APPENDIX

APPENDIX A - SUMMARY ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, FILED MAY 8, 2020

19-1052
Doe v. Merck & Co., Inc.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York on the 8th day of May, two thousand twenty.

Present: JOHN M. WALKER, JR.,
ROSEMARY S. POOLER,
GERARD E. LYNCH,
Circuit Judges.

JANE DOE, individually and as Parent/Guardian of Baby Doe,
BABY DOE,
Plaintiffs-Appellants,

v. 19-1052

MERCK & CO., INC., HEALTH AND HUMAN SERVICES, ALEX AZAR, in his official capacity as Secretary of Health and Human Services, STEPHEN HAHN, M.D. in his official capacity as Acting Commissioner of Food and Drugs (a division of HHS), UNITED STATES OF AMERICA,

Defendants-Appellees.[1]

Appearing for Appellants: Patricia Finn, Nanuet, N.Y.

Appearing for Appellees: Dino S. Sangiamo (Adam Possidente, Matthew T. McLaughlin, Mitchell Y. Mirviss, Davis S. Gray, *on the brief*), Venable LLP, New York, N.Y.

[1] The Clerk of Court is directed to amend the caption as above.

Layaliza Soloveichik, Assistant United States Attorney (Varuni Nelson, Assistant United States Attorney, *on the brief*), *for* Richard P. Donoghue, United States Attorney for the Eastern District of New York, Brooklyn, N.Y.

Appeal from the United States District Court for the Eastern District of New York (Block, *J.*).

ON CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the order of said District Court be and it hereby is **AFFIRMED**.

Appellants Jane Doe and Baby Doe ("Plaintiffs") appeal from the March 21, 2019 decision and order of the United States District Court for the Eastern District of New York (Block, *J.*) dismissing their complaint for failure to state a claim upon which relief can be granted. We assume the parties' familiarity with the underlying facts, procedural history, and specification of issues for review.

Plaintiffs are a mother and son who allege that the son, Baby Doe, developed autism as a result of thimerosal-containing vaccines ("TCVs"), the measles mumps rubella ("MMR") vaccine, or a combination of the two that he received as an infant. Plaintiffs brought suit against Merck as the manufacturer of the MMR vaccine that Baby Doe received in 1999, as well as the Department of Health and Human Services, the Secretary of Health and Human Services ("Secretary"), the Acting Commissioner of the Food and Drug Administration ("FDA"), and the United States (collectively, "the federal Defendants").

Plaintiffs' complaint alleges three counts. Count One claims that all defendants violated the National Childhood Vaccine Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa-1, *et seq.* Count Two alleges that Merck committed fraud and conspired to commit fraud. Count Three seeks declaratory and injunctive relief, primarily in the form of an order directing the Secretary to instruct the FDA to revoke Merck's license to manufacture the MMR vaccine.

We affirm the district court's decision to dismiss Count One claims against both Merck and the federal Defendants.[2] Regarding Merck, Plaintiffs allege that all of their Count One claims arise under the Vaccine Act, but that Act does not establish a private right of action against manufacturers, such as Merck. The Vaccine Act sets forth administrative procedures that must be exhausted in order for a petitioner to bring a state law tort claim against a private entity and precludes actions against manufacturers by petitioners who have not administratively exhausted. *See* 42 U.S.C. §§ 300aa-22(a), 300aa-11(a)(2). But neither these provisions nor any other in the Vaccine Act enable petitioners to sue private entities for alleged violations of the Act. As we held in *Olmsted v. Pruco Life Insurance Co. of New Jersey*, 283 F.3d 429, 432 (2d Cir. 2002), where "[n]o provision of [a statute] explicitly provides for a private right of action for violations of [specific provisions of that statute], . . . we must presume that Congress did not intend one." That presumption is reinforced here because the provisions in question focus on the "person regulated rather than the individuals protected." *Id.* at 432-33 (internal quotation marks

[2] Although the district court relied on different grounds in dismissing Count One, we are free to affirm on any ground that has support in the record. *See Wright v. Giuliani*, 230 F.3d 543, 547 (2d Cir. 2000).

and citation omitted). Moreover, Congress created a citizen-suit provision to allow claims against the Secretary for failure to perform an act or duty under the Act, 42 U.S.C. § 300aa-31, and "Congress's explicit provision of a private right of action to enforce one section of a statute suggests that omission of an explicit private right to enforce other sections was intentional." *Olmsted*, 283 F.3d at 433. The district court was therefore correct in dismissing Plaintiffs' claims against Merck under Count 1.

Although Plaintiffs may sue the Secretary—and only the Secretary—pursuant to 42 U.S.C. § 300aa-31, Plaintiffs' complaint contains no factual allegations articulating which duties were violated or how they were violated.[3] Plaintiffs' claims against the Secretary for violations of the Vaccine Act were thus properly dismissed. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." (internal quotation marks and citation omitted)).

We likewise affirm the district court's dismissal of Count Two. "Under New York law, to state a cause of action for fraud, a plaintiff must allege a representation of material fact, the falsity of the representation, knowledge by the party making the representation that it was false when made, justifiable reliance by the plaintiff and resulting injury." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 291 (2d Cir. 2006) (internal quotation marks and citations omitted). Here, however, there was no reliance. The relevant vaccines were given to Baby Doe in 1999, yet the earliest allegedly fraudulent act took place in June 2000. Accordingly, Plaintiffs cannot establish that they relied on the purportedly fraudulent conduct. *See id.* (explaining that plaintiff could not demonstrate reliance on a statement in making an investment because the investment predated the statement). And because Plaintiffs' fraud claim fails, so does their conspiracy-to-commit-fraud claim. *See Crigger v. Fahnestock & Co., Inc.*, 443 F.3d 230, 237 (2d Cir. 2006) ("Under New York law, civil conspiracy to commit fraud, standing alone, is not actionable if the underlying independent tort has not been adequately pleaded." (internal quotation marks, ellipses, and citation omitted)).

Finally, we affirm the district court's dismissal of Count Three. With respect to Plaintiffs' challenge to the FDA's licensing of Merck to manufacture the MMR vaccine, the district court's invocation of the doctrine of primary jurisdiction was not erroneous. Reliance on the doctrine of primary jurisdiction is "appropriate whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (internal quotation marks and citation omitted). Here, the relevant considerations counsel for the conclusion that on this matter the FDA has primary jurisdiction. The question of the efficacy and safety of Merck's vaccines "involves technical or policy considerations within the agency's particular field of expertise." *See id.* at 82-83. In addition, this type of licensing is within the agency's discretion under 42 U.S.C. § 262. *See Ellis*, 443 F.3d at 83. Moreover, uniformity would be more appropriately reached through application to one administrative agency rather

[3] Although Plaintiffs allege some facts in their briefing on appeal, Plaintiffs failed to allege any of these facts in their complaint despite having filed three different complaints in this action. Plaintiffs "should not be able effectively to amend a complaint through any document short of an amended pleading." *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 109 n.9 (3d Cir. 2002).

than the various courts. *See id.* at 82. And lastly, although the FDA provides for "citizen petitions," 21 C.F.R. § 10.30, there is no indication that Plaintiffs have filed one here. For these reasons, we agree with the district court that challenges to Merck's license should be directed in the first instance to the FDA.

With respect to Plaintiffs' challenge to New York's MMR-vaccine requirements, it is not apparent to us how any of the federal Defendants could be liable for New York's decision to require the MMR vaccine, and the State of New York is not a defendant in this suit. Indeed, Plaintiffs style this as a Fourteenth Amendment challenge, but the Fourteenth Amendment "applies to the states but not to the federal government." *See Noel v. Chapman*, 508 F.2d 1023, 1026 n.2 (2d Cir. 1975). Therefore, the district court correctly dismissed Count Three as well.

We have considered the remainder of Plaintiffs' arguments and find them to be without merit. Accordingly, the order of the district court hereby is AFFIRMED.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk

APPENDIX B - MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, FILED MARCH 21, 2019

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------x
JANE DOE, *individually and as Parent/Guardian of* BABY DOE,

Plaintiffs,

-against-

MERCK & CO. INC,; HEALTH AND HUMAN SERVICES; THOMAS PRICE, M.D., *in his official capacity as Secretary of Health and Human Services*; SCOTT GOTTLIEB, M.D., *in his official capacity as Commissioner of the Food and Drug Administration, a division of Health and Human Services*; and the UNITED STATES OF AMERICA,

Defendants.
----------x

MEMORANDUM AND ORDER
Case No. 16-CV-04005 (FB) (RLM)

Appearances:

For Doe:
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For Merck:
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For the Federal Defendants:
RICHARD P. DONOGHUE
United States Attorney's Office
Eastern District of New York
271 Cadman Plaza East
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Brooklyn, NY 11201
By: LAYALIZA K. SOLOVEICHIK

BLOCK, Senior District Judge:

Minor plaintiff Baby Doe and his mother, Jane Doe (collectively, "Doe"), has filed suit against (1) Merck & Co. Inc. ("Merck"); and (2) Health and Human Services, Thomas Price (in his official capacity as Secretary of Health and Human Services), Scott Gottlieb (in his official capacity as Commissioner of the Food and

Drug Administration), and the United States of America (collectively, "Federal Defendants"). Pending before the Court are Merck's and the Federal Defendants' respective motions to dismiss Doe's Third Amended Complaint ("TAC"). The Court grants both motions and dismisses the TAC with prejudice.

BACKGROUND

Doe alleges that Merck produced a measles, mumps, and rubella ("MMR") vaccine that was administered to him in 1999 and caused him to develop autism.[1] TAC ¶¶ 112, 117. New York Public Health Law requires students attending post-secondary educational institutions to be vaccinated for MMR, which includes receiving MMR booster shots. *See* N.Y. Pub. Health Law §§ 2164, 2165.[2] Doe worries that another dose of the vaccine could "seriously injure[] [him], substantially aggravate[] his existing condition," or even kill him. Doe Opp. Br. at 8.

The TAC, to put it mildly, is enigmatic. Notwithstanding the requirements of Federal Rule of Civil Procedure 8(a), the basis for its claims and the claims' respective causes of action are far from clear. Doe attempts to alleviate the confusion in his opposition brief. Although this arguably represents an impermissible

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[1] The Court uses the term "autism" as a shorthand for "autism spectrum disorder," which is a neurological disorder "affecting a person's ability to communicate, form relationships, and/or respond appropriately to the environment." Autism General Order #1, Dkt. No. 67 Ex. A n.2 ("Autism General Order #1").

[2] The parties dispute whether the Public Health Law also requires immunization for residents at group home living facilities. Because the Court's decision does not depend on the resolution of that question, it does not address it.

amendment to the complaint, *see O'Brien v. Nat'l Prop. Analytics Partners*, 719 F. Supp. 222, 229 (S.D.N.Y. 1989),[3] the Court uses Doe's brief as an aid in understanding the TAC.

The TAC contains three counts. In Count One, Doe alleges violations of the National Childhood Vaccine Act of 1986 ("Vaccine Act") by both Merck and the Federal Defendants, for which he seeks damages. He also seeks damages in Count Two, where he alleges that Merck committed fraud and conspired with the government to commit fraud, all in an effort to maintain the license for its MMR vaccine. Finally, in Count Three, Doe seeks declaratory and injunctive relief, asking the Court to revoke Merck's MMR license and enjoin New York from requiring the MMR vaccine booster shot as part of its Public Health Law.

To better understand these counts and why they are meritless, the Court supplies a brief summary of the relevant legal framework and prior related litigation.

A. The Vaccine Act and the Vaccine Court

"To stabilize the vaccine market and facilitate compensation [for injuries caused by vaccines], Congress enacted the [Vaccine Act] in 1986." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011). The Act established a no-fault liability scheme (colloquially called the "Vaccine Court") operated by the United States

[3] Not only are parties prohibited from using briefs as vehicles to amend complaints, but the Court also specifically disallowed any further amendments on December 20, 2016.

Court of Federal Claims. Petitioners who claim to have suffered a vaccine-related injury are required to file a claim in the Vaccine Court and name the Secretary of Health and Human Services as a defendant. A "Special Master" adjudicates the claim in a simplified proceeding with limited discovery and tight deadlines. So long as the alleged injury is listed in the "Vaccine Injury Table," the petitioner does not have to prove causation (injuries not included in the table may be asserted but still require a showing of causation). Dissatisfied petitioners may appeal the Special Master's decision to the Court of Federal Claims. Once a final judgment is issued, petitioners may either accept it or reject it and seek relief in a traditional tort suit. *See generally id.* at 228–30.

B. Omnibus Autism Proceeding

In the early 2000s, thousands of petitions were filed in the Vaccine Court on behalf of children who had developed autism. Some of the petitioners had received MMR vaccines, some had received vaccines containing the mercury-based preservative thimerosal (so-called "thimerosal containing vaccines" or "TCVs"), and some received combinations of the two. The Vaccine Injury Table did not include autism as a recognized injury for any of these vaccines.

To process the large number of petitions, the Office of Special Masters established an opt-in Omnibus Autism Proceeding ("OAP"), which was designed to determine causation through "test cases," with the results then applicable to the

remaining petitions. These test cases were grouped by the vaccines that the petitioners received: those that received MMR vaccines only, those that received TCVs only, and those that received both MMR vaccines and TCVs. Petitioners who opted into the OAP were bound by the results of the test cases. If, for example, the MMR-only test cases demonstrated that MMR vaccines caused autism, petitioners who alleged that they developed autism after receiving an MMR vaccine (but not a TCV) would not need to prove causation. Likewise, if the MMR-only test cases showed no causation, that result would be applicable to any MMR-only petitioner who had opted into the OAP. *See* Autism General Order #1 at 3–4.

Doe's case was selected as one of the TCVs-only test cases. TAC ¶ 116. In a decision that spanned over 200 pages, Special Master Vowell concluded that there was no scientific evidence of any causal link between TCVs and autism. *See CD v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250, at *1 & n.6, *201 (Fed. Cl. Mar. 12, 2010).[4] Doe did not appeal this result. He also did not file any separate petition in the Vaccine Court alleging that his autism was caused by the MMR vaccine (as opposed to by a TCV).

[4] Doe has waived the redaction of his name by citing to the Westlaw version of the Special Master's decision, which contains his full name. Fed. R. Civ. P. 5.2(h); *see* TAC ¶ 116. The Court adopts Doe's convention of using his initials in the caption when citing to that decision.

