United States Court of Appeals,

Fifth Circuit.

No. 94-30668

Summary Calendar.

Edward A. LEWIS, Plaintiff-Appellee,

v.

INTERMEDICS INTRAOCULAR, INC., Defendant-Appellant.

Louis ANGELLE, Plaintiff-Appellee,

v.

INTERMEDICS INTRAOCULAR, INC., Defendant-Appellant.

Joseph FERRARA, Plaintiff-Appellee,

v.

INTERMEDICS INTRAOCULAR, INC., Defendant-Appellant.

Joseph CARONIA, etc., Plaintiff-Appellee,

v.

INTERMEDICS INTRAOCULAR, INC., Defendant-Appellant.

Christopher BORDENAVE, Jr., etc., et al., Plaintiffs-Appellees,

v.

INTERMEDICS INTRAOCULAR, INC., Defendant-Appellant.

July 6, 1995.

Appeal from United States District Court for the Eastern District of Louisiana.

Before DUHÉ, WIENER and STEWART, Circuit Judges.

STEWART, Circuit Judge:

This appeal encompasses five consolidated personal injury actions which were originally filed in Louisiana state court but were removed to federal district court on the basis of diversity.

The suits arose because of problems plaintiffs allegedly suffered from intraocular lenses which had been surgically implanted into their eyes as treatment for their cataracts. The lenses were all manufactured by Intraocular Intermedics, defendant-appellant.

Congress enacted the Medical Device Amendments of 1976 (MDA) in order to vest regulatory power over medical devices in the Food and Drug Administration (FDA). The MDA established three categories of medical devices, each with different pre-marketing requirements, based upon the degree of risk to the public health and safety. The intraocular lenses in question are classified as Class III devices under the MDA. Class III devices receive the most rigorous level of scrutiny by the FDA. Usually, manufacturers of Class III devices must submit an extensive application for pre-market approval before such devices can be marketed. However, the Investigational Device Exemption (IDE), 21 U.S.C. § 360j(g), allows the FDA to exempt qualified devices from the requirements of the MDA. Thus, under the IDE a device may be marketed even though its safety and effectiveness have not been proven to the FDA. The FDA granted such an IDE to intraocular lenses and adopted federal regulations governing their clinical investigation. Pursuant to the federal regulations, intraocular lenses were to be tested on cataract patients who gave their informed consent for the lenses to be tested.

Each of the plaintiffs had intraocular lenses surgically implanted into their eyes. They all have allegedly encountered problems with them. Plaintiffs' suits allege that the lenses are

defective in design and manufacture and that Intermedics failed to properly warn them of alleged design and manufacturing defects and failed to inform them that the lenses were experimental and that there were alternative choices for cataract treatment. They allege that Intermedics is liable both under a theory of strict liability and for breach of warranty, either express or implied. Plaintiffs seek compensatory and punitive damages. In addition to asserting the state products liability-type causes of action described above, plaintiffs also state claims based upon various federal regulations.

Intermedics filed a motion for summary judgment, contending that all of plaintiffs' state tort claims regarding the safety and effectiveness of the lenses are preempted by the MDA. *See* 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(b). Plaintiffs opposed the motion, arguing that Congressional intent with respect to the IDE was not to preempt state tort law claims, but to encourage discovery and development of useful medical devices and to protect the public health. The FDA did not provide remedies for the public in the event of injury; therefore, plaintiff contends there is no federal preemption of remedies for damages caused by intraocular lenses.

The district court dismissed all of plaintiffs' state tort claims except those relating to the duty to obtain informed consent, because it concluded that federal law preempts any state law claim relating to the safety and effectiveness of the lenses. In so doing, the court relied upon a case from the Seventh Circuit

involving the issue of such federal pre-emption in the field of intraocular lenses, *Slater v. Optical Radiation Corp.,* 961 F.2d 1330 (7th Cir.), *cert. denied,* --- U.S. ----, 113 S.Ct. 327, 121 L.Ed.2d 246 (1992). In *Slater,* the plaintiff alleged injury to his eye caused by the implantation and removal of a defective anterior-chamber intraocular lens. The plaintiff alleged negligence relating to the testing, safety, and effectiveness of the lens, inadequate clinical testing, defective design, failure to warn, strict products liability, and breach of implied warranty.

The Seventh Circuit held that all of plaintiff's claims were state law claims relating to the safety or effectiveness of the lens, which claims were different from or in addition to federal law claims. Thus, the appellate court held that plaintiff's state law claims were preempted by federal law. *Id.* at 1333. However, the Seventh Circuit clearly stated that pre-emption of state claims is not unlimited:

> [Pre-emption] does not affect cases charging negligence in the implantation or removal of a lens, or complaining of contamination of the lens by bacteria or fungi or of *failure to obtain the patient's informed consent to the procedure.*

Id. at 1334 (emphasis added).

