CHARLES R. ASHTON, III and PENNY STARR-ASHTON, parents and natural guardians of MADIGAN ASHTON and LUCINDA ASHTON, et al.	:	**COURT OF COMMON PLEAS PHILADELPHIA COUNTY**
	:	**COMMERCE PROGRAM**
vs.	:	
AVENTIS PASTEUR, INC., individually and as successor in interest to CONNAUGHT LABORATORIES, INC., PASTEUR MERIEUX, and PASTEUR MERIEUX CONNAUGHT, et al.	:	**JULY TERM, 2002**
	:	**NO. 04026**
	:	Control #011926, #011965, #011982, #012004, #012017, #012035, #012036, #012044, #012045, #020310

ORDER and MEMORANDUM

AND NOW, to wit, this 22ND day of May , 2003, upon consideration of the Preliminary Objections of the defendants and the plaintiffs' response thereto, it is hereby ORDERED and DECREED said Preliminary Objections are SUSTAINED. The plaintiffs' Complaint is DISMISSED WITH PREJUDICE.

BY THE COURT:

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GENE D. COHEN, J.

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MEMORANDUM

COHEN, GENE D., J.

INTRODUCTION:

The instant action is a class action complaint brought by class representatives who seek actual damages and damages in the form of "medical monitoring" based upon injuries they and class members either currently have or may develop. The plaintiffs allege that vaccinations containing the chemical thimerosal were the source of their current and would-be injuries. The Court now has before it preliminary objections filed by all defendants -- manufacturers of the vaccines and thimerosal -- urging this Court to dismiss the plaintiffs' complaint and hold that for several reasons the plaintiffs have no cause of action. The Court hereby sustains said preliminary objections and dismisses the plaintiffs' complaint.

BACKGROUND:

The plaintiffs seek damages and "medical monitoring" alleging they were poisoned by the presence of the ingredient Thimerosal in childhood vaccinations they received.

Within a few years after birth most American children receive a series of vaccinations. The vaccines administered control the virulent consequences of such childhood diseases as measles, pertussis, rubella, polio, whooping cough, hepatitis, diphtheria and tetanus. These vaccines often contain either a killed bacteria or live but weakened viruses and, hence, can cause serious adverse affects. *See* O'Connell v. Shalala, 79 Fed. 3d 170, 172 (1st Cir. 1996) (citing Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, Institute of Medicine, Adverse Affects of Pertussis and Rubella Vaccines 1 (1991)). In 1996, responding to the possibility of a socio-medical catastrophe that might arise if the victims of the adverse consequences of childhood vaccinations made use of the tort liability system, Congress enacted the National Childhood Vaccine Injury Act of 1996, Pub. L. No. 99-660, 1986 U.S.C.C.N. (100 Stat.) 3755 (Codified as amended at 42 U.S.C. §§300aa-1 to 34) (1994). The purpose of the Vaccine Act was to establish a vaccine injury compensation program that would allow claimants to petition to receive compensation for vaccine-related injuries or death. Congress in its wisdom believed that to subject such injuries and deaths to the marketplace of the tort liability system would drive up the prices of vaccines and discourage vaccine manufacturers from remaining in the marketplace as well as leaving many sufferers of vaccine-caused injuries uncompensated. To receive compensation the claimant must petition the Court of Federal Claims and demonstrate by a preponderance of the evidence that (1) the vaccinated child suffered an injury listed on a table or a complication or "sequela" thereof, or (2) that the vaccine caused or significantly aggravated the child's injury or condition. *See* §§300aa-11 to 13 and 14. *See also* 42 C.F.R. §100.3 (1996). The Act in pertinent part requires that a person injured directly by a vaccine first bring a Vaccine Court proceeding. Id. §300aa-11(a)(2)(A). Then the statute gives that person the choice either to accept the court's award and abandon his tort rights (which the Act transfers to the federal

government, Id. §§300aa-17), or to reject the judgment and retain his tort rights. Id. §§300aa-21(a); 300aa-11(a)(2)(A)(i). A claimant can also keep his tort rights by withdrawing the Vaccine Court petition if the court moves too slowly. Id. §§300aa-21(b); 300aa-11(a)(2)(A)(ii).)

This new remedial system further interacts with traditional tort law suits by limiting punitive damage awards and bifurcating trials. The Act establishes a presumption of compliance with Food and Drug Administration requirements meaning the manufacturer provided proper directions and warnings and freeing the manufacturer from liability for not providing direct warnings to an injured person or his representatives. Id. §§300aa-23(a), 23(d), 22(c), 22(b)(1). *See* Schaeffer v. American Cyanimide Co., 20 Fed. 3d 1, 9 to 12 (1st Cir. 1994).

