autism claims.¹⁴⁵

B. *The Decision to Utilize Short-Form Petitions*

Shortly after the creation of the OAP, the Vaccine Court, through an Order issued by Chief Special Master Golkiewicz, announced that it would permit the filing of “short-form petitions” in the course of the OAP.¹⁴⁶ Such short-form petitions would not include the

142. Homeland Security Act of 2002, Pub. L. No. 107-296, §§ 1714–1717, 116 Stat. 2135, 2320–2321 (2002). For example, the definition of manufacturer was broadened to include institutions that manufacture “any vaccine set forth in the Vaccine Injury table, *including any component or ingredient of any such vaccine.*” *Id.* (emphasis added). Similarly, section 33(5) was amended by adding language stating that “an adulterant or contaminant shall not include any component or ingredient listed in a vaccine’s product license application or product label.” *Id.* The provision was attached to a large bill, and provides an interesting glimpse into federal lawmaking. See *Ferguson v. Aventis Pasteur, Inc.*, 444 F. Supp. 2d 755, 760–61 (E.D. Ky. 2006) (describing the legislative circumstances behind the Vaccine Act amendments); Sheryl Gay Stolberg, *A Capitol Hill Mystery: Who Aided Drug Maker?*, N.Y. TIMES, Nov. 29, 2002, at A35 (“[I]n a city where politicians have perfected the art of claiming credit for deeds large and small, not a single member of Congress—or the Bush administration—will admit to being the author of the [Eli] Lilly rider.”).

143. Consolidated Appropriations Resolution of 2003, Pub. L. No. 108-7, § 102(c), 117 Stat. 11, 528 (2003). The amendment noted, however, that it was a “non-prejudicial repeal” and specifically added that “[n]o inference shall be drawn” that this amendment “affects any change in that prior law, or that *Leroy v. Secretary of Health and Human Services* . . . was incorrectly decided.” *Id.*

144. See *Owens*, 203 F. Supp. 2d at 756 (holding that the plaintiffs “are required to file a [Vaccine Act] petition as a pre-requisite to filing any civil action seeking damages from the Vaccine Manufacturers for injuries to their children”).

145. See Autism General Order #1, *supra* note 7, at 1, 2002 WL 31696785, at *1 (noting the “influx of Program claims” and the potential for thousands more). Having such an influx would likely impose a hardship on the limited resources of the Vaccine Court, which is limited to no more than eight special masters. 42 U.S.C. § 300aa-12(c)(1) (2006).

146. See generally Discussion of Issue of Short-Form Petitions at 1-4, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. July 8, 2002), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism-ORD-20020708-Discussion%20of%20Short%20Forms.pdf>. According to the Vaccine Court, “[n]o

“affidavit[] and supporting documentation” listed in section 11(c) of the Act and instead would consist only of a claimant’s name and the statement that he is adopting the master autism petition for vaccine compensation.¹⁴⁷

A few months later, in *Stewart ex rel. Stewart v. Secretary of Health & Human Services*,¹⁴⁸ Special Master Hastings upheld the validity of “short-form petitions” under the terms of the Vaccine Act.¹⁴⁹ In that case, after a claim was filed using a “short-form petition,” the government moved to dismiss the claim arguing that because the short-form petition was not accompanied by an “affidavit[] and supporting documentation” it violated section 11(c) of the Vaccine Act.¹⁵⁰ Special Master Hastings rejected the government’s argument and relied on three main rationales to support his decision. First, he referenced “the history of the Program” to show that the government generally did not move to dismiss non-autism claims filed without medical records.¹⁵¹ Second, Special Master Hastings downplayed the language from section 11(c) of the Act defining what a petition is and what documents should accompany it;¹⁵² instead, he emphasized the discretion allotted to him under section 12(d), which provides that a special master can require the submission of evidence and other information that may be “reasonable and necessary.”¹⁵³ Finally, Special Master Hastings pointed to a change in the Rules of the Court

medical records need to be filed with such a short-form petition, though each petitioner or his counsel is encouraged to assemble, organize, and keep all relevant medical records so that they will be available for filing.” Autism General Order #1, at 7, 2002 WL 31696785, at *6.

147. A sample template of a short-form petition is available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf> (turn to page 11 of the PDF file).

148. No. 02-819V, 2002 WL 31965743, at *1 (Fed. Cl. Dec. 30, 2002).

149. *Id.* at *11.

150. *Id.* at *3.

151. *See id.* at *4 (“In a great many Program cases (probably a substantial majority) petitions have been filed with some medical records, but not all of those necessary for processing the case.”). In addition, Special Master Hastings criticized the government by commenting that:

[i]t is confusing to me how [the government] can take the position in this case that I have no discretion to do anything but dismiss the petition, but in other cases in which petitions were filed without medical records, [the government] *to this day* seems to have no objection to processing the cases.

Id. at *4 n.6.

152. *See id.* at *5 (“These provisions, thus, *specifically* give the special master broad discretion to determine the *timing* of submission of evidence in a Program proceeding, which evidence will nearly always include *medical records*.”).

153. *Id.* at *5 (citation omitted); *see also* 42 U.S.C. § 300aa-12(d)(3)(B) (2006) (noting that in conducting a proceeding on a petition a special master may require such evidence as may be reasonable and necessary).

of Federal Claims to show that he did not need to dismiss a petition filed without medical records.¹⁵⁴

The reasoning in *Stewart* is questionable for a number of reasons. For one, the opinion's criticism of the government's motion to dismiss is unfair because nothing in the Vaccine Act forces the government to take uniform positions when defending claims.¹⁵⁵ Furthermore, the opinion relies on incorrect logic because having discretion to order the filing of some "reasonable and necessary" records does not mean there is authority to control the filing of *all* records, especially when the later records are specifically enumerated in section 11(c), a provision of the Act that makes no mention of the special master's discretion.¹⁵⁶ In addition, it is possible the opinion amounts to an impermissible judicial modification of a federal statute inasmuch as the short-form petitions waive the requirements of section 11(c).¹⁵⁷ And finally, because as a waiver of sovereign immunity the terms of the Vaccine Act must be strictly construed, *Stewart* may be incorrect as a matter of statutory interpretation.¹⁵⁸

154. See *Stewart*, 2002 WL 31965743, at *5 ("[T]here is nothing in the statute or the rules of this court indicating that when a Program petition is filed without medical records, it must *automatically* be dismissed.").

155. See 42 U.S.C. § 300aa-13 (providing the guidelines for determining compensation and making no mention of whether the government is obligated to take uniform positions over time). More broadly, one principle of administrative law is that agencies are free to modify their legal positions regarding the statutes they administer. See *Bigelow v. Dep't of Def.*, 217 F.3d 875, 878 (D.C. Cir. 2000) (observing that an agency's litigation position need not represent some longstanding agency practice); *Mesa Verde Const. Co. v. N. Cal. Dist. Council of Laborers*, 861 F.2d 1124, 1146 (9th Cir. 1988) (Kozinski, J., dissenting) (noting that administrative agencies can "bend with the political winds" and that agencies "can change their outlook as often and easily as a chameleon changes its color").

156. Compare 42 U.S.C. § 300aa-12(d)(3)(B) (allowing the special master to order the filing of such documents that "may be reasonable and necessary"), with *id.* § 300aa-11(c) (describing specific documents that "shall" accompany a petition such as an "affidavit[]" and supporting documentation"). Moreover, the discretion mentioned in section 12(d)—the linchpin behind Special Master Hastings decision—is prefaced by the phrase "[i]n conducting proceedings *on a petition*" which necessarily incorporates the petition requirements expressly defined in section 11(c) of the Act. *Id.* § 300aa-12(d)(3)(B) (emphasis added).

157. Vaccine Court precedent and the Vaccine Rules make clear that special masters are not at liberty to change a statute enacted by Congress and further that they may only regulate matters not specifically provided for in the Vaccine Rules. See VACCINE R. FED. CL. 1 (noting the Chief Special Master is permitted to regulate the applicable practice only in matters not specifically provided for in the Vaccine Rules); *Greider v. Sec'y of Dep't of Health & Human Servs.*, 23 Cl. Ct. 348, 350 (1991) (declaring that special masters are "not at liberty to change a statute enacted by Congress. . . . [when] the language of the statute is crystal clear and it is supported by the legislative history, the court must defer to its clear meaning").

158. See *United States v. Nordic Vill.*, 503 U.S. 30, 33 (1992) (noting waivers of sovereign immunity should be construed strictly and in favor of the sovereign). Therefore, when section 11(c) of the Vaccine Act says a petition "shall" contain various supporting documentation, the obvious meaning is that these documents will

However, because neither party appealed the decision, the ruling stood and short-form petitions were allowed.

C. The Decision Not to Issue “Decisions”

While the Vaccine Act takes initial jurisdiction over “vaccine-related” claims, it provides two main ways to opt out of Vaccine Court before a special master issues a decision. First, under sections 12(g) and 21(b), a petitioner may withdraw from Vaccine Court if the special master has not made a decision on his petition in 240 days.¹⁵⁹ And second, under Rule 21 of the Vaccine Rules for the Court of Federal Claims, a petitioner may voluntarily dismiss his claim at any time without an order by the special master.¹⁶⁰

These opt out mechanisms provide a way for some petitioners to litigate their claims outside the Vaccine Court in either state or federal civil court. Indeed, some petitioners may prefer to litigate their vaccine claims in state court because there they would be able to obtain discovery documents from the vaccine manufacturers,¹⁶¹ be entitled to a jury trial (which might be more sympathetic given the nature of vaccine injury claims),¹⁶² and be eligible for greater damages awards.¹⁶³

In *Currie v. Secretary of Health & Human Services*,¹⁶⁴ Special Master Hastings concluded he would not issue “decisions” to claimants who elect to withdraw from the Program pursuant to Vaccine Rule 21.¹⁶⁵ Special Master Hastings did this to indicate that petitioners who left

be provided at the time of filing and not at some subsequent point further in the litigation. *Cf.* *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984) (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”).

159. 42 U.S.C. § 300aa-12(g)(1).

160. *See* VACCINE R. FED. CL. 21 (providing for the voluntary dismissal option).

161. Discovery documents from vaccine manufacturers were largely denied to plaintiffs in the course of the OAP. *See supra* note 24 (providing examples of various discovery requests that were denied).

