OFFICE OF SPECIAL MASTERS

No. 02-392V

Filed: October 11, 2002

DIANE and NICHOLAS LEROY, Individually and as Next Friends of NICHOLAS ARTHUR LEROY, a minor,	*	
Petitioners,	*	
v.	*	To Be Published
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael T. Gallagher, Houston, Texas, for petitioners.
Vincent J. Matanoski, Washington, D.C., for respondent.

RULING ON JURISDICTION

GOLKIEWICZ, Chief Special Master.

Petitioners filed for compensation under the National Vaccine Injury Compensation Program ("the Program") on April 24, 2002.[1] Petitioners claim that "a series of mercury-containing vaccines" caused Nicholas, their otherwise healthy child, to suffer developmental problems. Petitioners contest

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[1/] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§300aa-10 et seq. (2000). Hereinafter, individual section (§) references will be to 42 U.S.C. §300aa of the National Childhood Vaccine Injury Act of 1986 ("the Act" or "the Vaccine Act").

the court's jurisdiction over their claim. Petitioners do not challenge that Nicholas received vaccines covered by the Program or that their damages claim exceeds $1,000.[2] See Complaint at 3-5, filed April 24, 2002; 42 C.F.R. §100.3(a) (1997); §11(a)(2)(A). However, petitioners argue adamantly that their claim is beyond the scope of the Vaccine Act because their son suffers from "mercury poisoning [from the thimerosal preservative contained in the vaccines he received] and not from any condition associated with any therapeutic component in any of the vaccines" administered. Complaint at 5. Given the Leroys' stated position, the undersigned ordered the parties to brief whether jurisdiction over the subject matter of this claim is properly in this court. After considering the parties' arguments, the court finds that jurisdiction lies properly with the U.S. Court of Federal Claims.[3] The court's reasons follow.

PROCEDURAL HISTORY

Petitioners filed a petition for compensation on April 24, 2002, but argue that their claim is not covered by the Vaccine Act. Petitioners' injury claim is similar to over 875 other cases filed under the Program; the claims allege that a vaccine or series of vaccines caused the vaccinee to develop developmental problems which may fall within the diagnosis of autism spectrum disorder.[4] Like this case, the other claims state that thimerosal, a vaccine preservative, is responsible for the vaccinee's injury and is the basis for his or her claim for Program compensation. Working with a committee of petitioners' and respondent's lawyers, the court has implemented an efficient litigation

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[2/] Vaccines covered by the Program are outlined in the Vaccine Injury Table. §14(a), as amended, 42 C.F.R. §100.3(a) (1997). Petitioners must file their vaccine-related claim within the Act's statute of limitations period. §16(a). Filing an untimely petition is fatal to a claim; equitable tolling is not available to Program petitioners. See Brice v. Secretary of HHS, 240 F.3d 1367 (Fed. Cir. 2001), cert. denied sub nom., Brice v. Thompson, 122 S.Ct. 614 (2001). Petitions for Program compensation must be filed in this court within 36 months of the first symptom or manifestation of onset of the alleged vaccine-related injury. §16(a)(2). If the vaccinee died, claims on the decedent's behalf must be filed within 24 months of the death, and no later than 48 months after the first symptom or manifestation of onset of the injury from which the death resulted. §16(a)(3).

[3/] The court's ruling is limited to a finding of subject matter jurisdiction over this claim. The undersigned makes no determination as to whether petitioners' claim falls outside the court's jurisdiction due to some other legal defect, such as it was filed beyond the Act's statute of limitations period. Petitioners provide no evidence, but only assertions, as to the timeliness of their petition, see Complaint at 3, and any such issue will be resolved at a later time.

[4/] See Autism General Order #1 at 1, n. 2, Office of Special Masters, Chief Special Master Gary J. Golkiewicz (Fed. Cl. Spec. Mstr. July 3, 2002) (describing the symptoms of autism spectrum disorder to include "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") (citing National Institute of Mental Health, Publication 97-4023).

procedure for resolving the autism cases, see Autism General Order #1. Counsel and the court are diligently preparing the cases pursuant to that agreed upon procedure. Thus, resolving this jurisdictional issue is obviously critical.[5] Consequently, the undersigned ordered petitioners to brief the court on the jurisdictional issue raised by their petition and to state with particularity whether jurisdiction lies with the Court of Federal Claims. Petitioners filed their brief on June 18, 2002. See Petitioners' Brief in Support of the Jurisdictional Issues Raised in Their Petition ("Pet. Brief"). The government filed its response on July 19, 2002. See Response to Petitioners' Brief in Support of the Jurisdictional Issues Raised in Their Petition ("Resp. Brief"). Petitioners filed their reply on August 9, 2002. See Petitioners' Reply to Respondent's Response Concerning the Jurisdictional Issues Raised in the Petitioners' Brief ("Pet. Reply").

In sum, petitioners allege that the vaccine preservative, thimerosal, caused Nicholas's neurologic injury; that thimerosal is not a "constituent material" of the vaccines that he received, "nor does it have any therapeutic effect which would make it a necessary or essential part of any vaccine"; that the Act explicitly excludes thimerosal from coverage because it is an "adulterant" or "contaminant" of the vaccine; that, further, the Vaccine Act never contemplated thimerosal or autism claims; and finally, that thimerosal, because of its toxicity, is not a "constituent material" as defined by the Code of Federal Regulations setting forth regulations for preservatives used in licensed vaccines. Pet. Brief at 3-15. For the above reasons, petitioners argue that any claims alleging injuries arising from thimerosal are beyond this court's jurisdiction.

Respondent contends that petitioners' arguments are "without merit" for the following reasons: compensation has been granted to vaccinees for injuries sustained from a vaccine preservative, citing Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); "thimerosal is neither an adulterant or contaminant within the plain meaning of the Act"; thimerosal is not an adulterant or contaminant when used "within [the] prescribed limits of a valid biologics license"; and, the legislative history supports the proposition that "injuries allegedly related to thimerosal [must] be brought under the Program." Resp. Brief at 2, 4-12. Respondent argues further that thimerosal is a constituent of vaccines and the statute makes no distinction between the vaccine

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[5/] The issue of whether this court has jurisdiction over claims alleging injuries arising from the thimerosal component of a vaccine (or vaccines) has been the subject of litigation in other courts. See, e.g., Bertrand v. Aventis Pasteur Laboratories, Inc., 2002 WL 31194226 (D. Ariz. Sept. 23, 2002); Liu v. Aventis Pasteur, Inc., 2002 WL 31007709 (W.D. Tex. Aug. 23, 2002); Collins v. American Home Products Corporation, No. 01-979, slip op. (S.D. Miss. Aug. 1, 2002); Stewart v. American Home Products Corporation, No. 02-427, slip op. (S.D. Miss. Aug. 1, 2002); King v. Aventis Pasteur, Inc., 210 F. Supp. 2d 1201 (D. Or. June 7, 2002); Blackmon v. American Home Products Corporation, No. G-02-179, slip op. (S.D. Tex. May 8, 2002); Owens v. American Home Products Corporation, 203 F. Supp. 2d 748 (S.D. Tex. May 7, 2002); O'Connell v. American Home Products Corporation, No. G-02-184, slip op. (S.D. Tex. May 7, 2002). In most cases filed with the Court of Federal Claims, petitioners have accepted this court's jurisdiction over claims alleging a causal relationship between vaccination and autism disorders. To this court's knowledge, petitioners' counsel is the only practitioner at this time contesting jurisdiction. Mr. Gallagher currently has nearly 300 autism-related cases pending before this court.

antigens and the vaccine's constituent parts. Id. at 12-14. Finally, respondent contends that petitioners' legal position would lead to a "multiplicity of litigation," which is at odds with the Program's legislative purpose. Id. at 14-15.

In their reply, petitioners allege that their claim is not covered under the Program because thimerosal is not a vaccine, but a preservative that "poses a neurotoxic threat to its recipients"; thus, injuries attributable to the ethyl-mercury in thimerosal are not covered. Pet. Reply at 1, 9. Petitioners also restate that thimerosal is an adulterant and has no therapeutic effect. In this regard, they rely heavily on Special Master Edwards's Order in Geppert v. Secretary of HHS, No. 00-286V (Fed. Cl. Spec. Mstr. Mar. 21, 2001) (unpublished Order raising the issue whether thimerosal is an adulterant or contaminant and directing respondent to file a brief on the jurisdictional issue), for the proposition that injuries from mercury do not fall under the Vaccine Act. Id. at 2. They also rely on Magistrate Judge Ashmanskas's recommendation to the federal district court judge in King v. Aventis Pasteur, Inc., that a state court could find thimerosal-related injuries are not covered by the Program. Id. at 2-3. See also King v. Aventis Pasteur, Inc., No. 01-1305-AS, Findings and Recommendation, slip op. at 7-8 (D. Or. June 7, 2002). Petitioners further contest respondent's reliance on Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992). They aver that the Federal Circuit in that case did not find that the preservative caused the injury, and that Grant is distinguishable because the Leroys' son's injuries were caused by the toxin thimerosal and not by an antigen of the vaccines received, as was the case in Grant. Pet. Reply at 3-5. Finally, petitioners contend that irrespective of the Food and Drug Administration's ("FDA") licensing of thimerosal-containing vaccines, thimerosal could not be considered a "constituent material," or component part of a vaccine because it is toxic to the recipient, as evidenced by various agencies' actions. Id. at 5-8.

After considering the parties' arguments, the undersigned finds that subject matter jurisdiction lies properly with this court.

