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(Cite as: 203 F.Supp.2d 748)



[Briefs and Other Related Documents](#)

United States District Court,S.D. Texas,Galveston Division.

Jessica OWENS individually and as next friend to Jarrett Ross SCHAFER; Kenneth Brown and Cynthia Brown, individually and as next friends to Zachary Taylor Brown; and David Ward and Felicia Ward, individually and as next friends to Morgan Elizabeth Ward Plaintiffs,

v.

AMERICAN HOME PRODUCTS CORPORATION, et al. Defendants.

No. CIV.A.G-02-185.

May 7, 2002.

Parents and legal representatives of minors who were allegedly exposed to harmful levels of mercury via routine childhood vaccinations with vaccines containing thimerosal, a mercury laden preservative, brought a products liability suit in state court against manufacturers of the vaccines and manufacturers of thimerosal. Manufacturers removed the action from state court. On defense motions to dismiss, the District Court, [Kent, J.](#), held that: (1) thimerosal was not an “adulterant or contaminant,” but rather, a “constituent material” of the vaccines; (2) National Childhood Vaccine Injury Act did not bar parents' individual claims for loss of consortium, emotional distress and loss of services; (3) parents stated a viable claim for loss of consortium; (4) parents could not maintain a cause of action for loss of services; (5) parents could not recover on their derivative claims of emotional distress via a bystander action; and (6) Vaccine Act's tort suit bar did not apply to thimerosal manufacturers.

Ordered accordingly.

West Headnotes

[\[1\] Health 198H](#) [389](#)

[198H](#) Health

[198HII](#) Public Health

[198Hk383](#) Contagious and Infectious Diseases

[198Hk389](#) k. Vaccine Injury Programs; Government Liability. [Most Cited Cases](#)

(Formerly 96Hk389, 138k20.1 Drugs and Narcotics)

Thimerosal, a mercury laden preservative added to vaccines, was not an “adulterant or contaminant,” but rather, a “constituent material” of the vaccines, and thus, an action against the vaccine manufacturers arising from injuries allegedly caused by thimerosal involved a “vaccine-related” injury as defined by the National Childhood Vaccine Injury Act, such that the plaintiffs were required to file a National Vaccine Injury Compensation Program petition as a pre-requisite to filing any civil action seeking damages from the vaccine manufacturers; the manufacturers intentionally added thimerosal to vaccine formulas because it deterred microbial and fungal growth, thereby maintaining the safety, purity and potency of vaccines. Public Health Service Act, § § 2111(b)(1)(A), 2133(5), as amended, [42 U.S.C.A. § § 300aa-11\(b\)\(1\)\(A\), 300aa-33\(5\); 42 C.F.R. § 100.3.](#)

[\[2\] Statutes 361](#) [188](#)

[361](#) Statutes

[361VI](#) Construction and Operation

[361VI\(A\)](#) General Rules of Construction

[361k187](#) Meaning of Language

[361k188](#) k. In General. [Most Cited Cases](#)

When attempting to discern a statute's meaning, a court must initially look to the plain meaning of the statute's

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language.

[3] Health 198H 389**198H Health****198HII Public Health****198Hk383 Contagious and Infectious Diseases****198Hk389 k. Vaccine Injury Programs; Government Liability. [Most Cited Cases](#)**

(Formerly 96Hk389, 138k20.1 Drugs and Narcotics)

Parents of vaccinated children, none of whom alleged to have suffered a relevant injury after he or she received a vaccine, could not have filed a National Vaccine Injury Compensation Program petition with respect to their individual claims for loss of consortium, loss of services and emotional distress, and thus, the National Childhood Vaccine Injury Act did not bar their claims. Public Health Service Act, § 2111(a)(9), (b)(1)(A), (c)(1)(A), as amended, [42 U.S.C.A. § 300aa-11\(a\)\(9\), \(b\)\(1\)\(A\), \(c\)\(1\)\(A\)](#).

[4] Death 117 88**117 Death****117III Actions for Causing Death****117III(H) Damages or Compensation****117k80 Elements of Compensation****117k88 k. Loss of Society. [Most Cited Cases](#)**


Under Texas law, parents may recover for loss of companionship for the wrongful death of a child.

[5] Parent and Child 285 7.5**285 Parent and Child****285k7.5 k. Action by or on Behalf of Children for Loss of Parents' Services, Society or Consortium. [Most Cited Cases](#)**

Parents of minors who were allegedly exposed to harmful levels of mercury via routine childhood vaccinations with vaccines containing thimerosal, a mercury laden preservative, stated a viable claim for loss of consortium under Texas law.

[6] Parent and Child 285 7(.5)**285 Parent and Child****285k7 Actions for Injuries To, Loss of Services, Control, or Society of Child****285k7(.5) k. In General. [Most Cited Cases](#)**

Under Texas law, parents of minors who were allegedly exposed to harmful levels of mercury via routine childhood vaccinations with vaccines containing thimerosal, a mercury laden preservative, could not maintain a cause of action for loss of services based upon the children's alleged injuries.