162. The Vaccine Act does not provide for jury trials; the special master makes both findings of fact and conclusions of law. *See* 42 U.S.C. § 300aa-12(d) (describing one of the duties of the special masters as issuing findings of fact). *But see generally* *Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318 (Kan. 1986) (reversing a jury award of ten million dollars to a person injured by a vaccine in state court).

163. The Vaccine Act caps pain and suffering awards at \$250,000 and does not allow for punitive damages. 42 U.S.C. § 300aa-15(a)(2). By contrast, many jury verdicts result in compensatory and punitive damages awards far greater than the statutory amount set in the Vaccine Act. *Johnson*, 718 P.2d at 1320; W. Kip Viscusi, *The Blockbuster Punitive Damages Awards*, 53 EMORY L.J. 1405, 1428 tbl.1 (2004) (surveying sixty-four instances of juries awarding \$100 million or more in punitive damages).

164. No. 02-838V, 2003 WL 23218074, at *1 (Fed. Cl. Nov. 26, 2003).

165. *Id.* at *5.

the OAP by voluntarily dismissing their claims would still be barred from filing a civil claim because they did not meet the “judgment” requirement set forth in section 11(a).¹⁶⁶ Rather than issue a “decision,” Special Master Hastings declared he would issue either an Order Dismissing the Vaccine Petition or an Order Concluding Proceedings on the Merits.¹⁶⁷ Under this system, the clerk of the Court of Federal Claims was instructed not to enter a judgment on the claim.

As Special Master Hastings recognized, the decision in *Currie* does not completely foreclose filing a civil action after withdrawing from Vaccine Court.¹⁶⁸ Indeed, a close reading of section 11(a) establishes two mandatory requirements and one either/or requirement that must be met before commencing a civil action outside the Vaccine Court.¹⁶⁹ The two mandatory requirements are that a plaintiff (1) files a petition (2) in accordance with section 16 of the Vaccine Act.¹⁷⁰ In addition, a petitioner must show *either* (1) that the Court of Federal Claims issued a judgment on the petition and that judgment was subsequently rejected *or* (2) he withdrew the petition under section 21(b).¹⁷¹ Therefore, in light of the second permissive option available under section 11(a), the plaintiff may still withdraw under section 21(b) of the Vaccine Act and be able to commence a civil action.¹⁷²

166. Under section 12(e)(3) of the Vaccine Act, the special master’s “decision” triggers the issuance of a judgment. 42 U.S.C. § 300aa-12(e)(3).

167. *Currie*, 2003 WL 23218074, at *5.

168. *See id.* at *4 (indicating that Congress’s intent was that petitioners at least wait out the 240-day period before being authorized to withdraw from the Vaccine Act and commence a civil action).

169. 42 U.S.C. § 300aa-11(a)(2).

170. *Id.* § 300aa-11(a)(2)(A).

171. *Compare id.* § 300aa-11(a)(2)(A)(i) (permitting withdrawal if the Court of Federal Claims has issued a judgment under section 12 and the claimant elects to withdraw under section 21(a)), *with id.* § 300aa-11(a)(2)(A)(ii) (permitting withdrawal if such a person elects to withdraw such a petition under section 21(b)). Moreover, Special Master Hastings expressly acknowledged the Vaccine Act is designed to allow petitioners to leave Vaccine Court without ever obtaining a judgment. *See Stewart ex rel. Stewart v. Sec’y of Health & Human Servs.*, No. 02-819V, 2003 WL 22300298, at *13–14 (Fed. Cl. Sept. 3, 2003) (discussing how a petitioner may use section 21 to treat the Vaccine Court “as a 240-day delay before filing a tort suit” and that Congress “certainly understood that such a scenario might take place”).

172. Indeed, under section 21(b)(2) a petitioner may withdraw from the Vaccine Court if “the court fails to enter a judgment under section 300aa-12 of this title on the petition within 420 days” excluding time for suspension and time on remand. 42 U.S.C. § 300aa-21(b)(2); *see also Stewart*, 2003 WL 22300298, at *14 (noting a petitioner who withdraws after 240 days using section 21 “would still undoubtedly be free to file his tort suit”).

III. POTENTIAL PROBLEMS IN THE AFTERMATH OF THE OMNIBUS AUTISM PROCEEDING

As demonstrated above, there are several statutory twists and turns in section 11(a) of the Vaccine Act that govern the ability of claimants to leave Vaccine Court and pursue civil actions. Interestingly, when these provisions combine with the three decisions discussed above, as well as the length of time it has taken to conduct the OAP, the results could be problematic for petitioners looking to leave the Vaccine Court and file a civil claim. Indeed, as explored below, a scenario could develop where a plaintiff withdraws from the OAP intending to file a civil lawsuit but is barred from doing so because of two unmet requirements from section 11(a). Namely, the plaintiff never filed a “petition” under the Vaccine Act and further he never did so “in accordance with” section 16 of the Vaccine Act.¹⁷³ Further, if the plaintiff is sent back to Vaccine Court to exhaust his remedies there, the claim may even be dismissed by the Vaccine Court because it is either time-barred under the Vaccine Act’s statute of limitations, or in violation of section 11(b)(2) of the Vaccine Act, which limits claims to one petition per vaccine.¹⁷⁴ The following illustration shows how this might happen.

Consider the following hypothetical series of events. Parents of a child diagnosed with autism hear about the Vaccine Act and file a claim for vaccine compensation in Vaccine Court on September 1, 2002, and enter into the OAP.¹⁷⁵ Because of the decision in *Leroy*, they file the claim in Vaccine Court rather than in state or federal district court.¹⁷⁶ Further, relying on the reasoning and procedure set forth in General Order #1 and the decision in *Stewart*, they elect to utilize a short-form petition and do not submit any medical records.¹⁷⁷

173. See 42 U.S.C. § 300aa-11(a)(2) (setting forth the requirements that must be met before filing a civil action outside Vaccine Court).

174. See *infra* Part III.D (providing a hypothetical to demonstrate how a plaintiff might be prevented from re-entering the Vaccine Court).

175. Indeed, there was a surge of short-form petitions filed in the OAP in the aftermath of General Order #1. Compare Autism General Order #1, *supra* note 7, at 2, 2002 WL 31696785, at *2 (noting that more than 400 cases were filed as of July 2002), with *Stewart*, 2003 WL 22300298, at *3 (noting that more than 2500 short-form petitions had been filed by August 2003). Also, assume for the purposes of this scenario that the first symptoms and ultimate diagnosis of autism all occurred in 2002, therefore making the claim timely filed in light of section 16(a)(2) of the Vaccine Act.

176. See *Owens ex rel. Schafer v. Am. Home Prods. Corp.*, 203 F. Supp. 2d 748, 759 (S.D. Tex. 2002) (stating that claims against vaccine manufacturers fall squarely within the jurisdiction of the Vaccine Court).

177. Moreover, on several occasions throughout the OAP they are not told to file medical records by the court. *E.g.*, Autism Update-January 17, 2008, *supra* note 17, at 3 (emphasizing that the Vaccine Court is still not instructing all petitioners in the

Then, although concerned that the OAP is moving very slowly through the discovery process,¹⁷⁸ the family decides not to withdraw from the OAP due to the fear they will be barred from a subsequent civil action under the opinion in *Currie*.¹⁷⁹ More than six years pass as their claim languishes in the OAP while the Vaccine Court oversees discovery, receives expert reports, and hears *Cedillo* and the other test cases.¹⁸⁰ Moreover, throughout this time the family is repeatedly told by the Vaccine Court they do not need to file medical records.¹⁸¹ Then, perhaps sometime in the fall of 2008, imagine *Cedillo* is decided in favor of the government. At this point, now more than six years after filing their short-form petition, the plaintiffs decide they are sufficiently frustrated with the Vaccine Court and elect to withdraw their petition under section 21(b) of the Vaccine Act.¹⁸² A

OAP to file medical records). The rationale for this is that the petitioners' steering committee was in process of developing the scientific case over the general causation inquiry. See Ruling Concerning Issue of Time for Filing Expert Reports at 7, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Aug. 11, 2005), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Ruling%20Concerning%20Issue%20of%20Time.pdf> ("I see no reason not to let these petitioners keep their petitions pending.").

178. The discovery process took over four years to complete. See Autism Update-March 14, 2007, *supra* note 16, at 2 ("[E]fforts to produce material proceeded slowly . . . but we are now very pleased to report that the production process was completed on February 12, 2007."). Interestingly, according to one of the lawyers representing the petitioners, the discovery documents that were ultimately obtained were "a haystack without a needle—useless." Mauro, *supra* note 2.

179. See *Currie v. Sec'y of Health & Human Servs.*, No. 02-838V, 2003 WL 23218074, at *4 (Fed. Cl. Nov. 26, 2003) ("It would certainly seem to contravene the Congressional intent [of the Program] if a party could file a petition, voluntarily dismiss it the next day, and receive a 'judgment' that would entitle the party to then file a civil action against a vaccine manufacturer or administrator.").

180. For some insight into the delays encountered in the early stages of the OAP, see Ruling Concerning Issue of Time for Filing Expert Reports, *supra* note 177, at 3–4. There, Special Master Hastings attributed some of the delays in the OAP to the petitioners' "very extensive initial request for production of materials from government files, and later an extensive second request." *Id.* at 3. Also accounting for some of the delay was the government's "lengthy and cumbersome procedure involving review of the [discovery documents] (1) by FDA personnel, (2) by Department of Justice personnel, and (3) by personnel of the vaccine manufacturer that originally submitted the material for the license application." *Id.* at 4.

181. See Autism General Order #1, *supra* note 7, at 7, 2002 WL 31696785, at *6 ("No medical records need be filed with such a short-form petition . . ."); Autism Update-January 17, 2007, *supra* note 117, at 3 ("We again stress that at this time we will NOT be ordering records to be filed in ALL of the pending autism cases."). More recently, the special masters are selecting about 200 petitioners per month and asking them to file medical records; however the special masters are not requiring records to be filed in all pending OAP cases. See Autism Update-March 27, 2008, *supra* note 111, at 3–4 (discussing the process for submitting medical records but emphasizing that not all petitioners are required to submit records).

