No. 1-06-1174

CHRISTOPHER REILLY, a Minor by his Mother and Next Friend, DRUANNE REILLY, DRUANNE REILLY, and RONALD REILLY,		 Appeal from the Circuit Court of Cook County.
Plaintiffs-Appellants,)
)
V.)
WYETH f/k/a AMERICAN HOME PRODUCTS	2)
CORPORATION, BAXTER HEALTHCARE))
CORPORATION, BIOPORT CORPORATION,) No. 02 L 014697
AVENTIS PASTEUR, INC., MERCK & CO., IN)
CELLTECH PHARMACEUTICALS, INC. f/k/a)
MEDEVA PHARMACEUTICALS, INC.,)
SMITHKLINE BEECHAM CORPORATION)
d/b/a GLAXOSMITHKLINE, ELI LILLY AND)
COMPANY, SIGMA-ALDRICH CO.,)
SPECTRUM LABORATORY PRODUCTS, INC	Z.,)
And EMD CHEMICALS,) Honorable
) Lynn Egan,
Defendants-Appellees.)	Judge Presiding.

____JUSTICE THEIS delivered the opinion of the court:

Druanne Reilly, as mother and next friend of Christopher Reilly, brought this action

seeking recovery against defendants (vaccine defendants¹ and thimerosal defendants²) for her

¹ Wyeth F/k/a American Home Products Corporation, Baxter Healthcare Corporation, Bioport Corporation, Aventis Pasteur, Inc., Merck & Co., Inc., Celltech Pharmaceuticals, Inc. f/k/a Medeva Pharmaceuticals, Inc., Smithkline Beecham Corporation d/b/a Glaxosmithkline.

² Eli Lilly and Company, Sigma-Aldrich Co., Spectrum Laboratory Products, Inc., and EMD Chemicals.

son's autism, which was allegedly caused by his exposure to the mercury-based preservative, thimerosal, contained in several childhood vaccines. Druanne and her husband Ronald Reilly also individually brought an intentional infliction of emotional distress claim due to their son's injuries. The circuit court dismissed the minor plaintiff's claims pursuant to section 2-619(a)(1) of the Code of Civil Procedure (the Code) (735 ILCS 5/2-619(a)(1) (West 2004)) for failing to exhaust his remedies under the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act or Act) (42 U.S.C. §300aa-1 *et seq.* (2000)). Additionally, the circuit court dismissed the parents' intentional infliction of emotional distress claim pursuant to section 2-619(a)(9) of the Code (735 ILCS 5/2-619(a)(9) (West 2004)), finding that defendants' alleged conduct could not constitute extreme and outrageous conduct as a matter of law.

On appeal, plaintiffs contend that they are not precluded from filing a state court action against defendants because: (1) Christopher did not suffer a "vaccine-related injury" as that term is defined under the Act; (2) the thimerosal defendants are not vaccine manufacturers or administrators under the Vaccine Act; (3) Christopher is not "qualified" to file a petition under the Act because his petition is admittedly time-barred and the Act does not preempt state law; (4) the Act's lack of an equitable tolling provision violates Illinois public policy, which provides special protection to minors; and (5) the limitations period under the Act violates Christopher's due process and equal protection rights under the United States Constitution. Additionally, plaintiffs contend that the circuit court erred in dismissing their claim for intentional infliction of emotional distress. For the following reasons, we affirm the judgment of the circuit court in part and reverse and remand in part.

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BACKGROUND

As alleged in plaintiffs' complaint, Christopher was born in 1995 and was administered a series of routine childhood vaccinations over the course of two years that contained the mercurybased preservative thimerosal. He subsequently developed certain disabilities, and in October 1998, he was diagnosed with autism, a neurological disorder. Plaintiffs alleged that defendants manufactured or caused thimerosal to be placed into certain vaccines administered to Christopher and that the exposure to the thimerosal caused his autism. The complaint was brought under theories of product liability, breach of warranty, negligence, consumer fraud, and battery. Additionally, plaintiffs Druanne and Ronald Reilly brought individual claims for intentional infliction of emotional distress, essentially alleging that defendants intentionally or knowingly added a known dangerous substance into a product designed, sold, and distributed for injection into infants and toddlers.

Thereafter, defendants sought dismissal of all claims brought on behalf of Christopher based on the argument that the state court lacked subject matter jurisdiction over these claims. Specifically, defendants maintained that plaintiffs were required to exhaust the remedies provided for by the Vaccine Act in the United States Court of Federal Claims before proceeding in state court. Defendants also moved to dismiss the intentional infliction of emotional distress count pursuant to sections 2-615 and 2-619(a)(9) of the Code. 735 ILCS 5/2-615, 2-619(a)(9) (West 2004). They maintained that defendants' conduct was strictly regulated and approved by the Food and Drug Administration (FDA). In support, they appended to their motion the relevant provisions of the Code of Federal Regulations that outline the FDA's requirements for the

approval, manufacture, and labeling of vaccines. The trial court took judicial notice of these regulations.³ Based on this affirmative matter, defendants argued that the legitimate making and selling of FDA-approved thimerosal-containing vaccines could not constitute "extreme and outrageous" conduct. Defendants also argued that plaintiffs failed to plead the severe emotional distress element with the requisite specificity.

The circuit court dismissed the representative claims brought on behalf of Christopher without prejudice for lack of subject matter jurisdiction because they stemmed from a "vaccinerelated injury" covered under the Vaccine Act. Additionally, after several opportunities to amend, the court dismissed the intentional infliction of emotional distress claim with prejudice, finding that the federal regulations demonstrated that the manufacturing and selling of FDA-approved vaccines could not, as a matter of law, be characterized as extreme and outrageous conduct. Plaintiffs filed a timely appeal.