DISCUSSION

On a motion to dismiss, the Court accepts all factual allegations as true to determine whether they "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

A. Claims Against Merck

1. Count One

Doe explains that he brings Count One under 42 U.S.C. § 300aa-11(a)(2), *see* Doe Opp. Br. at 20, which establishes the procedure that allows plaintiffs to file suit against vaccine manufacturers after administratively exhausting the claim in the Vaccine Court. It would thus seem that Doe is alleging that Merck's MMR vaccine caused his autism, and that he is suing for that injury. As previously noted, however, Doe only alleged in the Vaccine Court that his injury was caused by a TCV, not an MMR vaccine. Because he has failed to exhaust his administrative remedies, the Court would lack jurisdiction over a claim against Merck for MMR-caused autism.[5]

In his opposition brief, Doe advances an altogether different explanation of

[5] Doe argues that his TCV petition should be construed as extending to an MMR petition as well. In support, he cites the Special Master's decision that noted that "the evidence adduced in the omnibus proceeding" could be used in "other cases." *CD*, 2010 WL 892250 at *2. Not only does it not follow that shared evidence constitutes interchangeable petitions, but the sharing of evidence was actually only available "in additional cases presenting *the same theory of causation.*" *Id.* (emphasis added).

his claim. He alleges that Merck "tamper[ed]" with a separate OAP test case petition "by furnishing [the government] with an eleventh hour witness," all in an effort "to discredit" that petitioner's "laboratory evidence" and "attack[]" her "theory of causation in her MMR case that relied upon preliminary research." Whatever this cryptic allegation may mean, it cannot form the basis of a § 300aa-11(a)(2) claim. No amount of "furnishing" or "discredit[ing]" perpetrated by Merck in the OAP could have resulted in a "vaccine-related injury or death" to Doe, not least of all because he received the vaccine in 1999 and the OAP did not begin until the 2000s.

2. Count Two

Doe alleges that Merck committed fraud in procuring and maintaining its license to manufacture and distribute its vaccines. He also alleges that Merck and the government have engaged in a civil conspiracy to commit fraud in furtherance of the same. In support of these allegations, Doe describes several events that all occurred in the 2000s and provides hazy insinuations of backroom deals and corporate-government plots aimed at concealing vital health information from the unwitting public. *See* TAC ¶¶ 171–200. In his opposition brief, Doe adds still more color to this claim. He summarizes the "legal issue for the District Court" as follows:

> [W]hat does [a current Merck executive who was formerly employed by the Center for Disease Control and Prevention] know about the causal link between MMR and Autism, allegedly identified in the original Atlanta Autism Studies, and how children with mitochondrial disorders that are vaccinated can become autistic[?]

Doe Opp. Br. at 23.

Even taken as true, none of Doe's allegations can form the basis of a valid fraud claim against Merck. Nor is it relevant that the government once employed an individual who now works for Merck, even if said individual knew then or knows now about a causal link between MMR vaccines and autism. Putting aside the particularity requirements for fraud of Federal Rule of Civil Procedure 9(b), every alleged statement or omission made by a Merck employee occurred *after* Doe received the vaccine in 1999. Thus, Doe cannot prove reliance, which is fatal to his fraud claim. *See Schlaifer Nance & Co. v. Estate of Warhol*, 119 F.3d 91, 98 (2d Cir. 1997). Furthermore, because Doe cannot prove fraud, he cannot prove conspiracy to defraud. *Crigger v. Fahnestock & Co, Inc.*, 443 F.3d 230, 237 ("Under New York law, civil conspiracy to commit fraud, standing alone, is not actionable if the underlying independent tort has not been adequately pleaded." (quoting *Vasile v. Dean Witter Reynolds Inc.*, 20 F. Supp. 2d 465, 482 (E.D.N.Y. 1998) (alterations omitted))); *see also Marcus v. AT&T Corp.*, 138 F.3d 46, 57 n.2 (2d Cir. 1998) (observing that federal common law fraud and New York state common law fraud have "practically identical" standards); TAC ¶ 169 (citing cases interpreting New York law).

3. Count Three

In Count Three, Doe requests that the Court revoke Merck's license for

distributing its MMR vaccine and enjoin New York from requiring the vaccine.

The Court declines to exercise primary jurisdiction to grant such relief. The proper body to consider revocation of a vaccine manufacturer's license is the Food and Drug Administration. *See Ellis v. Tribute Television Co.*, 443 F.3d 71, 81 (2006) (describing primary jurisdiction). Not only are vaccine safety and licensing issues peculiarly within the FDA's expertise and discretion, *see id.* at 82–83, but the FDA has specifically established procedures for citizens to petition the agency to take administrative action that it has authority over, *see* 21 C.F.R. §§ 10.25, 10.30. An administrative petition is the proper mechanism for requesting the relief Doe seeks, not a claim for injunctive relief in this Court.

As for New York's vaccination requirements, that request is properly directed at the State of New York, which is not a party to this lawsuit. Doe inexplicably urges the Court to treat Merck as a state actor "acting under color of state law, as an agent of the United States government in the distribution/sale of the MMR vaccine to children required to attend school in New York State." Doe Opp. Br. at 25. Doe provides no analysis as to how or why Merck's role in providing and distributing vaccines would make it a state actor, nor why its role as an "agent of the United States government" would obviate the need for New York to be represented in this

lawsuit.[6]

B. Claims Against the Federal Defendants

1. Count One

Doe explains that he brings Count One against the Federal Defendants under the so-called "citizen's action" of the Vaccine Act, 42 U.S.C. § 300aa-31. This section allows citizens to sue the Secretary of Health and Human Services "where there is alleged a failure of the Secretary to perform any act or duty [under the Act]."

Because § 300aa-31 only waives sovereign immunity as to the Secretary of Health and Human Services, the Court dismisses Count One as to all of the other Federal Defendants. As to the Secretary, Doe fails to allege any particular duty in which the Secretary was derelict. To the extent that duty is the general duty to ensure the safety of childhood vaccines, *see, e.g.*, 42 U.S.C. § 300aa-27, that claim is now precluded. As previously noted, Doe's OAP petition, which named the Secretary as defendant, only alleged that a TCV induced his autism. Doe could have but did not allege that an MMR vaccine induced his autism. Claim preclusion now bars that

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[6] Doe miscites *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), for the proposition that courts are required to "assess the constitutionality of each vaccination mandate individually," Doe Br. at 25, and that such mandates may only be allowed in "highly circumscribed situations," such as emergencies, epidemics, and the like, *id.* at 26. In *Jacobson*, the Court held that a Massachusetts mandate requiring smallpox vaccinations did not violate the Constitution. Doe's quotations are taken entirely out of context. *See Jacobson*, 197 U.S. at 38 (establishing what amounts to a rational basis test for vaccination mandates).

claim in this Court. *See Curtis v. Citibank, N.A.*, 226 F.3d 133, 139 (2d Cir. 2000).

2. Count Two

The TAC labels Count Two as "*Merck's* Fraud & Conspiracy to Commit Fraud" (emphasis added). Thus, by its own terms, Count Two is not brought as to the Federal Defendants. Furthermore, as explained *supra*, although the alleged conspiracy was with government officials, a conspiracy to commit fraud is not actionable without the underlying fraud.

3. Count Three

The Court declines to exercise jurisdiction to grant this relief. *See supra*.

CONCLUSION

In Doe's OAP petition, Special Master Vowell lamented that

> [u]nfortunately, the [Does] (and uncounted other parents of children with ASD) have relied upon practitioners and researchers who peddled hope, not opinions grounded in science and medicine. My heart goes out to parents like the [Does] who struggle daily, emotionally and financially, to care for their children, but I must decide cases based on the law and not sentiment.

2010 WL 892250, at *201. The Court must do likewise and dismisses the TAC with prejudice.

SO ORDERED.

/S/ Frederic Block
FREDERIC BLOCK
Senior United States District Judge

Brooklyn, New York
March 21, 2019

C-1

APPENDIX C - ORDER ENTERING JUDGMENT IN FAVOR OF THE DEFENDANTS MERCK & CO. INC., HEALTH AND HUMAN SERVICES, ALEX AZAR, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, STEPHEN M. HAHN, M.D., IN HIS OFFICIAL CAPACITY AS ACTING COMMISSIONER OF FOOD AND DRUG (A DIVISION OF HHS), AND THE UNITED STATES OF AMERICA, DISMISSING THE CASE WITH PREJUDICE, FILED MARCH 25, 2019, NO. 16-CV-04005

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------X
JANE DOE, individually and as Parent/Guardian of BABY DOE,

Plaintiff,

-against-

MERCK & CO. INC,; HEALTH AND HUMAN SERVICES; THOMAS PRICE, M.D., in his official capacity as Secretary of Health and Human Services; SCOTT GOTTLIEB, M.D., in his official capacity as Commissioner of the Food and Drug Administration, a division of Health and Human Services; and the UNITED STATES OF AMERICA,

Defendants.
----------X

JUDGMENT
16-CV-04005 (FB) (RLM)

A Memorandum and Order of Honorable Frederic Block, United States District Judge, having been filed on March 21, 2019, granting Merck's and Federal Defendants' respective motions to dismiss Doe's Third Amended Complaint; and dismissing the Third Amended Complaint with prejudice; it is

ORDERED and ADJUDGED that Merck's and Federal Defendants' respective motions to dismiss Doe's Third Amended Complaint are granted; and that the Third Amended Complaint is dismissed with prejudice.

Dated: Brooklyn, New York
March 22, 2019

Douglas C. Palmer
Clerk of Court

by: */s/ Jalitza Poveda*
Deputy Clerk

APPENDIX D - JUDGMENT IN DOE ET AL. V MERCK & CO, INC., ET AL., NO. 19-1052, UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, ENTERED JUNE 29, 2020

Case 19-1052, Document 126, 06/29/2020, 2872954, Page1 of 4

MANDATE

19-1052
Doe v. Merck & Co., Inc.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York on the 8th day of May, two thousand twenty.

Present: JOHN M. WALKER, JR.,
ROSEMARY S. POOLER,
GERARD E. LYNCH,
Circuit Judges.

JANE DOE, individually and as Parent/Guardian of Baby Doe,
BABY DOE,

Plaintiffs-Appellants,

v. 19-1052

MERCK & CO., INC., HEALTH AND HUMAN SERVICES, ALEX AZAR, in his official capacity as Secretary of Health and Human Services, STEPHEN HAHN, M.D. in his official capacity as Acting Commissioner of Food and Drugs (a division of HHS), UNITED STATES OF AMERICA,

Defendants-Appellees.[1]

Appearing for Appellants: Patricia Finn, Nanuet, N.Y.

Appearing for Appellees: Dino S. Sangiamo (Adam Possidente, Matthew T. McLaughlin, Mitchell Y. Mirviss, Davis S. Gray, *on the brief*), Venable LLP, New York, N.Y.

[1] The Clerk of Court is directed to amend the caption as above.

MANDATE ISSUED ON 06/29/2020

Layaliza Soloveichik, Assistant United States Attorney (Varuni Nelson, Assistant United States Attorney, *on the brief*), *for* Richard P. Donoghue, United States Attorney for the Eastern District of New York, Brooklyn, N.Y.

Appeal from the United States District Court for the Eastern District of New York (Block, *J.*).

ON CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the order of said District Court be and it hereby is **AFFIRMED**.

Appellants Jane Doe and Baby Doe ("Plaintiffs") appeal from the March 21, 2019 decision and order of the United States District Court for the Eastern District of New York (Block, *J.*) dismissing their complaint for failure to state a claim upon which relief can be granted. We assume the parties' familiarity with the underlying facts, procedural history, and specification of issues for review.

Plaintiffs are a mother and son who allege that the son, Baby Doe, developed autism as a result of thimerosal-containing vaccines ("TCVs"), the measles mumps rubella ("MMR") vaccine, or a combination of the two that he received as an infant. Plaintiffs brought suit against Merck as the manufacturer of the MMR vaccine that Baby Doe received in 1999, as well as the Department of Health and Human Services, the Secretary of Health and Human Services ("Secretary"), the Acting Commissioner of the Food and Drug Administration ("FDA"), and the United States (collectively, "the federal Defendants").

Plaintiffs' complaint alleges three counts. Count One claims that all defendants violated the National Childhood Vaccine Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa-1, *et seq.* Count Two alleges that Merck committed fraud and conspired to commit fraud. Count Three seeks declaratory and injunctive relief, primarily in the form of an order directing the Secretary to instruct the FDA to revoke Merck's license to manufacture the MMR vaccine.

We affirm the district court's decision to dismiss Count One claims against both Merck and the federal Defendants.[2] Regarding Merck, Plaintiffs allege that all of their Count One claims arise under the Vaccine Act, but that Act does not establish a private right of action against manufacturers, such as Merck. The Vaccine Act sets forth administrative procedures that must be exhausted in order for a petitioner to bring a state law tort claim against a private entity and precludes actions against manufacturers by petitioners who have not administratively exhausted. *See* 42 U.S.C. §§ 300aa-22(a), 300aa-11(a)(2). But neither these provisions nor any other in the Vaccine Act enable petitioners to sue private entities for alleged violations of the Act. As we held in *Olmsted v. Pruco Life Insurance Co. of New Jersey*, 283 F.3d 429, 432 (2d Cir. 2002), where "[n]o provision of [a statute] explicitly provides for a private right of action for violations of [specific provisions of that statute], . . . we must presume that Congress did not intend one." That presumption is reinforced here because the provisions in question focus on the "person regulated rather than the individuals protected." *Id.* at 432-33 (internal quotation marks

[2] Although the district court relied on different grounds in dismissing Count One, we are free to affirm on any ground that has support in the record. *See Wright v. Giuliani*, 230 F.3d 543, 547 (2d Cir. 2000).

and citation omitted). Moreover, Congress created a citizen-suit provision to allow claims against the Secretary for failure to perform an act or duty under the Act, 42 U.S.C. § 300aa-31, and "Congress's explicit provision of a private right of action to enforce one section of a statute suggests that omission of an explicit private right to enforce other sections was intentional." *Olmsted*, 283 F.3d at 433. The district court was therefore correct in dismissing Plaintiffs' claims against Merck under Count 1.

Although Plaintiffs may sue the Secretary—and only the Secretary—pursuant to 42 U.S.C. § 300aa-31, Plaintiffs' complaint contains no factual allegations articulating which duties were violated or how they were violated.[3] Plaintiffs' claims against the Secretary for violations of the Vaccine Act were thus properly dismissed. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." (internal quotation marks and citation omitted)).

We likewise affirm the district court's dismissal of Count Two. "Under New York law, to state a cause of action for fraud, a plaintiff must allege a representation of material fact, the falsity of the representation, knowledge by the party making the representation that it was false when made, justifiable reliance by the plaintiff and resulting injury." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 291 (2d Cir. 2006) (internal quotation marks and citations omitted). Here, however, there was no reliance. The relevant vaccines were given to Baby Doe in 1999, yet the earliest allegedly fraudulent act took place in June 2000. Accordingly, Plaintiffs cannot establish that they relied on the purportedly fraudulent conduct. *See id.* (explaining that plaintiff could not demonstrate reliance on a statement in making an investment because the investment predated the statement). And because Plaintiffs' fraud claim fails, so does their conspiracy-to-commit-fraud claim. *See Crigger v. Fahnestock & Co., Inc.*, 443 F.3d 230, 237 (2d Cir. 2006) ("Under New York law, civil conspiracy to commit fraud, standing alone, is not actionable if the underlying independent tort has not been adequately pleaded." (internal quotation marks, ellipses, and citation omitted)).