DISCUSSION

To maintain an action against the government for Program compensation, petitioners must show that their claim meets the filing prerequisites of the Vaccine Act. Section 11(a) is the gate-keeping provision of the statute which sets forth the general rules describing when a vaccinee may petition for compensation. See Amendola v. Secretary of HHS, 989 F.2d 1180, 1182-83 (Fed. Cir. 1993); see also Klahn v. Secretary of HHS, 31 Fed. Cl. 382, 385 (1994) ("The court's jurisdiction involves compliance with [these] gate-keeping provisions . . . ."). Among its various requirements, §11(a)(1) provides for "[a] proceeding for compensation under the Program for a vaccine-related injury or death." Section 33(5) of the Act defines "vaccine-related injury or death" as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table." §33(5). However, injuries associated with "an adulterant or contaminant intentionally added" to a Table vaccine are specifically excluded by the Act's definition of a "vaccine-related injury or death." Id. The jurisdictional issue raised in this case is whether an injury allegedly caused by the thimerosal preservative within a Table vaccine is a "vaccine-related injury" under §11(a)(1), as defined by §33(5) of the Vaccine Act. Petitioners' counsel advances a plethora of unsuccessful arguments to contest this court's jurisdiction over the Leroys' case. In short, petitioners ignore time-

honored legal principles, common definitions of relevant statutory language, congressionally-stated Program goals, relevant scientific evidence, and case law. The undersigned finds petitioners' numerous arguments, contending that Nicholas's injuries are not "vaccine-related," legally flawed and unsupported by the record.

I. The Scope of the Vaccine Act and the Doctrine of Sovereign Immunity

The Vaccine Act established a no-fault compensation Program, designed to curb the time and expense of traditional tort litigation.[6] Congress envisioned a system where awards to an injured vaccinee or a person suing on the vaccinee's behalf were to be made "'quickly, easily, and with certainty and generosity.'" Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994) (quoting H.R. Rep. No. 99-908, at 3, reprinted in 1986 U.S.C.C.A.N. 6344, 6344). See also Shalala v. Whitecotton, 514 U.S. 268, 270 (1995) (stating that "the [Act's] streamlining does not stop with the mechanics of litigation, but goes even to substantive standards of proof"). The Act directs an

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[6] The Program's structure fosters expedited review of a vaccine claim alleging that a Table vaccine caused the vaccinee's injury. §14; 42 C.F.R. §100.3. Congress created the Vaccine Injury Table, 42 U.S.C. §300aa-14(a), as amended, 42 C.F.R. §100.3(a), which affords petitioners a statutory presumption that the Table vaccine in question caused an injury, provided that a particular injury listed on the Vaccine Injury Table occurs within the specified time frame following the vaccine. Alternatively, the vaccinee may prove an off-Table claim, in other words, that the vaccine did in-fact cause the injury even though the injury itself or the onset period falls outside the Table's parameters. §§11(c)(1)(C)(ii)(I) and (II). Both theories assume that the evidence fails to show by a preponderance that a factor unrelated to the vaccine caused the injury. §13(a)(1)(B).

In off-Table claims, petitioners must establish causation utilizing traditional tort litigation standards. See, e.g., Grant v. Secretary of HHS, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992); Shyface v. Secretary of HHS, 165 F.3d 1344, 1351 (Fed. Cir. 1999); Terran v. Secretary of HHS, No. 95-451V, 1998 WL 55290, at *6 (Fed. Cl. Spec. Mstr. Jan. 23, 1998), aff'd, 41 Fed. Cl. 330 (1998), aff'd, 195 F.3d 1302 (Fed. Cir. 1999). In other words, petitioners must demonstrate by a preponderance of the evidence that the vaccine caused the alleged injury. §§11(c)(1)(C)(ii)(I) and (II); §13(a)(1)(A). For a detailed discussion of the appropriate analytical framework for resolving off-Table cases, see Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). Any sequela of the vaccine-related injury is compensable. §14(a), as amended, 42 C.F.R. §100.3(a).

Once filed, the Program petition is assigned to a special master who has 240 days to render a decision on the merits or otherwise resolve the case, excluding any periods of suspension allowed by the Act. §12(d)(3)(A). Although the Program's scheme is adversarial, there is no right to discovery and often little need for formal discovery; petitions are either filed complete with all the evidence attached as exhibits or the parties work cooperatively to gather information to complete the record. See the special masters' Guidelines for Practice Under the National Vaccine Injury Compensation Program for a complete description of the Program and the implementing procedures.

individual who is injured by a vaccine to file a Program petition with this court against the United States government, namely the Secretary for the Department of Health and Human Services, rather than vaccine manufacturers who provide the vaccines to doctors and hospitals or the doctors who administer the vaccines.[7] As the Federal Circuit recognized, the Vaccine Program "stems from Congress's recognition that '[w]hile most of the Nation's children enjoy great benefit from immunization programs, a small but significant number have been gravely injured.'" Knudsen, 35 F.3d at 549 (quoting H.R. Rep. No. 99-908, at 4, reprinted in 1986 U.S.C.C.A.N. at 6345). All persons alleging a vaccine-related injury are entitled to take advantage of the Program's "streamlined" process. Significantly, if the vaccinee misinterprets or ignores the Court of Federal Claims's jurisdiction over claims brought pursuant to the Vaccine Act, and instead, for whatever reason, files a civil action in state or federal court, the state or federal court must dismiss the claim until the vaccinee exhausts her remedies under the Program. §11(a)(2)(B). See also §11(a)(3).

The Vaccine Act constitutes the federal government's waiver of sovereign immunity which must be strictly construed "'in favor of the sovereign.'" United States v. Nordic Village, Inc., 503 U.S. 30, 34 (1992) (quoting McMahon v. United States, 342 U.S. 25, 27 (1951)). See also Holihan v. Secretary of HHS, 45 Fed. Cl. 201, 207 (1999); Childers v. Secretary of HHS, No. 96-194V, 1999 WL 218893, at *2 (Fed. Cl. Spec. Mstr. Mar. 26, 1999); Hoffman v. Secretary of HHS, No. 90-3451V, 1995 WL 103334, at *2 (Fed. Cl. Spec. Mstr. Feb. 21, 1995). "As a limited waiver of sovereign immunity, [the Vaccine Act] must be given a strict and narrow construction."[8] Holihan, 45 Fed. Cl. at 207. The Federal Circuit recently cautioned that "courts should be 'careful not to interpret [a waiver of sovereign immunity] in a manner that would extend the waiver beyond that which Congress intended.'" Brice v. Secretary of HHS, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (citing Block v. North Dakota, 461 U.S. 273, 287 (1983), as quoted in Stone Container Corp. v.

[7/] The Program allows vaccine manufacturers to produce vaccines necessary to maintain the public health, without fear of constant litigation when injuries occur, and at the same time ensures those individuals who are injured by vaccines receive compensation. See H.R. Rep. No. 99-908, at 3-5 (1986), reprinted in1986 U.S.C.C.A.N. at 6345-46. The Act prevents the vaccinee from filing a civil action without first obtaining a judgment from this court and electing to file a civil action, or alternatively, withdrawing her petition pursuant to the Act's provisions. §11(a)(2)(A). See also Shalala v. Whitecotton, 514 U.S. 268, 270 (1995) (examining and explaining §11(a) provisions).

[8/] In a thoughtful analysis of sovereign immunity as it applies to the Vaccine Act, Special Master Hastings recognized that the Supreme Court has said, "in construing a statute that waives sovereign immunity, a court must be careful not to 'assume the authority to narrow the waiver that Congress intended,'" and "a federal court should not 'as a self-constituted guardian of the Treasury, import immunity back into a statute designed to limit it.'" Childers v. Secretary of HHS, No. 96-194V, 1999 WL 218893, at *3 (Fed. Cl. Spec. Mstr. Mar. 26, 1999) (quoting, respectively, United States v. Kubrick, 444 U.S. 111, 118 (1979) and Indian Towing Co. v. United States, 350 U.S. 61, 69 (1955)). But, Special Master Hastings also concluded that Supreme Court precedent reinforces the notion that statutes waiving sovereign immunity must be construed strictly. Id. at *4.

United States, 229 F.3d 1345, 1352 (Fed. Cir. 2000)). Questions of jurisdiction and statutory interpretation must be analyzed and answered in light of these underlying principles.

II. Accepted Canons of Statutory Interpretation Support Subject Matter Jurisdiction

It is well settled that when interpreting statutory language, "[a] statute's words must be given their ordinary, contemporary, common meaning, absent an indication Congress intended them to bear some different import." Williams v. Taylor, 529 U.S. 420, 421 (2000). See also Smith v. United States, 508 U.S. 223, 228 (1993) (stating "[w]hen a word is not defined by statute, we normally construe it in accord with its ordinary or natural meaning"); Old Colony Railroad Co. v. Commissioner of Internal Revenue, 284 U.S. 552, 560 (1932) (stating "'[t]he legislature must be presumed to use words in their known and ordinary signification'") (quoting Levy's Lessee v. M'Cartee, 31 U.S. 102, 6 Pet. 102, 110 (1832)); City of Lincoln, Nebraska v. Ricketts, 297 U.S. 373, 376 (1936) (stating "[w]e give to the words their natural significance unless that leads to an unreasonable result plainly at variance with the evident purpose of the legislation"); Asgrow Seed Company v. Winterboer, 513 U.S. 179, 187 (1995) (stating "[w]hen terms used in a statute are undefined, we give them their ordinary meaning"); Terran v. Secretary of HHS, 195 F.3d 1302, 1310 (Fed. Cir. 1999) (stating "[t]he first and most important step when interpreting a statute is, of course, analyzing its text"). Thus, "[a]bsent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as *conclusive*." Consumer Product Safety Commission v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980) (emphasis added). Moreover, "'where Congress has clearly stated its intent in the language of a statute, a court should not inquire further.'" Hellebrand v. Secretary of HHS, 999 F.2d 1565, 1569 (Fed. Cir. 1993) (quoting Brookside Veneers, Ltd. v. United States, 847 F.2d 786, 788 (Fed. Cir. 1988), cert. denied, 488 U.S. 943 (1988) (citations omitted)).