ANALYSIS

In ruling on the circuit court's dismissal order, we are asked to address the subject matter jurisdiction of the circuit court with respect to the claims brought on behalf of Christopher. Defendants sought to dismiss these claims pursuant to section 2-619(a)(1) of the Code (735 ILCS 5/2-619(a)(1) (West 2004)). A section 2-619 motion to dismiss admits the legal sufficiency of the

³ Defendants also submitted a 1982 FDA "Advance Notice of Proposed Rulemaking" regarding over-the-counter drugs containing thimerosal for topical antimicrobial use (47 Fed. Reg. 436 (January 5, 1982) (to be codified at 21 C.F.R. pt. 333)), and other public records of the FDA and other agencies regarding the use of thimerosal as a preservative in vaccines. The trial court did not consider these documents because it ruled that defendants failed to meet the requisites of Supreme Court Rule 191 (145 Ill. 2d R. 191).

complaint and raises defects, defenses, or other matters that act to defeat the claim. <u>Cohen v.</u> <u>McDonald's Corp.</u>, 347 Ill. App. 3d 627, 632, 808 N.E.2d 1, 5 (2004). Specifically, it provides for the involuntary dismissal of a cause of action based on the court's lack of subject matter jurisdiction. <u>Kinn v. Prairie Farms/Muller Pinehurst</u>, 368 Ill. App. 3d 728, 730, 859 N.E.2d 99, 101 (2006). Our review is *de novo*. Kinn, 368 Ill. App. 3d at 730, 859 N.E.2d at 101.

Plaintiffs contend that the circuit court erred in granting dismissal on the basis that plaintiffs were required to exhaust their administrative remedies under the Vaccine Act. 42 U.S.C. §300aa-11 (2000). In order to fully understand plaintiffs' arguments, a basic understanding of the Vaccine Act's purpose and administrative framework is necessary.

Enacted in 1986, the Vaccine Act established a remedial no-fault compensation program for vaccine related injuries or death. 42 U.S.C. §300aa-10 <u>et seq.</u> (2000). The Act was designed to protect the nation's vaccine supply and to create a fair and easily-administered program to provide compensation for vaccine-related injuries. H.R. Rep. No. 99-908, at 5-7 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6346-48. The statute has a twofold policy: to expedite the award of damages and to protect vaccine manufacturers from burdensome litigation. H.R. Rep. No. 99-908, at 4 (986), *as reprinted in* U.S.C.C.A.N. 6344-45. The program requires that a person seeking compensation for a vaccine-related injury must first file a petition against the United States Secretary of Health and Human Services before traditional tort remedies may be pursued. 42 U.S.C. §300aa-11(a)(2)(A) (2000); <u>Shalala v.Whitecotton</u>, 514 U.S. 268, 270, 131 L. Ed. 2d 374, 378, 115 S. Ct. 1477, 1478 (1995) (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").

The claims are then heard by special masters appointed by the Court of Federal Claims, are adjudicated informally (42. U.S.C. §300aa-12(d)(2) (2000)), and are then accorded expeditious review by the Court of Federal Claims and the Federal Circuit Court of Appeals (42 U.S.C. §300aa-12(e)(2) (2000)); <u>Whitecotton</u>, 514 U.S. at 270, 131 L. Ed. 2d at 378, 115 S. Ct. at 1478). Compensation awards are paid from the Vaccine Injury Compensation Trust Fund, which is financed by excise taxes on certain vaccines. 42 U.S.C. §300aa-15(2) (2000); 26 U.S.C. §9510(b)(1) (2000). The Vaccine Act does not totally preempt all traditional tort remedies for covered damages. Rather, after the Court of Federal Claims renders a ruling on a claim, the claimant may accept or reject any award. If he accepts an award, he waives further tort rights; if he declines it, he may pursue traditional tort relief, with some restrictions. 42 U.S.C. §§300aa-21, 300aa-22 (2000).

Specifically pertinent to this appeal, section 300aa-11(a)(2)(A) of the Act provides in relevant part that:

"No person may bring a civil action for damages *** against a vaccine administrator or manufacturer in a State or Federal Court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine *** unless a petition has been filed *** for compensation under the Program for such injury." 42 U.S.C. §300aa-11(a)(2)(A) (2000).

The Act further provides that "[i]f a civil action which is barred under [the Act] is filed in a State

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or Federal court, the court shall dismiss the action." 42 U.S.C. §300aa-(a)(2)(B)(2000).

Plaintiffs raise various arguments contending that they are not required to exhaust their administrative remedies under the Vaccine Act before filing their claims on behalf of Christopher in state court. Initially, we address plaintiffs' argument that they are not required to comply with the Vaccine Act's procedural requirements because Christopher has not suffered a "vaccinerelated injury" as that term is defined in the Act. The Vaccine Act defines "vaccine-related injury" as follows:

> "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 (2006)], except that term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. §300aa-33(5) (2000).

Plaintiffs argue that they were harmed by thimerosal, and that thimerosal is not a vaccine but, rather, a preservative added to multidose vials to extend a vaccine's viable life. They allege that the thimerosal as used in the vaccines administered to Christopher falls under the exception because it is an "adulterant or contaminant" that was intentionally added to the vaccines. As a result, they maintain that they have at least established a question of fact that should not be decided by a motion to dismiss. We disagree.