[7] Damages 115 57.29**115 Damages****115III Grounds and Subjects of Compensatory Damages****115III(A) Direct or Remote, Contingent, or Prospective Consequences or Losses****115III(A)2 Mental Suffering and Emotional Distress****115k57.26 Injury or Threat to Another; Bystanders****115k57.29 k. Other Particular Cases. [Most Cited Cases](#)**

(Formerly 115k51)

Under Texas law, parents of minors who were allegedly exposed to harmful levels of mercury via routine childhood vaccinations with vaccines containing thimerosal, a mercury laden preservative, could not recover on their derivative claims of emotional distress via a bystander action; they did not witness and perceive the type of shocking


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accident contemplated by the bystander theory of recovery, but rather, they witnessed the routine vaccination of their children and the children's subsequent medical problems, and they did not even learn of the children's alleged mercury poisoning until the children's neurological problems were diagnosed by a physician, well after the suspect vaccines were administered.

[8] Damages 115  57.1**115 Damages****115III** Grounds and Subjects of Compensatory Damages**115III(A)** Direct or Remote, Contingent, or Prospective Consequences or Losses**115III(A)2** Mental Suffering and Emotional Distress**115k57.1** k. In General. [Most Cited Cases](#)


(Formerly 115k49)

Damages 115  57.10**115 Damages****115III** Grounds and Subjects of Compensatory Damages**115III(A)** Direct or Remote, Contingent, or Prospective Consequences or Losses**115III(A)2** Mental Suffering and Emotional Distress**115k57.8** Nature of Injury or Threat in General**115k57.10** k. Physical Illness, Impact, or Injury; Zone of Danger. [Most Cited Cases](#)


(Formerly 115k50)

Damages 115  57.23(2)**115 Damages****115III** Grounds and Subjects of Compensatory Damages**115III(A)** Direct or Remote, Contingent, or Prospective Consequences or Losses**115III(A)2** Mental Suffering and Emotional Distress**115k57.19** Intentional or Reckless Infliction of Emotional Distress; Outrage**115k57.23** Nature of Injury or Threat**115k57.23(2)** k. Physical Illness, Impact, or Injury; Zone of Danger. [Most Cited Cases](#)

(Formerly 115k50)

Damages 115  57.27**115 Damages****115III** Grounds and Subjects of Compensatory Damages**115III(A)** Direct or Remote, Contingent, or Prospective Consequences or Losses**115III(A)2** Mental Suffering and Emotional Distress**115k57.26** Injury or Threat to Another; Bystanders**115k57.27** k. In General. [Most Cited Cases](#)

(Formerly 115k49, 115k51)

Death 117  89**117 Death****117III** Actions for Causing Death**117III(H)** Damages or Compensation**117k80** Elements of Compensation**117k89** k. Mental Suffering or Emotional Distress of Plaintiff or Beneficiary. [Most Cited Cases](#)

In Texas, emotional distress damages are recoverable in a very limited set of circumstances: (1) as the foreseeable result of a breach of a duty arising out of certain special relationships; (2) for common law torts involving

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intentional or malicious conduct; (3) for wrongful death; (4) in personal injury cases where the defendant's conduct causes the plaintiff serious bodily injury; and (5) in bystander actions.

[\[9\] Damages 115](#) [57.27](#)

[115](#) Damages

[115III](#) Grounds and Subjects of Compensatory Damages

[115III\(A\)](#) Direct or Remote, Contingent, or Prospective Consequences or Losses

[115III\(A\)2](#) Mental Suffering and Emotional Distress

[115k57.26](#) Injury or Threat to Another; Bystanders

[115k57.27](#) k. In General. [Most Cited Cases](#)

(Formerly 115k51)

In Texas, bystanders may recover damages for mental anguish suffered as a result of witnessing a serious or fatal accident involving a close family member.

[\[10\] Damages 115](#) [57.27](#)

[115](#) Damages

[115III](#) Grounds and Subjects of Compensatory Damages

[115III\(A\)](#) Direct or Remote, Contingent, or Prospective Consequences or Losses

[115III\(A\)2](#) Mental Suffering and Emotional Distress

[115k57.26](#) Injury or Threat to Another; Bystanders

[115k57.27](#) k. In General. [Most Cited Cases](#)

(Formerly 115k51)

To successfully recover emotional distress damages under Texas law, a bystander plaintiff must establish that: (1) the plaintiff was located near the scene of the accident, as contrasted with one who was a distance away from it; (2) the plaintiff suffered shock as a result of a direct emotional impact upon the plaintiff from a sensory and contemporaneous observation of the accident, as contrasted with learning of the accident from others after its occurrence; and (3) the plaintiff and victim were closely related, as contrasted with an absence of any relationship or the presence of only a distant relationship.

[\[11\] Damages 115](#) [57.27](#)

[115](#) Damages

[115III](#) Grounds and Subjects of Compensatory Damages

[115III\(A\)](#) Direct or Remote, Contingent, or Prospective Consequences or Losses

[115III\(A\)2](#) Mental Suffering and Emotional Distress

[115k57.26](#) Injury or Threat to Another; Bystanders

[115k57.27](#) k. In General. [Most Cited Cases](#)

(Formerly 115k51)

Texas law requires a bystander's presence when the accident occurred and the contemporaneous perception of the accident for the bystander to recover emotional distress damages.