182. Indeed, it is entirely possible that no action will have been taken on plaintiffs' short-form petition, despite it sitting in the OAP for over six years. The Cedillos, for instance, filed their claim in 1998 and waited almost a decade for a hearing. Mauro, *supra* note 2; see also Wacek, *supra* note 106, at 326 ("The 'hurry up and wait' nature

short time later they initiate a civil action directly against a vaccine manufacturer by filing a complaint in state or federal district court.¹⁸³

If this scenario—which is likely given indications made by lawyers involved in the OAP¹⁸⁴ as well as the limited money available in the vaccine trust fund¹⁸⁵—transpires, these hypothetical plaintiffs can expect to encounter several problems with their civil action because they have not exhausted their options under the Vaccine Act.¹⁸⁶ First

of these vaccine/autism cases leaves parents in an uncomfortable dilemma because on one hand, their own attorneys [were] asking for time to compile scientific evidence that should be favorable to their clients; and on the other hand, these parents often need immediate relief to help pay for the medical costs of caring for their autistic children.”).

183. This portion of the scenario would work equally well if the plaintiffs prevail in any of the test cases before the Vaccine Court. For instance, a plaintiff may want to leverage a favorable decision from the Vaccine Court in a subsequent civil action where he may have different legal rights than in Vaccine Court. *See supra* notes 161–163 (discussing the differing treatment plaintiffs receive in Vaccine Court when compared to typical civil actions). Moreover, because his claim will have been pending for far more than 240 days, he will be entitled to withdraw under sections 12(g) and 21(b) withdrawal mechanism, and further according to the analysis above he will not be barred by not having a judgment. *See supra* Part II.C (describing why the decision in *Currie v. Sec’y of Health & Human Servs.*, 2003 WL 23218074, at *1 (Fed. Cl. Nov. 26, 2003) leaves open the option of filing a civil action).

184. Indeed, statements from several attorneys involved in the autism litigation indicate strong interest in bringing claims in civil court in the aftermath of the OAP. *See* Myron Levin, *Taking it to Vaccine Court*, L.A. TIMES, Aug. 7, 2004, at A24 (quoting Kevin Conway, a lawyer representing numerous OAP petitioners, saying vaccine “companies ‘are terrified’ of huge jury awards”); Kay Lazar, *Parents Seeking Dose of Precaution on Vaccines Urge Banning Use of Mercury*, BOSTON GLOBE, July 31, 2005, at 8 (quoting Jan Schlichtmann, a prominent trial attorney, saying “what goes into vaccines is of great interest to me”); Young, *supra* note 110, at A14 (quoting a lawyer representing several families saying the government’s concession of liability was “potentially explosive”). Furthermore, as far back as 2002, a Justice Department attorney involved in the OAP characterized one of the petitioners’ filings as an attempt to gain “enhanced rights in a subsequent civil action.” Todd Zwillich, *U.S. Government Asks Court to Seal Vaccine Records*, REUTERS HEALTH, Nov. 26, 2002, <http://www.whale.to/a/vacc.html>.

185. Simple calculation demonstrates that there is currently not enough money in the Vaccine Trust Fund to compensate the approximately 4900 claims should the special masters find in their favor. For example, government data shows there is currently \$2.5 billion in the trust and further that the average award paid out under the Vaccine Act is more than \$848,000. NATIONAL VACCINE INJURY COMPENSATION PROGRAM, *supra* note 90. Therefore, assuming each of the 4900 claims receives an award equal to the average payment of \$848,000, the total would come to more than \$4.2 billion dollars, far beyond the amount currently available in the vaccine trust fund. Moreover, because the cost of caring for someone with autism over their entire life is far more than \$848,000, it seems the \$4.2 billion liability figure could be a very low estimate. *See supra* note 103 (drawing on data suggesting it takes about \$3.2 million to care for a single person with autism over their lifetime). Thus, there may be added incentive to bring a civil claim against a vaccine manufacturer, who has more assets than the Vaccine Trust Fund. *E.g.*, Aaron Smith, *Merck Profit Strong, Sales Weak*, CNN, Apr. 21, 2008, <http://money.cnn.com/2008/04/21/news/companies/merck/?postversion=2008042108> (reporting the drug maker and vaccine manufacturer Merck earned \$3.3 billion in the first quarter of 2008).

186. In fact, because a number of the approximately 4900 vaccine claimants are acting in a pro se capacity, it is entirely possible the legal nuances of sections 11, 16,

of all, the plaintiffs never filed a “petition” as that term is specifically defined in section 11(c) of the Vaccine Act.¹⁸⁷ And second, they did not file their claim in Vaccine Court “in accordance with” section 16 of the Vaccine Act.¹⁸⁸ Moreover, because any due process or equal protection claims the plaintiffs might raise are unlikely to succeed, the court entertaining the civil action will have no choice but to dismiss the plaintiffs’ claim for lack of jurisdiction.¹⁸⁹ Finally, if the plaintiffs decide to re-enter Vaccine Court, they may be prevented from doing so because their claims are either prohibited by the one petition rule in section 11(b)(2) or made untimely under the Vaccine Act’s statute of limitations.¹⁹⁰

A. *The Plaintiffs Never Filed a “Petition” Under Section 11 of the Vaccine Act*

As discussed above, in order to properly leave the Vaccine Court, and thereby free themselves to file a civil action, the plaintiffs will need to meet the requirements of section 11(a) of the Vaccine Act.¹⁹¹ The first requirement is that plaintiffs cannot file a civil claim against a vaccine manufacturer unless they first file a “petition” in the Vaccine Court.¹⁹² With the decision in *Stewart* in mind, one likely defense a defendant-manufacturer may raise is that the plaintiffs’

and 21 of the Vaccine Act may slip past them. *See Heston ex rel. Heston v. Sec’y of Health & Human Servs.*, 41 Fed. Cl. 41, 46 (1998) (“It is the experience of this court that *petitioners under the Vaccine Act often are unfamiliar with litigation and have little experience with attorneys.*”) (emphasis added); *see also Turpin ex rel. Turpin v. Sec’y of Health & Human Servs.*, No. 99-564V, 2005 WL 1026714, at *2 (Fed. Cl. Feb. 10, 2005) (“Due to the complex nature of the Vaccine Act’s statutory scheme, this Court encourages *pro se* petitioners to seek legal representation.”); *Flores v. Sec’y of Health & Human Servs.*, 52 Fed. Cl. 294, 298 n.3 (2002) (“The court hopes that based on this opinion, the *pro se* petitioner can more fully understand the decisions reached by the court and the special master.”). Even experienced attorneys sometimes struggle with the contours of the Vaccine Act. *See Ray v. Sec’y of Dep’t of Health & Human Servs.*, No. 04-184V, 2006 WL 1006587, at *10 (Fed. Cl. Mar. 30, 2006) (lamenting certain “lapses in performance” with respect to an attorney with ample Vaccine Act experience).

187. 42 U.S.C. § 300aa-11(c) (2006).

188. *Id.* § 300aa-16.

189. *See Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94–95 (1998) (discussing the importance of addressing jurisdiction before proceeding to the merits of a case).

190. *See infra* Part III.D (discussing barriers plaintiffs would face trying to return to the Vaccine Court).

191. *See* 42 U.S.C. § 300aa-11(a)(2) (requiring the plaintiff to first file a petition in accordance with section 16 and then receive a judgment under section 12 before being able to properly leave the Vaccine Court); *see also supra* notes 167–172 and accompanying text (describing the impediments to a civil action imposed by section 11(a) of the Vaccine Act).

192. *See* 42 U.S.C. § 300aa-11(a)(2)(A) (“No person may bring a civil action . . . unless a petition has been filed.”).

claim must be dismissed because a “short-form petition” is not a “petition” under the Vaccine Act—meaning the state or federal court does not have jurisdiction to hear the claim.

Challenging the validity of short-form petitions might be an appealing and persuasive legal argument from the perspective of a vaccine manufacturer. Indeed, even Chief Special Master Golkiewicz recognized that short-form petitions contain far less information than traditional petitions.¹⁹³ For example, even when completely filled out, short-form petitions do not contain an affidavit and make no mention of the type of vaccine received, when or where the vaccine was received, or the timing or onset of any medical symptoms.¹⁹⁴ This falls far short of the specific definition of “petition” in section 11(c) of the Vaccine Act, namely that a petition “shall” be accompanied by an “affidavit[] and supporting documentation” which must include an assortment of medical documents, such as pre- and post-injury physician records and doctor’s notes.¹⁹⁵ Similarly, the Rules of the Court of Federal Claims make clear that Vaccine Act petitions “shall” be filed with medical records.¹⁹⁶ As such, the utter lack of required medical documentation is one reason to suggest a short-form petition is not technically a petition filed under section 11(c) of the Vaccine Act.¹⁹⁷

Furthermore, challenging the validity of short-form petitions could draw support from a variety of other legal sources. For instance, casting doubt upon the adequacy of short-form petitions would align with the interpretation of the Vaccine Act the government set forth in its briefs filed in *Stewart*. There, referring to the petition

193. See Discussion of Issue of Short-Form Petitions, *supra* note 146, at 1, (“The short-form petition would not contain a detailed account of the relevant vaccinations and the history of the vaccinee’s disorder, nor would it be accompanied by the medical records of the vaccinee’s injury.”).

194. For an analysis of a short-form petition compared to a regular petition, see *infra* note 197 and accompanying text.

195. See 42 U.S.C. § 300aa-11(c) (listing medical records that “shall” accompany a petition).

196. See VACCINE R. FED. CL. 2(e) (noting that every petition “shall” be accompanied by the records described in section 11(c) of the Vaccine Act).

197. Compare Sample Short Form Petition, available at <http://www.uscfc.uscourts.gov/OSM/Autism/Autism%20General%20Order1.pdf> (turn to page 11 of the PDF file), with 42 U.S.C. § 300aa-11(c) (stating that a petition “shall contain . . . an affidavit[] and supporting documentation . . . [including] maternal prenatal and delivery records, newborn hospital records (including all physicians’ and nurses’ notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results”).

requirements in section 11(c), the government argued that “the law is clear petitions must be filed with an affidavit and supporting documentation” and the “short form petition clearly does not meet this statutory requirement.”¹⁹⁸ It is well established that an executive agency’s interpretation of the statute it is entrusted to administer constitutes a body of expertise and informed judgment and may be entitled to some respect.¹⁹⁹ Indeed, even a government legal brief is eligible for some form of deference.²⁰⁰ Furthermore, neither state nor federal district courts are bound by decisions reached by special masters and therefore are not obliged to follow the decision in

198. Order Placing Additional Filings of Respondent Concerning *Stewart* into Master File at 6, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Oct. 20, 2003), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Order%20Placing%20More%20of%20Respondents%20Stewart%20Filings%20into%20Master%20File.pdf>. The government also argued that because short-form petitions do not oblige the petitioners to identify the vaccine received, when it was received, or the nature or timing of the onset of symptoms, they do not permit the Court to make even threshold determinations regarding its jurisdiction. *See id.* at 4–5 (citing a copy of the respondent’s motion to dismiss); *see also* Order Placing Respondent’s Filings Concerning *Stewart* Into Master File at 4, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Oct. 8, 2003), available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Order%20Placing%20Respondents%20Stewart%20Filings%20into%20Master%20File.pdf> (arguing that a proceeding for compensation under the Vaccine Act “shall be initiated” by the filing of a petition containing the matter prescribed by subsection (c)).