Finally, we affirm the district court's dismissal of Count Three. With respect to Plaintiffs' challenge to the FDA's licensing of Merck to manufacture the MMR vaccine, the district court's invocation of the doctrine of primary jurisdiction was not erroneous. Reliance on the doctrine of primary jurisdiction is "appropriate whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (internal quotation marks and citation omitted). Here, the relevant considerations counsel for the conclusion that on this matter the FDA has primary jurisdiction. The question of the efficacy and safety of Merck's vaccines "involves technical or policy considerations within the agency's particular field of expertise." *See id.* at 82-83. In addition, this type of licensing is within the agency's discretion under 42 U.S.C. § 262. *See Ellis*, 443 F.3d at 83. Moreover, uniformity would be more appropriately reached through application to one administrative agency rather

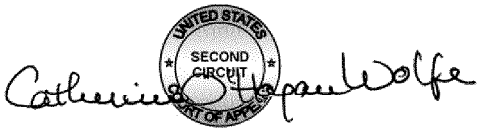
[3] Although Plaintiffs allege some facts in their briefing on appeal, Plaintiffs failed to allege any of these facts in their complaint despite having filed three different complaints in this action. Plaintiffs "should not be able effectively to amend a complaint through any document short of an amended pleading." *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 109 n.9 (3d Cir. 2002).

than the various courts. *See id.* at 82. And lastly, although the FDA provides for "citizen petitions," 21 C.F.R. § 10.30, there is no indication that Plaintiffs have filed one here. For these reasons, we agree with the district court that challenges to Merck's license should be directed in the first instance to the FDA.

With respect to Plaintiffs' challenge to New York's MMR-vaccine requirements, it is not apparent to us how any of the federal Defendants could be liable for New York's decision to require the MMR vaccine, and the State of New York is not a defendant in this suit. Indeed, Plaintiffs style this as a Fourteenth Amendment challenge, but the Fourteenth Amendment "applies to the states but not to the federal government." *See Noel v. Chapman*, 508 F.2d 1023, 1026 n.2 (2d Cir. 1975). Therefore, the district court correctly dismissed Count Three as well.

We have considered the remainder of Plaintiffs' arguments and find them to be without merit. Accordingly, the order of the district court hereby is AFFIRMED.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk



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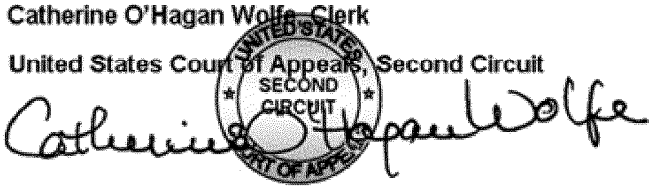
Catherine O'Hagan Wolfe, Clerk
United States Court of Appeals, Second Circuit



APPENDIX E - 42 U.S.C. §300AA – 1, ET SEQ. NATIONAL VACCINE INJURY COMPENSATION ACT, CHAPTER 6A, SUBCHAPTER XIX — VACCINES

42 USC CHAPTER 6A, SUBCHAPTER XIX: VACCINES

From Title 42—THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A—PUBLIC HEALTH SERVICE

SUBCHAPTER XIX—VACCINES

Prior Provisions

A prior subchapter XIX (§300aa et seq.), comprised of title XXI of the Public Health Service Act, act July 1, 1944, ch. 373, §§2101 to 2116, was renumbered title XXIII, §§2301 to 2316, of the Public Health Service Act, and transferred to subchapter XXI (§300cc et seq.) of this chapter, renumbered title XXV, §§2501 to 2514, of the Public Health Service Act, and transferred to subchapter XXV (§300aaa et seq.) of this chapter, renumbered title XXVI, §§2601 to 2614, of the Public Health Service Act, renumbered title XXVII, §§2701 to 2714, of the Public Health Service Act, and renumbered title II, part B, §§231 to 244, of the Public Health Service Act, and transferred to part B (§238 et seq.) of subchapter I of this chapter.

Part 1—National Vaccine Program

§300aa–1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

(July 1, 1944, ch. 373, title XXI, §2101, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756.)

Prior Provisions

A prior section 300aa–1, act July 1, 1944, §2102, was successively renumbered by subsequent acts and transferred, see section 238a of this title.
A prior section 2101 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

Effective Date

Pub. L. 99–660, title III, §323, Nov. 14, 1986, 100 Stat. 3784, as amended by Pub. L. 100–203, title IV, §4302(a), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(a), Nov. 26, 1991, 105 Stat. 1102, provided that: "Subtitle 1 of title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] shall take effect on the date of the enactment of this Act [Nov. 14, 1986] and parts A and B of subtitle 2 of such title [42 U.S.C. 300aa–10 et seq., 300aa–21 et seq.] shall take effect on October 1, 1988 and parts C and D of such title [42 U.S.C. 300aa–25 et seq., 300aa–31 et seq.] and this title [probably means provisions of title III of Pub. L. 99–660 other than those that enacted this subchapter and redesignated former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title; these other provisions amended sections 218, 242c, 262, 286, and 289f of this title and enacted provisions set out as notes under sections 201, 300aa–1, and 300aa–4 of this title] shall take effect on the date of the enactment of the Vaccine Compensation Amendments of 1987 [Dec. 22, 1987]."

Severability

Pub. L. 99–660, title III, §322, Nov. 14, 1986, 100 Stat. 3783, as amended by Pub. L. 101–239, title VI, §6602, Dec. 19, 1989, 103 Stat. 2293; Pub. L. 101–502, §5(g)(1), Nov. 3, 1990, 104 Stat. 1288, provided that:

"(a) In General.—Except as provided in subsection (b), if any provision [of] part A or B of subtitle 2 of title XXI of the Public Health Service Act [42 U.S.C. 300aa–10 et seq., 300aa–21 et seq.], as added by section 311(a), or the application of such a provision to any person or circumstance is held invalid by reason of a violation of the Constitution, both such parts shall be considered invalid.

"(b) Special Rule.—If any amendment made by section 6601 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239, amending sections 300aa–10 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] to title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] or the application of such a provision to any person or circumstance is held invalid by reason of the Constitution, subsection (a) shall not apply and such title XXI of the Public Health Service Act without such amendment shall continue in effect."

[Amendment by section 5(g)(1) of Pub. L. 101–502 to section 322(a) of Pub. L. 99–660, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

Evaluation of Program; Study and Report to Congress

Pub. L. 101–239, title VI, §6601(t), Dec. 19, 1989, 103 Stat. 2293, as amended by Pub. L. 102–168, title II, §201(b), Nov. 26, 1991, 105 Stat. 1103, directed the Secretary of Health and Human Services to evaluate the National Vaccine Injury Compensation Program under this subchapter and report results of such study to Committee on Energy and Commerce of House of Representatives and Committee on Labor and Human Resources of Senate not later than Jan. 1, 1993.

Related Studies

Pub. L. 99–660, title III, §312, Nov. 14, 1986, 100 Stat. 3779, directed Secretary of Health and Human Services, not later than 3 years after the effective date of this title (see Effective Date note above), to conduct, through studies by the Institute of Medicine of the National Academy of Sciences or other appropriate nonprofit private groups or associations, a review of pertussis vaccines and related illnesses and conditions and MMR vaccines, vaccines containing material intended to prevent or confer immunity against measles, mumps, and rubella disease, and related illnesses and conditions, make specific findings and report these findings in the Federal Register not later than 3 years after the effective date of this title, and at the same time these findings are published in the Federal Register, propose regulations as a result of such findings, and not later than 42 months after the effective date of this title, promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

Study of Other Vaccine Risks

Pub. L. 99–660, title III, §313, Nov. 14, 1986, 100 Stat. 3781, provided that:

"(a) Study.—

"(1) Not later than 3 years after the effective date of this title [see Effective Date note above], the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa–19]—

"(A) arrange for a broad study of the risks (other than the risks considered under section 102 [21 U.S.C. 382]) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act [42 U.S.C. 300aa–14], and

"(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

"(i) the circumstances under which any such vaccine should not be administered,

"(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

"(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

"(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

"(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

"(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa–19].

"(b) REVISION OF GUIDELINES.—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

"(c) FACTORS AFFECTING GUIDELINES.—Guidelines under subsection (a) shall take into account—

"(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

"(2) the medical and other characteristics of such potential recipients, and

"(3) the risks to the public of not having such vaccines administered.

"(d) DISSEMINATION.—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

"(1) physicians and other health care providers,

"(2) professional health associations,

"(3) State and local governments and agencies, and

"(4) other relevant entities."

REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION

Pub. L. 99–660, title III, §314, Nov. 14, 1986, 100 Stat. 3782, directed Secretary of Health and Human Services, not later than 1 year after the effective date of this title (see Effective Date note above) and after consultation with Advisory Commission on Childhood Vaccines and with other appropriate entities, to review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 300aa–14 of this title and by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines, and, if any such warning, instruction, or information is determined to be inadequate for such purpose in any respect, require at the same time that the manufacturers revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title.

STUDY OF IMPACT ON SUPPLY OF VACCINES

Pub. L. 99–660, title III, §316, Nov. 14, 1986, 100 Stat. 3786, provided that: "On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate—

"(1) an assessment of the impact of the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title, and enacting provisions set out as notes under this section and sections 201 and 300aa–1 of this title] on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act [42 U.S.C. 300aa–14], and

"(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children."

WAIVER OF PAPERWORK REDUCTION

Pub. L. 99–660, title III, §321, Nov. 14, 1986, 100 Stat. 3783, provided that: "Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this title and implementing the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title, and enacting provisions set out as notes under sections 201, 300aa–1, and 300aa–4 of this title]."

§300aa–2. Program responsibilities

(a) The Director of the Program shall have the following responsibilities:

(1) Vaccine research

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) Vaccine development

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) Safety and efficacy testing of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) Licensing of vaccine manufacturers and vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 263a of this title.

(5) Production and procurement of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) Distribution and use of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the Centers for Disease Control and Prevention and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) Evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) Coordinating governmental and non-governmental activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) Funding of Federal agencies

The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 300aa–3 of this title funds appropriated under section 300aa–6 of this title to supplement the funds otherwise available to such agencies for activities under the plan.

(b) In carrying out subsection (a) and in preparing the plan under section 300aa–3 of this title, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

(July 1, 1944, ch. 373, title XXI, §2102, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756; amended Pub. L. 102–531, title III, §312(d)(13), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 108–173, title IX, §900(e)(2)(F), Dec. 8, 2003, 117 Stat. 2372.)

Prior Provisions

A prior section 300aa–2, act July 1, 1944, §2103, was successively renumbered by subsequent acts and transferred, see section 238b of this title.
A prior section 2102 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

Amendments

2003—Subsec. (a)(7). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".
1992—Subsec. (a)(1), (3), (6), (7). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Encouraging Vaccine Innovation; Meetings

Pub. L. 114–255, div. A, title III, §3093(a), Dec. 13, 2016, 130 Stat. 1151, provided that: "The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics."

Grants for Research on Vaccine Against Valley Fever

Pub. L. 109–432, div. B, title IV, §402, Dec. 20, 2006, 120 Stat. 2994, authorized the Secretary of Health and Human Services to make grants for research on the development of a vaccine against coccidioidomycosis (commonly known as Valley Fever) before Oct. 1, 2012.

Demonstration Projects for Outreach Programs

Pub. L. 101–502, §2(b), Nov. 3, 1990, 104 Stat. 1285, provided that:
"(1) In general.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, may make grants to public and nonprofit private entities for the purpose of carrying out demonstration projects—
"(A) to provide, without charge, immunizations against vaccine-preventable diseases to children not more than 2 years of age who reside in communities whose population includes a significant number of low-income individuals; and
"(B) to provide outreach services to identify such children and to inform the parents (or other guardians) of the children of the availability from the entities of the immunizations specified in subparagraph (A).
"(2) Authorization of appropriations.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993."
[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

Supply of Vaccines

Pub. L. 101–502, §3, Nov. 3, 1990, 104 Stat. 1285, provided that:
"(a) In General.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period. Any proceeds received by the Secretary from the sale of vaccines from such supply shall be available to the Secretary for the purpose of purchasing vaccines for the supply. Such proceeds shall remain available for such purpose until expended.
"(b) Authorization of Appropriations.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995."
[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]
Pub. L. 100–177, title I, §110(b), Dec. 1, 1987, 101 Stat. 991, provided that:
"(1) In general.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period.
"(2) Authorization of Appropriations.—There are authorized to be appropriated to carry out paragraph (1) $5,000,000 for fiscal year 1988, and such sums as may be necessary for each of the fiscal years 1989 and 1990."
[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

§300aa–3. Plan

The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 300aa–2 of this title. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

(July 1, 1944, ch. 373, title XXI, §2103, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3757.)

Prior Provisions

A prior section 300aa–3, act July 1, 1944, §2104, which was renumbered section 2304 by Pub. L. 99–660, was transferred to section 300cc–3 of this title, prior to repeal by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

A prior section 2103 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

§300aa–4. Repealed. Pub. L. 105–362, title VI, §601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285

Section, act July 1, 1944, ch. 373, title XXI, §2104, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3757, related to national vaccine program report.

A prior section 300aa–4, act July 1, 1944, §2105, was repealed by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc–4 of this title.

A prior section 2104 of act July 1, 1944, was renumbered section 2304 by Pub. L. 99–660 and classified to section 300cc–3 of this title, and was repealed by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

§300aa–5. National Vaccine Advisory Committee

(a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

(b) The Committee shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

(3) advise the Director of the Program in the implementation of sections 300aa–2, 300aa–3, and 300aa–4 [1] of this title, and

(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 300aa–2, 300aa–3, and 300aa–4 [1] of this title.

(July 1, 1944, ch. 373, title XXI, §2105, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758.)

References in Text

Section 300aa–4 of this title, referred to in subsec. (b)(3), (4), was repealed by Pub. L. 105–362, title VI, §601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285.

Prior Provisions

A prior section 300aa–5, act July 1, 1944, §2106, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

A prior section 2105 of act July 1, 1944, was repealed by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc–4 of this title.

Termination of Advisory Committees

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] *See References in Text note below.*

§300aa–6. Authorization of appropriations

(a) To carry out this part other than section 300aa–2(9) of this title there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(b) To carry out section 300aa–2(9) of this title there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(July 1, 1944, ch. 373, title XXI, §2106, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–502, §4, Nov. 3, 1990, 104 Stat. 1286; Pub. L. 108–276, §2(c), July 21, 2004, 118 Stat. 842.)

Prior Provisions

A prior section 300aa–6, act July 1, 1944, §2107, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

A prior section 2106 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

Prior sections 300aa–7 to 300aa–9, act July 1, 1944, §§2108–2110, respectively, were successively renumbered by subsequent acts and transferred, see sections 238e to 238g, respectively, of this title.

Amendments

2004—Pub. L. 108–276 substituted provisions authorizing appropriations for fiscal years 2004 and 2005 for provisions authorizing appropriations for fiscal years 1991 through 1995 in subsecs. (a) and (b).

1990—Pub. L. 101–502 substituted provisions authorizing appropriations for fiscal years 1991 through 1995 for provisions authorizing appropriations for fiscal years 1987 through 1991 in subsecs. (a) and (b).