Relevant to the jurisdictional issue before this court, the Vaccine Act defines "vaccine-related injury or death" as "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*." §33(5) (emphasis added). Neither the statute nor the legislative history expressly defines "adulterant," "contaminant," or "vaccine." Petitioners allege that the thimerosal preservative is an adulterant or contaminant within the meaning of the Act, and thus, any injury allegedly caused by the thimerosal is excluded specifically by the Act's definition of "vaccine-related injury." See Pet. Brief at 4-5, 9-12. Petitioners contend further that because definitions of "vaccine" do not mention thimerosal specifically or preservatives generally, thimerosal cannot be a component of the vaccine itself. Id. at 8-9. To determine whether Congress intended to exclude from the Act's statutory scheme those injuries allegedly associated with thimerosal, the undersigned must first and foremost examine the *plain and ordinary meaning* of these three statutory terms.

Applying accepted canons of statutory interpretation and following a review of common dictionary definitions of the terms "adulterant" and "contaminant," the court finds that a preservative is not an intentionally added ingredient of the vaccine meant to make impure, inferior, or contaminated the vaccine end product. Rather, a preservative is the antithesis of these descriptions, as it actually prevents corruption of the vaccine. Upon further exploration of dictionary references,

the court also finds that the plain meaning of the term "vaccine" allows for the composition of different ingredients in the vaccine product, including a preservative such as thimerosal; therefore, a vaccine preservative is a constituent part or a component of the vaccine. Consequently, based upon the plain meaning of the statutory terms, any injury arising from the thimerosal preservative in vaccines is encompassed within the statutory definition of "vaccine-related injury," thereby granting jurisdiction over such claims to this court. To that end, the court's findings are well-supported by recent federal case law addressing the identical issue. The court's analysis follows.

A. The Preservative Thimerosal Is Neither an "Adulterant" Nor a "Contaminant" as Ordinarily Defined

Using accepted principles of statutory interpretation, several federal courts have decided that thimerosal is not an "adulterant" or "contaminant" within the meaning of the Vaccine Act and, therefore, excluded under the Program by the Act's definition of "vaccine-related injury." See, e.g., Liu v. Aventis Pasteur, Inc., 2002 WL 31007709 (W.D. Tex. Aug. 23, 2002); Owens v. American Home Products Corporation, 203 F. Supp. 2d 748 (S.D. Tex. May 7, 2002); O'Connell v. American Home Products Corporation, No. G-02-184, slip op. (S.D. Tex. May 7, 2002). See also Bertrand v. Aventis Pasteur, Labs., Inc., 2002 WL 31194226, at *5-*6 (D. Ariz. Sept. 23, 2002) (declining to resolve whether thimerosal is an adulterant or contaminant, but noting that "every federal court to have ruled on the issue has held that injuries resulting from Thimerosal contained in vaccines are vaccine-related under the meaning of the Act"); Liu, 2002 WL 31007709, at *2-*3 (citing Blackmon v. American Home Products Corporation, No. G-02-179, slip op. (S.D. Tex. May 8, 2002), as holding that thimerosal cases are vaccine-related cases under the meaning of the Vaccine Act, and citing Collins v. American Home Products Corporation, No. 01-979, slip op. (S.D. Miss. Aug. 1, 2002), as "dismissing thimerosal claims because Autism Order #1 'foreclose[d] any reasonable possibility that the plaintiffs have stated a currently cognizable claim against the resident defendants'"). In Owens and O'Connell,[9] Judge Kent concluded that plaintiffs' claims fell squarely

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[9/] While petitioners cite to Plaintiffs' Response in Opposition to Defendants' Motion to Dismiss in Owens v. American Home Products Corporation, they fail to cite directly to the decision in that case which is contrary to their position in this matter. See Owens v. American Home Products Corporation, 203 F. Supp. 2d 748 (S.D. Tex. 2002). ABA Model Rule of Professional Conduct 3.3 states that "[a] lawyer shall not knowingly: (1) make a false statement of material fact or law to a tribunal; . . . [or] (3) fail to disclose to the tribunal legal authority in the controlling jurisdiction known to the lawyer to be directly adverse to the position of the client." Model Rules of Prof'l Conduct R. 3.3 (1983). Comment 3 to Model Rule 3.3 likewise states that "[a] lawyer is not required to make a disinterested exposition of the law, but must recognize the existence of pertinent legal authorities." Model Rules of Prof'l Conduct R. 3.3 cmt (1983). Most states adopt the Model Rules or have similar variations in pertinent part. In this case, the Texas federal district court is not a controlling jurisdiction; however, petitioners' counsel was ethically obligated to reference Judge Kent's contrary findings given that the decision is directly on point to the jurisdictional issue raised in the case sub judice.

within the scope of the Act and should be decided by the Court of Federal Claims.[10] Relying on an accepted canon of statutory interpretation, the Owens court first looked to the plain meaning of the Vaccine Act's language. Since the statute explicitly precludes compensation for injuries arising from an "adulterant" or "contaminant," Judge Kent sought to define these terms. Recognizing that "adulterant" and "contaminant" are not defined by the Vaccine Act, the Owens court turned to dictionary definitions for guidance. It found that "[t]himerosal, when used in vaccines, fails to correspond with any of th[e] definitions [of adulterant and contaminant]."[11] Owens, 203 F. Supp. 2d at 755; O'Connell, slip op. at *7. He thus concluded that "[c]learly, the *plain language* of the Vaccine Act indicates that the [vaccinee's] injuries cannot be 'thimerosal-related' without being 'vaccine-related' as well." Owens, 203 F. Supp. 2d at 756 (emphasis added); O'Connell, slip op. at *9. Judge Kent further opined that "because the [vaccinee's] injuries are allegedly linked to a vaccine ingredient, their injuries are definitely 'vaccine-related.'" Owens, 203 F. Supp. 2d at 755; O'Connell, slip op. at *8 (citations omitted). The undersigned agrees completely with Judge Kent's well-reasoned analysis of this issue.

In support of their respective positions, petitioners and respondent cite the same, or slight variations of, definitions relied on by the Owens court.[12] For instance, Dorland's Illustrated Medical

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10/ Other federal district courts have followed Judge Kent's line of reasoning in Owens and O'Connell. See, e.g., Liu v. Aventis Pasteur, Inc., 2002 WL 31007709, at *2 (W.D. Tex. Aug. 23, 2002) (stating "it appears every federal court to have ruled on the issue has held injuries resulting from thimerosal contained in vaccines are vaccine-related under the meaning of the Vaccine Act") (citing Blackmon v. American Home Products Corporation, No. G-02-179, slip op. (S.D. Tex. May 8, 2002); Owens v. American Home Products Corporation, 203 F. Supp. 2d 748 (S.D. Tex. May 7, 2002)). See also Cheskiewicz v. Aventis Pasteur, Inc., 2002 WL 1880524, at *2 (E.D. Pa. Aug. 15, 2002) (discussing defendant's reliance on McDonald v. Abbott Labs., No. 02-77, slip op. (S.D. Miss. Aug. 1, 2002); Collins v. American Home Products Corporation, No. 01-979, slip op. (S.D. Miss. Aug. 1, 2002); and Stewart v. American Home Products Corporation, No. 02-427, slip op. (S.D. Miss. Aug. 1, 2002), for the proposition that claims arising from thimerosal are covered by the Vaccine Act). Like Owens and O'Connell, all three of the cases discussed in Cheskiewicz were cited as dismissing claims that were covered under the Vaccine Act. See Cheskiewicz, 2002 WL 1880524, at *2.

11/ Quoting The American Heritage Dictionary 58 (2d ed. 1992) and Stedman's Medical Dictionary 30 (27th ed. 2000) respectively, Judge Kent found "adulterant" defined as "a substance which makes an item impure, spurious, or inferior by adding extraneous or improper ingredients" and "[a]n impurity; an additive that is considered to have undesirable effect or to dilute the active material so as to reduce its therapeutic or monetary value." Owens, 203 F. Supp. 2d at 754-55. A contaminant was defined as "[s]omething that makes impure or corrupt by contact or mixture." Id. at 755 (quoting Webster's 9th New Collegiate Dictionary 283 (9th ed. 1991)).

12/ Petitioners and respondent cite numerous dictionaries defining "adulterant," "adulteration," and "contaminant," including The American Heritage College Dictionary 58 (2d ed. (continued...)