199. *See* *Christensen v. Harris County*, 529 U.S. 576, 591 (2000) (“What we said in a case involving an agency’s interpretation of its own regulations applies equally, in my view, to an agency’s interpretation of its governing statute . . .”); *see also* *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001) (observing that the views of an Administrator of a program “constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance”) (citation omitted); *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (“We have long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer.”).

200. *See* *Wax v. Aventis Pasteur Inc.*, 240 F. Supp. 2d 191, 194 (E.D.N.Y. 2002) (“[T]he court defers, for the purposes of this motion, to [the government’s] interpretation that injuries caused by thimerosal are ‘vaccine-related’ for the purposes of the Program.”); *see also* *Auer v. Robbins*, 519 U.S. 452, 462 (1997) (“Petitioners complain that the Secretary’s interpretation comes to us in the form of a legal brief; *but that does not . . . make it unworthy of deference.*”) (emphasis added); *United Seniors Ass’n Inc. v. Shalala*, 182 F.3d 965, 971 (D.C. Cir. 1999) (“Even if the legal briefs contained the first expression of the agency’s views, under the appropriate circumstances we would still accord them deference so long as they represented the agency’s ‘fair and considered judgment on the matter.’”); *Nat’l Wildlife Fed’n v. Browner*, 127 F.3d 1126, 1129 (D.C. Cir. 1997) (“The mere fact that an agency offers its interpretation in the course of litigation does not automatically preclude deference to the agency.”). *But see* *Thomas W. Merrill & Kristen E. Hickman, Chevron’s Domain*, 89 *GEO. L.J.* 833, 901 (2001) (noting that the Supreme Court’s rationale for *Chevron* clearly precludes giving *Chevron* deference to interpretations that are post-hoc rationalizations of agency counsel such as agency briefs.)

Stewart.²⁰¹ And finally, even if the court entertaining the civil lawsuit is unfamiliar with the Vaccine Act regime, determining whether or not something is a “petition” is a straightforward legal inquiry requiring only the comparison of a definitional component of the Vaccine Act with a sample short-form petition.²⁰²

Thus, in the scenario described above, the hypothetical plaintiffs, as well as any other plaintiff who has used a short-form petition in the OAP and is looking to file a civil action, may run into a considerable obstacle if a manufacturer defendant challenges the validity of a short-form petition.

B. The Plaintiffs Have Not Filed a Petition “in Accordance with” Section 16 of the Vaccine Act

Even assuming the state or federal court determines that a short-form petition is indeed a “petition” under the Act, the hypothetical plaintiffs are not yet out of the woods because they must still meet the second requirement of section 11(a) of the Vaccine Act. That requirement states that plaintiffs cannot file a civil action unless they previously filed their petition in Vaccine Court “in accordance with” section 16 of the Vaccine Act.²⁰³ Section 16 is the statute of limitations component of the Vaccine Act and states in relevant part that “no petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.”²⁰⁴ Again,

201. See *Wax*, 240 F. Supp. 2d at 194 (stating that federal district courts are not bound by decisions of special masters). Moreover, because the decision upholding short-form petitions is a *legal* and not *factual* determination, any reviewing court would owe it a reduced level of deference. See *Bradley v. Sec’y of Dep’t of Health & Human Servs.*, 991 F.2d 1570, 1574 (Fed. Cir. 1993) (“[T]he Claims Court judge reviews the special master’s decision essentially for legal error”); see also *Rasul v. Myers*, 512 F.3d 644, 654 (D.C. Cir. 2008) (“We review the district court’s legal conclusions *de novo*.”). Further, when district courts appoint masters under the Federal Rules of Civil Procedure, a district court would review the special master’s findings the same way an appellate court would review a district court’s findings. See *Cook v. Niedert*, 142 F.3d 1004, 1010 (7th Cir. 1998) (declaring that when reviewing a decision of a special master “the general rule is that the district court steps into the shoes of an appellate court and employs the same standards that an appellate court uses to review a lower court opinion.”). The U.S. Court of Appeals for the Seventh Circuit noted a district court would review a special master’s legal decision *de novo*. *Id.*

202. Indeed, courts have shown familiarity understanding and interpreting the provisions of the Vaccine Act. See *Doe v. Bayer Corp.*, 367 F. Supp. 2d 904, 909–10 (M.D.N.C. 2005) (offering a full and detailed description of the Vaccine Act and OAP); see also *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2–3 (1st Cir. 1994) (describing the legislative history, regulatory structure, and modifications to state tort law imposed by the Vaccine Act).

203. 42 U.S.C. § 300aa-11(a)(2) (2006).

204. *Id.* § 300aa-16(a)(2).

because a short-form petition contains no information that would allow the Vaccine Court to determine whether a claim was timely filed, another argument a defendant in a civil action may raise is that the Vaccine Court never determined whether the claim was timely filed and therefore the plaintiffs never filed a petition “in accordance with” section 16 of the Vaccine Act.²⁰⁵

Returning to the hypothetical scenario, if the only record the plaintiffs have filed in the Vaccine Court is a short-form petition, it would be difficult for the state or district court to conclude that this claim was filed in accordance with section 16 of the Vaccine Act. Indeed, because the short-form petition does not contain *any* medical information, a court cannot ascertain whether the claim was timely filed because there are no medical records upon which to base the decision.²⁰⁶ Moreover, even if the plaintiffs file medical records in the state or district court, determining when the “first symptom or manifestation of the onset of injury” occurred, especially in the context of a mysterious disease like autism which develops “insidiously over time,” is exceedingly difficult.²⁰⁷ Further, because the phrases “first symptom” and “manifestation of onset” of symptoms

205. See *Reilly ex rel. Reilly v. Wyeth*, 876 N.E.2d 740, 751–52 (Ill. App. Ct. 2007) (noting that “this language clearly and unambiguously prohibits both an action and a remedy in state or federal court *unless there has been a timely filing with the [Vaccine] court.*”) (emphasis added); see also *Strauss v. Am. Home Prods. Corp.*, 208 F. Supp. 2d 711 (S.D. Tex. 2002) (noting that a late filing in Vaccine Court does not translate into freedom to sue in civil court); *McDonald v. Lederle Labs.*, 775 A.2d 528, 532–33 (N.J. Super. Ct. App. Div. 2001) (finding a failure to file timely a Vaccine Act petition bars pursuit of a state tort action for vaccine related injury).

206. See Discussion of Issue of Short-Form Petitions, *supra* note 146, at 2–3 (according to the reasoning of Chief Special Master Golkiewicz, plaintiffs would be adopting the master petition autism petition and thereby alleging their claim was timely).

207. *Setnes ex rel. Setnes v. United States*, 57 Fed. Cl. 175, 181 (2003). The court in *Setnes* underscores the difficult issues involved in determining when the first symptom or manifestation of onset of first symptom occurs in autism cases. For instance, under medical standards it is possible to equate routine early childhood behaviors such as humming, babbling, kicking or screaming as manifestations of the onset of autism and therefore begin the running of the statute of limitations when a child is very young; however, the court in *Setnes* held that the claimant’s autism did not become manifest until the phrase “concern for [pervasive development disorder]” was noted in the records. *Id.* at 181; see also Discussion of Issue of “Short-Form” Petitions, *supra* note 146, at 3 (“[T]o determine when the first symptom of an autistic disorder occurred is a question of fact that might be quite complex in many cases.”) (emphasis added); *infra* note 209 (describing expertise of special masters). The Federal Circuit recently provided some clearer guidance as to how to determine when the first symptom or manifestation of onset occurs. See *Markovich v. Sec’y of Health & Human Servs.*, 477 F.3d 1353, 1360 (Fed. Cir. 2007) (holding that the first symptom or manifestation of onset for the purpose of the statute of limitations period is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large).

have different legal meanings,²⁰⁸ the decision whether a claim was filed in accordance with section 16 may be best left to the expertise of the Vaccine Court.²⁰⁹ Thus, in light of these factors, a manufacturer in a civil action may well put forth the argument that petitioners who filed a short-form petition never filed a petition in accordance with section 16 of the Vaccine Act.

As this discussion has indicated, although the court that receives the first civil action arising in the aftermath of *Cedillo* may be eager to examine the compelling scientific and medical issues relating to the cause of autism, it must first ensure it has proper jurisdiction over the claim. Thus, if that court accepts either of these jurisdictionally based arguments, it will have no choice but to dismiss the civil claim with instructions for the plaintiffs to re-file in the Vaccine Court to exhaust their administrative remedies there.²¹⁰ Accordingly, going back to the hypothetical plaintiffs, in what would be a strange but plausible outcome, a state or federal court may find that despite waiting over six years in the OAP, these plaintiffs have *still* not complied with their administrative exhaustion requirements under the Vaccine Act and instruct them to return to Vaccine Court.²¹¹

C. A Constitutional Challenge to the Omnibus Autism Proceeding is Unlikely to Succeed

Before deciding to return to the Vaccine Court, the hypothetical plaintiffs may consider raising a constitutional challenge to the OAP in the state or federal court. Indeed, one likely argument the plaintiffs might advance is that the OAP deprives them of due process because it limits their opportunity to be heard and also deprives them

208. See *Markovich*, 477 F.3d at 1357 (“A symptom may be indicative of a variety of conditions or ailments A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury.”).

209. See *Sword v. United States*, 44 Fed. Cl. 183, 188 (1999) (observing that “even more than ordinary fact-finders,” the special masters have a “unique ability . . . to adjudge cases in light of their own acquired specialized knowledge and expertise”); see also *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (“Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims.”).