The district court in the instant cases viewed the above language from the Seventh Circuit in *Slater* as persuasive and accordingly held that all of plaintiffs' claims except those relating to informed consent are preempted. The court based its determination on its finding that Congress clearly intended the federal government to be the sole governmental body regulating the safety and effectiveness of intraocular lenses, as evidenced by its

passage of the MDA. Because the products liability-type claims clearly related to the safety and effectiveness of the intraocular lenses themselves, those claims are preempted. However, the court concluded that failure to obtain informed consent does not relate directly to the safety and effectiveness of the lenses; thus, the district court excepted the informed consent claims from dismissal.

Intermedics subsequently urged the court to reconsider its ruling as to the informed consent claim in light of the Third Circuit's decision in *Gile v. Optical Radiation Corp.,* 22 F.3d 540 (3d Cir.), *cert. denied,* --- U.S. ----, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994). In *Gile,* the court addressed the question of whether a patient who had received an intraocular lens had a cause of action against the manufacturer based on an alleged failure to obtain informed consent. Our colleagues of the Third Circuit disallowed the claim because the plaintiff could not provide any support for her contention that she was entitled to bring an informed consent claim against the manufacturer under state law. The district court in the case at bar distinguished *Gile* and refused to dismiss the informed consent claim because it found that authority for plaintiffs' informed consent claims could be found in Louisiana Civil Code art. 2315. The district court allowed Intermedics to take an interlocutory appeal pertaining to the issue of whether federal law preempts plaintiffs' state law informed consent claims. *See* 28 U.S.C. § 1292(b).

We have reviewed *Slater* and *Gile* closely and have carefully considered whether plaintiffs can make out any state law cause of

action against a manufacturer for failure to obtain informed consent. We note at the outset that the above-cited language from *Slater* relating to informed consent is mere *dicta* because the plaintiff there did not argue that he did not give informed consent. Moreover, we believe that, in the above passage from *Slater* which refers to informed consent, the Court was merely pointing out that any claim which a plaintiff might have against a health care provider for malpractice or battery would not be preempted. The types of cases cited by the court which would not be preempted were predominantly claims that necessarily would be filed against the *physician,* not the manufacturer. For example, "cases charging negligence in the implantation or removal of a lens," *Id.,* clearly refers to malpractice actions, which can only be filed against a physician or health care provider, not a manufacturer. The court also noted that the tort of medical battery would not appear to be preempted by the MDA if a surgeon were to implant a lens without the patient's consent. However, such a claim clearly would be one against the *physician,* not a manufacturer of the product. *Gile* made this same observation.

The parties have briefed extensively the issue of whether the MDA preempts plaintiffs' state informed consent claims. However, before reaching the pre-emption issue we have to determine that, in the first instance, Louisiana law provides plaintiffs with a cause of action against a manufacturer for failure to obtain informed consent. In other words, the question of pre-emption is irrelevant if there is no otherwise applicable state informed consent claim

which could be preempted by the MDA. Thus, we conclude that if Louisiana does not recognize a cause of action for failure to obtain informed consent against a manufacturer, then Intermedics is entitled to summary judgment on these claims.

Does Louisiana recognize a cause of action for informed consent against a manufacturer?

Plaintiffs have sued under both the Louisiana Products Liability Act and La.Civ.C. art. 2315. However, on appeal plaintiffs argue that the Louisiana Products Liability Act is not applicable because the intraocular lenses were implanted in plaintiffs' eyes prior to the effective date of the Act, September 1, 1988.

The Louisiana Products Liability Act (LPLA), La.R.S. 9:2800.51, *et seq.,* "... establishes the exclusive theories of liability for manufacturers for damage caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in [the LPLA]." La.R.S. 9:2800.52. Thus, if the LPLA were applicable to this case, the text of La.R.S. 9:2800.52 would clearly preclude plaintiffs' cause of action against Intermedics for failure to obtain informed consent, because the LPLA contains no provision for such a cause of action. *See* 9:2800.51, *et seq.*

However, we cannot take such an easy path in our resolution of this pre-LPLA case. The LPLA does not apply retroactively to causes of action which accrued prior to the effective date of the Act. *Brown v. R.J. Reynolds Tobacco Co.,* 52 F.3d 524, 527 (5th Cir.1995); *Cates v. Sears, Roebuck & Co.,* 928 F.2d 679, 683 (5th

Cir.1991). The plaintiffs' claims for failure to obtain informed consent would have "accrued" at the time the manufacturer allegedly failed to obtain informed consent. In this case, that appears to have been prior to 1988 for all plaintiffs. Thus, the LPLA does not appear to be applicable.

Prior to the passage of the LPLA, legislative authority for all product liability-type claims flowed from Louisiana Civil Code Article 2315, Louisiana's general tort liability statutory provision. Article 2315 provides, in relevant part:

> Every act whatever of man that causes damage to another obliges him by whose fault it happened to repair it.