Dictionary 33 (27th ed. 1988) defines "adulterant" as "a substance used as an addition to another substance for sophistication or adulteration." "Adulteration" is defined as the "addition of an impure, cheap, or unnecessary ingredient to cheat, cheapen, or falsify a preparation; in legal terminology, incorrect labeling, including dosage not in accordance with the label." Id. A "contaminant" is defined as "something that causes contamination." Id. at 376. "Contamination" is "the presence of any substance or organism that makes a preparation impure." Id. Petitioners provide no persuasive evidence advancing a substantively different definition for "adulterant" or "contaminant." Nor do they provide any persuasive evidence in the record that Congress intended "adulterant" or "contaminant" to mean anything other than their plain meaning. Further, relevant to this discussion, a "preservative" is "a substance or preparation added to a product for the purpose of destroying or inhibiting the multiplication of microorganisms." Id. at 1353. Therefore, following Judge Kent's analysis, thimerosal is not an "adulterant" or "contaminant" as ordinarily defined. That is, by any ordinary meaning, a preservative is the antithesis of contaminant because a preserving agent actually prevents the impurity or corruption of the vaccine.[13] The same conclusion was reached in Owens:

> Thimerosal, when used in vaccines, fails to correspond with any of these definitions. Vaccine manufacturers intentionally add thimerosal to vaccine formulas because it deters microbial and fungal growth, thereby maintaining the safety, purity, and

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[12/](...continued)
1992); Webster's New World College Dictionary (3d ed. 1997); Webster's 9th New Collegiate Dictionary 283 (9th ed. 1991); Dorland's Illustrated Medical Dictionary (29th ed. 2000); Barron's Medical Guides: Dictionary of Medical Terms (4th ed. 2000); Taber's Encyclopedic Medical Dictionary (19th ed. 2001); Mosby's Medical, Nursing & Allied Health Dictionary (5th ed. 1998); Stedman's Concise Medical Dictionary for the Health Professions (4th ed. 2001); Stedman's Medical Dictionary 30 (27th ed. 2000); and Merriam-Webster's Medical Desk Dictionary (1996). Some definitions are duplicative of those quoted herein, but no definition differs significantly from the next.

[13/] The Institute of Medicine ("IOM") has explained:

> Thimerosal, an organic mercury compound that is metabolized to ethylmercury and thiosalicylate, has been used since the 1930s as a preservative in some vaccines. Food and Drug Administration (FDA) regulations require that preservatives be used in multidose vials of vaccines, except live viral vaccines, to prevent bacterial and fungal contamination (General Biologics Product Standards, 2000), which can lead to serious illness and death in recipients (Wilson, 1967). . . . Uses other than as a preservative contribute little to the final concentration of thimerosal in vaccines (Ball et al., 2001).

Immunization Safety Review, Institute of Medicine, Thimerosal-Containing Vaccines and Neurodevelopmental Disorders 13 (Kathleen Stratton et al. eds., 2001) ("IOM Thimerosal Report").

> potency of vaccines. . . . [T]himerosal cannot be said to "make impure or corrupt" a vaccine or to reduce a vaccine's therapeutic value. Furthermore, thimerosal cannot be characterized as having an undesirable effect or diluting the active material found within a vaccine. In fact, the opposite is true. As a preservative, thimerosal *prevents* a vaccine's corruption. Hence, neither the plain meaning of "adulterant" nor "contaminant" applies to thimerosal when, as here, it is purposefully used as an ingredient in the approved formulation of a vaccine.

Owens, 203 F. Supp. 2d at 755. The undersigned finds no persuasive or logical reason to deviate from this cogent analysis of this issue.

B. The Preservative Thimerosal Is a Component or a Constituent of the "Vaccine" as Ordinarily Defined

The meaning of "vaccine-related injury or death," which is defined by the Act as "an illness, injury, condition, or death associated with one or more of the [Table] vaccines," includes injuries allegedly caused by the thimerosal component of a vaccine. §33(5). Relying on the ordinary meaning of "vaccine," Judge Kent found in Owens that the vaccinee's claim was covered under the Program:

> A "vaccine" is defined as a "suspension of attenuated or killed microorganisms," Dorland's Medical Dictionary 1799 (27th ed. 1988), and "a preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms." Webster's 9th New Collegiate Dictionary 1301 (9th ed. 1991). Neither of these definitions indicate that a vaccine is comprised of microorganisms alone. On the contrary, they indicate that a vaccine is a "suspension" or "preparation" composed of both microorganisms and additional ingredients. And, as explained above, manufacturers of vaccines add thimerosal to the "preparation" or "suspension" of vaccines.

Owens, 203 F. Supp. 2d at 755 (footnotes omitted).

Here, petitioners offer definitions of the word "vaccine," all of which similarly define vaccine as a "suspension" or "preparation." See Pet. Brief at 8-9 (Mosby's Medical Dictionary (5th ed. 1998) ("[a] suspension of attenuated or killed microorganisms"); Stedman's Medical Dictionary (27th ed. 2000) ("a preparation"); Taber's Encyclopedic Medical Dictionary (19th ed. 1997) ("[a]ny suspension containing antigenic molecules"); Dorland's Illustrated Medical Dictionary (29th ed. 2000) ("[a] suspension of attenuated or killed microorganisms"); The Bantam Medical Dictionary (3d ed. 2000) ("a special preparation of antigenic material"); Compact American Medical Dictionary (3d ed. 1998) ("[a] preparation of a weakened or killed pathogen"); Webster's New World Medical Dictionary (2000) ("preparations of killed or modified microorganisms"); Merriam-Webster's Medical Desk Dictionary (1996) ("a preparation of killed microorganisms")). A "suspension" is "a preparation of a finely divided drug intended to be incorporated (suspended) in some suitable liquid vehicle before it is used, or already incorporated in such a vehicle." Dorland's Illustrated Medical Dictionary 1617 (27th ed. 1988). A "preparation" is "a medicine made ready for use." Id. at 1351.

Petitioners argue that none of the definitions of "vaccine" mention thimerosal, specifically, or a preservative, generally, leading one to conclude that a preservative is a non-component or non-constituent of the vaccine. Pet. Brief at 8. Petitioners' argument is unreasonably strained.

Once again, Judge Kent's analysis in Owens is persuasive. It is reasonable to construe the plain meaning of "vaccine" to encompass the thimerosal *component* because, within its ordinary usage, the term "vaccine" strongly implies the inclusion of bacterium and additional ingredients. See Owens, 203 F. Supp. 2d at 755. It is also clear from the FDA regulations cited in petitioners' brief, at 13-14 and Appendix 3, that those vaccines sold in multiple-dose vials indeed must contain such an additional ingredient, a preservative.[14] See 21 C.F.R. §610.15 (West 2002). Section 610.15 states in relevant part:

> Products in multiple-dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine; Poliovirus Vaccine Live Oral; viral vaccines labeled for use with the jet injector; dried vaccines when the accompanying diluent contains a preservative; or to an Allergenic Product in 50 percent or more volume in volume (v/v) glycerin.

21 C.F.R. §610.15(a). See also Owens, 203 F. Supp. 2d at 755, n. 10 (stating "[t]he FDA has long recognized that preservatives (i.e. thimerosal) are 'constituent materials' of vaccines. *See* 21 C.F.R. §610.15 (indicating that constituents of biological materials include ingredients, preservatives, diluents and adjuvants)"). That thimerosal is not mentioned by name in the regulation does not necessarily exclude it as an acceptable additive or as a component of the vaccine preparation. Moreover, nothing in the legislative history suggests that Congress intended the word "vaccine" to adopt a meaning different from its common usage. Indeed, throughout the House Report, the word "vaccine" is used in its ordinary sense. See generally H.R. Rep. 99-908, reprinted in 1986 U.S.C.C.A.N. 6344. The plain language of the statute is conclusive, in the absence of clear legislative intent to the contrary. See Consumer Product Safety Commission v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980). Hence, as Judge Kent recognized and as this court agrees, injuries allegedly arising from the thimerosal component (a vaccine ingredient) are reasonably construed as "definitely 'vaccine-related'" within the plain meaning of the language of the Vaccine Act. Owens, 203 F. Supp. 2d at 755; O'Connell, slip op. at *8.

III. The Legislative History Supports the Court's Analysis

It is a time-honored principle that "[t]he court will defer to the clear meaning of a statute when the language is sufficiently clear, and the plain meaning of the statute is supported by the legislative history." Klahn v. Secretary of HHS, 31 Fed. Cl. 382, 386 (1994). "The statutory language should be conclusive '*except in the rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters*.'" Warner Cable v. Doyle, 66 F.3d 867, 876 (7th Cir. 1995), cert. denied, 516 U.S. 1141 (1996) (citations omitted) (emphasis added), as quoted in DeRoche v. Secretary of HHS, No. 97-643V, 2002 WL 603087, at

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[14/] For a more detailed discussion of the FDA regulations, see Part V of this decision.

*28 (Fed. Cl. Spec. Mstr. Mar. 28, 2002). The Secretary argues that the legislative history supports "the finding that Congress intended that injuries allegedly related to thimerosal be brought under the Program." Resp. Brief at 10-11. The Secretary contends that "[g]iven the congressional purpose of channeling liability for vaccine injuries to the Program and the fact the vaccines chosen for coverage contained thimerosal, it is incongruous to argue that at the same time Congress extended coverage to these vaccines, it intended to define away that coverage for any injury related to thimerosal." Id. at 11. Additionally, the Secretary submits that not only is petitioners' argument legally in error, but it would undermine the Program's legislative purpose by leading to a "multiplicity of litigation." Id. at 14. Although the government cannot provide direct evidence in the legislative history relevant to the interpretation of "adulterant" or "contaminant," the respondent notes that Congress created a Table injury in response to a concern over possible hypersensitivity reactions to the inactivated polio vaccine because it contained trace amounts of antibiotics. Id. at 11. The government emphasizes this is an indication that Congress intended the Act to compensate vaccinees injured by *any* component of the vaccine. Id. The court finds the Secretary's arguments persuasive.[15]

The court's own review of the legislative history supports fully respondent's interpretation of the Act. The statute's purpose is to ensure vaccine safety and supply and reduce civil litigation while still providing compensation to injured vaccinees. See H.R. Rep. 99-908, at 3-5, reprinted in 1986 U.S.C.C.A.N. at 6344-46. The court may not read limitations into the definition of "vaccine-related injury" that are clearly at odds with the Program's congressionally-stated purpose. Distinguishing thimerosal-related injuries from vaccine-related injuries, as petitioners advocate, would likely result in a "multiplicity of litigation." See Resp. Brief at 14. That is, Program petitioners alleging injury resulting from both the vaccine antigen and its component parts would be required to maintain actions in two different courts: a Program claim in the Court of Federal Claims based upon the antigen-causing-injury theory, and a second action in state or federal civil court based upon a theory that injury resulted from the non-antigen component part of a vaccine. Id. This litigative scheme would clearly defeat the stated legislative purpose of the Act and expose manufacturers and administrators to the same litigation the Act was designed to reduce or eliminate. To be sure, the value by which Congress held these goals is unequivocally evident in the Act's express statutory scheme at §11(a). As the Federal Circuit has determined, the statute prevents petitioners from maintaining actions in two fora. See Flowers v. Secretary of HHS, 49 F.3d 1558 (Fed. Cir. 1995) (affirming the dismissal of a Program petition for lack of jurisdiction pursuant to §11(a)(5)(B), when a civil suit was still pending at the time petitioner filed her petition). The Act also does not allow a petitioner to continue under the Program if the vaccinee has previously collected a civil action award or settlement for his injury. See §11(a)(7) and §11(c)(1)(E). Thus, petitioners' interpretation of the statutory text violates the statutory scheme by promoting dual actions for compensation.