The issue of whether Christopher's injuries were "vaccine-related" as that term is defined in the statute concerns the construction of the statute, which is a question of law to be reviewed

de novo. <u>Vine Street Clinic v. HealthLink, Inc.</u>, 222 III. 2d 276, 282, 856 N.E.2d 422, 427-28 (2006). The primary objective of this court when construing the meaning of a statute is to ascertain and give effect to the intent of the legislature. <u>Vine Street Clinic</u>, 222 III. 2d at 282, 856 N.E.2d at 427-28. "The plain language of a statute is the most reliable indication of the legislature's objectives in enacting that particular law [citation], and when the language is clear, it [will] be applied as written without resort to aids or tools of interpretation." <u>DeLuna v. Burciaga</u>, 223 III. 2d 49, 59, 857 N.E.2d 229, 236 (2006).

Based on the allegations in the complaint, plaintiffs acknowledge that Christopher's injuries were allegedly caused by a preservative in the vaccines administered to him and therefore his injuries were at least "associated with" the vaccines. Nevertheless, plaintiffs allege that the exception for "adulterant" or "contaminant" applies here. Neither the Act nor its regulations specifically define the terms "adulterant" or "contaminant." Nevertheless, the dictionary defines "adulterant" as something that makes an item "corrupt, debased, or *** impure by the addition of a foreign or a baser substance." Webster's Third New International Dictionary 30 (1993). A "contaminant" is defined as something that corrupts or infects by contact or association. Webster's Third New International Dictionary 490 (1993). A "preservative" is defined as a substance added against "decay, discoloration, or spoilage." Webster's Third New International Dictionary 1794 (1993). Thus, under the plain meaning of those words, thimerosal, as used in the vaccines, is the antithesis of an adulterant or contaminant within the meaning of section 300aa-33(5) of the Act (42 U.S.C. §300aa-33(5) (2000)) because its purpose is to prevent the corruption of the vaccine. At the time the vaccine was made, it was "intentionally added" as an

approved ingredient in the formulation of a vaccine to preserve it. See 21 C.F.R. §610.15 (2006) ("[p]roducts in multi-dose containers shall contain a preservative"). Accordingly, injuries arising from a vaccine preservative are "vaccine-related injuries" under the Act.

Several other federal and state courts that have considered this issue have all held that under the plain meaning of the statute thimerosal is a constituent ingredient or component of the vaccine and not an adulterant or contaminant as a matter of law. <u>Moss v. Merck & Co.</u>, 381 F.3d 501, 503-04 (5th Cir. 2004); <u>John & Jane Doe 2 v. Ortho-Clinical Diagnostics</u>, Inc., 335 F. Supp. 2d 614, 622-23 (M.D.N.C. 2004); <u>Laughter v. Aventis Pasteur</u>, Inc., 291 F. Supp. 2d 406, 410 (M.D.N.C. 2003); <u>Murphy v. Aventis Pasteur</u>, Inc., 270 F. Supp. 2d 1368, 1375 (N.D. Ga. 2003); <u>Blackmon v. American Home Products Corp.</u>, 267 F. Supp. 2d 667, 673-75 (S.D. Tex. 2002); <u>Liu v. Aventis Pasteur</u>, Inc., 219 F. Supp. 2d 762, 767 (W.D. Tex. 2002); <u>Owens v. American Home Products Corp.</u>, 203 F. Supp. 2d 748, 754-55 (S.D. Tex. 2002); <u>Wax v. Aventis Pasteur</u>, <u>Inc.</u>, 240 F. Supp. 2d 191, 194 (E.D.N.Y. 2002); <u>Troxclair v. Aventis Pasteur</u>, Inc., 374 N.J. Super. 374, 864 A.2d 1147 (2005); <u>Cheskiewicz v. Aventis Pasteur</u>, Inc., 843 A.2d 1258, 1265-66 (Pa. Super. 2004).

We note that our supreme court has indicated that "uniformity of decision is an important consideration when state courts interpret federal statutes. [Citations.] * * * In the absence of a decision of the United States Supreme Court, which would definitively answer the question presented by this case, we elect to give considerable weight to the decisions of federal courts of appeals and federal district courts that have addressed this issue." <u>Sprietsma v. Mercury Marine</u>, 197 Ill. 2d 112, 119-20, 757 N.E.2d 75, 80 (2001), *rev'd on other grounds*, 537 U.S. 51, 154 L.

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Ed. 2d 466, 123 S. Ct. 518 (2002). We find no compelling reason here to construe the statute inconsistently with the federal courts' construction.

Additionally, although not binding authority, an administrative agency's interpretations of the statutory scheme it is entrusted to administer has been given deference. See <u>Chevron, U.S.A.</u>, <u>Inc. v. Natural Resources Defense Council, Inc.</u>, 467 U.S. 837, 844-45, 81 L. Ed. 2d 694, 704, 104 S. Ct. 2778, 2782-83 (1984). See also <u>Wax</u>, 240 F. Supp. 2d at 194 ("[T]he court defers, for the purposes of this motion, to HHS's interpretation that injuries caused by thimerosal in vaccines are 'vaccine-related' for purposes of the Program''). The Secretary of Health and Human Services, charged with the responsibility of administering the compensation program under the Act (42 U.S.C. §§300aa-10 through 300aa-34 (2000)), maintains that any injury claims allegedly caused by thimerosal in vaccines are "vaccine-related" and, therefore, require adjudication in the Court of Federal Claims. See, *e.g.*, The National Vaccine Injury Compensation Program at <u>http://www.hrsa.gov/vaccinecompensation</u> ("[c]omponents, such as thimerosal, that are added to microorganisms to create vaccines cannot and should not be considered adulterants or contaminants. Instead, preservatives and components, such as thimerosal, should be considered one of several elements that comprise vaccines'').