Part 2—National Vaccine Injury Compensation Program

Subpart A—Program Requirements

§300aa–10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program [1] for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(July 1, 1944, ch. 373, title XXI, §2110, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–239, title VI, §6601(b), Dec. 19, 1989, 103 Stat. 2285.)

Prior Provisions

A prior section 300aa–10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

A prior section 2110 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

Amendments

1989—Subsec. (c). Pub. L. 101–239 added subsec. (c).

Effective Date of 1989 Amendment

Section 6601(s) of Pub. L. 101–239, as amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–11 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] shall apply as follows:

"(A) Petitions filed after the date of enactment of this section [Dec. 19, 1989] shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] as amended by this section.

"(B) Petitions currently pending in which the evidentiary record is closed shall continue to proceed under the Program in accordance with the law in effect before the date of the enactment of this section, except that if the United States Court of Federal Claims is to review the findings of fact and conclusions of law of a special master on such a petition, the court may receive further evidence in conducting such review.

"(C) Petitions currently pending in which the evidentiary record is not closed shall proceed under the Program in accordance with the law as amended by this section.

All pending cases which will proceed under the Program as amended by this section shall be immediately suspended for 30 days to enable the special masters and parties to prepare for proceeding under the Program as amended by this section. In determining the 240-day period prescribed by section 2112(d) of the Public Health Service Act [42 U.S.C. 300aa–12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 U.S.C. 300aa–21(b)], as so amended, any period of suspension under the preceding sentence shall be excluded.

"(2) The amendments to section 2115 of the Public Health Service Act [42 U.S.C. 300aa–15] shall apply to all pending and subsequently filed petitions."

Effective Date

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, as amended, set out as a note under section 300aa–1 of this title.

[1] *So in original. Probably should be capitalized.*

§300aa–11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and

(II) such person elects under section 300aa–21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa–21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa–16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court [2] is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine. A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), 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, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(f) Maternal immunization

(1) In general

Notwithstanding any other provision of law, for purposes of this subpart, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

(2) Definition

As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1 except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term "mean".

(July 1, 1944, ch. 373, title XXI, §2111, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 100–203, title IV, §§4302(b), 4304(a), (b), 4306, 4307(1), (2), Dec. 22, 1987, 101 Stat. 1330–221, 1330-223, 1330-224; Pub. L. 101–239, title VI, §6601(c)(1)–(7), Dec. 19, 1989, 103 Stat. 2285, 2286; Pub. L. 101–502, §5(a), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 102–168, title II, §201(h)(1), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–43, title XX, §2012, June 10, 1993, 107 Stat. 214; Pub. L. 105–277, div. C, title XV, §1502, Oct. 21, 1998, 112 Stat. 2681–741; Pub. L. 106–310, div. A, title XVII, §1701(a), Oct. 17, 2000, 114 Stat. 1151; Pub. L. 114–255, div. A, title III, §3093(c)(2), (3), Dec. 13, 2016, 130 Stat. 1152.)

Codification

In subsecs. (a)(2)(A), (3), (4), (5)(A), (8), and (b)(1)(B), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 300aa–11, act July 1, 1944, §2112, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

A prior section 2111 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

Amendments

2016—Subsec. (b)(2). Pub. L. 114–255, §3093(c)(3), inserted at end "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine."

Subsec. (f). Pub. L. 114–255, §3093(c)(2), added subsec. (f).

2000—Subsec. (c)(1)(D)(iii). Pub. L. 106–310 added cl. (iii).

1998—Subsec. (c)(1)(D)(i). Pub. L. 105–277 struck out "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000" before ", or (ii) died".

1993—Subsec. (a)(10). Pub. L. 103–43 added par. (10).

1992—Subsec. (a)(1), (2)(A)(i)(I). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (a)(2)(A)(i), (ii). Pub. L. 102–168 realigned margins of cls. (i) and (ii).

1990—Subsec. (a)(2)(A). Pub. L. 101–502, §5(a)(1), substituted "unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—" and cls. (i) and (ii) for "unless—

"(i) a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death,

"(ii) the United States Claims Court has issued a judgment under section 300aa–12 of this title on such petition, and

"(iii) such person elects under section 300aa–21(a) of this title to file such an action."

Subsec. (a)(5)(A). Pub. L. 101–502, §5(a)(2), struck out "without prejudice" after "without prejudice or costs".

Subsec. (a)(5)(B). Pub. L. 101–502, §5(a)(3), substituted "plaintiff" for "plaintiff who".

Subsec. (d). Pub. L. 101–502, §5(a)(4), struck out "(d) except as provided in paragraph (3)," before "(d) Additional information".

Subsec. (e). Pub. L. 101–502, §5(a)(5), substituted "(e) Schedule" for "(e)(e) Schedule".

1989—Subsec. (a)(1). Pub. L. 101–239, §6601(c)(1), substituted "filing of a petition containing the matter prescribed in subsection (c)" for "filing of a petition" and inserted at end "The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title."

Subsec. (a)(2)(A)(i). Pub. L. 101–239, §6601(c)(2), struck out "under subsection (b) of this section" after "section 300aa–16 of this title,".

Subsec. (a)(5)(A). Pub. L. 101–239, §6601(c)(3)(A), substituted "petition to have such action dismissed without prejudice or costs" for "elect to withdraw such action".

Subsec. (a)(5)(B). Pub. L. 101–239, §6601(c)(3)(B), substituted "has pending" for "on October 1, 1988, had pending" and struck out "does not withdraw the action under subparagraph (A)" after "vaccine-related injury or death".

Subsec. (a)(6). Pub. L. 101–239, §6601(c)(4), substituted "November 15, 1988" for "the effective date of this subpart" in two places.

Subsec. (a)(8). Pub. L. 101–239, §6601(c)(5), added par. (8). Former par. (8) redesignated (9).

Subsec. (a)(9). Pub. L. 101–239, §6601(c)(5), (7), redesignated par. (8) as (9) and realigned margin.

Subsec. (c)(1). Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(1)" in introductory provisions.

Subsec. (c)(2). Pub. L. 101–239, §6601(c)(6)(B), (C), added par. (2) and redesignated former par. (2) as subsec. (d).

Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(2)".

Subsec. (c)(3). Pub. L. 101–239, §6601(c)(6)(C), (D), added par. (3). Former par. (3) redesignated subsec. (e).

Subsec. (d). Pub. L. 101–239, §6601(c)(6)(B), redesignated former subsec. (c)(2) as subsec. (d), expanded margin to full measure, inserted subsec. designation and heading, substituted "A petition may also include other available" for "all available", struck out "(including autopsy reports, if any)" after "relevant medical records", and substituted "administration of the vaccine." for "administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and".

Subsec. (e). Pub. L. 101–239, §6601(c)(6)(D), redesignated former subsec. (c)(3) as subsec. (e), expanded margin to full measure, inserted subsec. designation and heading, and substituted "The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition" for "appropriate".

1987—Subsec. (a)(1). Pub. L. 100–203, §4307(1), which directed that par. (1) be amended by substituting "with the United States Claims Court" for "with the United States district court for the district in which the petitioner resides or the injury or death occurred", was executed making the substitution for "with the United States district court for the district in which the petitioner resides or in which the injury or death occurred", as the probable intent of Congress.

Subsec. (a)(2)(A). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(2)(A)(ii). Pub. L. 100–203, §4307(2), substituted "the United States Claims Court" for "a district court of the United States".

Subsec. (a)(3). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(4). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(5)(A). Pub. L. 100–203, §4302(b)(2), substituted "after the effective date of this subpart" for "after the effective date of this subchapter".

Pub. L. 100–203, §4302(b)(1), substituted "who on the effective date of this subpart" for "who on the effective date of this part".

Subsec. (a)(5)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(6). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part" in two places.

Subsec. (a)(7). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Subsec. (a)(8). Pub. L. 100–203, §4304(a), added par. (8).

Subsec. (b)(1)(A). Pub. L. 100–203, §4304(b)(1), substituted "may, if the person meets the requirements of subsection (c)(1), file" for "may file".

Subsec. (b)(1)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (c)(1)(D). Pub. L. 100–203, §4304(b)(2), substituted "for more than 6 months" for "for more than 1 year", "and incurred" for ", (ii) incurred", and "(ii)" for "(iii)".

Change of Name

References to United States Claims Court deemed to refer to United States Court of Federal Claims, see section 902(b) of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 2000 Amendment

Pub. L. 106–310, div. A, title XVII, §1701(b), Oct. 17, 2000, 114 Stat. 1151, provided that: "The amendment made by subsection (a) [amending this section] takes effect upon the date of the enactment of this Act [Oct. 17, 2000], including with respect to petitions under section 2111 of the Public Health Service Act [42 U.S.C. 300aa–11] that are pending on such date."

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Pub. L. 102–168, title II, §201(i), Nov. 26, 1991, 105 Stat. 1104, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–12, 300aa–15, 300aa–16, 300aa–19, and 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title] shall take effect on the date of the enactment of this Act [Nov. 26, 1991].

"(2) The amendments made by subsections (d) and (f) [amending sections 300aa–12, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as if the amendments had been in effect on and after October 1, 1988."

Effective Date of 1990 Amendment

Pub. L. 101–502, §5(h), Nov. 3, 1990, 104 Stat. 1289, provided that: "The amendments made by subsections (f)(1) and (g) [amending section 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title and enacting provisions set out as a note under section 300aa–

12 of this title] shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) [amending this section and sections 300aa–12, 300aa–13, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as of September 30, 1990."

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[2] *See Change of Name note below.*

§300aa–12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa–11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa–11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa–11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa–11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's 2 judgment with such court of appeals.

(g) Notice

If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa–21(b) of this title or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be.

(July 1, 1944, ch. 373, title XXI, §2112, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3761; amended Pub. L. 100–203, title IV, §§4303(d)(2)(A), 4307(3), 4308(a), (b), Dec. 22, 1987, 101 Stat. 1330–222, 1330-224; Pub. L. 100–360, title IV, §411(o)(2), (3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(d)–(i), Dec. 19, 1989, 103 Stat. 2286–2290; Pub. L. 101–502, §5(b), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117; Pub. L. 102–168, title II, §201(c), (d)(1), (h)(2), (3), Nov. 26, 1991, 105 Stat. 1103, 1104; Pub. L. 102–572, title IX, §902(b), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(c), Aug. 10, 1993, 107 Stat. 646.)

Codification

In subsec. (c)(4), "on December 19, 1989," substituted for "upon the date of the enactment of this subsection" and "on the date of the enactment of this subsection".

In subsec. (d)(3)(D), "October 1, 1988," substituted for "the effective date of this part".

Prior Provisions

A prior section 300aa–12, act July 1, 1944, §2113, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

A prior section 2112 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

Amendments

1993—Subsec. (d)(3)(D). Pub. L. 103–66 substituted "30 months (but for not more than 6 months at a time)" for "540 days".

1992—Subsecs. (a), (c) to (g). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" and "Court of Federal Claims" for "Claims Court", wherever appearing.

1991—Subsec. (d)(3)(D). Pub. L. 102–168, §201(c), (h)(2), realigned margin and substituted "540 days" for "180 days".

Subsec. (g). Pub. L. 102–168, §201(h)(3), made technical amendment to underlying provisions of original Act.

Pub. L. 102–168, §201(d)(1), substituted "or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be" for "and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take certain actions" before period at end.

1990—Subsec. (d)(3)(D). Pub. L. 101–502, §5(b)(1), added subpar. (D).

Subsec. (g). Pub. L. 101–502, §5(b)(2), added subsec. (g).

1989—Subsec. (a). Pub. L. 101–239, §6601(d), substituted "and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction" for "shall have jurisdiction (1)", ". The United States Claims Court may issue" for ", and (2) to issue", and "deems" for "deem".

Subsec. (b)(1). Pub. L. 101–239, §6601(f), substituted "In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28." for "The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 300aa–11(b) of this title. Except as provided in paragraph (2), no other person may intervene in any such proceeding."

Subsec. (c). Pub. L. 101–239, §6601(e)(2), added subsec. (c). Former subsec. (c) redesignated (d).
Subsec. (d). Pub. L. 101–239, §6601(e)(1), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).
Subsec. (d)(1). Pub. L. 101–239, §6601(g)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Following receipt of a petition under subsection (a) of this section, the United States Claims Court shall designate a special master to carry out the functions authorized by paragraph (2)."
Subsec. (d)(2) to (4). Pub. L. 101–239, §6601(g)(2), added pars. (2) to (4) and struck out former par. (2) which prescribed functions of special masters.
Subsec. (e). Pub. L. 101–239, §6601(h), substituted "Action by United States Claims Court" for "Action by court" as heading and amended text generally. Prior to amendment, text read as follows:
"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.
"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.
"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed."
Pub. L. 101–239, §6601(e)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).
Subsec. (f). Pub. L. 101–239, §6601(i), inserted "within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals" after "with such court of appeals".
Pub. L. 101–239, §6601(e)(1), redesignated subsec. (e) as (f).
1988—Subsec. (c)(2). Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(a), see 1987 Amendment note below.
Subsec. (e). Pub. L. 100–360, §411(o)(2), made technical amendment to directory language of Pub. L. 100–203, §4307(3)(C), see 1987 Amendment note below.
Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(b), see 1987 Amendment note below.
1987—Subsec. (a). Pub. L. 100–203, §4307(3)(A), substituted "United States Claims Court" for "district courts of the United States" and "the court" for "the courts".
Subsec. (c)(1). Pub. L. 100–203, §4307(3)(B), substituted "the United States Claims Court" for "the district court of the United States in which the petition is filed".
Subsec. (c)(2). Pub. L. 100–203, §4308(a), as added by Pub. L. 100–360, §411(o)(3)(A), inserted ", shall prepare and submit to the court proposed findings of fact and conclusions of law," in introductory provisions and struck out subpar. (E) which read as follows: "prepare and submit to the court proposed findings of fact and conclusions of law."
Subsec. (e). Pub. L. 100–203, §4308(b), as added by Pub. L. 100–360, §411(o)(3)(A), inserted "within 60 days of the date of the judgment" after "petition filed".
Pub. L. 100–203, §4307(3)(C), as amended by Pub. L. 100–360, §411(o)(2), substituted "the United States Claims Court" for "a district court of the United States" and "for the Federal Circuit" for "for the circuit in which the court is located".
Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e) and struck out former subsec. (e) relating to administration of an award.
Subsec. (f). Pub. L. 100–203, §4303(d)(2)(A), struck out subsec. (f) which related to revision of an award.
Subsec. (g). Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e).

Change of Name

"United States magistrate judges" substituted for "United States magistrates" in subsec. (c)(6)(C) pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by section 201(d)(1) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 240-day period prescribed in subsec. (d) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Termination of Reporting Requirements

For termination, effective May 15, 2000, of provisions in subsec. (c)(6)(E) of this section relating to reporting annually to the Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 13 of House Document No. 103–7.