[15/] Although the courts are the final arbiters on issues of statutory interpretation, an administrative agency's interpretations of the statutory scheme they are entrusted to administer have been given considerable deference. See Chevron, USA, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844-45 (1984).

Compliance with the legislative purpose and the statutory scheme was discussed at length by the Federal Circuit in Amendola v. Secretary of HHS, 989 F.2d 1180 (Fed. Cir. 1993). As in the case sub judice, Amendola involved the interpretation of §11(a) of the Act (specifically §§11(a)(4) and (a)(5)), which encompasses "the gate-keeping provisions" of the Vaccine Act.[16] Amendola, 989 F.2d at 1182. See also Klahn v. Secretary of HHS, 31 Fed. Cl. 382, 385 (1994). Judge Plager, writing for the panel in Amendola, cautioned that statutory interpretation is an art "constrained by the fundamental obligation of the judicial branch to implement, not rethink, the purpose of the legislative branch."[17] Amendola, 989 F.2d at 1182. Judge Plager wrote: "When the legislative purpose is incorporated in a complex piece of legislation, such as those establishing a major regulatory or entitlement program, the meaning of any particular phrase or provision cannot be securely known simply by taking the words out of context and treating them as self-evident."[18] Id. In the case of the Vaccine Act, Judge Plager determined that "Congress'[s] purpose is both clear and

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16/ The gate-keeping provisions are as follows. Section 11(a)(1) requires that a petitioner allege a vaccine-related injury or death and serve a petition for compensation on the Secretary of the Department of Health and Human Services. Section 11(a)(2) describes when an injured vaccinee can sue civilly, specifically only if his or her claim is less than $1,000, or the vaccinee stays in the Program for a required period of time after which the vaccinee chooses to withdraw from the Program, or the vaccinee rejects the judgment in this court. *De minimis* claims can be filed in either state or federal court. §11(a)(2)(A). Section 11(a)(3) limits suits against vaccine administrators and manufacturers, unless the vaccinee complies with §11(a)(2). Sections 11(a)(4) permits the filing of Program petitions where pre-Act civil suits resulted in a denial of damages or dismissal with prejudice. Section 11(a)(5) limits when a vaccinee with a pending civil action may bring an action here. Similarly, §§11(a)(6) through (a)(8) lay ground rules for whether a vaccinee may bring a petition under the Program.

17/ The Amendolas filed a Program petition after they had already brought a state civil action against the administrating physician for their son's injuries which resulted in an unfavorable judgment in 1989. Amendola, 989 F.2d at 1181. The government moved to dismiss under §11(a)(5)(A) of the statute, which allowed vaccinees with civil suits pending when the Act became effective to dismiss the civil suit without prejudice prior to judgment or by October 1, 1990 (whichever occurred first), and file a petition in this court. The special master granted the government's motion, reasoning that the Amendolas' civil case had already gone to judgment in 1989, precluding them from filing a claim in this court under the Vaccine Act. Amendola v. Secretary of HHS, No. 90-766V, 1991 WL 43027 (Cl. Ct. Spec. Mstr. Mar. 14, 1991). The Federal Circuit ultimately affirmed the dismissal. Amendola v. Secretary of HHS, 989 F.2d 1180 (Fed. Cir. 1993).

18/ Judge Plager relied upon the "rather straightforward homily . . . captured in the more pretentious proposition that parts of a statute *in pari materia* must be construed together." Amendola, 989 F.2d at 1182. In interpreting the interplay between subsections (a)(4) and (a)(5) of §11, Judge Plager construed subsection (a)(4) as prohibiting a plaintiff who had a civil suit pending on the effective date of the Act from taking the suit to judgment, then after receiving an unfavorable judgment, bringing a petition under the Act. Id. at 1184.

clearly evidenced by the statutory framework. The statute provides a strong bias in favor of bypassing the civil litigation route in favor of compensation claims under the Act." Id. at 1184. Judge Plager noted further that "[c]learly, the motivating factor behind enactment of the legislation was the desire to protect the vaccine supply by shielding manufacturers from exposure to liability resulting from the small but nevertheless statistically significant incidence of unavoidable injury or death from widespread use of the vaccine." Id. at 1186.

Although Judge Plager analyzed a different subsection of §11(a) than is at issue here, he interpreted a gate-keeping provision consistent with the statutory scheme which evinced Congress's strong preference for an alternative forum for resolving vaccine claims. Following the Federal Circuit's direction, the undersigned will not improperly "rethink" the purpose for the Vaccine Act. As Judge Plager correctly implied, that is a job for Congress. Amendola, 989 F.2d at 1182. Notably, there is legislation addressing provisions of the Vaccine Act currently pending before Congress. See, e.g., Vaccine Injury Compensation Reform Act, H.R. 2056, 107th Cong. (2001); National Vaccine Injury Compensation Program Improvement Act of 2002, H.R. 3741, 107th Cong. (2002). If Congress desires to exclude from the Vaccine Act injuries that allegedly result from a component of a vaccine, such as the thimerosal preservative, thus enabling vaccinees to seek initial relief in civil court, Congress has the power to do so. This court does not. In its final analysis, the court's interpretation of "vaccine-related injury" under §11(a)(1) and §33(5) is fully consistent with the legislative history and the statutory scheme.[19]

[19/] Incidentally, the Amendolas also argued that their negligence and malpractice suit against the physician was not a "'civil action for damages' as contemplated by the Act." Amendola, 989 F.2d at 1181, 1185-86. From their perspective, the Vaccine Act was only meant to protect manufacturers and administrators from strict liability claims. Id. at 1186. Judge Plager analyzed their argument in the context of §33(5). Id. Recognizing that the only exclusion to the definition of "vaccine-related injury" is an injury associated with a "foreign substance" or an "extraneous material," Judge Plager dismissed the Amendolas' argument that their civil court claim was not one contemplated by the Act. Id. In further rejecting petitioners' position that the injury was not "vaccine-related," he wrote: "If this were a situation in which the direct cause of the injury was a contaminated needle, or the doctor's negligent dropping of an infant patient, or other negligence facially *unrelated to the vaccine's effects*, then [petitioners' arguments] might require further examination." Id. at 1186-87. Petitioners in the instant case cite Amendola for the proposition that adulterant or contaminant "extends to the addition of 'foreign' substances or 'extraneous' materials." Pet. Brief at 11. However, the scenarios that Judge Plager suggest, in dicta, require "further examination" are not similar to the case we have here, where Nicholas's alleged injury arises directly from a required vaccine component added to some of the vaccines on his immunization schedule. To the contrary, Nicholas's case is similar to the situation in Amendola where the child allegedly suffered an adverse reaction to *a series* of DPT shots.

IV. Petitioners' Supplemental Legal Arguments Disputing Jurisdiction Are Unpersuasive

Petitioners present other legal arguments in support of their claim, all of which the court finds unpersuasive.

First, petitioners rely on language from Special Master Edwards's Order in Geppert v. Secretary of HHS, No. 00-286V (Fed. Cl. Spec. Mstr. Mar. 21, 2001) (unpublished order raising the issue whether thimerosal is an adulterant or contaminant and directing respondent to file a brief on the jurisdictional issue), as further proof that claims based on thimerosal are not within this court's jurisdiction. Pet. Brief at 5-6; P. Reply at 2. The language referenced by petitioners reads:

> A simple, lay reading of the plain language of § 300aa-33(5) suggests that the Act does not encompass injuries related to "mercury, aluminum and other materials" in vaccines. A cursory review of the legislative history does not yield support for a contrary interpretation.

Order at 2. A closer examination of the entire Order reveals that this passage simply expresses the special master's tentative analysis of the jurisdictional issue raised by the statute, rather than his final legal "conclusion," as petitioners contend. Indeed, in the Order, Special Master Edwards directed respondent to brief the issue of whether an injury allegedly arising from the thimerosal component of a vaccine is a "vaccine-related injury" within the meaning of the Vaccine Act. In response to that Order, the Secretary filed a brief in support of the special master's jurisdiction over the claim. Based on respondent's position and petitioners' apparent acquiescence to jurisdiction by this court,[20] Special Master Edwards determined that "he [did] not have to render an interpretation of 42 U.S.C. § 300aa-33(5)" and directed further proceedings in the case. See Geppert v. Secretary of HHS, No. 00-286V, Order at 1 (Fed. Cl. Spec. Mstr. Oct. 12, 2001) (unpublished). Clearly, Geppert provides no persuasive support for petitioners' contention that this court is an improper forum for their case.