Furthermore, in 2002, the Court of Federal Claims ruled that thimerosal-related claims were subject to its jurisdiction after construing the statutory definition of "vaccine-related injury." See <u>Leroy v. Secretary of Department of Health & Human Services</u>, No. 02-392V (Fed. Cl. 2002). By Autism General Order No.1, the Court of Federal Claims established a schedule for adjudicating these autism-related claims and those proceedings are ongoing. <u>In re Claims For</u>

<u>Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental</u> <u>Disorder</u>, 2002 WL 31696785 (Fed. Cl. July 3, 2002), 2007 WL 1983780 (Fed. Cl. May 25, 2007). Accordingly, based upon the plain meaning of the statute, the federal courts' construction, as well as the construction given by the agency charged with administering the Act, injuries caused by thimerosal are "vaccine-related injuries" that fall within the scope of the Act.

Nevertheless, the Act's exhaustion requirement does not apply to all vaccine-related lawsuits. Rather, it applies to only those suits brought against a "vaccine administrator or manufacturer." 42 U.S.C. §300aa-11(a)(2)(A) (2000). Plaintiff contends that the thimerosal defendants are not vaccine manufacturers or administrators and, therefore, plaintiffs are not required to exhaust their administrative remedies before pursuing their claims against these defendants in state court.

The Act does not define "vaccine," but it does define "manufacturer" as "any corporation, organization or institution, whether public or private *** which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table." 42 U.S.C. §300aa-33(3) (2000). Thus, based on the definition as provided in the Act, the statute governs suits against a "manufacturer" that manufactures the vaccine as a whole under its own label and manufactures only those vaccines listed in the Vaccine Injury Table. The definition does not include manufacturers that sell only the component parts of a vaccine to a vaccine manufacturer.

In evaluating this same issue, under the same factual scenario, the United States Court of Appeals for the Fifth Circuit has also considered this specific language and has held that under the plain meaning of the Act, the thimerosal manufacturers are not vaccine manufacturers. <u>Moss v.</u>

<u>Merck & Co.</u>, 381 F.3d 501, 504 (5th Cir. 2004). "Its status as a vaccine component no more makes [t]himerosal a 'vaccine' than does the inclusion of a piston under the hood of an automobile make that object an 'engine.'" <u>Moss</u>, 381 F.3d at 504. The court reasoned as follows:

"Thimerosal is part of the finished product, to be sure, but it is not the finished product itself, and on its face the statute governs only lawsuits filed against manufacturers of a completed vaccine shipped under its own label and listed in the Vaccine Injury Table. Not surprisingly, [t]himerosal is not sold as a vaccine, nor is it listed in the statute's table." Moss, 381 F.3d at 504.

We find the federal court of appeals construction to be well reasoned. See also <u>Holder v. Abbott</u> <u>Laboratories, Inc.</u>, 444 F.3d 383 (5th Cir. 2006); <u>McDonal v. Abbott Laboratories</u>, 408 F.3d 177 (5th Cir. 2005) (applying the reasoning of <u>Moss</u>); <u>Blackmon</u>, 267 F. Supp. 2d at 678 ("[b]ecause [defendant] allegedly supplies thimerosal (a raw material) to the [v]accine [m]anufacturers, but does not manufacture or administer vaccines itself, [p]laintiffs' claims against [defendant] are not subject to the Vaccine Act's tort suit bar"); <u>Owens</u>, 203 F. Supp. 2d at 758-59 (in a case preceding <u>Moss</u>, the court held that although thimerosal claims were vaccine-related, the manufacturers who supplied thimerosal to vaccine manufacturers, but did not manufacture the vaccine, were not subject to the Vaccine Act).

Nevertheless, in the present case, the thimerosal defendants assert that suits against them must be dismissed in order to comply with the legislative intent behind the Act, reiterating that the

purpose of the Act is to reduce civil litigation and "resolve a national vaccine crisis." In support, defendants string cite numerous opinions, including unpublished opinions that do not specifically address the definition of "manufacturer" under the Act. These cases either focus on whether thimerosal-based claims are "vaccine-related" as defined by the Act rather than whether thimerosal manufacturers are vaccine "manufacturers," or rely on an outdated version of the statute. To the extent that these opinions are nonprecedential and or not directly on point, we do not consider them here.

The only published case cited by defendants addressing this issue is a federal district court case from the eastern district of Kentucky, Ferguson ex rel. Ferguson v. Aventis Pasteur, Inc., 444 F. Supp. 2d 755 (E.D. Ky. 2006), which essentially disagreed with the interpretation in Moss, concluding that the thimerosal defendants were vaccine manufacturers under the Act. In doing so, the court in Ferguson relied heavily on Leroy, No. 02-392V, an unpublished opinion of the Court of Federal Claims in which the court was not asked to construe the statutory definition of a vaccine manufacturer but, rather, was faced with a jurisdictional challenge premised on the notion that thimerosal was an adulterant or contaminant. Leroy, slip op. at 5. As discussed in Moss, the Leroy decision "stands for nothing more than the unremarkable proposition that a [t]himerosal-related injury, occurring as a result of the administration of a vaccine, is a vaccine-related injury within the meaning of the Vaccine Act." Moss, 381 F.3d at 504. As Moss further reiterates, that does not end the inquiry within the meaning of section 300aa-11(a)(2)(A) of the Act because a claim is subject to the Act only if it alleges a vaccine-related injury *and* is filed against a vaccine manufacturer. Moss, 381 F.3d at 504.