Review by 3-Judge Panel

Section 322(c) of Pub. L. 99–660, as added by Pub. L. 101–502, §5(g)(2), Nov. 3, 1990, 104 Stat. 1288, and amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that: "If the review authorized by section 2112(f) [42 U.S.C. 300aa–12(f)] is held invalid because the judgment of the United States Court of Federal Claims being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Court of Federal Claims. Such panel shall not include the judge who participated in such judgment."
[Enactment of section 322(c) of Pub. L. 99–660 by section 5(g)(2) of Pub. L. 101–502, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

[1] *So in original. Probably should be a reference to the United States Court of Federal Claims.*

[2] *So in original. Probably should be a reference to the United States Court of Federal Claims.*

§300aa–13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and

(B) that 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.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa–11 of this title.

(July 1, 1944, ch. 373, title XXI, §2113, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3763; amended Pub. L. 100–203, title IV, §4307(4), Dec. 22, 1987, 101 Stat. 1330–224; Pub. L. 101–239, title VI, §6601(j), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 101–502, §5(c), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Prior Provisions

A prior section 300aa–13, act July 1, 1944, §2114, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

A prior section 2113 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

Amendments

1992—Subsec. (c). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

1990—Subsec. (c). Pub. L. 101–502 inserted "the" after "special masters of".

1989—Subsecs. (a)(1), (b). Pub. L. 101–239, §6601(j)(1), substituted "special master or court" for "court" wherever appearing.

Subsec. (c). Pub. L. 101–239, §6601(j)(2), inserted "special masters of" after "established by the".

1987—Subsec. (c). Pub. L. 100–203 substituted "the United States Claims Court" for "a district court of the United States".

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days

C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III. Polio Vaccines (other than Inactivated Polio Vaccine).	
A. Paralytic polio	
—in a non-immunodeficient recipient	30 days
—in an immunodeficient recipient	6 months
—in a vaccine-associated community case	Not applicable
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV. Inactivated Polio Vaccine.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) Vaccines recommended for use in pregnant women

The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.

(July 1, 1944, ch. 373, title XXI, §2114, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3764; amended Pub. L. 101–239, title VI, §6601(k), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 103–66, title XIII, §13632(a)(2), Aug. 10, 1993, 107 Stat. 645; Pub. L. 114–255, div. A, title III, §3093(c)(1), Dec. 13, 2016, 130 Stat. 1152.)

Prior Provisions

A prior section 300aa–14, act July 1, 1944, §2115, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

A prior section 2114 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

Amendments

2016—Subsec. (e)(3). Pub. L. 114–255 added par. (3).

1993—Subsec. (e). Pub. L. 103–66 amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: "The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table."

1989—Subsec. (a). Pub. L. 101–239, §6601(k)(1), substituted "(b)(2)" for "(c)(2)" in items I.D. and II.C. in table.

Subsec. (b)(3)(B). Pub. L. 101–239, §6601(k)(2), substituted "300aa–11 of this title" for "300aa–11(b) of this title".

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Revisions of Vaccine Injury Table

The Vaccine Injury Table as modified by regulations promulgated by the Secretary of Health and Human Services is set out at 42 CFR 100.3.

Pub. L. 103–66, title XIII, §13632(a)(3), Aug. 10, 1993, 107 Stat. 646, provided that: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a))."

§300aa–15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa–16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e)).[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before October 1, 1988, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before October 1, 1988, in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa–11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa–21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa–12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa–21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa–21(a) of this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1988, shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title XXI, §2115, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3767; amended Pub. L. 100–203, title IV, §§4302(b), 4303(a)–(d)(1), (e), (g), 4307(5), (6), Dec. 22, 1987, 101 Stat. 1330–221 to 1330-223, 1330-225; Pub. L. 100–360, title IV, §411(o)(1), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(c)(8), (l), Dec. 19, 1989, 103 Stat. 2286, 2290; Pub. L. 101–502, §5(d), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(e), (f), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–531, title III, §314, Oct. 27, 1992, 106 Stat. 3508; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(b), Aug. 10, 1993, 107 Stat. 646.)

REFERENCES IN TEXT

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in subsec. (f)(3), is title II of Pub. L. 99–177, Dec. 12, 1985, 99 Stat. 1038. Part C of the Act is classified generally to subchapter I (§900 et seq.) of chapter 20 of Title 2, The Congress. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Codification

In subsecs. (a), (b), (e)(2), (f)(4)(B), (i), and (j), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 300aa–15, act July 1, 1944, §2116, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

A prior section 2115 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

Amendments

1993—Subsec. (j). Pub. L. 103–66 substituted "$110,000,000 for each succeeding fiscal year" for "$80,000,000 for each succeeding fiscal year".

1992—Subsecs. (e)(1), (f)(2). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

Subsec. (j). Pub. L. 102–531 increased authorization for fiscal year 1993 from $80,000,000 to $110,000,000.

1991—Subsec. (f)(4)(A). Pub. L. 102–168, §201(e)(1)(A), (2), struck out "of the proceeds" after "portion" and substituted "Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "trust fund".

Subsec. (f)(4)(B). Pub. L. 102–168, §201(e)(1)(B), which directed substitution of "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion" for "paid in 4 equal installments of which all or portion of the proceeds" was executed by making the substitution for "paid in 4 equal annual installments of which all or a portion of the proceeds" to reflect the probable intent of Congress.

Subsec. (f)(4)(C). Pub. L. 102–168, §201(f), added subpar. (C).

1990—Subsec. (e)(2). Pub. L. 101–502, §5(d)(1), inserted "of compensation" before "limited to the costs".

Subsec. (f)(2). Pub. L. 101–502, §5(d)(2)(A), substituted "section 300aa–21(a)" for "section 300aa–21(b)".

Subsec. (f)(4)(B). Pub. L. 101–502, §5(d)(2)(B), substituted "subsection (j)" for "subsection (i)" and "the limitation on civil actions prescribed by section 300aa–21(a) of this title" for "section 300aa–11(a) of this title".

Subsec. (j). Pub. L. 101–502, §5(d)(3), inserted before period at end of first sentence ", and $80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B)".

1989—Subsec. (b). Pub. L. 101–239, §6601(l)(1), substituted "may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—" and cls. (1) to (3) for "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000."

Subsec. (e)(1). Pub. L. 101–239, §6601(l)(2)(A), substituted "In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover" for "The judgment of the United States Claims Court on a petition filed under section 300aa–11 of this title awarding compensation shall include an amount to cover".

Pub. L. 101–239, §6601(l)(2)(B), (C), substituted "the special master or court may award an amount of compensation to cover" for "the court may include in the judgment an amount to cover" and "the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition" for "the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action".

Subsec. (e)(2). Pub. L. 101–239, §6601(l)(2)(D), which directed amendment of par. (2) by substituting "the special master or court may also award an amount of compensation" for "the judgment of the court on such petition may include an amount", could not be executed because of the prior amendment by Pub. L. 101–239, §6601(c)(8)(B), see Amendment note below.

Pub. L. 101–239, §6601(c)(8), substituted "and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed" for "and elected under section 300aa–11(a)(4) of this title to withdraw such action" and "in awarding compensation on such petition the special master or court may include" for "the judgment of the court on such petition may include".

Subsec. (e)(3). Pub. L. 101–239, §6601(l)(2)(E), substituted "awarded as compensation by the special master or court under paragraph (1)" for "included under paragraph (1) in a judgment on such petition".

Subsec. (f)(3). Pub. L. 101–239, §6601(l)(3)(A), inserted "under the Program and the costs of carrying out the Program" after "Payments of compensation".

Subsec. (f)(4)(A). Pub. L. 101–239, §6601(l)(3)(B), struck out "made in a lump sum" after "the Program shall be" and inserted "and shall be paid from the trust fund in a lump sum of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner" after "elements of the compensation".

Subsec. (f)(4)(B). Pub. L. 101–239, §6601(l)(3)(C), substituted "determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum" for "paid in 4 equal annual installments".

Subsec. (g). Pub. L. 101–239, §6601(l)(4)(A), inserted "(other than under title XIX of the Social Security Act)" after "State health benefits program".

Subsec. (h). Pub. L. 101–239, §6601(l)(4)(B), inserted before period at end ", except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act".

Subsec. (i)(1). Pub. L. 101–239, §6601(l)(5), which directed amendment of par. (1) by substituting "(j)" for "(i)", could not be executed because "(i)" did not appear.

Subsec. (j). Pub. L. 101–239, §6601(l)(6), struck out "and" after "fiscal year 1991," and inserted ", $80,000,000 for fiscal year 1993" after "fiscal year 1992".

1988—Subsec. (i)(1). Pub. L. 100–360, §411(o)(1)(A), substituted "by the Secretary from appropriations under subsection (j)" for "from appropriations under subsection (i)".

Subsec. (j). Pub. L. 100–360, §411(o)(1)(B), inserted "to the Department of Health and Human Services".

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Pub. L. 100–203, §4303(d)(1)(A), struck out last two sentences which read as follows: "Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum."

Subsec. (a)(1). Pub. L. 100–203, §4303(c), struck out last sentence of subpars. (A) and (B) each of which read as follows: "The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa–11(c)(1)(D)(ii) of this title."

Subsec. (b). Pub. L. 100–203, §4303(e), substituted "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount

that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000" for "shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e)(1). Pub. L. 100–203, §4307(5), substituted "of the United States Claims Court" for "of a court" in two places.

Subsec. (e)(2). Pub. L. 100–203, §4302(b), substituted "effective date of this subpart, filed a" for "effective date of this subchapter, filed a" and "effective date of this subpart in preparing" for "effective date of this part in preparing".

Subsec. (f). Pub. L. 100–203, §4303(d)(1)(B), (g), added par. (4) and redesignated a second subsec. (f), relating to the Program not being primarily liable, as subsec. (g).

Subsec. (f)(2). Pub. L. 100–203, §4307(6), substituted "United States Claims Court" for "district court of the United States".

Subsecs. (g), (h). Pub. L. 100–203, §4303(g), redesignated a second subsec. (f), relating to the Program not being liable, as (g) and redesignated former subsec. (g) as (h).

Subsecs. (i), (j). Pub. L. 100–203, §4303(a), (b), added subsecs. (i) and (j).

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by section 201(f) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

Amendment by Pub. L. 101–239 applicable to all pending and subsequently filed petitions, see section 6601(s)(2) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

[1] *So in original. Probably should be preceded by another closing parenthesis.*

§300aa–16. Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before October 1, 1988, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa–11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action or (2) an election is made under section 300aa–21(b) of this title to withdraw the petition.

(July 1, 1944, ch. 373, title XXI, §2116, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3769; amended Pub. L. 100–203, title IV, §4302(b)(2), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(m)(1), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(e), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(2), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 103–66, title XIII, §13632(a)(1), Aug. 10, 1993, 107 Stat. 645.)

Codification

In subsec. (a)(1) to (3), "October 1, 1988" and "October 1, 1988," substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 2116 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

Amendments

1993—Subsec. (b). Pub. L. 103–66 substituted "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file" for "such person may file".

1991—Subsec. (c). Pub. L. 102–168 substituted "or (2)" for ", (2)" and struck out ", or (3) the petition is considered withdrawn under section 300aa–21(b) of this title."

1990—Subsec. (a)(1). Pub. L. 101–502, §5(e)(1), substituted "28 months" for "24 months" and inserted before comma at end "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months

after the date of administration of the vaccine".

Subsec. (c). Pub. L. 101–502, §5(e)(2), substituted "and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action, (2) an election is made under section 300aa–21(b) of this title to withdraw the petition, or (3) the petition is considered withdrawn under section 300aa–21(b) of this title" for "and ending on the date a final judgment is entered on the petition".

1989—Subsec. (c). Pub. L. 101–239 substituted "300aa–11 of this title" for "300aa–11(b) of this title".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this subchapter" in pars. (1) to (3).

Effective Date of 1991 Amendment

Amendment by Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–17. Subrogation

(a) General rule

Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated [1] to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) Disposition of amounts recovered

Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(July 1, 1944, ch. 373, title XXI, §2117, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3770; amended Pub. L. 100–203, title IV, §4307(7), Dec. 22, 1987, 101 Stat. 1330–225; Pub. L. 101–239, title VI, §6601(m)(2), Dec. 19, 1989, 103 Stat. 2291.)

Amendments

1989—Subsec. (b). Pub. L. 101–239 substituted "the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "the trust fund which has been established to provide compensation under the Program".

1987—Subsec. (a). Pub. L. 100–203 struck out par. (1) designation before "Upon" and struck out par. (2) which read as follows: "In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 300aa–15 of this title for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1)."

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] *So in original. Probably should be "subrogated".*

§300aa–18. Repealed. Pub. L. 100–203, title IV, §4303(d)(2)(B), Dec. 22, 1987, 101 Stat. 1330–222

Section, act July 1, 1944, ch. 373, title XXI, §2118, as added Nov. 14, 1986, Pub. L. 99–660, title III, §311(a), 100 Stat. 3771, provided for annual increases for inflation of compensation under subsections (a)(2) and (a)(4) of section 300aa–15 of this title and civil penalty under section 300aa–27(b) of this title.

§300aa–19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of October 1, 1988. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5 for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa–27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 300aa–25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

(July 1, 1944, ch. 373, title XXI, §2119, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3771; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(g), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–531, title III, §312(d)(14), Oct. 27, 1992, 106 Stat. 3505.)

Codification

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1992—Subsec. (a)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1991—Subsec. (c). Pub. L. 102–168 inserted "present at the meeting" before period at end.

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part" in last sentence.

Termination of Advisory Commissions

Advisory commissions established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a commission established by the President or an officer of the Federal Government, such commission is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a commission established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

References in Other Laws to GS–16, 17, or 18 Pay Rates

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SUBPART B—ADDITIONAL REMEDIES

§300aa–21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa–12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa–11 of this title shall file with the clerk of the United States Court of Federal Claims —

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, 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. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa–11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa–11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa–12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa–12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa–12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa–11 of this title shall, except as provided in section 300aa–16(c) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, ch. 373, title XXI, §2121, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3772; amended Pub. L. 100–203, title IV, §§4304(c), 4307(8), 4308(c), Dec. 22, 1987, 101 Stat. 1330–224, 1330-225; Pub. L. 100–360, title IV, §411(o)(3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(n), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(f), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(3), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Codification

In subsec. (a), "October 1, 1988," and "October 1, 1988" substituted for "the effective date of this part".

Amendments

1992—Subsecs. (a), (b). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (b). Pub. L. 102–168 substituted "Continuance or withdrawal of petition" for "Withdrawal of petition" in heading, redesignated introductory provisions of par. (1) as introductory provisions of subsec. (b) and substituted "a notice in writing choosing to continue or to withdraw the petition" for "a notice in writing withdrawing the petition", redesignated subpars. (A) and (B) of former par. (1) as pars. (1) and (2), respectively, and realigned margins, struck out at end of former par. (1) "If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph.", and struck out par. (2) which read as follows: "If a special master or the court does not enter a decision or make a judgment on a petition filed under section 300aa–11 of this title within 30 days of the provision of the notice in accordance with section 300aa–12(g) of this title, the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under paragraph (1)."

1990—Subsec. (a). Pub. L. 101–502, §5(f)(1), in closing provisions, inserted after second sentence "If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, 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." and inserted "for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988" after "actions" in last sentence.