Second, petitioners rely on the federal magistrate's conclusion in King v. Aventis Pasteur, Inc., No. 01-1305-AS, Findings and Recommendation, slip op. (D. Or. June 7, 2002). Pet. Brief at 7-8. Following the defendant manufacturer's removal of the case to federal court, the federal magistrate declined to find federal question jurisdiction over claims by plaintiffs alleging that thimerosal caused the vaccinee to sustain injury. King, slip op. at 3-5; see also Pet. Brief at Appendix 2. The magistrate recommended the case's remand on the belief that the state court was the appropriate forum for plaintiffs' claim even though the defendants' defense involved the interpretation of §11(a) and §33(5) of the Vaccine Act. King, slip op. at 3-5. The magistrate

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[20/] Special Master Edwards wrote: "Indeed, in the special master's view, petitioners have acquiesced to the special master's jurisdiction – first, by filing a Program petition, and second, by electing to have their petition remain pending before the special master after the expiration of 420 days from the filing of the petition." Geppert v. Secretary of HHS, No. 00-286V, Order at 1, n.1 (Fed. Cl. Spec. Mstr. Oct. 12, 2001) (unpublished).

determined that Congress did not "craft an exclusive federal remedy for all vaccine-related injuries," but allowed the state courts to retain jurisdiction over certain vaccine claims. Id. at 4-5. For diversity jurisdiction purposes, in further determining whether plaintiffs had viable claims against the doctors administering the vaccinations, Magistrate Judge Ashmanskas ruled that although the doctors were covered by the Act as "vaccine administrators," "a state court could find the injuries were not 'vaccine-related.'" Id. at 6-7. He stated:

> [I]t is entirely possible that the state court would find that Plaintiffs' injuries, which are attributed solely to the toxic mercury found in Thimerosal, do not qualify as "an illness, injury, condition or death associated with one or more of the vaccines set forth in the Vaccine Injury Table" and are not covered by the Act.

Id. at 7-8. The federal district court judge ultimately adopted the federal magistrate's findings and recommendations. See King v. Aventis Pasteur, Inc., 210 F. Supp. 2d 1201 (D. Or. June 7, 2002).[21]

[21/] Other federal district courts have declined to find federal question jurisdiction over tort claims alleging injury from the thimerosal component of a vaccine. See, e.g., Doherty v. Pasteur, 2002 WL 1034044 (N.D. Cal. May 17, 2002); Garcia v. Aventis Pasteur, Inc., 2002 U.S. Dist. LEXIS 15122 (W.D. Wash. Apr. 23, 2002); Demos v. Aventis Pasteur, No. 01-04504-CIV-GRAHAM, slip op. (S.D. Fla. Mar. 21, 2002). The district courts have based their analyses on the "'well-pleaded complaint rule,' which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint." Doherty, 2002 WL 1034044, at *1; see also Garcia, 2002 U.S. Dist. LEXIS 15122, at *5-*6; Demos, slip op. at 15-16. Defendants have argued, in support of removal, that the Vaccine Act created and/or preempted plaintiffs' causes of action or state law and that the claims involve substantial federal questions in the interpretation of the scope of the Vaccine Act. Doherty, 2002 WL 1034044, at *1-*3; Garcia, 2002 U.S. Dist. LEXIS 15122, at *4-*10; Demos, slip op. at 15. The federal district courts rejected these arguments, concluding that the Vaccine Act neither created nor preempted the state claims or law because the statute explicitly contemplated the state courts as alternative fora for the tort claims. Doherty, 2002 WL 1034044, at *2 ("It is axiomatic that a federal remedy that leaves intact alternative civil fora cannot be the basis for 'creation' of claims that may be brought in those fora.") (citation and footnote omitted); Demos, slip op. at 15-17. That is, the Act simply postponed, rather than eliminated, the pursuit of civil suits in state or federal court. Doherty, 2002 WL 1034044, at *3. The courts have also determined that the federal issues were not substantial enough to confer federal question jurisdiction. Doherty, 2002 WL 1034044, at *3; Demos, slip op. at 16. See also Bertrand v. Aventis Pasteur Laboratories, Inc., 2002 WL 31194226 (D. Ariz. Sept. 23, 2002). But see Cheskiewicz v. Aventis Pasteur, Inc., 2002 WL 1880524, at *1 (E.D. Pa. Aug. 15, 2002) (finding that the complaint did not raise a federal question and noting that defendants, at oral argument, "expressly disclaimed any argument that [the Vaccine Act] create[d] a federal question"). Conversely, more recently in Liu v. Aventis Pasteur, Inc., 2002 WL 31007709, at *1-*3 (W.D. Tex. Aug. 23, 2002), the federal district court dismissed plaintiffs' claim brought before it on federal question jurisdiction, finding that the plaintiffs must exhaust their remedies first under the Vaccine Program.

The undersigned finds little persuasive value in the magistrate's findings and recommendation. As respondent notes, the federal district court never reached the issue of whether thimerosal is an adulterant for purposes of the Vaccine Act, nor, as of this time, has the state court on remand. Moreover, Magistrate Judge Ashmanskas's suggestive words focus not on whether plaintiffs' injuries are vaccine-related because thimerosal is an adulterant or contaminant, but focus instead on whether thimerosal-related injuries flow from *vaccines set forth in the Vaccine Injury Table*. See King, slip op. at 7-8. Whether the injury was caused by thimerosal in the vaccine or by some other component in the vaccine begs the question as to the proper fora for addressing that issue. As discussed infra, this court finds no basis for distinguishing between the component parts of the vaccine and, thus, finds the King analysis inapposite.

Furthermore, the magistrate's analysis depends on cases with fact scenarios that are dissimilar to the factual allegations made in this case. Magistrate Judge Ashmanskas wrote: "Thimerosal is not listed as a vaccine in the Vaccine Injury Table, which courts have tended to construe in an extremely narrow and strict manner." King, slip op. at 7. See also Pet. Brief at 7. In support of this statement, he relied on two cases where the special master or judge found the vaccinee did not "receive" a vaccine within the meaning of §11(c)(1)(A) and §14(a) of the Act. In Brausewetter v. Secretary of HHS, petitioner received an injection of Hyper-Tet which was "created from the blood plasma of people whom ha[d] been immunized with the tetanus toxoid." Brausewetter v. Secretary of HHS, No. 99-278V, 1999 WL 562700, at *1 (Fed. Cl. Spec. Mstr. July 16, 1999). The special master rejected the claimant's arguments that he had directly or indirectly "received" a tetanus toxoid-containing vaccine as set forth in the Vaccine Injury Table.[22] Id. at *2. Because the Hyper-Tet inoculation did not actually contain tetanus toxoid, petitioner did not "personally" receive a Table vaccine. Id. Mr. Brausewetter also did not "indirectly" receive a tetanus toxoid-containing vaccine under §11(c)(1)(A); he actually received injections of tetanus antibodies produced by third parties whom were administered directly the vaccine components. Id. at *3. The magistrate also cites Staples v. Secretary of HHS, 30 Fed. Cl. 348 (1994). In that case, tried and decided by the undersigned, petitioner was denied compensation under the Program when she contracted paralytic polio from her children who received the inactivated polio vaccine ("IPV"). The Vaccine Act limits compensation for injuries from *community contact-related* incidences to those sustained from contact with a live virus oral polio vaccine ("OPV") recipient. Staples, 30 Fed. Cl. 348, 350-51, 354-60 (1994). Thus, petitioner in that case neither "received" a Table vaccine directly nor contracted her illness from a person administered OPV. Id. at 359. Both Staples and

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[22/] See also Melton v. Secretary of HHS, No. 01-105V, 2002 WL 229781 (Fed. Cl. Spec. Mstr. Jan. 25, 2002) (ruling that an *in utero* unborn child had not "received" the vaccine as required under §11(c)(1)(A) when the vaccine was administered to a mother while she was pregnant); Burch v. Secretary of HHS, No. 99-946V, 2001 WL 180129 (Fed. Cl. Spec. Mstr. Feb. 8, 2001) (ruling that as a matter of law the *in utero* unborn child had not "received" the vaccine as required under §11(c)(1)(A)). But see Rooks v. Secretary of HHS, 35 Fed. Cl. 1 (1996) (holding that an *in utero* child "received" a vaccine within the meaning of §11(c)(1)(A) when the vaccine was administered to a mother while she was pregnant).

Brausewetter involved factual scenarios wholly different from the one here. Without a doubt, Nicholas personally received a series of Table vaccines covered under the Program; he further sustained, allegedly, developmental problems arising from a component of some of those vaccines. The magistrate judge's reliance on these cases again reveals the focus of his analysis: whether thimerosal-related injuries flow from vaccines set forth in the Vaccine Injury Table, rather than whether thimerosal is an adulterant or contaminant. See King, slip op. at 7-8. See also Pet. Brief at 7 (stating incorrectly that "Federal Magistrate Ashmansks [sic] . . . recently concluded that it was 'entirely possible' that a state court would find Thimerosal to be an 'adulterant'"). Thus, the cases cited by Magistrate Judge Ashmanskas are not "directly in line" with the factual or jurisdictional issues raised in this case, as petitioners aver, and his finding based on these decisions is unpersuasive. See Pet. Brief at 8.