[\[12\] Health 198H](#) [389](#)

[198H](#) Health

[198HII](#) Public Health

[198Hk383](#) Contagious and Infectious Diseases

[198Hk389](#) k. Vaccine Injury Programs; Government Liability. [Most Cited Cases](#)

(Formerly 138k17.1 Drugs and Narcotics)

Claims against suppliers of thimerosal, a raw material, to vaccine manufacturers were not subject to the National Childhood Vaccine Injury Act's tort suit bar; the suppliers did not manufacture or administer vaccines themselves. Public Health Service Act, § § 2111(b)(1)(A), 2133(5), as amended, [42 U.S.C.A. § § 300aa-11\(b\)\(1\)\(A\)](#), [300aa-33\(5\)](#); [42 C.F.R. § 100.3](#).

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[John A. Scully](#), Cooper & Scully, Dallas, TX, [John A. Scully](#), Houston, TX, [Marcos A. Adrogué](#), Cooper & Scully, PC, Houston, TX, for Spectrum Chemical Manufact.

ORDER GRANTING IN PART AND DENYING IN PART WYETH, AVENTIS, MERCK AND SMITH KLINE'S MOTION TO DISMISS, DENYING SIGMA AND EM'S MOTION TO DISMISS, ORDERING PLAINTIFFS TO CONDUCT JURISDICTIONAL DISCOVERY OF GDL AND DENYING DEFENDANTS' REQUEST FOR ORAL ARGUMENT AS MOOT

[KENT](#), District Judge.

Plaintiffs Jessica Owens, individually and as legal representative of her minor child Jarrett Ross Schafer (“Jarrett”); Kenneth Brown and Cynthia Brown, individually and as legal representatives of their minor child Zachary Taylor Brown (“Zachary”); and David Ward and Felicia Ward, individually and as legal representatives of their minor child Morgan Elizabeth Ward (“Elizabeth”); bring this products liability lawsuit against Defendants Sigma Aldrich Corporation (“Sigma Corp.”); Sigma Aldrich, Inc. (“Sigma Inc.”); Eli Lilly and Company (“Eli Lilly”); The Dow Chemical Company (“Dow”); EM Industries, Inc. (“EM”); Wyeth (“Wyeth”) f/k/a American Home Products, Corp.; Aventis Pasteur, Inc. (“Aventis”) f/k/a Connaught Laboratories f/d/b/a Pasteur Merieux Connaught; Merck and Company, Inc. (“Merck”); Smith Kline Beecham Corporation (“Smith Kline”) d/b/a GlaxoSmithKline; Spectrum Laboratory Products, Inc. (“Spectrum”); and GDL International, Inc. (“GDL”) pursuant to Texas state law. Now before the Court are three Motions to Dismiss filed by various Defendants: (1) a Motion to Dismiss pursuant to [Fed.R.Civ.P. 12\(b\)](#) and the National Childhood Vaccine Injury Act (“Vaccine Act”), [42 U.S.C. § § 300aa-1-300aa-34](#), filed by Wyeth, Aventis, Merck and Smith Kline; (2) a Motion to Dismiss pursuant to the Vaccine Act and [Fed.R.Civ.P. 19](#) filed by Sigma Corp. and Sigma Inc. (collectively, “Sigma”) and joined by EM; and (3) a Motion to Dismiss for Lack of Personal Jurisdiction filed by GDL. For the reasons articulated below, Wyeth, Aventis, Merck and Smith Kline's Motion to Dismiss pursuant to the Vaccine Act is **GRANTED IN PART** and **DENIED IN PART**, Sigma and EM's Motion to Dismiss pursuant to the Vaccine Act is **DENIED** and Plaintiffs are hereby **ORDERED** to conduct jurisdictional discovery of GDL before responding to that Defendant's Motion to Dismiss.

I. Background

While they were infants, Jarrett, Zachary and Elizabeth were allegedly exposed to harmful levels of mercury via routine childhood vaccinations administered to them by their pediatricians. All or some of the vaccines contained thimerosal, a mercury laden preservative. At that time, vaccine manufacturers routinely added thimerosal to multiple-use vials of vaccines to extend each vial's shelf life. The thimerosal (and thus, mercury) introduced into the children's bodies by way of vaccination allegedly afflicted them with serious and lasting neurological injuries. Plaintiffs filed this action in a Texas state court *752 seeking damages for the children's personal injuries both individually and on behalf of their children (as legal representatives). In their Original Petition, Plaintiffs assert four causes of action (strict liability, negligence, gross negligence and conspiracy) against two distinct categories of

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Defendants: (1) the manufacturers of thimerosal containing vaccines-Wyeth, Aventis, Merck and Smith Kline (“Vaccine Manufacturers”); and (2) the manufacturers of thimerosal itself-Eli Lilly, EM, Sigma, Dow, Spectrum and GDL (“Chemical Manufacturers”).^{FN1} Defendants subsequently removed the action pursuant to this Court's diversity jurisdiction.

FN1. In their Original Petition Plaintiffs do not distinguish between the Vaccine Manufacturers and the Thimerosal Manufacturers. The Court finds, however, that making such a distinction is essential.