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Additionally, we reject <u>Ferguson</u>'s resort to the legislative history of the Act where the plain meaning of a vaccine manufacturer is ascertainable and unambiguous. <u>Kunkel v. Walton</u>, 179 Ill. 2d 519, 534, 689 N.E.2d 1047, 1054 (1997) (where the language is clear, it will be given effect without resort to other aids of construction). However, even if we were to consider the legislative history of the Act, we find that it does not support the thimerosal defendants' asserted construction. In its original enactment, Congress explicitly stated that the compensation system under the Vaccine Act was targeted to protect the manufacturers of vaccines. H.R. Rep. No. 99-908, at 3, *as reprinted in*1986 U.S.C.C.A.N. 6344. In 1987, the Act was amended to include vaccine administrators. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, §4306, 101 Stat. 1330, 1330-224 (1987). In considering the import of this legislative history, the Court of Federal Claims in <u>Schumacher v. Secretary of Department of Health & Human Services</u>, 2 F.3d 1128, 1133 (Fed. Cir. 1993), held that "Congress did not intend the Vaccine Act to bar civil actions against any party other than a vaccine administrator or manufacturer." <u>Schumacher</u>, 2 F.3d at 1133.

Thereafter, on November 25, 2002, the Vaccine Act was again amended by the passage of the Homeland Security Act of 2002, Pub. L. No.107-296, §§1714 to 1717, 116 Stat. 2320, 2321 (2002), which, in part, amended section 300aa-33(3) of the Vaccine Act by specifically including in the definition of "manufacturer," those who manufacture "any component or ingredient of any such vaccine." Homeland Security Act of 2002, Pub. L. No.107-296, §1714, 116 Stat. 2320 (2002). However, this definition was short-lived as it was repealed in February 2003. Consolidated Appropriations Resolution, 2003, Pub. L. No.108-7, §102, 117 Stat. 528 (2003).

In section 102(c) of the repeal, identified as "Rule of Construction," Congress indicated:

"No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107-296), or from this repeal, regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107-296). Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02-392V (October 11, 2002), was incorrectly decided." Consolidated Appropriations Resolution, 2003, Pub. L. No. 108-7, §102(c), 117 Stat. 528 (2003).

Additionally, section 102(d) of the repeal, which is identified as "Sense of the Congress," indicates that to ensure an adequate supply of vaccines and encourage the development of new vaccines, steps should be taken to ensure that manufacturers of components or ingredients of vaccines are adequately protected. Within six months of the repeal, Congress directed the relevant Senate and House committees to report a bill addressing these issues. Consolidated Appropriations Resolution, 2003, Pub. L. No.108-7, §102(d), 117 Stat. 529 (2003). Congress has yet to pass any such legislation.

Thus, given that we are not to make any inferences from the amendment and subsequent repeal, that the unpublished <u>Leroy</u> decision did not specifically address the issue of who is a vaccine manufacturer, and that Congress has not spoken further on the issue, we rely on the plain

meaning of the statute to hold that thimerosal manufacturers are not vaccine manufacturers. "[O]nly the most extraordinary showing of contrary intentions from [the legislative history] would justify a limitation on the 'plain meaning' of the statutory language." <u>Garcia v. United States</u>, 469 U.S. 70, 75, 83 L. Ed. 2d 472, 477-78, 105 S. Ct. 479, 482 (1984). Accordingly, plaintiffs' claims against the thimerosal defendants may proceed in state court.

We next consider plaintiffs' contention that the Vaccine Act requires that Christopher be "qualified" to file a petition in the Court of Federal Claims (42 U.S.C. §300aa-11(a)(9) (2000)) and that he is not "qualified" because his petition would admittedly be time-barred pursuant to section 300aa-16(a)(2) of the Act (42 U.S.C. §300aa-16(a)(2) (2000)). As a result, they assert that the representative claims against the vaccine manufacturers may properly be brought in state court.

This court has previously rejected plaintiffs' contention. In <u>Dickey v. Connaught</u> <u>Laboratories, Inc.</u>, 334 Ill. App. 3d 1048, 1052, 777 N.E.2d 974, 978 (2002), after examining the statutory scheme, we held that the right to litigate in state court is lost if the party fails to first follow the federal statutory guidelines. There, the court focused on the language of section 300aa-11(a)(2) of the Act (42 U.S.C. §300aa-11(a)(2) (2000)) and noted that subparagraph (A) of that section provides in pertinent part that no state court action may be filed and no damages awarded unless a petition has been filed " 'in accordance with section 300aa-16 of this title.' " <u>Dickey</u>, 334 Ill. App. 3d at 1052, 777 N.E.2d at 978, quoting 42 U.S.C. §300aa-16(a)(2). Section 300aa-16 of the Act provides in relevant part that "no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date

of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." 42 U.S.C. §300aa-16(a)(2) (2000). The court further explained that " 'if a civil action which is barred under subparagraph (A) is filed in State or Federal court, the court shall dismiss the action.' " <u>Dickey</u>, 334 Ill. App. 3d at 1052, 777 N.E.2d at 978, quoting 42 U.S.C. §300aa-11(a)(2)(B) (2000).

Based on the plain language of the statute, taking these sections together, the court in <u>Dickey</u> held that "this language clearly and unambiguously prohibits both an action and a remedy in state or federal court unless there has been a timely filing with the claims court." <u>Dickey</u>, 334 Ill. App. 3d at 1052, 777 N.E.2d at 978. See also <u>Strauss v. American Home Products Corp.</u>, 208 F. Supp. 2d 711 (S.D. Tex. 2002); <u>Cheskiewicz</u>, 843 A.2d at 1264.

