United States Court of Appeals
Fifth Circuit
F I L E D
August 16, 2004
Charles R. Fulbruge III
Clerk

In the United States Court of Appeals for the Fifth Circuit

No. 03-30958

SCOTT MOSS, INDIVIDUALLY AND ON BEHALF OF AMBER MOSS;
JANICE MOSS,

Plaintiffs-Appellants,

VERSUS

MERCK & COMPANY, ET AL.,

Defendants,

MERCK & COMPANY,
AVENTIS PASTEUR INC.,
INDIVIDUALLY AND AS SUCCESSOR IN INTEREST,
ALSO KNOWN AS CONNAUGHT LABORATORIES INC.,
ALSO KNOWN AS PASTEUR MERIEUX, ALSO KNOWN AS PASTEUR MERIEUX CONNAUGHT;
ELI LILLY & COMPANY, AND WYETH,

Defendants-Appellees,

Appeal from the United States District Court
for the Western District of Louisiana

Before SMITH, BENAVIDES, and PICKERING, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

Plaintiffs Scott and Janice Moss ("the Mosses"), the parents of a young child who, they allege, developed autism as a result of receiving vaccines containing mercury, wish to pursue state law tort claims for injuries they suffered as a result of the child's condition. Although their claims are not barred by the literal terms of the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act"), 42 U.S.C. § 300aa-1 *et seq*., defendants urge the alternate theories that the statute is broad enough implicitly to preempt any claims it fails directly to address, and that the purpose of the statute requires us to construe its express terms broadly and in a way that robs the plaintiffs of the right to sue.

In the district court, defendants Merck & Company, Aventis Pasteur Inc., and Wyeth, Inc. (the "Vaccine Defendants"), obtained a dismissal on the ground that the Vaccine Act precludes the Mosses' pursuit of a tort remedy for a vaccine-related injury. *Cf.* FED. R. CIV. P. 12(b)(1). Defendant Eli Lilly & Company ("Eli Lilly"), the manufacturer of Thimerosal, the mercury-containing preservative used in several childhood vaccines, obtained a dismissal on the ground that it too is a vaccine manufacturer entitled to the protections of the Vaccine Act. Relying on the text of the statute and eschewing the defendants' invitation to rewrite a complex federal regulatory scheme to suit their purposes, we reverse and remand with instruction.

I.

A.

Eli Lilly seeks to be treated on like terms as the Vaccine Defendants. Because Thimerosal is not a vaccine, its producers are not vaccine manufacturers as that term is defined in the Vaccine Act, 42 U.S.C. § 300aa-33(3), so they are not entitled to the protections of the Act's restriction on the filing of suits.[1]

The Vaccine Act is a remedial program designed to provide swift compensation for persons injured by vaccines, while ensuring that the nation's supply of vaccines isn't unduly threatened by the costs and risks of tort litigation. To that end, victims of a "vaccine-related injury or death," as that term is defined in 42 U.S.C. § 300aa-33(5), are barred from seeking redress in the courts unless they have first filed a claim for recovery in a specialized Vaccine Court.[2] *See* § 300aa-11(a)(2)A).

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[1] The Mosses initially pursued claims against Eli Lilly for Amber's injuries as well as their own, but withdrew all except the claims seeking redress for injuries incurred in a personal capacity, primarily through loss of consortium with Amber. We reject the Vaccine Defendants' contention, premised on a strained construction of § 300aa-11(a)(2)(B), that the entire suit should be dismissed because it once contained claims that did not properly belong in federal court. Even assuming Amber could not pursue her claims against Eli Lilly in federal court (a proposition we need not decide but is nevertheless strongly in doubt given our conclusion that Eli Lilly is not a vaccine manufacturer), the district court did not abuse its discretion in allowing the Mosses to amend their pleadings. *Cf. Bass v. Parkwood Hosp.*, 180 F.3d 234, 241 (5th Cir. 1999).

[2] We use the term "Vaccine Court" as shorthand for the adjudicative procedures set up for (continued...)

Operating under lower standards of proof, claimants can seek a compensatory award from the government, acceptance of which causes them to waive any further tort rights. *See* § 300aa-21(a). The claimant may instead decline the award and pursue traditional tort relief, but with certain restrictions such as an inability to recover punitive damages. *See* §§ 300aa-21(a), 300aa-22. *See also Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.) (detailing the restrictions on suits).