II. The Vaccine Act

The “[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken. Use of vaccines has prevented thousands of children's deaths each year and has substantially reduced the effects resulting from disease.” H.R.Rep. No. 99-908, at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345. However, while most children enjoy measurable benefit from immunization programs, “a small but significant number of have been gravely injured.” *Id.* Two significant concerns accompany these vaccine-related injuries: the inconsistency, expense, delay and unpredictability of the tort system in compensating claims of vaccine-injured children; and the instability and uncertainty of the childhood vaccine market inevitably caused by the risks of tort litigation. *See id.* at 7, 1986 U.S.C.C.A.N. at 6348. Fortunately, the National Vaccine Injury Compensation Program (“Program”) ameliorates these concerns. The Program provides an avenue of recovery for injuries and deaths traceable to vaccinations that works with greater ease and on a faster timetable than the civil tort system.^{FN2} *See Shalala v. Whitecotton, 514 U.S. 268, 269, 115 S.Ct. 1477, 1478, 131 L.Ed.2d 374 (1995)*. In effect, it “ensure[s] that all children who are injured by vaccines have access to sufficient compensation for their injuries,” H.R.Rep. No. 99-908 at 6345-6346, and “free[s] manufacturers from the specter of large, uncertain tort liability, and thereby ... keep[s] manufacturers in the market.” Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4 (1st Cir.1994).

FN2. The Program became effective on October 1, 1988.

The Program, set forth in the Vaccine Act, requires that vaccine-related claims are initially heard by special masters in the United States Court of Federal Claims (“Vaccine Court”), adjudicated informally and then accorded expeditious review. *See Whitecotton, 514 U.S. at 270, 115 S.Ct. at 1478*. This system streamlines the claims process by establishing standards of proof, under which individuals who suffer injuries within specified intervals after being administered a vaccine, benefit from a presumption that a vaccine caused those injuries. *See 42 U.S.C. § 300aa-11(c)(1)(C)(i), 300aa-13(a)(1), 300aa-14; Haggerty v. Wyeth Ayerst Pharm., 79 F.Supp.2d 182, 184 (E.D.N.Y.2000)*. A Program claimant may not file a civil action against a vaccine manufacturer or administrator unless the claimant initially files a timely petition in accordance with the Program's guidelines.^{FN3} *See 42 U.S.C. § 300aa-11(2)(A); Whitecotton, 514 U.S. at 270, 115 S.Ct. at 1478* (explaining that a *753 claimant alleging an injury after the Vaccine Act's effective date “must exhaust the Act's procedures ...before filing any *de novo* civil action in state or federal court”). If a claimant seeks compensation in a state or federal court for vaccine-related injuries prior to exhausting his or her remedies under the Vaccine Act, the Court must dismiss the action. *See 42 U.S.C. § 300aa-11(a)(2)(B)*. Simply put, individuals who qualify as Program claimants *must* file petitions in the Vaccine Court in order to pursue any vaccine-related claims at all.^{FN4} Nonetheless, if an individual who prevails in the Vaccine Court is ultimately dissatisfied with his or her Program award, that individual may reject the award and pursue a traditional tort action in any forum.^{FN5} *See 42 U.S.C. § 300aa-21(a)*.

FN3. A proper claimant, or “petitioner,” under the Vaccine Act is “any person who has sustained a vaccine-related injury,” or the legal representative of such person. 42 U.S.C. § 300aa-11(b)(1)(A).

FN4. There are a few exceptions. *De minimis* claims for less than \$1,000 may be brought in state or federal courts without prior filing under the Vaccine Program. *See 42 U.S.C. § 300aa-11(a)(2)(A)*. However, the Vaccine Act requires that any vaccine-related action seeking an unspecified amount of damages (such as the instant lawsuit) be filed under the Program. *See id.*

[FN5](#). Under the Program, the compensation awarded to a petitioner for a vaccine-related injury may include actual and un-reimbursable expenses and projected expenses for medical or other remedial care determined to be reasonably necessary; actual and anticipated lost earnings; and actual and projected pain and suffering subject to a statutory cap of \$250,000. *See* [42 U.S.C. § 300aa-15\(a\)](#). Punitive and exemplary damages are prohibited. *See* [42 U.S.C. § 300aa-15\(d\)](#). Reasonable attorneys' fees and costs are awarded even if the petition is denied, so long as the special master determines that the petition was brought in good faith and that a reasonable basis for asserting the claim existed. *See* [42 U.S.C. § 300aa-15\(c\)](#). In the event that a petitioner chooses to reject a Program award, the Vaccine Act limits the tort remedies that become available. For instance, the Vaccine Act establishes compliance with Food and Drug Administration ("FDA") requirements as a partial defense for manufacturers, *see* [42 U.S.C. § 300aa-22\(b\)\(2\)](#), and requires tort suits to be tried in three phases (liability, general damages and punitive damages). *See* [42 U.S.C. § 300aa-23\(a\)](#). Moreover, a manufacturer's compliance with FDA guidelines generally precludes an award of punitive damages. *See* [42 U.S.C. § 300aa-23\(d\)](#).