Further provisions of the Vaccine Act address the real issue of concern in these cases and that is whether the vaccine in question caused injury or death. There are two ways to prove causation under the Act. The Vaccine Injury Table lists certain injuries and conditions which if found to occur within a prescribed period of time following vaccination, create a rebuttable presumption of causation. In such "on table" cases petitioners do not need to show proof of actual causation. For instance, if a petitioner proves that her child received a DPT vaccine on July 20, 1998 and that she suffered an encephalopathy within three days thereafter or anaphylactic shock within 24 hours thereafter, causation is presumed. The Act's Qualifications and Aids to Interpretation further define the compensable conditions. A petitioner is no longer burdened with the onerous task of proving that the vaccine actually caused the condition in question. In the vast majority of cases the presumption of causation does not, however, obviate expert medical testimony. A qualified witness must still attest that the victim suffered the particular medical condition for which the compensation is being sought.

Where the symptoms fall outside the statutory time frames the petitioner must present evidence of causation and fact. The legislative history instructs that "simple similarity to conditions or time periods listed in the table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. Petitioner need not, however, prove causation to a scientific certainty. Rather the petitioner must show a "logical sequence of cause and affect".

Once the petitioner establishes a *prima facie* case, the burden then shifts to the respondent who must prove by a preponderance of the evidence that the claimed injury is attributable to some factor unrelated to the vaccine. Such factors may not include "any idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor, injury, illness, or condition". In part because of belated participation by the respondent, the precise scope of the alternate cause injury has yet to be defined. Although the alternate cause determination is usually fact specific, the claims court has held as a matter of fact that proof of Sudden Infant Death Syndrome is insufficient to dispel the Act's presumption of causation. *See e.g.,* Daniel Green and Sandra Green, as legal representatives of the Estate of Chad Green v. Secretary of the Department of Health and Human Services, 19 Cl. Ct. 57 (1989).

The system thus establishes 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). *See also,* Haggerty v. Wyeth Ayerst Pharmceutical Co., 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 (i.e., the person or organization on behalf of whom the person administered the

vaccination) unless the claimant initially files a timely petition in accordance with the program's guidelines. *See* Shalala v. Whitecotton, 514 U.S. 268, 270 (1995) and 42 U.S.C. §300aa-11(2)(A), explaining that a 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. 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. *See* 42 U.S.C. §300aa-21(a).

Under the Vaccine Act, then, a person may not sue in state or federal court for more than $1,000 for a vaccine-related injury unless that person has first filed a petition in Vaccine Court within thirty-six months of the injury. The plaintiffs herein seek to circumvent this bar by claiming (a) they need not file petitions under the Act because the statute of limitations under the Act has expired, and (b) they are not injured. To quote from the plaintiffs' surreply memorandum of law:

> "Without question, the Vaccine Act does not provide relief to the children for whom plaintiffs request medical monitoring relief. As set forth in plaintiffs' Memorandum in Opposition, this case presents a textbook example of the circumstances where medical monitoring should be awarded: *asymptomatic* children who need testing as a result of defendants' tortious conduct in order to determine the extent, if any, of damage caused by direct injection of mercury into their bodies, so early diagnosis or mitigation can occur. These children are *asymptomatic* and therefore unable to obtain relief from the Act. No amount of verbal calisthenics can change that fact."

Initially, and making reference to the amended complaint which is the subject matter of these proceedings, in conjunction with the foregoing assertion that "these children" are not injured and the plaintiffs' duties under the Vaccine Act, the Court's attention is inevitably drawn to the allegations in the complaint. Pages 6 and 7 of the complaint -- a class action -- name three representatives of the class. One is Madigan Ashton. She is described as "diagnosed with an Autism Spectrum Disorder (ASD); Pervasive Developmental Disorder, Not Otherwise Specified (PDD/NOS)." The next class representative plaintiff is Samuel Kaplan, a minor child who "has been diagnosed with an Autism Spectrum Disorder (ASD); Pervasive Developmental Disorder, Not Otherwise Specified (PDD/NOS)." Another plaintiff, Robbie Powell, a minor, according to the complaint "has been diagnosed with an Autism Spectrum Disorder (ASD); Pervasive Developmental Disorder, Not Otherwise Specified (PDD/NOS)." And the fourth plaintiff, Lucinda Ashton, is described as having "achieved the neurological, social and developmental milestones anticipated for a child of her age." From pages 12 through 21 the complaint relates in detail the medical histories of each child, including their exposure to the vaccines in question. Each account of each child concludes with the statement, "In all [plaintiff] was poisoned with 237.5 micrograms of toxic mercury from the vaccines containing thimerosal." Overall, then, the Court has before it four plaintiffs, all "poisoned", three with injuries that the complaint alleges, inferentially if not directly, were caused by their thimerosal-containing vaccinations.