The Vaccine Act does not apply to all vaccine-related lawsuits, however, but only those brought against a "vaccine administrator or manufacturer." § 300aa-11(a)(2)(A). The Act defines "vaccine 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." § 300aa-33(3). Still, the statute does not define the term "vaccine," requiring us to ascertain the meaning of that word through ordinary principles of statutory construction. In the absence of a controlling definition, we interpret statutes according to their plain, ordinary meaning.[3]

Under the plain meaning of the Vaccine Act, Eli Lilly is not a vaccine manufacturer, so the Mosses are not barred from suing it. It is settled that Thimerosal, when used as a preservative, is a component of a vaccine rather than an adulterant. *Leroy v. Sec'y of Health & Human Servs.*, 2002 U.S. Claims LEXIS 284, *18-*19 (Fed. Cl. 2002) (citing cases). Nonetheless, its status as a vaccine component no more makes Thimerosal a "vaccine" than does the inclusion of a piston under the hood of an automobile make that object an "engine."

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, Thimerosal is not sold as a vaccine, nor is it listed in the statute's table.

If a plaintiff is able to trace his injury to the manufacturer of a chemical that does not, in and of itself, qualify for protection under the Vaccine Act, there is nothing in the Act that prevents him from going to court and attempting to prove that his injuries were caused by that chemical. The burden of proof at trial may be complicated by the difficulty inherent in demonstrating that the injury was proximately caused by that singular component, rather than the vaccine itself, but this does not mean the Vaccine Act prevents plaintiffs from trying; it only prohibits them from filing the Thimerosal-based claim against the manufacturer of a vaccine, something Eli Lilly cannot claim to be solely on the basis of its manufacture of Thimerosal.

B.

Eli Lilly argues that our conclusion contradicts the Vaccine Court's analysis in *Leroy*. Specifically, it reads *Leroy* as having decided that victims of Thimerosal-related injuries are free to pursue claims for relief in the Vaccine

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[2](...continued)
processing claims under the Vaccine Act. *See* 42 U.S.C.§ 300aa-12. The "Vaccine Court" consists of a special master under the jurisdiction of the Court of Federal Claims.

[3] *Pioneer Inv. Servs. Co. v. Brunswick Assocs. Limited P'ship*, 507 U.S. 380, 388 (1993); *Conn. Bank of Commerce v. Republic of Congo*, 309 F.3d 240, 260 (5th Cir. 2002).

Court, and that today's decision gives rise to the prospect of double recovery.

We disagree. In *Leroy*, the Vaccine Court was presented with a jurisdictional challenge premised on the notion that Thimerosal is present in vaccines only as an adulterant or contaminant. *Leroy*, 2002 U.S. Claims LEXIS 284, at *10. Because the Vaccine Act does not apply to injuries caused by those sorts of impurities, *see* § 300aa-33(5), the classification of Thimerosal under one of those headings would have left plaintiffs free to sue vaccine manufacturers in traditional courts so long as they argued that it was the Thimerosal and not the vaccine that caused their injuries. The Vaccine Court rejected the challenge, however, concluding that Thimerosal is a component of the vaccines in which it is found. *Id.* at *27-*29. As a result, the Vaccine Court concluded, the Vaccine Act encompasses claims filed *against a manufacturer or administrator* of a vaccine premised on the allegation that an injury was caused by a vaccine containing Thimerosal. *Id.* at *66.

Leroy, therefore, stands for nothing more than the unremarkable proposition that a Thimerosal-related injury, occurring as a result of the administration of a vaccine, is a vaccine-related injury within the meaning of the Vaccine Act. That does not end our inquiry, however, because a claim is barred under the statute only if it alleges a vaccine-related injury and is filed against a vaccine manufacturer. § 300aa-11(a)(2)(A). It is this latter requirement that Eli Lilly fails to meet, and, as a result, the Vaccine Act affords it no cover from the Mosses' claims.

II.