Subsec. (b). Pub. L. 101–502, §5(f)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "If the United States Claims Court fails to enter a judgment under section 300aa–12 of this title on a petition filed under section 300aa–11 of this title within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed, the petitioner may submit to the court a notice in writing withdrawing the petition. An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made. A person who has submitted a notice under this subsection may, notwithstanding section 300aa–11(a)(2) of this title, thereafter maintain a civil action for damages in a State or Federal court without regard to this subpart and consistent with otherwise applicable law."

1989—Subsec. (a). Pub. L. 101–239, §6601(n)(1)(A), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: "After the judgment of the United States Claims Court under section 300aa–11 of this title on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—".

Pub. L. 101–239, §6601(n)(1)(B), amended last sentence generally. Prior to amendment, last sentence read as follows: "If a person elects to receive compensation under a judgment of the court or is deemed to have accepted the judgment of the court, such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered."

Subsec. (b). Pub. L. 101–239, §6601(n)(2), substituted "within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title)" for "within 365 days" in first sentence and amended second sentence generally. Prior to amendment, second sentence read as follows: "Such a notice shall be filed not later than 90 days after the expiration of such 365-day period."

1988—Subsec. (a). Pub. L. 100–360 added Pub. L. 100–203, §4308(c), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4308(c), as added by Pub. L. 100–360, substituted "the court's final judgment" for "the entry of the court's judgment" in concluding provisions.

Pub. L. 100–203, §4307(8), substituted "the United States Claims Court" for "a district court of the United States" and "the court" for "a court" in three places.

Subsecs. (b), (c). Pub. L. 100–203, §4304(c), added subsec. (b) and redesignated former subsec. (b) as (c).

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by Pub. L. 102–168 effective as in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by section 5(f)(1) of Pub. L. 101–502 effective Nov. 14, 1986, and amendment by section 5(f)(2) of Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 420-day period prescribed in subsec. (b) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Effective Date

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa–23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

(July 1, 1944, ch. 373, title XXI, §2122, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3773; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

Codification

In subsecs. (b)(1), (c), "October 1, 1988" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsecs. (b)(1), (c). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

§300aa–23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa–11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa–22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

(July 1, 1944, ch. 373, title XXI, §2123, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §§4302(b)(1), 4307(9), Dec. 22, 1987, 101 Stat. 1330–221, 1330-225; Pub. L. 101–239, title VI, §6601(o), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (d)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

Codification

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1992—Subsec. (e). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" in two places.

1989—Subsec. (e). Pub. L. 101–239 substituted "finding of fact or conclusion of law" for "finding", "special master" for "master appointed by such court", and directed substitution of "the United States Claims Court and subsequent appellate review" for "a district court of the United States" which was executed by inserting "and subsequent appellate review" after "the United States Claims Court" the second place it appeared to reflect the probable intent of Congress and the amendment by Pub. L. 100–203, §4307(a), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e). Pub. L. 100–203, §4307(9), substituted "the United States Claims Court" for "a district court of the United States" in two places.

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

SUBPART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN UNITED STATES

§300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Codification

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsec. (b)(1), (3). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Effective Date

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–26. Vaccine information

(a) General rule

Not later than 1 year after December 22, 1987, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

(4) such other relevant information as may be determined by the Secretary.

(d) Health care provider duties

On and after a date determined by the Secretary which is—

(1) after the Secretary develops the information materials required by subsection (a), and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

(July 1, 1944, ch. 373, title XXI, §2126, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3775; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(p), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–531, title III, §312(d)(15), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–183, title VII, §708, Dec. 14, 1993, 107 Stat. 2242.)

Codification

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1993—Subsec. (a). Pub. L. 103–183, §708(c), inserted "or to any other individual" after "to the legal representatives of any child".

Subsec. (b). Pub. L. 103–183, §708(a), struck out "by rule" after "revised" in introductory provisions and substituted "and 60" for ", opportunity for a public hearing, and 90" in par. (1).

Subsec. (c). Pub. L. 103–183, §708(b), inserted in introductory provisions "shall be based on available data and information," after "such materials", added pars. (1) to (4), and struck out former pars. (1) to (10) which read as follows:

"(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

"(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

"(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

"(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

"(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

"(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

"(7) the contraindications to (and bases for delay of) the administration of the vaccine,

"(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

"(9) a summary of—

"(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and

"(B) the availability of the Program, and

"(10) such other relevant information as may be determined by the Secretary."

Subsec. (d). Pub. L. 103–183, §708(c), (d), in concluding provisions, inserted "or to any other individual" after "to the legal representatives of any child", substituted "supplemented with visual presentations or oral explanations, in appropriate cases" for "or other written information which meets the requirements of this section", and struck out "or other information" after "Such materials".

1992—Subsec. (b)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1989—Subsec. (c)(9). Pub. L. 101–239 amended par. (9) generally. Prior to amendment, par. (9) read as follows: "a summary of relevant State and Federal laws concerning the vaccine, including information on—

"(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

"(B) the availability of the Program, and".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

(July 1, 1944, ch. 373, title XXI, §2127, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(q), Dec. 19, 1989, 103 Stat. 2292.)

Codification

In subsecs. (a)(1), (c), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1989—Subsecs. (b), (c). Pub. L. 101–239 added subsec. (b) and redesignated former subsec. (b) as (c).
1987—Subsecs. (a)(1), (b). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Change of Name

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–28. Manufacturer recordkeeping and reporting

(a) General rule

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after December 22, 1987—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, ch. 373, title XXI, §2128, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Codification

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

SUBPART D—GENERAL PROVISIONS

§300aa–31. Citizen's actions

(a) General rule

Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

(July 1, 1944, ch. 373, title XXI, §2131, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 100–203, title IV, §4305, Dec. 22, 1987, 101 Stat. 1330–224.)

Amendments

1987—Subsec. (c). Pub. L. 100–203, which directed that subsec. (c) be amended by substituting "to any plaintiff who substantially prevails on one or more significant issues in the action" for "to any party, whenever the court determines that such award is appropriate", was executed by making the substitution for "to any party, whenever the court determines such award is appropriate", to reflect the probable intent of Congress.

Effective Date

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

(July 1, 1944, ch. 373, title XXI, §2132, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778.)

§300aa–33. Definitions

For purposes of this part:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 300aa–28 of this title, such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 300aa–19 of this title.

(B) The term "Vaccine Injury Table" means the table set out in section 300aa–14 of this title.

(July 1, 1944, ch. 373, title XXI, §2133, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 107–296, title XVII, §§1714–1716, Nov. 25, 2002, 116 Stat. 2320, 2321; Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.)

Amendments

2003—Pars. (3), (5), (7). Pub. L. 108–7 repealed Pub. L. 107–296, §§1714–1717, and provided that this chapter shall be applied as if the sections repealed had never been enacted. See 2002 Amendment notes below.

2002—Par. (3). Pub. L. 107–296, §1714, which directed amendment of first sentence by substituting "any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine" for "under its label any vaccine set forth in the Vaccine Injury Table" and of second sentence by inserting "including any component or ingredient of any such vaccine" before period at end, was repealed by Pub. L. 108–7.

Par. (5). Pub. L. 107–296, §1715, which directed insertion of "For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label." at end, was repealed by Pub. L. 108–7.

Par. (7). Pub. L. 107–296, §1716, which directed addition of par. (7), was repealed by Pub. L. 108–7, §102(a). Par. (7) read as follows: "The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label."

Effective Date of 2002 Amendment

Pub. L. 107–296, title XVII, §1717, Nov. 25, 2002, 116 Stat. 2321, which provided that the amendments made by sections 1714, 1715, and 1716 (amending this section) shall apply to all actions or proceedings pending on or after Nov. 25, 2002, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding, was repealed by Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.

Construction of Amendments

Pub. L. 108–7, div. L, §102(b), (c), Feb. 20, 2003, 117 Stat. 528, provided that:

"(b) Application of the Public Health Service Act.—The Public Health Service Act (42 U.S.C. 201 et seq.) shall be applied and administered as if the sections repealed by subsection (a) [repealing sections 1714 to 1717 of Pub. L. 107–296, which amended this section and enacted provisions set out as a note under this section] had never been enacted.

"(c) Rule of Construction.—No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296), or from this repeal [repealing sections 1714 to 1717 of Pub. L. 107–296], regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296) [Nov. 25, 2002]. Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02–392V (October 11, 2002), was incorrectly decided."

§300aa–34. Termination of program

(a) Reviews

The Secretary shall review the number of awards of compensation made under the program to petitioners under section 300aa–11 of this title for vaccine-related injuries and deaths associated with the administration of vaccines on or after December 22, 1987, as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on December 22, 1987.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) Report

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 300aa–21(a) of this title exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after December 22, 1987, may be filed under section 300aa–11 of this title.

Section 300aa–11(a) of this title and subpart B of this part shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	**Total number of awards by the end of the period reviewed**
12 months after December 22, 1987	150
13th through the 15th month after December 22, 1987	188
16th through the 18th month after December 22, 1987	225
19th through the 21st month after December 22, 1987	263
22nd through the 24th month after December 22, 1987	300
25th through the 27th month after December 22, 1987	338
28th through the 30th month after December 22, 1987	375
31st through the 33rd month after December 22, 1987	413
34th through the 36th month after December 22, 1987	450
37th through the 39th month after December 22, 1987	488
40th through the 42nd month after December 22, 1987	525
43rd through the 45th month after December 22, 1987	563
46th through the 48th month after December 22, 1987	600.

(July 1, 1944, ch. 373, title XXI, §2134, as added Pub. L. 100–203, title IV, §4303(f), Dec. 22, 1987, 101 Stat. 1330–222.)

CODIFICATION

In subsecs. (a) and (b), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

APPENDIX F - CHILD DOE/77 V. SECRETARY OF HEALTH AND HUMAN SERVICES, MMR VACCINE; THIMEROSAL-CONTAINING VACCINES, AUTISM SPECTRUM DISORDER; FINDING OF ENTITLEMENT; DAMAGES DECISION BASED ON PROFFER, SPECIAL MASTER CAMPBELL-SMITH, PUBLISHED AUGUST 27, 2010

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(E-Filed: July 21, 2010; Re-Issued: July 22, 2010;
Re-Issued for Redaction: July 23, 2010; Re-issued for Redaction: August 27, 2010)

CHILD DOE/77, a minor, by [redacted] Parents and Natural Guardians, JANE DOE/77 AND JOHN DOE/77, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	MMR Vaccine; Thimerosal-Containing Vaccines; Autism Spectrum Disorder; Finding of Entitlement; Damages Decision Based On Proffer [redacted] Special Master Campbell-Smith **TO PUBLISH**

Clifford J. Shoemaker, Vienna, VA, for petitioners

Catharine E. Reeves, Washington, DC, for respondent

CAMPBELL-SMITH, Special Master

DECISION AWARDING DAMAGES[1]

[1] Vaccine Rule 18(b) provides that all of the decisions of the special masters will be made available to the public unless an issued decision contains trade secrets or commercial or financial information that is privileged or confidential, or the decision contains medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. When a special master issues a decision or substantive order, the parties have 14 days within which to move for the redaction of privileged or confidential information before the document's public disclosure.

On October 25, 2002, petitioners, John and Jane Doe/77, filed a petition on behalf of their minor child seeking compensation under the National Vaccine Injury Compensation Program ("the Vaccine Program") for a vaccine-related injury.[2]

Respondent has conceded that petitioners are entitled to compensation due to the significant aggravation of Child Doe/77's pre-existing mitochondrial disorder based on an MMR vaccine Table presumptive injury of encephalopathy, which eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela.

Based on the persuasive factors supporting petitioner's vaccine claim and respondent's election not to challenge petitioner's claim, the undersigned finds that petitioner is entitled to compensation under the Vaccine Program. Accordingly, a determination of damages is appropriate.

On July 20, 2010, respondent filed a Proffer on Award of Compensation (Proffer). On July 20, 2010, petitioners orally accepted respondent's Proffer. Based on the record as a whole, the undersigned finds that petitioners are entitled to an award as stated in the Proffer. Pursuant to the terms stated in the attached Proffer, the court awards petitioners:

1. A lump sum payment of $1,507,284.67, representing compensation for life care expenses expected to be incurred during the first year after judgment ($624,713.32), lost future earnings ($674,410.67) and pain and suffering ($208,160.68), in the form of a check payable to petitioners, as the court appointed guardian(s)/conservator(s) of the estate of Child Doe/77, for the benefit of Child Doe/77. No payments shall be made until petitioners provide respondent with documentation establishing that they have been appointed as the guardian(s)/conservator(s) of Child Doe/77's estate;

2. A lump sum payment of $140,109.67, representing compensation for past unreimbursable expenses, payable to John and Jane Doe/77, petitioners;

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[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

3. A lump sum payment of $7,821.81, representing compensation for satisfaction of the State of [redacted] Medicaid lien, payable jointly to petitioner and

[redacted] Department of Community Health Subrogation Unit
[redacted]
[redacted]
[redacted]
Attn: [redacted]

4. An amount sufficient to purchase an annuity contract(s), subject to the conditions described in paragraph II. D. of the attached Proffer, paid to the life insurance company(ies) from which the annuity(ies) will be purchased.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[3]

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia Campbell-Smith
Special Master

[3] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.

F-4

[redacted]

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

[redacted], a minor, by her Parents and Natural Guardians, [redacted],	)	
Petitioners,	)	No. [redacted]V
v.	)	Special Master Campbell-Smith
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

RESPONDENT'S PROFFER ON AWARD OF COMPENSATION

I. Items of Compensation

A. Life Care Items

The respondent engaged life care planners Suzanne Labansky, MSN, CRRN, CCM, CLCP, MSC, and Ginger Walton, MSN, FNP, CNCLP, and petitioners engaged life care planner Terry Kennedy Arnold, RN, CDMS, CRRN, CLCP, CNLCP, to provide an estimation of [redacted] future vaccine injury-related needs. All items of compensation identified in the life care plan are supported by the evidence and are illustrated by the chart entitled **Appendix A: Items of Compensation for** [redacted], attached hereto as Tab A.[1] Respondent proffers that [redacted] should be awarded all items of compensation set forth in the life care plan and illustrated by the chart attached at Tab A. Petitioners agree.

[1] The chart at Tab A illustrates the annual benefits provided by the life care plan. The annual benefit years run from the date of judgment up to the first anniversary of the date of judgment, and every year thereafter up to the anniversary of the date of judgment.

[redacted]

B. Lost Future Earnings

The parties agree that based upon the evidence of record, [redacted] will never be gainfully employed. Therefore, respondent proffers that [redacted] should be awarded full lost future earnings as provided under the Vaccine Act, 42 U.S.C. § 300aa-15(a)(3)(B). Respondent proffers that the appropriate award for [redacted] lost future earnings is $674,410.67. Petitioners agree.

C. Pain and Suffering

Respondent proffers that [redacted] should be awarded $208,160.68 in actual and projected pain and suffering. This amount reflects that the award for projected pain and suffering has been reduced to net present value. See 42 U.S.C. § 300aa-15(a)(4). Petitioners agree.