210. See *Reilly*, 876 N.E.2d at 751 (finding the language of the Vaccine Act unambiguously prohibits both an action and a remedy in state or federal court unless there has been a timely filing with the Vaccine Court); see also *Dickey v. Connaught Labs., Inc.*, 777 N.E.2d 974 (Ill. App. Ct. 2002) (same).

211. *Accord Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995) (explaining that a plaintiff must exhaust the Vaccine Act’s procedures before filing a de novo civil action in state or federal court).

of their right to bring a tort claim.²¹² Alternatively, they might argue that the Vaccine Act's statute of limitations violates their right to equal protection because it necessarily treats autism differently from other injuries. Because the onset of autism is less dramatic and far more subtle than the onset of other illnesses covered by the Vaccine Act such as encephalopathy or anaphylactic shock,²¹³ the petitioners may have less notice that the statute of limitations on their claim is running.²¹⁴ While these may appear to be plausible legal arguments, the legal framework under which a court analyzes a constitutional challenge to the Vaccine Act, as well as jurisprudence from previous challenges to the Act, suggests these sorts of legal challenges are unlikely to succeed.

As an initial matter, the Vaccine Act is reviewed using a "rational basis" standard.²¹⁵ This is the case because the Act is a federally provided compensation scheme, because it does not implicate any fundamental rights, and because it does not discriminate on the basis of race or gender.²¹⁶ Generally, federal statutes evaluated under this standard are deemed constitutional if there is any reasonably conceivable set of facts that could provide a rational basis to support the statute.²¹⁷ Moreover, in the area of social welfare, a statute does

212. See *Hamdi v. Rumsfeld*, 542 U.S. 507, 533 (2004) ("Parties whose rights are to be affected are entitled to be heard; and in order that they may enjoy that right they must first be notified."); *Matthews v. Eldridge*, 424 U.S. 319, 333 (1976) ("The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful matter.'").

213. See 42 C.F.R. § 100.3(a) (2007) (providing a Vaccine Injury Table that shows for the MMR vaccine, the time period for anaphylactic shock is only four hours and the time period for encephalopathy is five to fifteen days).

214. See *supra* note 206 (discussing the difficulties in determining the symptoms or onset of autism or other pervasive development disorders).

215. Under a rational basis review, the court is required to compare the content of a statute to its purported purpose, and to determine whether the law constitutes a reasonable means of accomplishing a legitimate end or purpose of state government. See, e.g., *U.S.A. Baseball v. City of New York*, 509 F. Supp. 2d 285, 295 (S.D.N.Y. 2007) (finding that a city ordinance preventing the use of metal baseball bats by high school students "has a rational relationship to the legitimate purpose of protecting the public safety . . . and therefore the ordinance does not fail").

216. See *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 787 (Fed. Cir. 1996) ("[T]he Vaccine Act does not implicate any 'fundamental right,' for a 'non-contractual claim to receive funds from the public treasury enjoys no constitutionally protected status."); *Blackmon v. Am. Home Prods. Corp.* 328 F. Supp. 2d 647, 656 (S.D. Tex. 2004) (indicating the Vaccine Act is reviewed under a rational basis standard). See generally ERWIN CHERMERINSKY, CONSTITUTIONAL LAW, PRINCIPLES AND POLICIES 667–689 (3d ed. 2006) (describing three levels of judicial scrutiny applied to federal statutes and the legal framework for evaluating cases under the rational basis standard).

217. See *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313–15 (1993) (noting a classification need not form a perfect fit between means and ends to satisfy rational basis scrutiny).

not violate the Equal Protection Clause merely because the classifications made by its laws are imperfect or even if the law works to the disadvantage of a particular group.²¹⁸

While no court has squarely addressed a constitutional challenge to the OAP, several other aspects of the Vaccine Act have been upheld. For example, the provision of the Act providing a two-year statute of limitations provision for claims regarding death, as opposed to a longer three-year limit for non-death claims, has been upheld.²¹⁹ In addition, the provision allowing administrative rulemaking to amend the Vaccine Injury Table,²²⁰ and the clause setting forth the eligibility requirement of incurring at least \$1,000 in un-reimbursable medical expenses before filing a claim,²²¹ have been found constitutional under a rational basis standard of review. Furthermore, two courts specifically upheld the constitutionality of the Vaccine Act when faced with equal protection claims challenging how the Vaccine Act's statute of limitations treats injuries with latent and subtle onsets such as autism.²²² Finally, with respect to potential due process challenges, the Act does not deprive plaintiffs of any property right to bring a tort action because that right only becomes vested once a final

218. See *Romer v. Evans*, 517 U.S. 620, 632 (1996) (noting a law will be upheld under the rational basis standard “even if the law seems unwise or works to the disadvantage of a particular group”); see also *Dandridge v. Williams*, 397 U.S. 471, 485 (1970) (“If the classification has some ‘reasonable basis,’ it does not offend the Constitution simply because . . . ‘in practice it results in some inequality.’”) (quoting *Lindsley v. Natural Carbonic Gas Co.*, 220 U.S. 61, 78 (1911)).

219. See *Leuz v. Sec’y of Health & Human Servs.*, 63 Fed. Cl. 602 (2005) (holding that section 16(a)(3) of the Vaccine Act does not violate due process or equal protection rights because the provision is rationally related to a legitimate government purpose); *Blackmon*, 328 F. Supp. 2d at 647 (finding the statute of limitations provision within the Vaccine Act did not violate due process because the provision was reasonably calculated to preserve a legislative goal of limiting vaccine manufacturers’ liability); *Reilly v. Wyeth*, 876 N.E.2d 740, 754 (Ill. App. Ct. 2007) (concluding that there is “no constitutional infirmity with the [Vaccine] Act”).

220. See *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1314 (Fed. Cir. 1999) (“We therefore conclude that § 300aa -14(c) of the Vaccine Act does not violate the Presentment Clause.”). In the same case, the Federal Circuit concluded the authority to modify the Vaccine Injury Table via rulemaking is not an unconstitutional delegation of legislative power. See *id.* at 1314–15 (explaining that Congress provided ample guidance and limits on the Secretary’s ability to revise the Vaccine Injury Table).

221. See *Black*, 93 F.3d at 781 (finding the requirement from section 11 of the Act that a claimant incur over \$1000 in unreimbursable expenses before bringing suit is constitutional).

222. See *Blackmon*, 328 F. Supp. 2d at 655 (“There exists a clear, logical connection between the means employed—a neutral limitation on claims—and the legislative goal pursued—limitation of vaccine manufacturers’ exposure to liability.”). The court in *Blackmon* concluded that the limitations provision of the Vaccine Act did not violate the equal protection component of the Fifth Amendment. *Id.*

judgment has been entered.²²³ And further, plaintiffs in the OAP *will* ultimately have an opportunity to be heard, but must wait until after the conclusion of the test cases and the general causation inquiry.²²⁴

Therefore, because any constitutional challenge to the OAP would most likely be evaluated under the rational basis standard, and because the OAP bears a rational relationship to the government objectives of providing some level of compensation to persons injured by vaccines while also insuring the stability and predictability of the childhood vaccine system,²²⁵ it is unlikely the hypothetical plaintiffs would be successful on any sort of constitutional challenge to the Vaccine Act.²²⁶

D. *Plaintiffs May Be Prevented from Re-entering Vaccine Court*

At this point, assuming the hypothetical plaintiffs return to Vaccine Court to exhaust their administrative requirements,²²⁷ two additional problems emerge. First, section 11(b)(2) of the Vaccine Act states that only one “petition” may be filed with respect to “each administration of a vaccine.”²²⁸ Thus, according to the Vaccine Court’s holding in *Stewart*, the plaintiffs have *already* filed a “petition”

223. See *Leuz*, 63 Fed. Cl. at 611 (“Because petitioners have not been deprived of any property right, they suffered no procedural due process violation.”); *Reilly*, 876 N.E.2d at 754 (observing that the “plaintiffs have not been deprived of any property right and therefore cannot claim they suffered a due process violation”); see also *Hammond v. United States*, 786 F.2d 8, 12 (1st Cir. 1986) (noting that “rights in tort do not vest until there is a final, unreviewable judgment”); *Ducharme v. Merrill-Nat’l Lab.*, 574 F.2d 1307, 1309 (5th Cir. 1978) (“[A] plaintiff has no vested right in any tort claim for damages . . .”).

224. See Autism General Order #1, *supra* note 7, at 3, 2002 WL 31696785, at *3–4 (noting that after the general causation inquiry is done, the court will turn and apply those standards to the individual cases).

225. See H.R. REP. NO. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348 (noting the twin purposes of the Vaccine Act).

226. See *CHEMERINSKY*, *supra* note 216, at 678 (observing that the Supreme Court generally has been very deferential to the government when applying the rational basis test and adding it is very rare for the Supreme Court to find that a law fails the rational basis test).

227. See *Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995) (“A claimant alleging that more than \$1,000 in damages resulted from a vaccination . . . *must exhaust the Act’s procedures . . . before filing any de novo civil action in state or federal court.*”) (emphasis added). While it is possible the Vaccine Court will not allow them to refile the petition—see *infra* Part III.D—petitioners could get around this obstacle by alleging a different vaccine was responsible for the alleged injuries. See 42 U.S.C. § 300aa-11(b)(2) (2006) (“Only one petition may be filed with respect to each administration of a vaccine.”). Moreover, a due process claim challenging the legitimacy of the Vaccine Act stands little chance of success. See *supra* Part III.C (explaining that the Vaccine act does not deprive plaintiffs of the right to bring a cause of action or any property and thus the Act is likely to survive a due process challenge).

228. 42 U.S.C. § 300aa-11(b)(2).

and therefore may be unable to re-enter Vaccine Court.²²⁹ Moreover, even if the plaintiffs manage to avoid this provision,²³⁰ a second problem develops. Namely, because it has been so long since the original short-form petition was filed,²³¹ the current claim is time-barred because it is outside the three-year statute of limitations period imposed by section 16 of the Vaccine Act.²³² The discussion below explores this outcome in more detail.