III. Vaccine Manufacturers' Motion to Dismiss

In this case, it is undisputed that Plaintiffs have not filed a petition in the Vaccine Court in accordance with the Program. In their Motion to Dismiss, filed March 28, 2002, the Vaccine Manufacturers highlight this fact and argue that Plaintiffs' failure to file a Program petition requires the Court to dismiss all claims filed against them pursuant to [Fed.R.Civ.P. 12\(b\)](#).^{[FN6](#)} In response, Plaintiffs contend that they are not required to file a petition in the Vaccine Court because the children's injuries fall outside the scope of the Vaccine Act. Thus, the Court must initially determine whether Plaintiffs are required to file a Program petition for: (1) the claims they have filed on behalf of their children ("Representative Claims"); or (2) their individual claims that are derivative of the children's injuries ("Individual Claims").

[FN6](#). Although the Vaccine Manufacturers do not specify which provision of [Rule 12\(b\)](#) they are moving for dismissal under, the Court assumes that they are seeking a dismissal under [Rule 12\(b\)\(3\)](#) for improper venue, or in the alternative, under [Rule 12\(b\)\(6\)](#) for failure to state a claim upon which relief can be granted. *See* [Fed.R.Civ.P. 12\(b\)\(3\)](#); [Fed.R.Civ.P. 12\(b\)\(3\)](#).

Representative Claims Filed Against the Vaccine Manufacturers

[\[1\]](#) A proper claimant under the Vaccine Act is "any person who has sustained *754 a vaccine-related injury" or the legal representative of that person. [42 U.S.C. § 300aa-11\(b\)\(1\)\(A\)](#). Therefore, if the children sustained "vaccine-related injuries," Plaintiffs are proper claimants under the Vaccine Act with respect to the Representative Claims. The Vaccine Act defines "vaccine-related injury" as "an illness, injury, condition or death associated with one or more of the vaccines set forth in the Vaccine Injury Table [[42 C.F.R. § 100.3](#)], except that term does not include an illness, injury, condition, or death associated with an adulterant or a contaminant intentionally added to such a vaccine."^{[FN7](#)} [42 U.S.C. § 300aa-33\(5\)](#). Plaintiffs maintain that because thimerosal is an "adulterant or contaminant intentionally added to ...a vaccine," this lawsuit does not involve a "vaccine-related" injury as defined by the Vaccine Act.^{[FN8](#)} Conversely, the Vaccine Manufacturers contend that thimerosal is not an "adulterant or contaminant," but rather, a "constituent material" of vaccines. The Court agrees with the Vaccine Manufacturers.

[FN7](#). The vaccines currently listed in the Vaccine Injury Table are diphtheria, tetanus, pertussis, measles, mumps, rubella, poliovirus, hepatitis B, haemophilil influenzae type b, varicella zoster virus, rotavirus and streptococcus pneumoniae. *See* [42 C.F.R. § 100.3](#) (Vaccine Injury Table). In addition to listing eligible vaccines, the Vaccine Injury Table also lists types of injuries associated with each vaccine. *See id.* Individuals who suffer a listed injury after being dosed with the corresponding vaccine make out a *prima facie* case for compensation that may be rebutted only by proof that such injury was caused by factors unrelated to the vaccine. *See* [42 U.S.C. § 300aa-11\(c\)\(1\)\(C\)\(i\)](#), [300aa-13\(a\)\(1\)\(B\)](#). Individuals who suffer injuries not listed in the Vaccine Injury Table may still obtain compensation, but they must prove by a preponderance of the evidence that the injury was in fact caused by a listed vaccine. *See id.*

[FN8](#). The Court notes that Plaintiffs' Original Petition does not specify which thimerosal containing vaccines were administered to the children. Rather, the Petition generally refers to vaccines that are “routinely administered to children” according to the “typical immunization schedule during the first 18 months of life.” The Recommended Childhood Immunization Schedule published by the Centers for Disease Control and Prevention (“CDC”) specifies that the routine vaccinations for American children within their first eighteen months are (1) hepatitis B vaccine; (2) diphtheria, tetanus and pertussis vaccine; (3) haemophilus influenzae type b vaccine; (4) poliovirus vaccine; (5) measles-mumps-rubella vaccine; and (6) varicella zoster virus vaccine. *See Morbidity and Mortality Weekly Report* (Centers for Disease Control and Prevention) Vol. 44 Nos. 52 & 52, January 5, 1996, at 942 (Figure 1). Thus, the Court presumes that the reference to vaccines “routinely administered to children” in Plaintiffs' Original Petition refers to the six CDC-recommended vaccines. And because all six of these vaccines are covered by the Vaccine Injury Table, *see* [42 C.F.R. § 100.3](#), the Court further assumes that the children's injuries are “table injuries” within the scope of the Vaccine Act. This assumption is supported by the fact that Plaintiffs do not assert that the children were injured by an unlisted vaccine in response to the Vaccine Manufacturers' Motion to Dismiss.

[\[2\]](#) When attempting to discern a statute's meaning, a court must initially look to the plain meaning of the statute's language. *See Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54, 112 S.Ct. 1146, 117 L.Ed.2d 391 (1992). Here, because “adulterant” and “contaminant” are not specifically defined by the Vaccine Act, dictionary definitions provided the Court with guidance as to the plain meaning of these terms. The definition of an “adulterant” is “a substance which makes an item impure, spurious, or inferior by adding extraneous or improper ingredients.” *The American Heritage Dictionary* 58 (2d ed.1992). A medical dictionary similarly defines adulterant as “[a]n impurity; an additive that is considered to have an undesirable effect or to dilute the active material so as to *755 reduce its therapeutic or monetary value.” *Stedman's Medical Dictionary* 30 (27th ed.2000). And a contaminant is “[s]omething that makes impure or corrupt by contact or mixture.” *Webster's 9th New Collegiate Dictionary* 283 (9th ed.1991).