We agree with the court in <u>Dickey</u> that the plain language of the Act provides that a party may not sue in state court unless it has first filed a petition in the Court of Federal Claims within the requisite 36-month period. Additionally, we find plaintiffs' construction of the statute untenable. A statute should be construed such that no term is rendered meaningless or superfluous. <u>Duncan v. Walker</u>, 533 U.S. 167, 174, 150 L. Ed. 2d 251, 259, 121 S. Ct. 2120, 2125 (2001). Under plaintiffs' construction, injured parties could choose to wait until the limitations period expired under the Act and then seek redress in state court against the vaccine manufacturers, thereby making the exhaustion requirements optional and essentially superfluous. This construction is therefore inconsistent with the legislative purpose of the Act.

In a related argument, plaintiffs contend that Congress did not intend to preempt their state law claims where their ability to file a petition in the Court of Federal Claims is time-barred.

Plaintiffs' argument conflates the distinction between preemption and exhaustion of remedies. In <u>Dickey</u>, we explained that although the Vaccine Act does not preempt state law, Congress "may mandate that a party first timely file with an administrative agency before the party may proceed to a state civil action." <u>Dickey</u>, 334 Ill. App. 3d at 1051, 777 N.E.2d at 977. The court cited <u>McAfee v. 5th Circuit Judges</u>, 884 F.2d 221 (5th Cir. 1989), in support , in which there was no preemption violation even though the Federal Tort Claims Act required a claimant to timely present a claim to the appropriate federal agency as a prerequisite to filing their suit. <u>Dickey</u>, 334 Ill. App. 3d at 1051-52, 777 N.E.2d at 977. We find no reason to depart from this reasoned conclusion and find that plaintiffs' cited authority was also addressed and rejected as inapplicable in <u>Dickey</u>. 334 Ill. App. 3d at 1053, 777 N.E.2d at 978.

We next address plaintiffs' contention that the lack of an equitable tolling provision under the Act for minors runs counter to Illinois public policy, which provides special protection for minor's rights and allows them to bring a tort action two years after attaining the age of 18 (735 ILCS 5/13-211 (West 2004)). The United States Court of Appeals for the Federal Circuit has strictly construed the Vaccine Act's statute of limitations and has held that the equitable tolling doctrine is not available for claims arising under the Act. <u>Brice v. Secretary of Health & Human</u> <u>Services</u>, 240 F.3d 1367, 1373-74 (Fed. Cir. 2001). The court in <u>Brice</u> reasoned that where the statute provides for specific exceptions to the limitations provision, the court "[was] not inclined to create other exceptions not specified by Congress." <u>Brice</u>, 240 F.3d at 1373. Additionally, the court relied on the legislative scheme, which includes other strict deadlines and was designed to emphasize a quick resolution of claims. The court held that to allow equitable tolling would

conflict with that legislative intent. Brice, 240 F.3d at 1373-74.4

We find no conflict with Illinois public policy. Indeed, to the extent that the federal administrative framework of the Vaccine Act implicates Illinois public policy, Illinois has consistently held that time limitations upon bringing actions before administrative agencies are matters of jurisdiction which cannot be tolled. Fredman Brothers Furniture Co. v. Department of Revenue, 109 Ill. 2d 202, 209-10, 486 N.E.2d 893, 895 (1985); Robinson v. Human Rights Comm'n, 201 Ill. App. 3d 722, 729, 559 N.E.2d 229, 233 (1990) (requirement under Human Rights Act that charge be filed within 180 days after violation was committed is jurisdictional and not subject to defense of tolling). Similarly, the Vaccine Act's limitations period is also jurisdictional and lacks equitable tolling. Brice v. Secretary of Health and Human Services, 55 Fed. Cl. 366, 369 (Fed. Cl. 2003), aff'd, 358 F.3d 865 (Fed. Cir. 2004); Brice, 240 F.3d at 1373-74. Accordingly, in light of the lack of equitable tolling in similar circumstances under Illinois law, it cannot be said that the Vaccine Act is inconsistent with Illinois public policy.

Furthermore, in <u>Dickey</u>, this court rejected plaintiffs' argument, finding that Congress considered public policy in its drafting of the Act, that it was focused on affording an injured party an expedited procedure while keeping vaccine manufacturers in the market, and that its objectives would not be realized if a claim was subject to protracted litigation. <u>Dickey</u>, 334 Ill. App. 3d at 1053-54, 777 N.E.2d at 978-79. For all of the foregoing reasons, we find no merit to plaintiffs'

⁴ We note that access to state tort remedies and their applicable statutes of limitation is not entirely abolished under the Act but, rather, is deferred. Thus, where a petition proceeds in the Court of Federal Claims, state statutes of limitation are explicitly stayed. 42 U.S.C. 300aa-21(c), 300aa-16(c) (2000).

public policy argument.

We next consider plaintiffs' constitutional claims. Plaintiffs contend that section 300aa-16(a)(2) of the Act (42 U.S.C. §300aa-16(a)(2) (2000)) violates Christopher's rights to due process and equal protection under the fifth amendment. They assert that the Act provides children who suffer from latent injuries such as autism with the same 36-month time frame to file their petition for compensation as children who suffer injuries with clear and immediate onsets, identified as so-called "on-table" injuries which are specifically listed in the Vaccine Act Injury Table. 42 U.S.C. §300aa-14 (2000). Plaintiffs argue that the lack of a discovery rule for latent "off-table" injuries precludes any reasonable opportunity to pursue a claim until after the statute of limitations has run because these claims cannot be easily traced to the vaccine.