Moreover, as respondent argues, "the Vaccine Act has broad scope over claims related to vaccinations[,] . . . related not only to the vaccine itself, but also to those related to misadventures from the act of administering the vaccine." Resp. Brief at 4 (citing Pociask v. Secretary of HHS, No. 96-569V, 1999 WL 199053 (Fed. Cl. Spec. Mstr. Mar. 24, 1999) (compensating petitioner for her arm abscess after she experienced a reaction to the tetanus vaccine); Amorella Moore v. Secretary of HHS, No. 91-1558V, 1992 WL 182194 (Fed. Cl. Spec. Mstr. July 13, 1992) (awarding damages for sterile arm abscess resulting from the DPT vaccine). Petitioners' claim is more in line with these two cases involving vaccinees who sustained an injury from the administration of a Table vaccine even though the specific injury is not designated as a Table injury. In sum, petitioners' reliance on King does little to support their interpretation of §11(a)(1) or §33(5).

V. Relevant Evidence from the Scientific Community Is Persuasive

While there is an absence of legislative history that directly addresses this vaccine-preservative issue, pertinent evidence from the scientific community tends to refute petitioners' claims that thimerosal is a separate entity of a vaccine or that it is an "adulterant" or "contaminant" within the meaning of the Vaccine Act. An examination of the research and directives of the Food and Drug Administration and the Institute of Medicine ("IOM") reveals strong support for the proposition that the thimerosal preservative is, indeed, a component or constituent of its parent vaccine. The same information also tends to support the proposition that a substance must be improperly added to a vaccine before it can be considered an "adulterant" or "contaminant" under §33(5) of the Vaccine Act.

A. FDA Regulations and the Federal Food, Drug and Cosmetic Act Support the Court's Interpretation of the Disputed Statutory Language

1. The Preservative Thimerosal Is a Component or a Constituent of the Vaccine

Petitioners argue that thimerosal is toxic to the recipient, "has no therapeutic effect," and thus, cannot be a component of any vaccine, even though they concede thimerosal is an approved preservative in childhood vaccines. See, e.g., Pet. Brief at 3-5; Pet. Reply at 5-7. They further allege that "[o]nly the vaccine and its component parts, the parts designed and intended to prevent the targeted disease, are part of the vaccine." Pet. Brief at 4. They note that thimerosal has been removed from "numerous vaccines" and, in its absence, the vaccines are "carrying out their intended purpose of preventing targeted diseases." Id. Thus, if thimerosal is indeed a "component," its removal should render the vaccine ineffective.[23] Id.

Petitioners offer, other than argument, no support for their proposition that to be a component part of a vaccine, thimerosal must be "intended to prevent the targeted disease." As shown supra in Part II (subpart B), the accepted definition of "vaccine" is vastly broader. Thimerosal has an accepted, FDA-approved role as a preservative. Petitioners concede that point. Pet. Reply at 6-7 ("[T]he thimerosal might actually be fulfilling the purpose for its intentional inclusion . . . ."). Petitioners' creative argument that thimerosal's limited role as an FDA-approved preservative nonetheless renders it not part of the vaccine is just that, creative. As with much of petitioners' arguments, no support is given and none can be found.

With respect to the FDA guidelines, petitioners repeatedly discount the fact that thimerosal remains an FDA-approved component of the vaccines at issue. Pet. Brief at 13-14; Pet. Reply at 5-8. Respondent argues persuasively that FDA regulations treat preservatives as a constituent part of vaccines, and thus are "part and parcel" of vaccines. Resp. Brief at 11. Furthermore, respondent points out that all vaccines must be manufactured in accordance with FDA-approved specifications as set forth in an effective biologics license. Id. at 9. To obtain approval for a biologics license, the applicant must show that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C.A. §262(a) (West 2002). Further, to maintain a biologics license, the licensee must comply with FDA regulations. Resp. Brief at 9. In the case at bar, all vaccines are licensed as such. The FDA requires a preservative, like thimerosal, to be added to licensed vaccines sold in multiple dose vials. See 21 C.F.R. §610.15 (stating "[p]roducts in multiple dose containers shall contain a preservative"). See also IOM Thimerosal Report at 13. As emphasized in Owens, thimerosal was an FDA-approved preservative in many drugs since the 1930s. See Owens, 203 F. Supp. 2d at 755 (citing the Statement by William Egan, Ph.D., FDA, before the Committee on Government Reform, U.S. House of Representatives, July 18, 2002). See also IOM Thimerosal Report at 19. The vaccines in question were approved through this comprehensive licensing

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[23/] Respondent counters that a component part of a vaccine (like thimerosal) can be removed without altering the effectiveness of the vaccine (as, indeed, is the case with thimerosal). Resp. Brief at 13. Respondent illustrates this rebuttal by submitting that the cell wall (arguably a "component") of the whole-cell bordatella pertussis was removed without reducing the vaccine's effectiveness. Id.

process. In fact, only recently has thimerosal's utility been questioned.[24] Nonetheless, respondent persuasively notes that the "FDA has found no ground upon which to order a recall of vaccines containing thimerosal as a preservative or to revoke or suspend the approved licenses for such vaccines." Resp. Brief at 9. Petitioners' argument is devoid of legal and scientific support.

2. The Preservative Thimerosal Is Neither an "Adulterant" Nor a "Contaminant"

Petitioners further contend that because thimerosal is toxic and not a necessary vaccine component, it is an "adulterant" or "contaminant" within the meaning of the Vaccine Act. Pet. Brief at 10, 14-15; Pet. Reply at 6-8. Today, this court finds that the preservative thimerosal is not an "adulterant" or "contaminant" within the meaning of §33(5). Even if it is ultimately found that thimerosal is harmful to the recipient, this legal finding remains valid because thimerosal's intended purpose, *at the time it was intentionally added*, was to preserve vaccines, not corrupt them.[25] Petitioners' inflammatory statements that thimerosal was added to vaccines only for profit and without regard to the public health are unsupported and irrelevant to the jurisdictional issue.[26]

While finding superficially attractive petitioners' theory that if a preservative is toxic, it should not be considered a part of the vaccine pursuant to 21 C.F.R. §610.15 (providing that preservatives serving as a constituent material should be "sufficiently nontoxic"), public health officials have not determined that licenses for vaccines containing thimerosal should be revoked

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[24] In October 2001, the IOM issued a report after it examined "whether or not the use of vaccines containing the preservative thimerosal can cause neurodevelopmental disorder in vaccinees." IOM Thimerosal Report at 13. The IOM did not have sufficient evidence "to accept or reject" a causal relationship between thimerosal and neurodevelopmental disorders. Id. at 57. Nevertheless, the report recommends additional research in order to assess the risk of exposure to thimerosal. Id. The concern over the use of thimerosal in vaccines arose when the FDA discovered that children were being exposed to doses of ethyl mercury, an organic mercury, that exceeded the federal safety standards for another form of organic mercury; their exposure to ethyl mercury was attributed to the thimerosal preservative. Id. at 13. The American Academy of Pediatrics and the U.S. Public Health Service issued a joint statement recommending the removal of thimerosal from childhood vaccines in 1999 based upon this information. Id. All vaccines in the recommended childhood immunization schedule that are given to children six years of age and younger are now available thimerosal-free. Id. at 13-14.

[25] Of course, this court's rejection of petitioners' toxicity arguments for jurisdictional purposes does not prevent them from later demonstrating, in the general and specific causation phases of the case, that the thimerosal component of the vaccines administered to their son was in-fact toxic and injurious.

[26] In an attempt to muster some support for their allegations that the thimerosal preservative is toxic, petitioners append various exhibits to their Reply Brief, none of which support their plea that jurisdiction more properly lies with another court.

because their toxicity reached levels incompatible with FDA regulations. See Pet. Brief at 14; Resp. Brief at 9. Respondent aptly points out that adopting petitioners' interpretation of adulterant or contaminant presupposes that an FDA-approved preservative is harmful. Resp. Brief at 5. For example, petitioners conclude prematurely that "[t]he undisputed reality of its inclusion has been nothing short of neurologic poisoning to thousands of unsuspecting recipients." Pet. Reply at 5. Evidence supporting such a medical conclusion has yet to be presented. The only relevant medical evidence at the court's disposal is from the IOM publication (below at subpart B), which supports the opposite finding.

Respondent also refers to the Federal Food, Drug and Cosmetic Act ("FDCA"), enacted prior to the Vaccine Act and referenced by the Act itself, for a definition of "adulterant." Further insisting that the court adopt this definition, respondent cites Lorillard v. Pons, 434 U.S. 575, 580-81 (1978), and American Federation of Government Employees v. United States, 46 Fed. Cl. 586, 599-600 (2000), for the proposition that "Congress normally can be presumed to have had the knowledge of the interpretation given to the incorporated law, at least in so far as it affects a new statute." Resp. Brief at 10. Respondent states that the FDCA defines "adulterated" as "putrid, unsanitary or, 'if it is a drug . . . its manufacture, processing, packing, or holding, do not conform to or are not operated or administered in conformity with current good manufacturing practice.'" Id. (quoting 21 U.S.C. §351(a)(2)(B)). Respondent argues that "[i]t would be incongruous to find that a vaccine component added in compliance with current good manufacturing practices referenced by the FDCA is also an adulterant under that same Act." Id.

This court agrees with respondent's position. "Adulterated" is clearly defined by the FDCA and its meaning is consistent with those ordinary definitions outlined and accepted earlier in the court's discussion. It seems illogical to interpret "adulterant" under the Vaccine Act to encompass an approved ingredient in a vaccine, which is mandated by and in full compliance with FDA regulations.[27] Petitioners have not produced a scintilla of evidence or any persuasive argument to suggest otherwise.