D. Past Unreimbursable Expenses

Evidence supplied by petitioners documents their expenditure of past unreimbursable expenses related to [redacted] vaccine-related injury. Respondent proffers that petitioners should be awarded past unreimbursable expenses in the amount of $140,109.67. Petitioners agree.

E. Medicaid Lien

Respondent proffers that [redacted] should be awarded funds to satisfy the State of [redacted] Medicaid lien in the amount of $7,821.81, which represents full satisfaction of any right of subrogation, assignment, claim, lien, or cause of action the State of [redacted] may have against any individual as a result of any Medicaid payments the State of [redacted] has made to or on behalf of [redacted] from the date of her eligibility for benefits through the date of judgment

[redacted]

in this case as a result of her vaccine-related injury suffered on or about July 19, 2000, under Title XIX of the Social Security Act.

II. Form of the Award

The parties recommend that the compensation provided to [redacted] should be made through a combination of lump sum payments and future annuity payments as described below, and request that the special master's decision and the Court's judgment award the following:

A. A lump sum payment of $1,507,284.67, representing compensation for life care expenses expected to be incurred during the first year after judgment ($624,713.32), lost future earnings ($674,410.67) and pain and suffering ($208,160.68), in the form of a check payable to petitioners, as the court-appointed guardian(s)/conservator(s) of the estate of [redacted], for the benefit of [redacted]. No payments shall be made until petitioners provide respondent with documentation establishing that they have been appointed as the guardian(s)/conservator(s) of [redacted] estate;

B. A lump sum payment of $140,109.67, representing compensation for past un-reimbursable expenses, payable to [redacted], petitioners;

C. A lump sum payment of $7,821.81, representing compensation for satisfaction of the State of [redacted] Medicaid lien, payable jointly to petitioners and

[redacted] Department of Community Health
Subrogation Unit
[redacted]

Petitioners agree to endorse this payment to the State of [redacted]

[redacted]

D. An amount sufficient to purchase an annuity contract(s), subject to the conditions described below, that will provide payments for the life care items contained in the life care plan, as illustrated by the chart at Tab A attached hereto, paid to the life insurance company(ies)[2] from which the annuity(ies) will be purchased. Compensation for Year Two (beginning on the first anniversary of the date of judgment) and all subsequent years shall be provided through respondent's purchase of an annuity(ies), which annuity(ies) shall make payments directly to petitioners as guardian(s)/conservator(s) of the estate of [redacted], for the benefit of [redacted], only so long as [redacted] is alive at the time a particular payment is due. At the Secretary's sole discretion, the periodic payments may be provided to petitioners in monthly, quarterly, annual or other installments. The "annual amounts" set forth in the chart at Tab A describe only the total yearly sum to be paid to petitioners and do not require that the payment be made in one annual installment.

1. Growth Rate

Respondent proffers that a four percent (4%) growth rate should be applied to all non-medical life care items, and a five percent (5%) growth rate should be applied to all medical life care items. Thus, the benefits illustrated in the chart at Tab A that are to be paid through annuity

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[2] The Life Insurance Company must have a minimum of $250,000,000 capital and surplus, exclusive of any mandatory security valuation reserve. The Life Insurance Company must have one of the following ratings from two of the following rating organizations:

a. A.M. Best Company: A++, A+, A+g, A+p, A+r, or A+s;

b. Moody's Investor Service Claims Paying Rating: Aa3, Aa2, Aa1, or Aaa;

c. Standard and Poor's Corporation Insurer Claims-Paying Ability Rating: AA-, AA, AA+, or AAA;

d. Fitch Credit Rating Company, Insurance Company Claims Paying Ability Rating: AA-, AA, AA+, or AAA.

[redacted]

payments should grow as follows: four percent (4%) compounded annually from the date of judgment for non-medical items, and five percent (5%) compounded annually from the date of judgment for medical items. Petitioners agree.

2. Life-contingent annuity(ies)

Petitioners will continue to receive the annuity payments from the Life Insurance Company(ies) only so long as [redacted] is alive at the time that a particular payment is due. Petitioners shall provide written notice to the Secretary of Health and Human Services and the Life Insurance Company(ies) within twenty (20) days of [redacted] death.

3. Guardianship

No payments under section II. A. shall be made until petitioners provide the Secretary with documentation establishing their appointment as the guardian(s)/conservator(s) of [redacted] estate. If petitioners are not authorized by a court of competent jurisdiction to serve as guardian(s)/conservator(s) of the estate of [redacted] at the time a payment is to be made, any such payment shall be paid to the party or parties appointed by a court of competent jurisdiction to serve as guardian(s)/conservator(s) of the estate of [redacted] upon submission of written documentation of such appointment to the Secretary.

III. Summary of Recommended Payments Following Judgment

A.	Lump Sum paid to petitioners, as guardian(s)/conservator(s) of the estate of [redacted] for Yr 1 life care expenses, lost future earnings, and pain and suffering:	**$1,507,284.67**
B.	A lump sum paid to petitioners:	**$ 140,109.67**
C.	Reimbursement of the Medicaid lien:	**$ 7,821.81**

[redacted]

D. An amount sufficient to purchase the annuity contract(s) described above in section II. D.

Respectfully submitted,

TONY WEST
Assistant Attorney General

TIMOTHY P. GARREN
Director
Torts Branch, Civil Division

MARK W. ROGERS
Deputy Director
Torts Branch, Civil Division

/s/Catharine E. Reeves
CATHARINE E. REEVES
Assistant Director
Torts Branch, Civil Division
U.S. Department of Justice
P.O. Box 146
Benjamin Franklin Station
Washington, D.C. 20044-0146
Telephone: (202) 307-1400

Dated: July 20, 2010

APPENDIX G - AUTISM GENERAL ORDER #1, IN RE: CLAIMS FOR VACCINE INJURIES RESULTING AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER, VARIOUS PETITIONERS V. SECRETARY OF HEALTH AND HUMAN SERVICES, JULY 3, 2002

OFFICE OF SPECIAL MASTERS

(Filed: July 3, 2002)

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER	**AUTISM MASTER FILE** To be published
VARIOUS PETITIONERS,	
v.	
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	

AUTISM GENERAL ORDER #1

A. Background

This Autism General Order #1 is being issued by the Office of Special Masters ("OSM"), to address an unusual situation facing the National Vaccine Injury Compensation Program ("Program.")[1] This situation arises out of concern in recent years that certain childhood vaccinations might be causing or contributing to an apparent increase in the diagnosis of a type of serious neurodevelopmental disorder known as "autism spectrum disorder," or "autism" for short.[2] Specifically, it has been alleged that cases

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[1]The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq*. (2000). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. § 300aa (2000).

[2]An autism spectrum disorder is a brain disorder affecting a person's ability to communicate, form relationships, and/or respond appropriately to the environment. Such disorders sometimes result in death. The "spectrum" of such disorders includes relatively high-functioning persons with speech and language intact, as well as persons who are mentally retarded, mute, or with serious language delays. Symptoms may include, but are not limited to, avoidance of eye contact, seeming "deafness," abrupt loss of language,

of autism, or neurodevelopmental disorders similar to autism, may be caused by Measles-Mumps-Rubella ("MMR") vaccinations; by the "thimerosal" ingredient contained in certain Diphtheria-Tetanus-Pertussis ("DTP"), Diphtheria-Tetanus-acellar Pertussis ("DTaP"), Hepatitis B, and Hemophilus Influenza Type B ("HIB") vaccinations; or by some combination of the two.

To date, over 400 cases alleging a causal relationship between such vaccinations and autism disorders have been filed in this court; more than 300 of those cases have been filed in the past six months. Moreover, numerous civil lawsuits against vaccine manufacturers, alleging that the thimerosal ingredient caused autism, have been filed in courts around the country. One recent ruling in such a suit determined as a matter of law that such claims of vaccinees against vaccine manufacturers must be dismissed and brought to this court as Program claims. See *Owens v. American Home Products Corp.*, 2002 WL 992094 (S.D. Tex. May 7, 2002).

As a result of the influx of Program claims and the potential for many more such claims, the OSM has held a series of meetings with an informal advisory committee to address the task of dealing with these claims. This committee consisted of petitioners' counsel who represent many such current and potential Program claimants, along with legal and medical representatives of the Secretary of Health and Human Services. (*See* Ex. C for a list of the participants in that advisory committee.) The participating petitioners' counsel, who are in contact with many other petitioners' counsel, have estimated that due to the *Owens* decision, approximately 3,000 to 5,000 such Program petitions (or possibly even more) are likely to be filed with this court during the next several months.

Processing such a large number of cases will stretch thinly the resources of both the court and the bar. It is in the interests of all that the 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. This Autism General Order #1 and the procedure detailed herein resulted from extensive discussions with the parties' representatives, and from the special masters' experience in handling other groups of cases presenting common issues. 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.

During the advisory committee meetings, petitioners' representatives proposed a timetable for resolving the general causation issues involved in these cases which extended well over two years. In response, the OSM established one overriding principle governing all suggestions, proposals, and requests--the OSM's decision on the causation issues shall be rendered within two years after the filing of this

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unawareness of environment, physical abusiveness, inaccessibility, fixation, bizarre behavior, "flapping," repetitive and/or obsessive behavior, insensitivity to pain, social withdrawal, and extreme sensitivity to sounds, textures, tastes, smells, and light. National Institute of Mental Health, Publication 97-4023.

General Order. The OSM's subsequently adopted procedure and schedule contained herein are designed to meet that two-year time frame.

B. Proposal of petitioners' representatives

Autism cases are not new to the court; a number have been pending for several years. However, in those pending cases, petitioners' counsel continue to request more time for the science to crystalize, to obtain experts, and in general to prepare their proof concerning the difficult medical and legal causation issues. Similarly, in the advisory committee discussions described above, petitioners' representatives have stated that they are not prepared to present their causation case at this time. Rather, petitioners request extensive discovery--documents, studies, and raw data from government agencies and possibly vaccine manufacturers--information relevant to the general causation issues, through this court's discovery process.

Accordingly, petitioners' representatives in the advisory committee meetings have proposed a general procedure by which the OSM could process the claims described above, both those already filed and those about to be filed. They propose that the OSM utilize a two-step procedure: first, conduct an inquiry into the *general causation issues* involved in these cases-- *i.e.*, whether the vaccinations in question can cause autism and/or similar disorders, and if so in what circumstances; and then, second, apply the conclusions reached in that general inquiry to the individual cases. They propose that the OSM establish an "Autism Master File" with respect to the general causation issues, which would be open to inspection by any interested persons, and which would constitute an evidentiary record with respect to the general causation issues. They propose that a team of petitioners' lawyers be selected to represent the interests of all petitioners in these autism cases during the course of this general causation inquiry. They propose that the proceeding begin with a lengthy period of discovery concerning the general causation issues, followed by a designation of experts for each side, an evidentiary hearing, and a ruling on the general causation issues. Finally, the special master's determination on the general causation issues would be applied to the individual cases.

During the meetings of the informal advisory group, respondent's representatives did not oppose petitioners' general plan, as set forth above, that the OSM conduct a general inquiry into the causation question, then apply the conclusions reached in that inquiry to the individual cases.

C. Procedure adopted by the OSM

After considering carefully the practical and thoughtful advice from petitioners' and respondent's representatives presented during the meetings of the advisory committee, the OSM responds to the challenge presented by this influx of cases with the following procedures.

First, the OSM adopts the general approach to these cases suggested by the participants in the informal advisory committee. That is, the OSM will utilize a two-step procedure: First, the OSM will inquire into the *general causation issues* involved in these cases--*i.e.*, whether the vaccinations in question

can cause autism and/or similar disorders, and if so in what circumstances; and then, second, the conclusions reached in that general inquiry will be applied to the individual cases. As proposed, the OSM will authorize a team of attorneys to represent the interests of all petitioners in these autism cases during the course of this general causation inquiry, which is officially entitled the "Omnibus Autism Proceeding." The inquiry will proceed as generally proposed by petitioners' attorneys--*i.e.*, a period for any court-approved discovery concerning the general causation issues, followed by a designation of experts for each side, an evidentiary hearing, and finally a special master's ruling on the general causation issues. Subsequently, the general causation conclusions will be applied to the individual cases.

The court will, as proposed, establish an "Autism Master File" with respect to the general causation issues involved in these cases. That file will be open to inspection by any interested persons, and will constitute an evidentiary record with respect to the general causation issues. All evidence relevant to the general causation issues, including transcripts of any evidentiary hearings, will be placed into that file. The first documents placed into that master file will be this Autism General Order #1 and the attachments hereto.

In accordance with § 300aa-12(d)(1), the Chief Special Master hereby designates Special Master George Hastings to preside over the Omnibus Autism Proceeding, and to make any necessary rulings on the general causation issues.

Representing the interests of petitioners in the Omnibus Autism Proceeding will be a Petitioners' Steering Committee. This committee will be comprised of counsel who are representing Program petitioners in autism cases. Currently, the vast majority of pending Program autism cases have been filed by a small number of law firms. The OSM invited attorneys from those firms to participate in the informal advisory committee described above. Those counsel have organized the initial Petitioners' Steering Committee, whose members are set forth at Ex. D to this Order. Other counsel who are interested in serving on the Steering Committee may contact the members of that committee to express their interest. The OSM believes that membership on the Steering Committee should be determined by petitioners' counsel, interacting among themselves. The Committee shall keep the presiding special master apprised, however, of changes in its membership. The Committee shall designate two attorneys as "lead counsel," authorized to sign and file documents on behalf of the Committee into the Autism Master File, and to represent the Committee at status conferences. In the unlikely event that disputes arise as to the Committee membership, the presiding special master shall be informed immediately and will resolve any issues.

Similarly, respondent shall designate two "lead counsel" for respondent in the Omnibus Autism Proceeding, who will be authorized to file documents on behalf of respondent into the Autism Master File, and to represent respondent at status conferences.

When either "party" to the Omnibus Autism Proceeding--*i.e.*, the Petitioners' Steering Committee or respondent--files documents into the Autism Master File, if the document is less than 20 pages, the party shall file an original and two copies. For documents of 20 or more pages, an original and one copy will suffice. By rule, the Clerk of the Court will file the original in the Autism Master File and send the copy or

copies to the presiding special master. Unless requested, separate mailings to the presiding special master are unnecessary. The Steering Committee will serve a copy of each filed document on each of the two designated lead counsel for respondent. The respondent will serve a copy of each filed document on each member of the Steering Committee.

Attached to this General Order as Exhibit A is the "Master Autism Petition for Vaccine Compensation" ("Master Petition"). This document was drafted and presented to the OSM by the Petitioners' Steering Committee. It sets forth the general allegation that a vaccinee's autistic disorder or similar disorder was caused by one or more of the MMR and thimerosal-containing vaccinations. It provides that any Program petitioner filing a "Short-Form Autism Petition for Vaccinee Compensation," in a form similar to that set forth as Exhibit B to this General Order, represents that such petitioner's claim meets the criteria set forth in the Master Petition. As will be detailed below, by filing such a short-form petition, a petitioner will elect into the Omnibus Autism Proceeding, and simultaneously opt to stay case-specific proceedings on his own petition until the conclusion of the Omnibus Autism Proceeding.