The Mosses' suit against the Vaccine Defendants relies on Louisiana tort law and seeks recompense for injuries incurred in a personal capacity. Just as the Vaccine Act does not protect all defendants, it does not apply to all tort suits having some connection to the administration of a vaccine. Rather, the restriction on filing tort claims applies only to those who have "sustained a vaccine-related injury or death and who [are] qualified to file a petition for compensation under the Program." § 300aa-11(a)(9). In this way, the Vaccine Act treats "the tort suit procedural bar and Vaccine Court compensation as opposite sides of the same coin." *Schafer*, 20 F.3d at 5. The program delays the filing of only those tort claims for which it first provides an alternate source of compensation.

To file a petition for compensation, a claimant must be either a person who has sustained a vaccine-related injury, orSSif the victim is a minor, disabled or deceasedSSthat person's legal representative. § 300aa-11(b)(1)(A). Any person who fits one of those descriptions and "meets the requirements of subsection (c)(1) of this section" may file a petition for compensation. *Id.*

Of singular importance is the requirement in § 300aa-11(c)(1)(A) that the claimant be able to state in an affidavit that he "received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine." Because Scott and Janice Moss neither received a vaccine nor contracted polio from someone who did, they are unable to satisfy the requirements of subsection (c)(1). As a result, they are ineligible to file a petition, *see* § 300aa-11(b)(1)(a), and the Vaccine Act's restriction on the filing of tort suits does not

apply to them, *see* § 300aa-11(a)(9).[4]

That much is plain on the face of the statute, but the lack of statutory ambiguity does not stop the Vaccine Defendants from arguing that a literal application of the regulatory scheme "will thwart the intent and purpose of the Act, and interfere with its operation." Because the Vaccine Act was motivated by a desire to unburden vaccine manufacturers from the costs and risks of tort litigation, the argument goes, the Act should be construed as barring those claims as well.

We disagree. If it is indeed the case that loss-of-consortium claims frustrate this complex federal regime, Congress can enact a change. For all we know, this possibility *was* considered, and a conscious decision was made not to regulate consortium claims. Either way, it is not for this court to decide what Congress should have done, but only to apply a statute that on its face has nothing to say about consortium claims. Because the Vaccine Act neither provides a mechanism for their recovery on a loss of consortium suit, nor openly bars their right to pursue remedies afforded by state tort law, the Mosses may pursue their claims.[5]

As an alternate strain of their defense, the Vaccine Defendants contend that the district court properly dismissed the Mosses' claims because they are implicitly preempted by the Vaccine Act. We reject this argument, too, for we will not lightly infer that Congress has implicitly preempted state claims using an instrument that explicitly preempts other claims, s*ee, e.g., Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995), and the Vaccine Defendants offer no persuasive reason to make that inferential leap in this case. *Accord Schafer*, 20 F.3d at 6-7.

Congress could not have been much more plain in its desire *not* to preempt tort claims filed by persons who are ineligible to recover in the Vaccine Court.[6] We therefore agree with the First Circuit thatSSassuming *arguendo* that state tort law permits claims for loss of consortium (and about which we express no opinion)SSthere is nothing in the Vaccine Act that implicitly or explicitly prevents this suit from going forward. *Schafer*, 20 F.3d at 2.

III.

For the foregoing reasons, the judgment is REVERSED and the Mosses' claims reinstated. At oral argument, the Mosses represented that they would be satisfied with an order staying their suit until the Vaccine Court renders a

[4] The Mosses are eligible to file a claim with the Vaccine Court, but only in their capacity as Amber's legal representatives, and only to seek redress of her injuries. *See* § 300aa-11(b)(1)(A); *Head v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 546, 547 n.1 (1992).

[5] It is also far from obvious that this result will wreak the apocalyptic results foretold by the Vaccine Defendants. The same observation was made in *Schafer*, with a concurrence openly calling on Congress to revisit the issue. *Schafer*, 20 F.3d at 7 (Stahl, J., concurring). In light of the fact that (continued...)

[5](...continued)
Congress took no action to amend the statute in the intervening decade, it is not unreasonable to conclude that the consequences of today's holding are not so extreme as the Vaccine Defendants would have us believe.

[6] *Cf.* § 300aa-11(a)(9) ("This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.").

decision on the award, if any, to Amber. The case is therefore REMANDED with instruction to stay the proceeding pending a result in the Vaccine Court, and for any further proceedings that are not inconsistent with this opinion.