A short summary of three recent Supreme Court decisions is helpful in order to understand the importance of section 16 to the Vaccine Act. First, in 2006, in *Arbaugh v. Y & H Corp.*,²³³ the Supreme Court considered whether a numerical provision in the Civil Rights Act formed part of a court's subject matter jurisdiction or instead was something that delineated a substantive ingredient of a claim for relief.²³⁴ In a unanimous holding,²³⁵ Justice Ginsberg concluded the provision at issue was a substantive one, not a jurisdictional one.²³⁶ However, in reaching this conclusion, the Court created a "bright-line" test for whether a statutory provision is jurisdictional.²³⁷ According to the test, "[i]f the Legislature clearly states that a threshold limitation on a statute's scope shall count as jurisdictional, then courts and litigants will be duly instructed . . ." ²³⁸ However, "when Congress does not rank a statutory limitation on coverage as

229. See *Stewart ex rel. Stewart v. Sec'y of Health & Human Servs.*, No. 02-819V, 2002 WL 31965743, at *11 (Fed. Cl. Dec. 30, 2002) (upholding the use of short-form petitions).

230. In order to find that a petition was ever filed a special master would need to disagree with the ruling in *Stewart*. See *supra* Part II.B (questioning the holding in *Stewart*). In the alternative, the plaintiffs could avoid the rule of section 11(b)(2) by alleging a different vaccine was the cause of the injury. 42 U.S.C. § 300aa-11(b)(2) (noting the limitations for filing a petition with respect to each vaccine administered).

231. Indeed, even if the hypothetical claimant was diagnosed with autism the day the short-form petition was filed, on September 1, 2002, the claim would still be untimely because it would have needed to be filed by September 1, 2005. 42 U.S.C. § 300aa-16(a)(2). In the hypothetical, the plaintiff is trying to re-enter Vaccine Court in 2008 or 2009, several years beyond the expiration of the statute of limitations period.

232. See *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367, 1368 (Fed. Cir. 2001) (dismissing petition after finding that equitable tolling is not allowed under the Vaccine Act).

233. 546 U.S. 500 (2006).

234. *Id.* at 503. Title VII of the Civil Rights Act of 1964 makes it unlawful "for an employer . . . to discriminate," amongst other things, on the basis of sex. 42 U.S.C. § 2000e-2(a)(1) (2006). Employer is defined to include only those having "fifteen or more employees." *Id.* § 2000e(b).

235. The holding was 8-0; Justice Alito did not participate in the case. *Arbaugh*, 546 U.S. at 502.

236. *Id.* at 516.

237. *Id.*

238. *Id.* at 515.

jurisdictional, courts should treat the restriction as nonjurisdictional in character.”²³⁹ Second, in *Bowles v. Russell*,²⁴⁰ the Supreme Court held that a federal appeals court lacked jurisdiction to hear an appeal when the claimant filed the appeal three days after the relevant statute of limitations period had elapsed.²⁴¹ Justice Thomas’s majority opinion noted that “[j]urisdictional treatment of statutory time limits makes good sense.”²⁴² Finally, in *John R. Sand & Gravel Co. v. United States*,²⁴³ the Court affirmed a decision by the Court of Appeals for the Federal Circuit to consider sua sponte a statute of limitations issue imposed by the Tucker Act.²⁴⁴ In language especially relevant to Vaccine Act proceedings, Justice Breyer noted that some statutes of limitations “seek not so much to protect a defendant’s case-specific interest in timeliness *as to achieve a broader system-related goal, such as facilitating the administration of claims*,” and further added that the Supreme Court “has long interpreted the court of claims limitation statute as setting forth this . . . more absolute, kind of limitations period.”²⁴⁵

Taken together, these decisions establish that section 16 of the Vaccine Act is a jurisdictional provision that must be considered by

239. *Id.* at 516. The Vaccine Court considered the impact of *Arbaugh* in *Rydzewski v. Secretary of Health & Human Services*, No. 99-571V, 2007 WL 949759, at *8 (Fed. Cl. Mar. 12, 2007). There, Special Master Moran concluded that the requirements set out in section 11(c) of the Vaccine Act go to the merits of a case and are not jurisdictional; however, the opinion did not reach a conclusion regarding the provisions of section 16. *See id.* at *4–8 (deciding that jurisdiction is not dependent upon proof that a petitioner was administered a covered vaccine but rather a petitioner can establish jurisdiction by putting forth allegations that the petitioner received a vaccine covered by the program).

240. 127 S. Ct. 2360 (2007).

241. *See id.* at 2362–63 (noting that the time period for filing an appeal is mandatory and should not be susceptible to equitable modification). In the facts of that case, the plaintiff was instructed by the judge that he had seventeen days to file his appeal; however, the rule at issue stated only that the plaintiff had fourteen days to file an appeal. *Id.*; FED. R. APP. P. 4(a)(6).

242. *Bowles*, 127 S. Ct. at 2365. Justice Thomas also noted that “[b]ecause Congress decides whether federal courts can hear cases at all, it can also determine when, and under what conditions, federal courts can hear them.” *Id.*; *see also* *United States v. Curry*, 47 U.S. 106, 113 (1848) (“The power to hear and determine a case like this is conferred upon the court by acts of Congress . . . and we have no power to dispense with any of these provisions, nor to change or modify them.”).

243. 128 S. Ct. 750 (2008).

244. *Id.* at 753. *John R. Sand & Gravel* concerned a takings claim brought against the government under the Tucker Act, 28 U.S.C. § 2501 (2006). *Id.* After conceding the claim was timely, the government ultimately won on the merits in the Court of Federal Claims. *Id.* On appeal, the Court of Appeals for the Federal Circuit considered the six-year statute of limitations provided by the statute as jurisdictional and raised the issue on its own. *Id.* The Federal Circuit determined the claim was untimely and dismissed the case without reaching the merits. *Id.*; *John R. Sand & Gravel Co. v. United States*, 457 F.3d 1345, 1353 (Fed. Cir. 2006).

245. *John R. Sand & Gravel*, 128 S. Ct. at 753–54 (emphasis added).

the Vaccine Court as an initial matter.²⁴⁶ Indeed, section 16 of the Vaccine Act declares in part that “no petition may be filed for compensation under the Program . . . after the expiration of thirty-six months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury”²⁴⁷ This language makes section 16 a jurisdictional provision because it goes to the “achieve[ment] [of] a broader system-related goal” Justice Breyer described in *John R. Sand & Gravel*.²⁴⁸ Indeed, one of the main reasons for establishing the Vaccine Act was to limit the liability of vaccine manufacturers in civil court, and having a clear limitations period on lawsuits helps achieve that goal.²⁴⁹ Furthermore, because section 16 provides clear time limits, it is a clear congressional statement on limiting vaccine-related tort actions and therefore passes the bright-line test articulated by Justice Ginsberg in *Arbaugh*.²⁵⁰ As such, because section 16 is a jurisdictional provision, it will present a dilemma for the Vaccine Court faced with the unusual situation of the hypothetical plaintiffs who try to re-enter Vaccine Court after withdrawing from the OAP but are dismissed from federal or state court.

As discussed above, the Vaccine Court will have two options when confronted with the situation of the hypothetical plaintiffs. On one hand, the Vaccine Court may rely on the earlier decision in *Stewart* and find that the original short-form petition is sufficient to count as a petition.²⁵¹ If this is the case, then the Vaccine Court may actually be forced to dismiss this claim because section 11(b)(2) of the Vaccine Act is clear that “[o]nly one petition may be filed with

246. See *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998) (“The requirement that jurisdiction be established as a threshold matter . . . is ‘inflexible and without exception.’”) (quoting *Mansfield, C. & L.M.R. Co. v. Swan*, 111 U.S. 379, 382 (1884)).

247. 42 U.S.C. § 300aa-16(a)(2) (2006).

248. *John R. Sand & Gravel*, 128 S. Ct. at 753.

249. See *id.* (listing facilitation of the administration of claims, limiting the scope of waivers of sovereign immunity, and promoting judicial efficiency as examples of things that achieve a broader system related goal).

250. See *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 515-16 (2006) (observing that when the legislature clearly states a threshold limitation on a statute’s scope shall count as jurisdictional, then courts and litigants will be duly instructed and treat the provision as jurisdictional). Indeed, Congress clearly sought to limit the liability of vaccine manufacturers and set up an easy to administer system by passing the Vaccine Act. See H.R. REP. NO. 99-908, at 7 (1986), reprinted in 1986 U.S.C.A.N. 6344, 6348 (“Just as important, the Committee believes that once this system is in place and manufacturers have a better sense of their potential litigation obligations, a more stable childhood vaccine market will evolve.”).

251. See generally *Stewart ex rel., Stewart v. Sec’y Health & Human Servs.*, No. 02-819V, 2002 WL 31965743, (Fed. Cl. Dec. 30, 2002) (concluding short-form petitions are permissible under the Vaccine Act).

respect to each administration of a vaccine.”²⁵² On the other hand, even if the plaintiffs’ claim references a different vaccine, or the Vaccine Court decides the filing of the original short-form petition was not technically the filing of a petition,²⁵³ the plaintiffs’ second claim may still be dismissed because that claim is likely time-barred under section 16 of the Vaccine Act.²⁵⁴ Although the outcome appears harsh, the Vaccine Court does not have jurisdiction to adjudicate time-barred claims, and is also without legal authority to waive or toll the Vaccine Act’s statute of limitations.²⁵⁵

Indeed, because section 16 is a jurisdictional component of the Vaccine Act,²⁵⁶ the Vaccine Court must consider whether the second Vaccine Act petition is timely in order to ensure it has proper jurisdiction over the claim.²⁵⁷ This inquiry will be guided by the nature of the Vaccine Act as a waiver of sovereign immunity, meaning its terms must be construed strictly with any ambiguities resolved in favor of the sovereign.²⁵⁸ Returning to the facts in the hypothetical, it

252. 42 U.S.C. § 300aa-11(b)(2); *see also* *Stewart ex rel. Stewart v. Sec’y of Health & Human Servs.*, No. 02-819V, 2003 WL 22300298, at *13–14 (Fed. Cl. Sept. 3, 2003) (remarking how Congress hoped many claimants would be satisfied with their “day in court” and be dissuaded from filing tort suits); *Gorski v. Sec’y of Health & Human Servs.*, No. 97-156V, 1997 WL 739497, at *3 n.6 (Fed. Cl. Nov. 13, 1997) (stating that section 11(b)(2) “forbids the filing of *more than one petition* with respect to a single vaccination”).