The Vaccine Act's limitations period is subject to a rational-basis standard of review. <u>Black v. Secretary of Health & Human Services</u>, 93 F.3d 781, 787 (Fed. Cir. 1996). Under the rational-basis test, statutes are presumed to be valid if the classification drawn by the statute bears a rational relationship to a legitimate governmental interest, "even if the law seems unwise or works to the disadvantage of a particular group, or if the rationale for it seems tenuous." <u>Romer</u> <u>v. Evans</u>, 517 U.S. 620, 632, 134 L. Ed. 2d 855, 866, 116 S. Ct. 1620, 1627 (1996).

Initially, plaintiff fails to articulate any real invidious discrimination between the time frame for filing for children with "on-table" injuries and those with "off-table" injuries. Rather, the two classes of children are treated the same. The statute does not begin to run until the "manifestation of onset" of the injury. 42 U.S.C. §300aa-16(a)(2) (2000). For example, although a child with encephalopathy may have knowledge of an immediate injury, a child with a latent defect has until

the injury manifests itself for the statute to begin to run. Accordingly, in both instances, the statute does not begin to run until the claimant discovers the injury.

Plaintiffs' argument was also considered and rejected in <u>Blackmon v. American Home</u> <u>Products Corp.</u>, 328 F. Supp. 2d 647 (S.D. Tex. 2004). There, in examining the rational-basis test, the court reiterated that an essential purpose of the Vaccine Act was to ensure the continued availability of vaccines on the market. "The Act reflects a policy judgment by Congress that this legislative goal required some protection for vaccine manufacturers against tort suits." <u>Blackmon</u>, 328 F. Supp. 2d at 655, citing <u>Schafer v. American Cyanamid Co.</u>, 20 F.3d 1, 4 (1st Cir. 1994). The court found the three-year limitations period to be logically connected to that legitimate legislative goal. <u>Blackmon</u>, 328 F. Supp. 2d at 655. "There exists a clear, logical connection between the means employed-a neutral limitation on claims-and the legislative goal pursuedlimitation of vaccine manufacturers' exposure to liability." <u>Blackmon</u>, 328 F. Supp. 2d at 655.

Plaintiffs additionally object to the limitations provision on due process grounds. They assert that they have been deprived of a protected property interest in their state cause of action because they are barred under the Act's time limitation and would be unable to seek relief in state court. They argue that the Vaccine Act's limitations period deprives them of any reasonable opportunity to pursue a claim in the Court of Federal Claims until after the statute of limitations has run due to the latent nature of autism and its complex causal link to thimerosal.

Plaintiffs argue that "[i]t is well established that the [p]laintiffs' cause of action is a protected property interest" citing Logan v. Zimmerman Brush Co., 455 U.S. 422, 71 L. Ed. 2d 265, 102 S. Ct. 1148 (1982), in support. Nevertheless, in Leuz v. Secretary of Health & Human

Services, 63 Fed. Cl. 602, 610 (2005), the court addressed this very issue and held that the plaintiffs had, in fact, not been deprived of any vested property rights. Therein, the court explained that the due process protection of property interests only applies to interests that a person has already acquired, and that a tort claim only becomes vested once a final judgment has been rendered in the claimant's favor. Leuz, 63 Fed. Cl. at 610. Although recognizing that in Logan, 455 U.S. at 429 n.4, 71 L. Ed. 2d at 273 n.4,102 S. Ct. at 1154 n.4, the Supreme Court held that in some instances, petitioners may have a "species of 'property' " right in a state law claim, the Leuz court distinguished Logan, finding that the plaintiffs "never had a right to pursue a state tort claim for compensation for *** alleged vaccine-related injuries without first filing a petition for those injuries under the Vaccine Act." Leuz, 63 Fed. Cl. at 610-11. The court further explained, "the only property rights petitioners had to sue a manufacturer for alleged vaccinerelated injuries necessarily flowed through the Vaccine Act." Leuz, 63 Fed. Cl. at 611. Under the same rationale in the present case, plaintiffs have not been deprived of any property right and, therefore, cannot claim they suffered a due process violation. Accordingly, for all of the foregoing reasons, we find no constitutional infirmity with the Act, and hold that the trial court properly dismissed those representative claims alleged against the vaccine manufacturers.

Having dismissed the representative claims brought on Christopher's behalf against the vaccine manufacturers, we now consider plaintiffs' individual claims for intentional infliction of emotional distress. It is undisputed that this claim is not subject to the Vaccine Act because the parents individually have not suffered a "vaccine-related injury" (42 U.S.C. §300aa-11(b)(1)(A) (2000)). Rather, defendants maintain that the cause of action must be dismissed pursuant to both

section 2-615 and 2-619(a)(9) of the Code. 735 ILCS 5/2-615, 2-619(a)(9) (West 2004).

A section 2-619(a)(9) motion to dismiss permits involuntary dismissal where "the claim asserted against defendant is barred by other affirmative matter avoiding the legal effect of or defeating the claim." 735 ILCS 5/2-619(a)(9) (West 2004). Affirmative matter is "something in the nature of a defense which negates the cause of action completely or refutes crucial conclusions of law or material fact contained in or inferred from the complaint." <u>Illinois Graphics Co. v.</u> <u>Nickum</u> 159 Ill. 2d 469, 486, 639 N.E.2d 1282, 1290 (1994). The moving party thus admits the legal sufficiency of the complaint, but asserts an affirmative defense or other matter to defeat the plaintiff's claim. <u>Kedzie & 103d Currency Exchange, Inc. v. Hodge</u>, 156 Ill. 2d 112, 115, 619 N.E.2d 732, 735 (1993).