The very general wording of art. 2315 provides very little instruction as to whether a cause of action may be maintained under it for a manufacturer's failure to obtain informed consent. We have found no Louisiana cases which would support such a claim against a manufacturer. Thus, at first it seems unclear whether a manufacturer has a tort duty under Louisiana state law to obtain informed consent. However, for elaboration we do not resort to the common law in other states. Louisiana, being a Civil Law state, would not recognize a common law duty on the part of a manufacturer to obtain informed consent.[1] Thus, even if under the common law in other states such a duty exists, Louisiana would not necessarily

[1]In Louisiana, case law is not considered positive law. *See* La.Civ.C. art. 1. Even jurisprudence from within this civilian jurisdiction is not considered binding authority on other Louisiana courts, because Louisiana does not recognize *stare decisis. A fortiori,* common law concepts developed through the case law in other jurisdictions would not be binding on Louisiana courts. *See Principal Health Care of La., Inc. v. Lewer,* 38 F.3d 240, 245, n. 5 (5th Cir.1984).

allow it.

However, notwithstanding the very general language in art. 2315, the Louisiana legislature has spoken specifically on the issue of informed consent in another statute. Louisiana Revised Statutes 40:1299.40 outlines the procedures by which patients in Louisiana are to be informed of the risks of medical treatment and also governs tort suits against a "physician or other health care provider" for failure to obtain informed consent. The Louisiana Uniform Consent Law, La.R.S. 40:1299.40 clearly does not apply to manufacturers. Although plaintiffs might argue that Intermedics might qualify as some "other health care provider" under the statute, the 1990 amendments to the statute and the case law do not support such a view. The statute was amended in 1990 to make it clear that only a physician or health care provider who will actually perform the procedure is required to obtain informed consent. *Davis v. St. Charles Gen. Hosp.,* 598 So.2d 1244 (La.App. 4th Cir.1992), was decided based upon the law as it was worded prior to the 1990 amendment, just as this case will be. *Davis* held that a referring physician had no duty to obtain informed consent. If a referring physician has no duty, *a fortiori,* a manufacturer has no duty under state law. Thus, there can be no recovery against a manufacturer under the Uniform Consent Statute.

Louisiana Revised Statutes 40:1299.40 is a more specific law than the very general tort provision, La.Civ.C. art. 2315; thus, we conclude that Louisiana provides no cause of action against a manufacturer for failure to obtain informed consent. The maxim

"*lex generalis non derogat speciali*" implies that a special law controls as to the particular matter made the subject of special legislation. *Louisiana Imp. Co. v. Baton Rouge Elec. & Gas Co.,* 114 La. 534, 38 So. 444 (1905). The Uniform Consent Law, La.R.S. 40:1299.40, is special legislation aimed specifically at the duty to obtain informed consent; therefore, it should be applied to this issue rather than Article 2315, which is very general. Because "legislation is the solemn expression of legislative will," *see* La.Civ.C. art. 2, we do not find that the legislature intended for art. 2315 to serve as a catch-all to maintain plaintiffs' causes of action against the manufacturer when the very specific informed consent law clearly excludes such claims.

This conclusion also makes sense when considered against the backdrop of products liability-type claims which plaintiffs have asserted and which were dismissed by the district court because they are preempted by federal law. Even if we were to conclude that plaintiffs' claim that the manufacturer failed to obtain informed consent could be analogized to a products liability claim for failure to warn of a product's dangers, plaintiffs still could not maintain their claims. If plaintiffs' products liability claims for recovery due to the lenses' dangers are preempted, then it would seem ridiculous to say that a claim for failure to warn about these dangers could survive. In other words, if a claim for damages due to the dangers *themselves* cannot survive, *a fortiori,* a claim for failure to warn of the dangers should not be cognizable.

Moreover, we also note that *Gile* provides support for our determination that an informed consent claim does not automatically flow from an assertion of negligence. In *Gile,* the plaintiff asserted both negligence and products liability claims against the manufacturer, but the court determined that she stated no state law claim, because the duty to obtain informed consent is imposed upon the physician, not the manufacturer. Although *Gile* did not arise in Louisiana, it is illustrative of the concept that a general tort duty not to be negligent is not enough to bring a manufacturer within the purview of an informed consent claim.

Based upon the above, we conclude that Louisiana law does not recognize plaintiffs' state claims against Intermedics for failure to obtain informed consent. It is irrelevant to our inquiry whether *Slater* is correct in its view that a state law claim for failure to obtain informed consent is preempted by federal law, because in the first instance Louisiana does not recognize a cause of action against a manufacturer for failure to obtain informed consent *which could be preempted* by federal law. The district court erred in denying Intermedics' summary judgment as to the informed consent claims. The only remaining claims are based upon the federal regulations which Intermedics allegedly violated in not obtaining informed consent *as required by federal law*. These claims were not the subject of the instant motion for summary judgment. Although plaintiffs' seemingly conceded in this appeal that Congress did not provide them with a private right of action against Intermedics for violation of the federal regulations, we do

not deal with the remaining federal law claims because they were not the subject of this appeal.

Conclusion

Based upon the foregoing, we REVERSE the district court's denial of Intermedics' motion for summary judgment as to plaintiffs' state law informed consent claims, we RENDER summary judgment as to those claims, and REMAND for a determination of plaintiffs' rights in their remaining claims against Intermedics under federal law.

Motion to Strike

Plaintiffs have filed a motion to strike portions of Intermedics' reply brief which relate to the pre-emption issue. Because our resolution of the case on state law grounds pretermits a discussion of preemption, the motion to strike is DISMISSED as moot.