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 potency of vaccines. In fact, thimerosal has been widely used as a vaccine preservative since the 1930s, *see* Statement by William Egan, Ph.D., FDA, before the Committee on Government Reform, U.S. House of Representatives, July 18, 2000, and its use satisfies the FDA's requirement that preservatives be added to vaccines distributed in multi-use vials. *See* [21 C.F.R. § 610.15\(a\)](#) (“Products in multiple-dose containers shall contain a preservative”). As such, thimerosal 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 precise 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.

The remainder of the language used by Congress to define “vaccine-related injury” (i.e. “associated with one or more ...vaccines”) likewise requires a finding that the Representative Claims are covered by 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. [FN9](#) And, as explained above, manufacturers of vaccines add thimerosal to the “preparation” or “suspension” of vaccines. [FN10](#)

[FN9](#). A suspension is “a class of pharmacopeial preparations of finely divided undissolved drugs [or in this case, microorganisms] ... dispersed in liquid vehicles for oral or parenteral use.” *Stedman's Medical Dictionary* 1713 (26th ed.1995). A preparation is “a medicinal substance made ready for use.” *Webster's 9th New Collegiate Dictionary* 929 (9th ed.1991).

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FN10. The 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).

Therefore, because the children's injuries are allegedly linked to a vaccine ingredient, their injuries are definitely “vaccine-related.” See, e.g., Brausewetter v. Sec'y of Health and Human Servs., No.99-278V, 1999 WL 562700, at *3 (Fed.Cl. July 16, 1999) (stating that claims fall under the Vaccine Act when a claimant is exposed to the “chemical/biological components of the tetanus vaccine”); Pannell v. Sec'y of Health and Human Servs., No. 94-658V, 1995 WL 432643, at *2 (Fed.Cl. July 7, 1995) (referring to “vaccine-related injury” as one “caused by the vaccine or by something contained therein”); see also *756Grant v. Sec'y of Health and Human Servs., 956 F.2d 1144, 1149-50 (Fed.Cir.1992) (affirming award where vaccine's preservative was an alleged cause of claimant's injury). Clearly, the plain language of the Vaccine Act indicates that the children's injuries cannot be “thimerosal-related” without being “vaccine-related” as well. ^{FN11} Therefore, Plaintiffs are required to file a Program petition as a pre-requisite to filing any civil action seeking damages from the Vaccine Manufacturers for injuries to their children. Accordingly, the Vaccine Manufacturers' Motion to Dismiss is **GRANTED** with respect to the Representative Claims asserted against them. These claims are hereby **DISMISSED WITHOUT PREJUDICE** and Plaintiffs are urged to re-file such claims in the Vaccine Court if they so desire.

FN11. In this case, because the language of the Vaccine Act unambiguously and specifically indicates that injuries caused by vaccine preservatives (i.e.thimerosal) are within its scope, it is clear that Congress has spoken to the precise question at issue. And the Court has given effect to such Congressional intent. However, the Court's decision would remain the same even if Congressional intent was not clearly expressed. In that event, the Court would have adopted the position taken by the Secretary of the Department of Health and Human Services (“Secretary”). See Chevron U.S.A. v. Nat'l Resources Def. Council, Inc., 467 U.S. 837, 843-44, 104 S.Ct. 2778, 2781-82, 81 L.Ed.2d 694 (1984) (explaining that when Congress has not directly spoken to an issue, courts must adopt the interpretation of the administrative agency charged with the duty of enacting the regulation in question “unless they are arbitrary, capricious, or manifestly contrary to the statute”). The Secretary, who is charged with the responsibility of administering the Program, see 42 U.S.C. § § 300aa-10-300aa34, maintains that any injury claims allegedly caused by thimerosal in covered vaccines are “vaccine related” and therefore, thimerosal-related claims against vaccine manufacturers require adjudication by the Vaccine Court. See, e.g., The National Vaccine Injury Compensation Program web-page, available at < <http://www.hrsa.gov/osp/vicp/quanda.htm> > (“Because thimerosal is not an adulterant or contaminant, individuals who have claims relating to thimerosal in vaccines covered under the [Vaccine Act] ... must first file the claim with the [Program] before pursuing any other civil litigation”).

Individual Claims Against the Vaccine Manufacturers

Having dismissed the Representative Claims against the Vaccine Manufacturers, the Court now turns to Plaintiffs' Individual Claims for loss of consortium, emotional distress and loss of services. In their Motion to Dismiss, the Vaccine Manufacturers argue that Plaintiffs are also required to file a Program petition as a pre-requisite to asserting the Individual Claims. Moreover, the Vaccine Manufacturers assert that even if the Individual Claims are not barred by the Vaccine Act, Plaintiffs' causes of action for loss of consortium, loss of services and emotional distress cannot be maintained in accordance with Texas law. The Court will address each of these contentions in turn.