253. In order to reach the conclusion that a short-form petition is not a petition, the Vaccine Court would need to disagree with the decision in *Stewart*. *See supra* Parts III.A.–B (discussing *Stewart*, 2002 WL 31965743, and arguing that a short-form petition is insufficient to qualify as a regular petition).

254. *See supra* note 231 (showing why the hypothetical claim is now time-barred in Vaccine Court).

255. *See* *Brice v. Sec’y of Health & Human Servs.*, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (holding that the Vaccine Act’s statute of limitations is a condition on the waiver of sovereign immunity because 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’”) (quoting *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000)).

256. *See supra* notes 246–250 (discussing the jurisdictional requirement for asserting a claim under the Vaccine Act).

257. Indeed, in *Kay v. Secretary of Health & Human Services*, 80 Fed. Cl. 601, 604 (2008), the Court of Federal Claims declared that “*John R. Sand & Gravel* reinforces the conclusion reached by the Federal Circuit as to the scope of the Vaccine Act . . . that the statute of limitations set forth in a congressional waiver of sovereign immunity establishes a limitation on the Court of Federal Claims’ exercise of jurisdiction.”

258. *See* *Lane v. Pena*, 518 U.S. 187, 192 (1996) (observing that strict construction of waivers of sovereign immunity is “firmly grounded in our precedents”); *United States v. Nordic Vill. Inc.*, 503 U.S. 30, 34 (1992) (declaring that a statutory waiver of sovereign immunity must be construed strictly and narrowly in favor of the government); *United States v. Sherwood*, 312 U.S. 584, 586 (1941) (noting the terms of the United States waiver of sovereign immunity, including any statute of limitations, define the extent of the court’s jurisdiction); *see also* *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000) (“A statute of limitations is a condition on the waiver of sovereign immunity by the United States. Although

appears fairly clear the second claim is untimely. For instance, the short-form petition there was filed September 1, 2002.²⁵⁹ Thus, even assuming all the symptoms and manifestations of the injury occurred that same day, according to section 16(a)(2) of the Act, any other “petition” must be filed before “the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset” of the injury, or September 1, 2005.²⁶⁰ In the hypothetical, however, the plaintiff is not looking to return to Vaccine Court until late 2008 at the absolute earliest, well beyond the thirty-six month limitations period provided by the Act.²⁶¹ Furthermore, the Vaccine Court is not permitted to waive²⁶² or toll the statute of limitations.²⁶³ Finally, the government would not be estopped from raising claims questioning the Vaccine Court’s jurisdiction under section 16 of the Vaccine Act²⁶⁴ because claims of estoppel may not be asserted by a claimant who is seeking the payment of money against the government.²⁶⁵

To conclude, the plaintiffs’ situation upon returning to Vaccine Court does not look promising. Assuming a federal district court

courts ‘should not construe such a time-bar provision unduly restrictively, *they must be careful not to interpret it in a manner that would extend the waiver beyond that which Congress intended.*’ (citation omitted) (emphasis added).

259. See *supra* note 175 (explaining that a surge of short-form petitions and cases were filed in the summer of 2002 after the issuance of Autism General Order #1).

260. 42 U.S.C. § 300aa-16(a)(2) (2006); see *Johns-Manville Corp. v. United States*, 893 F.2d 324, 327 (Fed. Cir. 1989) (“[W]here the court has no jurisdiction, it has no power to do anything but strike the case from its docket . . .”); see also *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94–95 (1998) (stating that jurisdiction must be established in every case before it can be heard and adjudicated).

261. See *supra* note 182 (discussing how some plaintiffs in Vaccine Court have waited close to a decade before having their claim heard).

262. *E.g.*, *Jones v. Sec’y of Health & Human Servs.*, 78 Fed. Cl. 403, 406 (2007) (affirming special master’s decision dismissing case holding he lacked authority to waive the statute of limitations).

263. See *Brice v. Sec’y of Health & Human Servs.*, 240 F.3d 1367, 1374 (Fed. Cir. 2001) (holding that equitable tolling is not allowed in Vaccine Act claims).

264. The doctrine of equitable estoppel is a judicial remedy by which a party may be precluded from asserting a right to which he otherwise would have been entitled, if that party’s act or omission has induced another to act to his detriment. *Henry v. United States*, 14 Cl. Ct. 795, 799 (1988); see *Webb v. Sec’y Health & Human Servs.*, No. 91-373V, 1992 WL 19309, at *7 (Cl. Ct. Jan. 17, 1992) (denying plaintiff from estopping government from asserting a statute of limitations defense).

265. See *Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414, 419 (1990) (“From our earliest cases, we have recognized that equitable estoppel will not lie against the Government as it lies against private litigants.”); *Lamb v. Sec’y of Health & Human Servs.*, 24 Cl. Ct. 255, 258 (1991) (affirming special master’s decision the government was not estopped from asserting a bar to petitioner’s claim even when the petitioner relied on incorrect legal advice).

judge determines short-form petitions are not petitions,²⁶⁶ the plaintiffs will be sent back to Vaccine Court facing a strong likelihood of dismissal there as well. The dilemma for the Vaccine Court will be whether or not a “petition” was originally filed in Vaccine Court. If so, then the plaintiffs may be barred because of the one petition rule set out in section 11(b)(2) of the Vaccine Act. However, if no petition was filed, or a different allegation is made, the plaintiffs may still be dismissed on statute of limitations grounds. Although these options travel down different legal paths, the end point is the same—a dismissal of the plaintiffs’ claim.

IV. SOME RECOMMENDATIONS

The illustration above is meant to provide an overview of some of the overlooked consequences that may befall certain petitioners who opt out of the OAP to file a civil action in state or federal court. Of course, the harsh scenario depicted could be avoided at several points along the way. For one, the plaintiffs could file a traditional petition accompanied by medical records and other supporting documentation in Vaccine Court in the first place and have the Special Master make a decision on the claim under section 12 of the Vaccine Act.²⁶⁷ In addition, the plaintiffs could name a thimerosal manufacturer, and not a vaccine manufacturer, as a defendant in the civil action and thereby bypass the restrictions of section 11(a) of Vaccine Act which only prohibits civil actions against *vaccine manufacturers*.²⁶⁸ Further, the plaintiffs could bring a claim in state or federal court alleging a legal theory not covered by the Vaccine Act,

266. See *supra* Part III.A (explaining that the limited information provided in short-form petitions may provide a basis for courts to rule that short-form petitions are not petitions).

267. Assuming the claim was timely filed, this would meet all the requirements of section 11 of the Vaccine Act and therefore, assuming the plaintiffs reject the judgment under section 21(a), they could proceed with a civil action. 42 U.S.C. §§ 300aa-11(a), 21(a).

268. Indeed, section 11(a) of the Vaccine Act mentions only “vaccine [] manufacturers” and says nothing about thimerosal manufacturers. *Id.* § 300aa-11(a)(2)(A). Several federal courts have held that thimerosal manufacturers are not vaccine manufacturers and are therefore not entitled to the protections afforded by the Vaccine Act. See, e.g., *Moss v. Merck & Co.*, 381 F.3d 501, 506 (5th Cir. 2004) (allowing lawsuit against thimerosal manufacturer to proceed); see also Beverly Jones Sill, Note, *Toussaint v. Merck & Co.: Opening the Door to Thimerosal Vaccine Litigation in Civil Court?*, 21 GA. ST. U. L. REV. 773, 773 (2005) (remarking that a decision allowing parents to proceed with a claim against a thimerosal manufacturer may represent a “crack in the armor that has shielded thimerosal’s manufacturers from civil court claims made on behalf of thousands of children”).

such as loss of consortium or fraud.²⁶⁹ And finally, once the test cases are decided, it is possible Congress may step in and amend the Vaccine Act in some fashion to avoid any unduly harsh outcome to petitioners.²⁷⁰

Still, in light of the fact that a program designed for speed and efficiency may close nearly all legal doors to people it was specifically designed to help it is necessary to consider some amendments to the Vaccine Act to ensure this situation does not occur in the future. The discussion below briefly considers three different amendments that would help the Vaccine Act run more smoothly and avoid the problems identified in this Comment.

A. *Attach a “No Omnibus” Provision to Section 12 of the Vaccine Act*

Although it initially seemed practical, the conduct of the OAP deviated far from the original schedule and presents a variety of unintended consequences.²⁷¹ After all the time spent sorting through various motions and discovery, the Vaccine Court ended up where it arguably should have been in the first place—adjudicating claims on a case-by-case basis and using those standards to help judge the remaining ones.²⁷² However, given the lengthy time span of the OAP, it is possible some claimants will wait for perhaps a decade before the Vaccine Court actually hears their individual claims.²⁷³ Moreover, the OAP is not the first time the Vaccine Court decided to conduct an omnibus style proceeding. Indeed, in 1992–93 the court undertook

269. See *Ferguson ex rel. Ferguson v. Aventis Pasteur, Inc.*, 444 F. Supp. 2d 755, 762 (E.D. Ky. 2006) (allowing plaintiffs’ state fraud claim against vaccine manufacturer to proceed); *Maurice v. Eli Lilly & Co.*, No. 04-3105, 2005 WL 3542902, at *6 (E.D. La. Nov. 7, 2005) (“[T]his Court noted in its Order and Reasons of November 5, 2002, Congress could have swept loss of consortium claims and lost wages claims within the purview of the Act, but it did not do so.”); *Owens ex rel. Schafer v. Am. Home Prods. Corp.*, 203 F. Supp. 2d 748, 756 (S.D. Tex. 2002) (noting the Vaccine Act does not cover claims for loss of consortium).

270. See Helia Garrio Hull, *Induced Autism: The Legal and Ethical Implications of Inoculating Vaccine Manufacturers From Liability*, 34 CAP. U. L. REV. 1, 42 n.329 (2005) (describing congressional action to try and extend the Vaccine Act statute of limitations provision from three to six years).

271. See *Ruling Concerning Issue of Time for Filing Expert Reports*, *supra* note 177, at 3 (“The actual course of the [OAP], quite obviously, has deviated from [the] initial schedule [T]he discovery process has taken much longer than initially anticipated.”) (emphasis added).

272. See Response to “PSC Update Re Test Case Designations” and Respondent’s “Motion for Appropriate Relief” at 1–2, *Omnibus Autism Proceeding*, Autism Master File (Fed. Cl. Apr. 27, 2007) available at <http://www.usfc.uscourts.gov/sites/default/files/autism/42707%20motion%20for%20app%20relief.pdf> (arguing the decision to split the OAP into separate test cases calls into question the utility of further omnibus processing).