B. The Institute of Medicine's Report Does Not Support Petitioners' Toxicity Argument

The only other available evidence addressing thimerosal's potential toxicity is a recent publication by the Institute of Medicine. In 2001, the IOM Immunization Safety Review Committee, comprised of a fifteen member panel, all of whom possess expertise in various fields, such as pediatrics, neurology, immunology, internal medicine, infectious diseases, genetics, epidemiology, biostatistics, and public health, explored the medical issue. The IOM committee assessed the scientific plausibility of whether thimerosal can be associated with neurodevelopmental injury. Reviewing both published and unpublished reports and data, the committee examined biologic plausibility, causality, the health risks associated with vaccine-preventable diseases, and

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[27/] Judge Kent found likewise in Owens: "[N]either the plain meaning of 'adulterant' nor 'contaminant' applies to thimerosal when, as here, it is *purposefully used as an ingredient in the approved formulation of a vaccine*." Owens, 203 F. Supp. 2d at 755 (emphasis added).

the specific adverse event in question. IOM Thimerosal Report, Executive Summary at 2. Due to insufficient evidence "to accept or reject" a causal relationship between thimerosal and neurodevelopmental disorders, the IOM's report was ultimately inconclusive. IOM Thimerosal Report at 57. Rather, the IOM merely recommended a response by public health officials in the areas of policy review and analysis, public health and biomedical research and communications. Id.

Despite the IOM's inconclusive findings, petitioners nonetheless proffer the argument that "a preservative [thimerosal] which is toxic to the recipient becomes an adulterant."[28] Petitioners cite an FDA regulation which provides that all preservatives introduced into a drug "shall be sufficiently non-toxic so that the amount present in the recommend [sic] dose of the product will not be toxic to the recipient." Pet. Brief at 14. Further, petitioners contend that public health officials agree that "thimerosal is dangerous, it poses a neurotoxic threat to recipients." Pet. Reply at 1. They base this on their belief that "[thimerosal] was removed from vaccines due to its toxicity and contaminating effect." Id. Again, petitioners rely upon unsupported extrapolations from scientific reviews for their baseless conclusions. The scientific community has not reached the consensus petitioners advance. For the reasons discussed supra, thimerosal, as an FDA-approved preservative, is in all respects part of the vaccine as "vaccine" is defined in scientific parlance. In light of the aforementioned pronouncement from the IOM, the undersigned finds petitioners' argument inconsistent with the scientific community's current posture.[29]

VI. The Court of Federal Claims Has Exercised Jurisdiction Over Similar Claims

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[28] Incidentally, petitioners offer only one definition, for "adulteration," which includes the word "toxic." See P. Brief at 10 ("The addition or substitution of an impure, weaker, cheaper, or possibly toxic substance in a formulation or product.") (quoting Taber's Encyclopedic Medical Dictionary (19th ed. 2001)). In light of the evidence from the FDA, FDCA, and the IOM, this court cannot accept petitioners' unreasonably strained application of this definition.

[29] The law establishing the Vaccine Program, P.L. 99-660, charged the Institute of Medicine of the National Academy of Sciences to review the medical and scientific literature regarding risks associated with the various vaccines covered under the Program. In light of the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the reviewing committees, the court has given considerable weight to the IOM's findings. See Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418, at *2 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). See also Salmond v. Secretary of HHS, No. 91-123V, 1999 WL 778528, at *5 (Fed. Cl. Spec. Mstr. Sept. 16, 2000) (recognizing that the special masters have consistently afforded deference to the IOM's conclusions in vaccine cases largely because of "its mandate and independent role in reviewing existing literature relating to the adverse consequences of vaccines").

As respondent notes, the Court of Federal Claims has previously exercised jurisdiction over a case involving a preservative that allegedly worsened or triggered injury. Resp. Brief at 4. In Grant v. Secretary of HHS, No. 88-70V, 1990 WL 293410 (Cl. Ct. Spec. Mstr. July 13, 1990), the undersigned awarded compensation to a vaccinee who was administered a Quadrigen vaccine. The court was persuaded by the government's medical studies but distinguished them from the facts before him because of the uniqueness of the Quadrigen vaccine. The court found persuasive petitioners' evidence "that pertussis as part of the Quadrigen vaccine has a heightened potential to cause serious harm." Grant, 1990 WL 293410, at *7. The undersigned explained that:

> Quadrigen was developed by Parke-Davis as a quadruple antigen product combining pertussis vaccine with diphtheria and tetanus toxoids and with the Salk polio vaccine. All vaccines require a *preservative to keep them sterile and one problem encountered by Parke-Davis with the development of Quadrigen was the selection of an appropriate preservative.* Ultimately, benezethonium chloride (trade name Phemerol) was selected . . . . Later research indicated that the use of Phemerol caused certain endotoxins in the pertussis vaccine to leak out from the bacterial cell into the fluid which was injected causing fever leading to convulsions and brain damage.

Id. (emphasis added). This phenomenon was referred to by experts as the leakage theory. Id. at *8 (citing Ezagui v. Dow Chemical Corp., 598 F.2d 727 (2d Cir. 1979) (discussing the "Phemerol [preservative] causes leakage" theory which was found to proximately cause personal injury to the vaccinee). The court treated the injury as vaccine-related even though it was caused by a "combination of the pertussis vaccine with *other in [sic] Quadrigen chemicals*," a preservative to be exact, that materially increased the risk of injury. Id. at *10 (emphasis added).

Throughout the court's consideration of whether the vaccinee suffered a Table injury, whether petitioners established a prima facie case of causation-in-fact, and whether a factor unrelated to the vaccine caused the injury, the court never questioned that the vaccinee's injury was a "vaccine-related injury" within the meaning of the Act. In fact, the undersigned stated that "overwhelming evidence supports a finding that Quadrigen is capable of causing exactly the symptoms that occurred to Scott and no other apparent cause of these symptoms was ever brought to light." Id. at *10. The Secretary appealed the court's findings arguing that the undersigned improperly weighed the evidence to reach a final conclusion that the vaccinee was entitled to an award. See Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Neither the Secretary nor the petitioners ever questioned the undersigned's jurisdiction to decide the ultimate causation issue – nor did the Court of Federal Claims or the Federal Circuit, sua sponte. Instead, on *de novo* review of the Court of Federal Claims's decision, the Federal Circuit affirmed the undersigned's award, finding the court "relied on a preponderance of relevant scientific and medical evidence about the *particular nature* of the Quadrigen." Id. at 1149 (emphasis added). The Circuit "discern[ed] nothing arbitrary, capricious, or unlawful in that reliance." Id. The Federal Circuit quoted the undersigned's findings about the Quadrigen vaccine: "'[M]ost persuasive, however, was the evidence that pertussis as part of the Quadrigen vaccine has a heightened potential to cause serious harm . . . .'" Id. at 1148. Further, the undersigned "gave great weight to testimony about the uniqueness of Quadrigen," which revealed that "Quadrigen uses preservative agents" which when combined with pertussis bacteria can cause neurological damage. Id. at 1149. Thus, clearly

the key to both the special master's decision in Grant and the Federal Circuit's affirmance of that decision was the *preservative's* role as a trigger for injury, without which petitioners would not have prevailed on causation.

Petitioners in the instant case attempt to distinguish their case by alleging it is *solely* the thimerosal's *toxicity* which "neurologically poisoned" their son, not the preservative's combination with any other part of or antigen in the vaccine, as was the case in Grant.[30] Pet. Brief at 1-2. Petitioners argue the Federal Circuit "found the preservative(s) . . . did not cause the damage, [but that] the celluar [sic] structure of the pertussis caused the harm. For the Respondents to claim the preservative(s) used in Quadrigen were injurious is simply inaccurate." Pet. Reply at 4. Petitioners draw too fine a distinction here between their case and Grant. The Federal Circuit affirmed the undersigned's findings which were based largely on evidence that the addition of the preservative Phemerol to the Quadrigen vaccine made its administration harmful to the recipient. But for the role of Phemerol, the Federal Circuit found persuasive respondent's epidemiologic evidence against causation. Grant, 956 F.2d at 1148-49. Thus, the triggering role of the preservative, Phemerol, was the evidentiary difference in Grant. Given that the preservative's role is key to the causation theory in the case sub judice, just as it was in Grant, again a case over which the Court of Federal Claims and the Federal Circuit exercised jurisdiction, the court sees no compelling reason why petitioners' claim is not likewise covered by the Vaccine Act.

CONCLUSION

[30/] As a related argument, petitioners contend that it is the toxicity of thimerosal which makes the preservative an "adulterant" or "contaminant" under the Act. This argument was fully addressed in Part V of this decision.

Based on the aforesaid discussion, the court finds that the thimerosal preservative in vaccines is not an "adulterant" or "contaminant" under §33(5) of the Vaccine Act. Consequently, any injury or death arising from the thimerosal component is encompassed within the statutory definition of "vaccine-related injury or death," thereby granting jurisdiction over such claims to this court. Therefore, petitioners alleging an injury or death from the thimerosal preservative in vaccines are statutorily obligated to file their claim against a manufacturer or administrator of the vaccine in the Court of Federal Claims, *in the first instance*. Thus, petitioners' claim is properly before this court.

While petitioners have the right to pursue this case in civil court, they are first obligated to either submit to this court's jurisdiction for 240 days (excluding suspension periods) or until a judgment is rendered, whichever occurs first. Petitioners shall contact the undersigned's law clerk, Chris Hartley, at (202) 504-2183, by **October 25, 2002,** to schedule a status conference in order to discuss how they intend to proceed in this case.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master