DISCUSSION:

Preliminary Objections pursuant to Pa.R.C.P. 1028(a)(1) and Pa.R.C.P. 1028(a)(4)

(a) *This Court lacks jurisdiction under the Vaccine Act -- Plaintiffs are Qualified Claimants under the Act.*

Without reiterating the foregoing discussion, it should be plain that this Court has

no jurisdiction to entertain the vaccine-related claims of the plaintiffs for the following reasons. This Court holds that the plaintiffs are persons who would qualify to file original actions under the Vaccine Act because they do allege damages for vaccine-related injuries. Each plaintiff alleges that he or she was "poisoned" by the substance thimerosal added to a series of vaccines. No amount of verbal calisthenics can conceal the fact that plaintiffs do allege injuries, even if they are incubating injuries that may manifest themselves later in time. The plaintiffs Ashton, Kaplan and Powell definitely assert injuries in the form of learning disorders. And, as stated, all four plaintiffs unequivocally state they were poisoned. Being poisoned is being injured. Being injured involves the plenary jurisdiction of the Vaccine Act. Plaintiffs claims are precluded for this reason.

(b) *This Court lacks jurisdiction under the Vaccine Act -- Thimerosal-related Injuries are "Vaccine-related"*.

Every court that has had the opportunity to rule on this issue has held that thimerosal is not an "adulterant or contaminant" of the vaccines at issue, but a preservative inherent to the production of a vaccine. *See* McDonell v. Abbott Laboratories, C.A. No. 3:02 CV 437 LN slip opinion at pp. 2-3 (S.D.Miss. August 1, 2002); and Liu v. Aventis Pasteur, Inc., 219 F.Supp. 2d 7622 (W.D.Tex. 2002). What is more, an opinion by a fellow judge of this Court, Cheskiewicz et al. v. Aventis Pasteur, Inc., et al., May Term, 2002 #0952 (DiNubile, J. December 16, 2002) analyzes the very same contention -- that thimerosal is an ingredient outside of the content of the vaccines thus enabling a separate state-related tort action to be brought against the manufacturers who use thimerosal -- and holds that thimerosal does not fall within an exception or foreign substances added to vaccines. As the defendant vaccine manufacturers correctly point it is the unanimous position of the Secretary of United States Department of

Health and Human Services, the Vaccine Court and the Federal District and state trial courts that confronted the issue that thimerosal claims are covered by the Vaccine Act.

(c) *This Court lacks jurisdiction under the Vaccine Act -- Plaintiffs were Qualified Claimants even though untimely.*

The plaintiffs through their lawyers support their identities as state tort plaintiffs by claiming that they failed to file their claims "within three years from the onset of a vaccine-related injury" and it is the latent nature of their purported injuries that caused them to do so. For this contorted reason the plaintiffs believe they are exempted from filing a petition in the Vaccine Court. This argument was rejected by the court in Cheskiewicz, *supra.* This Court will re-emphasize the rejection. The Court can simply re-recite the language of Cheskiewicz to dismiss the complaint on these grounds:

> "One cannot simply wait out the three-year limitations period and then file a civil tort action free from all substantive and procedural limitations under the Vaccine Act. It is clear that plaintiffs' attempts to commence this suit in District Court and subsequently this Court are to circumvent the requirements of the Act. If the instant suit were permitted, then every litigant who did not want to first assert claims in Vaccine Court simply could wait out the 36 month requirement if the tort actions were not barred by the statute of limitations and then commence their actions in federal or state courts. Such an approach is counter to the intent of Congress." *See* McDonald v. Lederle Labs, 775 A.2d 528, 532 (N.J.Super.Ct.App.Div. 2001) (affirming the lower court's dismissal of the suit under circumstances similar to the instant case).