Vaccine Act Petition

[3] By its own terms, the Vaccine Act's proscription against bringing a civil action for damages prior to the filing of a Program petition “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.” 42 U.S.C. § 300aa-11(a)(9). As such, Plaintiffs are not barred from bringing their Individual Claims against the Vaccine Manufacturers unless they are “qualified to file a petition.” An individual becomes eligible to file a petition if he or she suffers a specified injury after receiving a vaccine. See 42 U.S.C. § § 300aa-11(b)(1)(A), 300aa-11(c)(1)(A). Thus, unless an individual received a vaccine

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(or is the legal representative of such an individual), that individual cannot file a petition in *757 the Vaccine Court. See [Schafer, 20 F.3d at 7](#); [Head v. Sec'y of Health and Human Servs., 26 Cl.Ct. 546, 547 n. 1 \(1992\)](#), *aff'd*, [996 F.2d 318 \(Fed.Cir.1993\)](#). In this case, none of the Plaintiffs allege to have “suffered a relevant injury... after he or she received a vaccine.” Accordingly, Plaintiffs need not (and cannot, for that matter) file a Program petition with respect to their Individual Claims, and are consequently permitted to file such claims in this forum. See [Schafer, 20 F.3d at 5](#) (explaining that the Vaccine Act's tort suit ban does not apply to individuals who cannot file petition in the Vaccine Court except in a representative capacity); [Head, 26 Cl.Ct. at 550](#) (holding that an award to a mother in her individual capacity in an action arising from vaccine-related injuries received by her daughter did not bar the daughter's subsequent action under the Vaccine Act); [McDonald v. Lederle Labs., 341 N.J.Super. 369, 775 A.2d 528, 535 \(2001\)](#) (“The [Vaccine] Act does not preclude parents from filing an individual civil action for losses incurred by them.”). Having determined that Plaintiffs' Individual Claims are not barred by the Vaccine Act, the Court now considers the merits of these claims under Texas law.

Loss of Consortium

[4] [5] In [Sanchez v. Schindler, 651 S.W.2d 249 \(Tex.1983\)](#), the Texas Supreme Court recognized that injuries to the familial relationship are significant injuries worthy of compensation. See *id.* at 251. Accordingly, parents may recover for loss of companionship for the wrongful death of a child. See *id.* At least two Texas courts have extended the *Sanchez* holding to cover situations involving a non-fatally injured child. See [Roberts v. Williamson, 52 S.W.3d 343, 352 \(Tex.App.-Texarkana 2001\)](#) (“To hold that a parent cannot recover [for the loss of consortium of a non-fatally injured child] would ignore the basic idea behind recovery for loss of consortium: to attempt to compensate for the loss of love and companionship”), *petition for review filed* (August 20, 2001); [Enochs v. Brown, 872 S.W.2d 312, 322 \(Tex.App.-Austin 1994, no writ\)](#) (“Within the [Texas] Supreme Court's express recognition of a common law cause of action for a serious injury to a spouse or parent lies the implicit recognition of a parent's claims for loss of companionship for a similar injury to a child”); *Cf.* [Reagan v. Vaughn, 804 S.W.2d 463, 466 \(Tex.1990\)](#) (“[T]he two relationships likely to be most severely affected by a negligent injury to a person are the husband and wife relationship and that of parent and child[.]”) Therefore, in light of these decisions, the Court concludes that Plaintiffs have stated a viable claim for loss of consortium under Texas law.

Loss of Services

[6] On the other hand, the Texas Supreme Court rejected the “antiquated concept of the child as an economic asset,” when it explained that “[t]he real loss sustained by a parent is not the loss of any financial benefit to be gained from the child, but is the loss of love, advice, comfort, companionship and society.” [Sanchez, 651 S.W.2d at 251](#). Therefore, the Court concludes that, as a matter of Texas law, Plaintiffs cannot maintain a cause of action for loss of services based upon the children's alleged injuries.

Emotional Distress

[7] [8] Similarly, Plaintiffs cannot recover on their derivative claims of emotional distress. In Texas, emotional distress damages are recoverable in a very limited set of circumstances: (1) as the foreseeable result of a breach of a duty arising out of certain special relationships; (2) for common law torts involving intentional or malicious conduct; (3) for wrongful death; (4) in personal injury cases where the defendant's conduct causes the plaintiff serious bodily injury; and (5) in bystander *758 actions. See [Verinakis v. Med. Profiles, Inc., 987 S.W.2d 90, 95 \(Tex.App.-Houston \[14th Dist.\] 1998, pet. denied\)](#). In this case, Plaintiffs have not alleged any facts signaling a special relationship, intentional or malicious conduct or wrongful death. And the only personal injuries alleged were incurred by the children-not by Plaintiffs. Thus, the only possible avenue by which Plaintiffs may attempt to recover emotional distress damages is the bystander action. However, given the facts of this case, this method proves similarly inapplicable.