Once a defendant satisfies the initial burden of presenting affirmative matter, the burden then shifts to the plaintiff to establish that the defense is "unfounded or requires the resolution of an essential element of material fact before it is proven." <u>Kedzie & 103d Currency Exchange</u>, <u>Inc.</u>, 156 Ill. 2d at 116, 619 N.E.2d at 735. Because a dismissal under section 2-619(a)(9) resembles the grant of a motion for summary judgment, an appeal from such a dismissal is the same in nature as an appeal following a grant of summary judgment and is afforded *de novo* review. <u>Kedzie & 103d Currency Exchange</u>, Inc., 156 Ill. 2d at 116, 619 N.E.2d at 735.

To state a cause of action for intentional infliction of emotional distress, plaintiffs must allege that (1) the conduct was truly extreme and outrageous; (2) the actor either intended that his conduct inflict severe emotional distress, or knew that there was a high probability that the conduct would cause severe emotional distress; and (3) the conduct, in fact, caused severe

emotional distress. <u>Feltmeier v. Feltmeier</u>, 207 Ill. 2d 263, 268-69, 798 N.E.2d 75, 80 (2003). The complaint must be "'specific, and detailed beyond what is normally considered permissible in pleading a tort action.'" <u>Welsh v. Commonwealth Edison Co.</u>, 306 Ill. App. 3d 148, 155, 713 N.E.2d 679, 684 (1999), quoting <u>McCaskill v. Barr</u>, 92 Ill. App. 3d 157, 158, 414 N.E.2d 1327, 1328 (1980).

Whether conduct could be deemed "extreme and outrageous" is evaluated objectively based on all of the facts and circumstances. <u>McGrath v. Fahey</u>, 126 III. 2d 78, 90, 533 N.E.2d 806, 811 (1988). The nature of a defendant's conduct must be "so extreme as to go beyond all possible bounds of decency, and to be regarded as intolerable in a civilized community." <u>Kolegas v. Heftel Broadcasting Corp.</u>, 154 III. 2d 1, 21, 607 N.E.2d 201, 211 (1992), quoting Restatement (Second) of Torts §46, Comment *d*, at 73 (1965) (" 'recitation of the facts to an average member of the community would arouse his resentment against the actor, and lead him to exclaim, "Outrageous" ' ").

Plaintiffs alleged the following facts with respect to their intentional infliction of emotional distress claim. Christopher was administered a series of vaccines containing the mercury-based preservative thimerosal between 1995 and 1997. Defendants either manufactured, designed and/or distributed thimerosal or manufactured, designed and/or distributed these childhood vaccines containing thimerosal, representing that these products were safe to administer to children, yet knowing that thimerosal caused or potentially caused severe neurological disorders such as autism in these children. In support of this allegation, plaintiffs alleged that by 1982, defendants knew or should have known that thimerosal was a toxin and that they had "actual

knowledge that including thimerosal into vaccine products as a preservative administered to children would potentially cause significant and permanent neurological injury to children." Additionally, plaintiffs alleged that "[i]n 1999 the [FDA] discovered that children were receiving more than 100 times the Environmental Protection Agency's limit for mercury by the time they reached 18 months of age," and "required the removal of [t]himerosal from all over-the-counter drugs." Plaintiffs further alleged that "[i]n 2001, the [FDA] issued a statement warning pregnant women and young children from eating fish containing high levels of mercury for fear that the consumption of substances [containing] mercury may cause neurological damage to children." Additionally, plaintiffs alleged that in 1999 and 2000 it was recommended that thimerosal be removed from all childhood vaccines.

As affirmative matter to rebut those allegations, defendants submitted the relevant federal regulations pertinent to the approval, manufacture, and labeling of vaccines by the FDA. For example, section 601.2(d) of the Code of Federal Regulations provides that the issuance of a license shall constitute a determination that the product meets the requisite safety standards. 21 C.F.R. §601.2(d) (2006). Section 610.15 provides in pertinent part that "[a]ny preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient." 21 C.F.R. §610.15 (2006).

Based upon plaintiffs' allegations and the affirmative matter, plaintiffs cannot establish that defendants engaged in "extreme and outrageous conduct" or that defendants intended or knew that there was a high probability that their conduct would cause severe emotional distress. According to plaintiffs' allegations, it was not until two years after Christopher was administered

these vaccines that the FDA or other health agencies announced that the amount of thimerosal in vaccines could potentially cause adverse neurological side effects. Prior to that time, it is undisputed that these vaccines were FDA-approved in accordance with a national public health policy (See 42 U.S.C. §300aa-1 (2000)).

Plaintiffs' allegation that defendants knew by 1982 that thimerosal was a toxic substance cannot alone support extreme and outrageous conduct where defendants' affirmative matter established that under the requisite federal regulations, the FDA determined that the amount of thimerosal used was "sufficiently nontoxic." See 21 C.F.R. §610.15(a) (2006). Thus, it cannot be said that defendants' actions in manufacturing or distributing FDA-approved vaccines to Christopher rose to the level of extreme and outrageous conduct or that severe emotional distress was substantially certain to result from their conduct. Accordingly, the trial court properly dismissed the intentional infliction of emotional distress count as a matter of law pursuant to section 2-619(a)(9). 735 ILCS 5/2-619(a)(9) (West 2004). Due to our disposition, we need not address defendants' motion pursuant to section 2-615 of the Code.

For all of the foregoing reasons, we affirm the circuit court order dismissing the representative claims brought on behalf of Christopher against the vaccine manufacturers for lack of subject matter jurisdiction, but reverse that part of the order as it relates to the thimerosal manufacturers, and affirm the dismissal of count VII for intentional infliction of emotional distress.

Affirmed in part and reversed in part; cause remanded in part. QUINN, P.J., and CUNNINGHAM, J., concur.