273. For instance, the Cédillos filed their vaccine claim in 1998. Mauro, *supra* note 2.

an inquiry into whether the rubella vaccine was causally related to the development of persistent joint pain and related symptoms.²⁷⁴ This rubella omnibus proceeding lasted “well into 2001”²⁷⁵ and lingering issues stemming from that proceeding were being decided as recently as February, 2008.²⁷⁶

The best way to ensure this does not happen again is to amend section 12(d) of the Vaccine Act, the section that provides for the powers of the special masters, to include a provision that declares “special masters do not have the power to conduct omnibus proceedings.” This will be beneficial because it will force the special masters to adjudicate claims in a case-by-case fashion,²⁷⁷ avoid the time-consuming issues such as the extent of third party discovery,²⁷⁸ and render moot decisions such as whether to issue “Orders Concluding Proceedings” as opposed to “Decisions” on a claim and whether to provide for interim attorneys’ fees.²⁷⁹ However, after the modification the special masters would still retain flexibility and discretion when conducting proceedings on a single case.²⁸⁰ Given the delays encountered in the OAP, the likelihood of the adjudication of individual claims extending far into the future, and the original purpose of the Vaccine Act, a “no omnibus” provision would be helpful.

274. See *O’Connell v. Sec’y of Health & Human Servs.*, 63 Fed. Cl. 49, 55 (2004) (recounting the history of the rubella omnibus general causation inquiry in 1992–93 and noting that “[t]he ‘rubella arthropathy omnibus’ proceeding lasted well into 2001”).

275. *Id.*

276. *Zatuchni v. Sec’y of Health & Human Servs.*, 516 F.3d 1312, 1312 (Fed. Cir. 2008). This was a rubella case filed in 1994, but was still in litigation concerning the appropriate amount of damages in 2008. See *id.* at 1314–15 (discussing procedural history).

277. See *Stewart ex rel. Stewart v. Sec’y of Health & Human Servs.*, No. 02-819V, 2002 WL 31965743, at *7 (Fed. Cl. Dec. 30, 2002) (“I conclude that the statute, viewed as a whole, affords the special master with broad *discretion* to determine *when* a petitioner must file the required documents.”); Ruling Concerning Issue of Time for Filing Expert Reports, *supra* note 177, at 7 (“I conclude as a matter of law . . . that I have *discretion* to allow such petitioners to keep their petitions pending . . . as long as is appropriate under all the circumstances of each case.”).

278. See Ruling Concerning Motion for Discovery from Merck Re MMR Vaccine at *supra* note 24, at 9, 2004 WL 1660351, at *7 (“There is extremely little case law relating to discovery questions during the 15-year history of the Vaccine Act.”).

279. See *Iannuzzi v. Sec’y of Health & Human Servs.*, 78 Fed. Cl. 1, 1 (2007) (reversing special master decision to award attorneys fees for work related to the general causation inquiry in the OAP).

280. See 42 U.S.C. § 300aa-12(d)(3)(B) (stating the special master’s authority comes from conducting proceedings “*on a petition*”) (emphasis added).

B. Amend Section 11 of the Act to Prohibit the Use of Short-Form Petitions

In light of the problems that may result from utilizing short-form petitions, it makes sense to modify section 11(c) of the Vaccine Act to reach a compromise between the ideal situation—where all medical records are filed initially—and the reality that many claims come in with few records, if any at all.²⁸¹ The best middle-ground, therefore, is to amend section 11(c) to prohibit short-form petitions and also require some threshold amount of medical records sufficient to enable the Vaccine Court to determine it has jurisdiction over the claims and for the government to fulfill its role in evaluating claims.²⁸² The minimum amount of records needed by the Vaccine Court to assess whether it has jurisdiction over a claim are: (1) a vaccination record showing the vaccine received and the country in which it was received;²⁸³ (2) all relevant medical records documenting the onset or significant aggravation of the alleged injury;²⁸⁴ and (3) an affidavit by a parent or other guardian to attest to the claim.²⁸⁵ These categories of records are sufficient for the Vaccine Court to ensure it has jurisdiction over the claim and also sufficient for the government to conduct a meaningful review of the petition to see whether it warrants compensation under the terms of the Act.²⁸⁶ The amendment would also simplify section 11(c) by making a blanket referral to “relevant medical records,” thereby placing the burden on

281. See *Stewart*, 2002 WL 31965743, at *4 (“[I]n a substantial number of cases . . . petitions have been filed without *any* [medical] records at all”); Discussion of Issue of “Short-Form” Petitions, *supra* note 146, at 2 (noting that “[i]n a great many Program cases . . . petitions have been filed with some medical records”). Having a claim filed without any medical records is problematic in light of the Supreme Court decisions regarding statute of limitations and the nature of the Vaccine Act as a waiver of sovereign immunity. See *supra* Part III.D (discussing how the Vaccine Act’s statute of limitations cannot be equitably tolled and as a waiver of sovereign immunity, the Vaccine Act will be strictly construed). It seems that if the only document a court has is a single piece of paper, that piece of paper is not sufficient for the court to conclude it has jurisdiction to proceed with the claim. See *supra* Part III.A (questioning the holding in *Stewart*, 2002 WL 31965743).

282. See 42 U.S.C. § 300aa-11(a), (c) for the provisions regarding the Vaccine Act jurisdiction and documents required in a petition for compensation.

283. Indeed, the Vaccine Court only has jurisdiction over those claims alleging an injury from a vaccine covered by the Vaccine Injury Table and also those vaccines that were administered in the United States or in its trust territories. 42 U.S.C. § 300aa-11(c)(1)(A).

284. See *id.* § 300aa-11(c) (listing the documents that shall accompany a petition).

285. See *id.* § 300aa-11(c)(1) (describing the affidavit required).

286. These items are just a simplified version of what is already required in section 11(c) of the Vaccine Act. *Id.* Moreover, requiring that relevant medical records be filed would enable the Vaccine Court to evaluate any statute of limitations issues. *Id.* § 300aa-16.

the special master and the government to determine whether additional records are needed.²⁸⁷

C. Increase The Number of Special Masters

One of the rationales for conducting the OAP was to avoid overwhelming the Vaccine Court with an influx of claims.²⁸⁸ This concern is not without merit because section 12(c) of the Vaccine Act allows for a maximum of only eight special masters in the Court of Federal Claims.²⁸⁹ However, now that the OAP is nearing the end of the general causation inquiry, and given what is likely to happen in the aftermath via appeals and processing individual claims, it seems the Vaccine Court and its eight special masters may be ill-equipped to process the remaining 4900 autism claims in a timely fashion.²⁹⁰ This time concern is underscored by information from a federal government survey, which found the average time it takes to decide *non-autism* vaccine claims is already well over 800 days.²⁹¹

Amending the statute to increase the maximum number of special masters from eight to twelve would be beneficial in a number of respects. For one, it would surely help the Vaccine Court adjudicate the bulk of the remaining autism claims in a timely and fair fashion.²⁹² Moreover, having additional special masters would likely reduce the overall time it takes to process a claim, thereby bringing the Vaccine Act more in line with the 240/420 day time period envisioned by section 12(g), and reducing the average case processing time in other

287. See H.R. REP. NO. 101-247, at 509 (1989), *reprinted in* 1989 U.S.C.C.A.N. 1906, 2235 (calling upon the government and the special masters to rededicate themselves to providing an expeditious, non-adversarial, and fair system in overseeing the Vaccine Act).

288. See *supra* note 117 (explaining the administrative burden on the Vaccine Court was one reason for conducting the OAP).

289. 42 U.S.C. § 300aa-12(c)(1).

290. See Autism General Order #1, *supra* note 7, at 1, 2002 WL 31696785, at *1 (“Processing such a large number of cases will stretch thinly the resources of both the court and the bar.”).

291. For instance, a federal government evaluation considered the Vaccine Injury Compensation Program to be performing at an “adequate” level. See Program Assessment, Vaccine Injury Compensation Program, <http://www.whitehouse.gov/omb/expectmore/summary/10003807.2005.html> (last visited Oct. 4, 2008) (stating that the program has made short term progress but still contains design-related problems). This evaluation also indicated the average time it takes to process vaccine claims, from filing to payment of damages, over the years 2005, 2006, and 2007 were 894 days, 834 days, and 1,337 days, respectively. *Id.*

292. Indeed, given the amount of medical records probably involved in each petition, it could take a special master fair amount of time to reach a conclusion on the merits of the claim. For instance, in the *Cedillo* test case there were over 200,000 pages filed. See *supra* note 19 (describing the extensive testimony of eighteen expert witnesses involved in the *Cedillo* case).

cases.²⁹³ And finally, having many special masters issuing decisions in a timely manner would increase the credibility of the Vaccine Court and the National Childhood Vaccine Injury Compensation Program as a whole.

CONCLUSION

The debate over vaccines and autism, whether in the context of legal appeals, scientific and medical research, or media commentary is sure to go on long after *Cedillo*. Despite the flaws and delays, the OAP was a noble attempt by the Vaccine Court to balance the needs of thousands of petitioners with the policy of ensuring limited liability for vaccine manufacturers. Some of the long-term procedural consequences of the OAP, however, and the effects they may have on certain petitioners have been largely overlooked. Most notably, the decision by the Vaccine Court to utilize short-form petitions could result in a host of problems for petitioners who exit the OAP and attempt to proceed with a civil action in state or federal court. As this Comment has illustrated, filing a short-form petition in Vaccine Court could result in the procedural anomaly where a plaintiff who opts out of the OAP is subsequently barred from state court because of unmet Vaccine Act requirements and perhaps even barred from returning to the Vaccine Court because of provisions within the Vaccine Act. While there are ways to avoid this harsh result, that it could happen at all demonstrates one problem with conducting a grand omnibus style proceeding in a federal program of limited jurisdiction designed to adjudicate claims quickly and on a case-by-case basis. The recommendations proposed, such as eliminating short-form petitions and increasing the amount of special masters, would address the problems that may linger in the aftermath of the OAP and bring the Vaccine Act back towards its original purpose—offering a fair and streamlined alternative to civil tort litigation.

293. 42 U.S.C. § 300aa-12(g).