The Vaccine Act by its terms unambiguously bars civil actions for damages for alleged vaccine-related injury "unless a petition has been filed in accordance with §300aa-16 of this title." That section provides that "no petition for compensation shall be filed for [a vaccine-related] injury after the expiration of 36 months from the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such

injury." 42 U.S.C. 300aa-16(a)(2). Plaintiffs have admittedly missed filing under the foregoing provision within the acceptable period of time. Because this Court holds that only the Vaccine Court has jurisdiction over their claims, their claims must be dismissed with prejudice.

(d) *Plaintiffs Fail to State a Claim Upon Which Relief Can Be Granted.*

In what this Court views as largely a rhetorical instrument aimed at circumventing the requirements of the Vaccine Act, the plaintiffs base their state tort claim on a right to "medical monitoring" for injuries yet to be ascertained. The Court agrees with the defendants in holding that without an underlying tort no relief for medical monitoring can be asserted. *See* Redland Soccer Club, Inc. v. Department of the Army, 696 A.2d 137 (Pa. 1997). The Supreme Court in Redland held that proof of a defendant's negligence is a required element of a cause of action for medical monitoring. The complaint by its terms suggests no proof of the defendants' negligence. The substance at issue is a prescription drug. As the defendants point out, manufacturers of prescription drugs can be held negligent only on a failure to warn formulation. Were the manufacturers' alleged failures to warn issued to doctors insufficient then the manufacturers may be negligent. *See* Demmler v. SmithKlineBeecham, 671 A.2d 1151, 1155 (Pa. Super. 1995) allocatur denied 684 A.2d 557 (Pa. 1996). The plaintiffs are not suing the doctors who administered the vaccinations, so there is no proof that the prescribing doctors were independently aware of the risks at issue. Therefore, proximate cause is not pleaded and thus absent.

The Court further holds that none of the attempted tort formulations the plaintiffs raise in their complaint have a basis under Pennsylvania law. For example, the plaintiffs allege the vaccine defendants negligently failed to test their vaccines and negligently

designed, manufactured and packaged them by using multi-dose vials which require thimerosal as a preservative. *See* Paragraphs 163, 165 and 195(a) and (c) of the Amended Complaint. Again, a brother jurist in this Court has held that negligent failure to test is not an independent tort under Pennsylvania law. *See* In re: Phenylpropanolamine Litigation #0001, September Term, 2001 (Tereshko, J.).

(e) *Remaining Counts.*

1. Fraud

While it may not be necessary for this Court to address the specific counts of the complaint, having held that the Vaccine Act applies exclusively to the plaintiffs' claims, the Court will specifically dismiss all remaining claims as having no basis under the law. What is more, plaintiffs' claim for fraud is not specifically pleaded as required by Rule 1019(b) of the Pennsylvania Rules of Civil Procedure. *See* Bash v. Bell Telephone Co., 601 A.2d 825, 831 (Pa.Super. 1992). Plaintiffs' claim for loss of consortium is not actionable not only because there is some ambiguity whether or not the plaintiffs are alleging loss of filial consortium due to injury or some other cause, but because this is not a recognized cause of action in Pennsylvania. *See* Quinn v. City of Pittsburgh, A. 353 (Pa. 1914); McCaskill v. Philadelphia Housing Authority, 615 A.2d 382, 384 (Pa.Super. 1992); Jackson v. Tastykake, 648 A.2d 1214, 1217 (Pa.Super. 1994).

2. Preliminary Objections as applied to the Vaccine suppliers

This Court specifically rejects as without authority the plaintiffs' claim that the suppliers of thimerosal occupy a separate class apart from that of the vaccine manufacturers and, therefore, regardless of the Court's ruling on the motion of the vaccine manufacturers, should remain as defendants in this matter. The law contradicts this

position. The Vaccine Court in Leroy v. Secretary of HHS No. 02-392V at 12 (Ct. Fed. Cl. Office of Special Masters, October 11, 2002) held that the term "vaccine" included the constituents of the vaccine and this takes in thimerosal as well. The Court agrees with the defendants thimerosal suppliers and distributors that the ingredient is interchangeable with the vaccine for the purposes of the defendants' jurisdictional defense. Thus the exclusive jurisdiction of the Vaccine Act should, this Court holds, apply to the manufacturers, suppliers and distributors of thimerosal as well.

CONCLUSION:

Because the class plaintiffs have not stated a cause of action cognizable under Pennsylvania law, and principally because their claims are cognizable under the exclusive jurisdiction of the federal Vaccine Act, all defendants' preliminary objections will be sustained and the plaintiffs' complaint is dismissed with prejudice.

BY THE COURT:

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GENE D. COHEN, J.

Dated: May 22, 2003