D. <u>The Autism Master Schedule</u>

To meet the court's self-imposed two-year timetable for decision, the Omnibus Autism Proceeding will be conducted according to an Autism Master Schedule, appended to this General Order as Exhibit E. This schedule has been determined through cooperative discussions at the advisory committee meetings. Petitioners' representatives proposed the first draft of the schedule. They proposed a schedule covering two years, from issuance of an initial General Order (*i.e.*, this Order) until the date of an evidentiary hearing on the general causation issues, with an additional unspecified period of time obviously needed for the presiding special master to analyze the evidence introduced at the hearing and produce a written opinion. In that proposed schedule, essentially 470 of the 730 days in the two-year period were devoted to the discovery process. The first proposal extended beyond two years and thus was rejected by the OSM. After discussion, petitioners submitted a revised schedule which shortened the discovery period to 410 days, moved the hearing date up, and built in sufficient time to decide the causation issues within the two-year period. This second proposal is adopted, with slight modifications and three observations.

First, and foremost, the OSM expects that the parties will act promptly and vigorously to *adhere* to this schedule, if not move more quickly. Because the interests of thousands of petitioners are affected, the presiding special master will be disinclined to allow the Omnibus Autism Proceeding to slip behind schedule. In fact, 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.

Second, the OSM recognizes that two years is a relatively long time to ask petitioners to wait for a ruling on the general causation issues. Congress clearly envisioned rulings on Program petitions rendered in a much shorter time frame. However, the short decision-making time periods provided in the Program statute were obviously based upon the assumption that most Program claims would present far different issues than those presented in these autism cases. The assumption clearly was that in most Program cases

the question for the special master would simply be whether petitioner's case fit within one of the "Table Injury" categories set forth at § 300aa-14(a). It was also assumed that even in those relatively few cases where no Table Injury was alleged and a petitioner attempted to prove that the vaccine "actually caused" an injury, the petitioner would file *along with his petition* all of his proof concerning the causation issue, including a report from an expert supporting the claim. In contrast, in these autism claims petitioners have requested a period of 500 days from now--almost a year-and-one-half--before filing expert reports explaining and supporting their theory of causation. These reports will follow a lengthy discovery period of a type clearly never envisioned by Congress. However, it is clear to the OSM that the reality of the difficult medical issues involved and the stringent legal standards applied to causation cases justifies petitioners' request for a reasonable discovery opportunity and the extended time for filing expert reports. Unfortunately, resolution of the general causation inquiry must await longer than Congress envisioned and the OSM would ideally wish; but it is clear to all involved that without the requested extended time frames, petitioners would be unable to prosecute their claims. In this instance, quick justice would mean no justice.

Third, the above pages have referenced the "general causation issues." The OSM recognizes that the Omnibus Autism Proceeding is in its earliest phase. While petitioners' representatives have mentioned multiple potential theories of causation, until discovery is completed and expert reports are filed it will not be known whether one or more causation theories are at issue. As noted above, there have been suggestions that autistic disorders can be caused by (1) MMR vaccinations; (2) the thimerosal component of the DTP, DTaP, Hepatitis B, and HIB vaccinations; and/or (3) a combination of (1) and (2). Accordingly, the presiding special master, working with the parties' representatives, will decide at a later date the most efficient procedure for resolving the causation issues, depending upon the development of the causation theories put forth by Petitioners' Steering Committee.

E. <u>Opting into, or out of, the Omnibus Autism Proceeding</u>

All persons with pending petitions or potential Program claims involving an autistic or autistic-like disorder should assess their own cases in light of the Omnibus Autism Proceeding. Many petitioners with pending claims have already requested and have been granted stays in their own cases until the conclusion of the Omnibus Proceeding.[3] The presiding special master will conduct no case-specific proceedings in those "stayed" cases until the conclusion of the Omnibus Proceeding, unless otherwise requested by a party. The OSM will keep all petitioners or their counsel updated as to the progress of the Omnibus Proceeding. After the Omnibus Proceeding is concluded by the special master's ruling concerning the general causation issues, the individual cases will then be addressed. If the ruling on the general causation issues appears favorable to an individual petitioner's case, the petitioner will be ordered to demonstrate that his or her case qualifies for compensation under the general ruling, and proceed to a damages

[3]Such cases will be officially transferred from the docket of the originally-assigned special master to the docket of Special Master Hastings, the special master presiding over the Omnibus Autism Proceeding.

determination. If the general ruling, on the other hand, appears unfavorable to an individual petitioner's case, then the petitioner will be given the opportunity to introduce additional supportive case-specific evidence, including expert reports, or to dismiss the case for want of proof. The court will determine how to process individual cases, following the resolution of the general causation issues, only after ample time and opportunity is granted to each petitioner to review the evidence from the Omnibus Proceeding, to consult with counsel and medical experts, and then to make a reasoned choice.

Any petitioner with a *pending* autism-related claim, who has not yet requested to have proceedings in his own case stayed for the duration of the Omnibus Autism Proceeding, may do so simply by filing a Notice to Stay Proceedings, similar to that contained at Ex. F to this General Order. Once that is done, no case-specific proceedings will be held in that case until further notice, and that case will be treated as described in the previous paragraph.

Persons who have autism-related claims for which they have *not yet filed* Program petitions, and who wish to have their cases stayed during the Omnibus Autism Proceeding, may file their petitions by filing a "Short-Form Autism Petition for Vaccine Compensation" in a form similar to the one set forth as Ex. B to this General Order.[4] No medical records need 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 if, and when, the petitioner is directed to do so by the special master. Once such a short-form petition is filed, no case-specific proceedings will be held in the case during the course of the Omnibus Autism Proceeding, and the case will be treated as described above.

One important caveat, however, is drawn to the attention of all petitioners and their counsel! There may be cases involving autistic-like disorders which manifested following an injury defined in the Vaccine Injury Table. That is, a vaccinee may have suffered an episode involving a severe acute encephalopathy within 72 hours after a pertussis vaccination (DTP or DTaP), or 5 to 15 days after an MMR vaccination. If so, such an acute encephalopathy and any residual effects thereof would be *presumed* to be vaccine-caused pursuant to the Vaccine Injury Table. *See* 42 C.F.R. § 100.3(a) (10-1-97 version of CFR).[5] However, this would apply only to cases falling within the current Vaccine Injury Table's definition of "acute encephalopathy," in which the vaccinee suffered a sudden, dramatic, and severe change in level of consciousness lasting at least 24 hours. 42 C.F.R. § 100.3(b)(2)(i)(A) and (D). The incident must have been "sufficiently severe so as to require hospitalization," though actual hospitalization at the time need not have occurred. 42 C.F.R. § 100.3(b)(2)(i). Autism cases involving Table Injuries have been compensated under the Program. If in a particular case there exist medical records

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[4]The OSM acknowledges that respondent opposes the use of a short-form petition. The court's reasoning on this topic will be set forth in a separate document.

[5]Note that the Vaccine Injury Table contained in the statute at § 300aa-14(a) is *not* applicable to Program petitions filed since March 10, 1995. For any petition filed on or after March 24, 1997, the applicable Vaccine Injury Table is found at 42 C.F.R. § 100.3 (1997).

demonstrating that such a qualifying "acute encephalopathy" occurred within the appropriate time frame, petitioner or counsel should bring that to the assigned special master's attention so that, if appropriate, the case can be processed without delay as a Table Injury.

Finally, petitioners should note that even after electing to have their case stayed pending the conclusion of the Omnibus Autism Proceeding, such election is not irrevocable. That is, if at a future time a petitioner determines that his own case should be separated from the Omnibus Autism Proceeding and processed separately, with the petitioner introducing case-specific proof of causation, such petitioner may request that a special master analyze his case. A special master will be assigned and the case will be processed as expeditiously as possible.

F. Obtaining Information About the Progress of the Omnibus Autism Proceeding

As noted above, during the course of the Omnibus Autism Proceeding, the individual autism cases will be stayed, with no case-specific proceedings conducted. During that time, however, the OSM will keep the petitioners in such cases well informed as to the progress of the Omnibus Autism Proceeding, by two devices.

First, the OSM from time-to-time will issue additional Autism General Orders detailing the progress of the Omnibus Autism Proceeding. Such general orders will be sent to all counsel, or petitioners appearing *pro se*, in autism cases.

Secondly, a specific page on this court's internet website will be devoted to the Omnibus Autism Proceeding. Relevant filed documents and periodic updates regarding the proceedings will be posted on that site. This page may be accessed by logging onto this court's website at www.uscfc.uscourts.gov, then clicking on the "Special Masters" icon.

G. Conclusion

The Office of Special Masters is determined to process these autism petitions as swiftly and efficiently as possible, while giving all interested parties a fair opportunity to present their claims and evidence. We appreciate the assistance of all petitioners, petitioners' counsel, and respondent's representatives in this challenging endeavor.

Gary J. Golkiewicz
Chief Special Master
For the Office of Special Masters

EXHIBIT A

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER	AUTISM MASTER FILE
VARIOUS PETITIONERS,	
v.	
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	

MASTER AUTISM PETITION FOR VACCINE COMPENSATION

Pursuant to the Autism General Order #1 issued by the Office of Special Masters of this Court on July 3, 2002, this Master Autism Petition for Vaccine Compensation is hereby placed into the Omnibus Autism Master File created in the Office of the Clerk of this Court. As detailed in that Autism General Order #1, any petitioner desiring that his or her Vaccine Act claim be processed along with the other "Omnibus Autism" cases may file a "Short-Form Autism Petition for Vaccine Compensation" similar to that contained at Ex. B to the Autism General Order #1. **Any petitioner who files such a short-form petition will be deemed to be representing that such petitioner's own particular claim meets the following criteria:**

1. The petitioner alleges a vaccine-related injury and/or death, and requests compensation under the National Vaccine Injury Compensation Program, codified at 42 U.S.C. §§ 300aa-10 *et seq*. (Supp. 1996).

2. No civil action against a vaccine manufacturer or administrator for the vaccine-related injury or death alleged by the petitioner is pending. No person has previously collected an award or settlement of a civil action for damages for the vaccine-related injury or death being claimed.

3. As a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder* or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the "thimerosal" ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two.

4. The vaccinee received the vaccination or vaccinations in question in the United States, or otherwise in compliance with 42 U.S.C. § 300aa-11(c)(1)(B).

5. The petition is being filed within three years after the first symptom of the disorder, or within three years after the first symptom of a vaccine-caused significant aggravation of the disorder. (If the vaccine-related death is alleged, the petition is being filed within two years after the date of death and no later than 48 months after onset of the injury from which death resulted.)

6. The vaccine-related injury either has persisted for more than six months or resulted in death.

Therefore, by filing a "Short-Form Autism Petition for Vaccine Compensation," a petitioner will be deemed to be seeking an award under the National Vaccine Injury Compensation Program. Such a petitioner will be deemed to have deferred specific compensation demands, pursuant to 42 U.S.C. § 300aa-11(e), until the issue of entitlement to compensation is determined.

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*An autism spectrum disorder is a brain disorder affecting the petitioner's ability to communicate, form relationships, and/or respond appropriately to the environment. Such disorders sometimes result in death. The "spectrum" of such disorders includes relatively high-functioning persons with speech and language intact, as well as persons who are mentally retarded, mute, or with serious language delays. Symptoms may include, but are not limited to, avoidance of eye contact, seeming "deafness," abrupt loss of language, unawareness of environment, physical abusiveness, inaccessibility, fixation, bizarre behavior, "flapping," repetitive and/or obsessive behavior, insensitivity to pain, social withdrawal, and extreme sensitivity to sounds, textures, tastes, smells, and light. National Institute of Mental Health, Publication 97-4023.

EXHIBIT B

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

* *

_____,
parent(s) of
_____, a minor,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

No. [leave blank_____]
Special Master [leave blank___]

SHORT-FORM AUTISM PETITION FOR VACCINE COMPENSATION

The petitioners, on behalf of their minor child, hereby petition for compensation under the National Vaccine Injury Compensation Program, and adopt the MASTER AUTISM PETITION FOR VACCINE COMPENSATION.

_____
Date

Check One:
Attorney ☐
Pro Se ☐

Sign:_____
Print Name:_____
Address:_____
City, State, Zip:_____
Phone Number:_____
Fax Number:_____

CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached Autism Petition for Vaccine Compensation was sent by First Class or Certified Mail on _____, to:

Secretary of Health and Human Services
c/o Director, Bureau of Health Professions
5600 Fishers Lane, Suite 8-05
Rockville, MD 20857

_____
Signature of person mailing Petition

EXHIBIT C

AUTISM ADVISORY COMMITTEE PARTICIPANTS

Participants from the Office of Special Masters

Chief Special Master Gary Golkiewicz
Special Master George Hastings
Special Master John Edwards

Petitioners' Counsel Participants

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Ghada A. Anis
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Participants Representing Respondent

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Vince Matanoski
U.S. Department of Justice

Vito Caserta, M.D., Chief Medical Officer
National Vaccine Injury Compensation Program
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U.S. Department of Health & Human Services

Deborah Harris
Office of General Counsel, Public Health Division
U.S. Department of Health & Human Services

Vernessa Pollard, Assistant Chief Counsel
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EXHIBIT D

AUTISM PETITIONERS' STEERING COMMITTEE

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EXHIBIT E

OMNIBUS AUTISM PROCEEDING

MASTER SCHEDULING ORDER

July 3, 2002	Autism General Order #1
August 2, 2002	Petitioners file discovery requests, setting forth the discovery sought from any party or entity subject to the control of respondent agency
September 3, 2002	Respondent files response and any objections to petitioners' discovery requests
September 17, 2002	Conference on discovery requests
October 8, 2002	Hearing on discovery requests
February 3, 2003	Petitioners file supplemental discovery requests setting forth any additional and/or third-party discovery sought
March 3, 2003	Respondent and/or third parties file response and any objections to supplemental discovery requests
March 17, 2003	Conference on supplemental discovery requests
April 3, 2003	Hearing on supplemental discovery requests
August 22, 2003	Discovery completed
August 22, 2003	Petitioners designate experts for Omnibus Hearing
October 21, 2003	Respondent designate experts for Omnibus Hearing
November 21, 2003	Petitioners file expert reports with supporting authorities
January 21, 2004	Respondent file expert reports with supporting authorities
February 20, 2004	Any additional motions, objections, statements of interest, etc., must be filed
March 22, 2004	Omnibus evidentiary hearing
May 3, 2004	Post-hearing briefs due

July 3, 2004 Decision on causation issues

EXHIBIT F

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

* *	*
--- and ---,	*
parents of	*
----------	*
Petitioner[s],	*
	*
v.	*
	*
SECRETARY OF HEALTH AND	*
HUMAN SERVICES,	*
	*
Respondent.	*
	*
* *	*

NOTICE TO DEFER PROCEEDINGS IN AUTISM CASE

The petitioner[s] in this case believe[s] that the causation question in the case may be related to the general causation issues to be addressed in the Omnibus Autism Proceeding, and request[s] that case-specific proceedings in this case be deferred pending completion of the Omnibus Autism Proceeding.

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Counsel for Petitioner[s]

[or Petitioner appearing pro se]