[9] [10] [11] In Texas, bystanders may recover damages for mental anguish suffered as a result of witnessing a serious or fatal accident involving a close family member. See [City of Tyler v. Likes, 962 S.W.2d 489, 496](#)

([Tex.1997](#)). In order to successfully recover emotional distress damages, a bystander plaintiff must establish that: (1) the plaintiff was located near the scene of the accident, as contrasted with one who was a distance away from it; (2) the plaintiff suffered shock as a result of a direct emotional impact upon the plaintiff from a sensory and contemporaneous observation of the accident, as contrasted with learning of the accident from others after its occurrence; and (3) the plaintiff and victim were closely related, as contrasted with an absence of any relationship or the presence of only a distant relationship. See [United Servs. Auto Ass'n v. Keith](#), 970 S.W.2d 540, 541-42 ([Tex.1998](#)). Texas law requires the bystanders's presence when the accident occurred and the contemporaneous perception of the accident. See [id.](#) at 542.

Here, Plaintiffs clearly did not witness and perceive the type of shocking accident contemplated by the bystander theory of recovery. Rather, Plaintiffs witnessed the routine vaccination of their children and the children's subsequent medical problems that are allegedly linked to thimerosal. Moreover, Plaintiffs did not even learn of the children's alleged mercury poisoning until the children's neurological problems were diagnosed by a physician, well after the suspect vaccines were administered. However anguishing these belated circumstances may have been, the bystander theory is inapplicable to the facts of this case, as a matter of Texas law.

As stated above, although none of the Individual Claims are barred by the Vaccine Act, Plaintiffs' derivative claims for loss of services and emotional distress cannot be maintained in conformity with Texas law. On the other hand, Plaintiffs' cause of action for loss consortium remains viable. As such, the Vaccine Manufacturers' Motion to Dismiss is hereby **GRANTED IN PART** with respect to Plaintiffs' Individual Claims for loss of services and emotional distress; and hereby **DENIED IN PART** with respect to Plaintiffs' Individual Claims for loss of consortium. The Court further **ORDERS** that Plaintiffs' Individual Claims for loss of services and emotional distress against the Vaccine Manufacturers are **DISMISSED WITH PREJUDICE**.

IV. Sigma's Motion to Dismiss

[12] The Court now turns to the Motion to Dismiss filed by Sigma on March 22, 2002 and joined by EM on March 27, 2002 (both Sigma and EM are Chemical Manufacturer Defendants). ^{FN12} Sigma and EM contend that the Vaccine Act also requires dismissal of the Representative Claims and Individual Claims brought against them. This argument contains a fatal flaw, however, because the Vaccine *759 Act only prohibits the filing of any civil action against a "vaccine *manufacturer or administrator*" prior to the filing of a Program petition. [42 U.S.C. § 300aa-11\(2\)\(A\)](#) (emphasis added). Because Sigma and EM allegedly supplied thimerosal (a raw material) to the Vaccine Manufacturers, but do not manufacture or administer vaccines themselves, Plaintiffs' claims against Sigma and EM are not subject to the Vaccine Act's tort suit bar. Nevertheless, for the reasons discussed previously in conjunction with the Individual Claims against the Vaccine Manufacturers, Sigma and EM's Motion to Dismiss is hereby GRANTED IN PART with respect to Plaintiffs' derivative claims for loss of services and emotional distress. Those claims are hereby DISMISSED WITH PREJUDICE. Regarding all other claims asserted by Plaintiffs against Sigma and EM, their Motion to Dismiss is hereby DENIED. ^{FN13}

^{FN12}. On May 1, 2002, Sigma filed a second Motion to Dismiss and alternatively, a Motion to Stay. The Court is not making any ruling on Sigma's second Motion to Dismiss at this time. The Court will address that Motion, along with Sigma's request for a stay, after Plaintiffs have responded thereto.

^{FN13}. Sigma and EM's Motion to Dismiss also argues for a dismissal pursuant to [Fed.R.Civ.P. 19](#) in the event that the Court dismisses "any other Defendant or other Defendants." Because the Court has not dismissed any Defendants (only certain claims), the Court does not need to address Sigma and EM's [Rule 19](#) request.

V. GDL's Motion to Dismiss

The Court recently issued an Order denying Plaintiffs leave to conduct jurisdictional discovery of GDL pending further Order of the Court. Having determined that Plaintiffs' claims against the Chemical Manufacturers are not barred by the Vaccine Act, the Court finds that such discovery is indeed warranted. As such, the Court hereby

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ORDERS that Plaintiffs have sixty (60) days from the date of this Order to conduct discovery pertaining solely to whether this Court may validly exercise personal jurisdiction over GDL. At the end of that time period, Plaintiffs are **ORDERED** to file their Response to GDL's Motion to Dismiss for Lack of Personal Jurisdiction. The Court will rule on that Motion as soon as it can be reached.

In conclusion, the Court reiterates that all Representative Claims asserted against the Vaccine Manufacturers fall squarely within the jurisdiction of the Vaccine Court and are hereby **DISMISSED WITHOUT PREJUDICE**. Hence, the only claims against the Vaccine Manufacturers that Plaintiffs may properly assert in this forum are those seeking compensation for loss of consortium. On the other hand, Plaintiffs' Representative Claims and Individual Claims against the Chemical Manufacturers are subject to adjudication in this forum, with the exception of Plaintiffs' derivative claims for emotional distress and loss of services. GDL's Motion to Dismiss remains pending. Finally, this Order renders the Vaccine Manufacturers' Request for Oral Argument on their Motion to Dismiss **MOOT**. The Court will address all other pending concerns as soon as they are ripe for consideration.

IT IS SO ORDERED.

S.D.Tex.,2002.

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