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Commonwealth of Kentucky

Court of Appeals

NO. 2015-CA-001103-MR

JOYCE CALES AND
JACK CALES — APPELLANTS

v.

APPEAL FROM FAYETTE CIRCUIT COURT
HONORABLE PAMELA R. GOODWINE, JUDGE
ACTION NO. 14-CI-01774

BAPTIST HEALTHCARE SYSTEM, INC.,
D/B/A CENTRAL BAPTIST HOSPITAL — APPELLEE

OPINION
AFFIRMING IN PART AND
REVERSING AND REMANDING

** ** ** ** **

BEFORE: KRAMER, CHIEF JUDGE; NICKELL AND THOMPSON, JUDGES.

THOMPSON, JUDGE: The appellants, Joyce Cales and Jack Cales, filed this action against Medtronic Inc., and Medtronic Sofamor Danek USA (collectively referred to as Medtronic) and Baptist Healthcare System, Inc., d/b/a Central Baptist

Hospital. At the center of the litigation is the off-label use of a bone morphogentic protein (BMP) combined with a Peek Capstone surgical fusion cage.[1]

The Fayette Circuit Court granted Baptist Healthcare's motion to dismiss filed pursuant to Kentucky Rules of Civil Procedure (CR) 12.02 on the basis that the appellants' product liability claims are pre-empted by federal law. It further held that if not pre-empted, their product liability claims are precluded by Kentucky's "middleman" statute contained in Kentucky's Product Liability Act. Addressing the medical negligence claim, the circuit court ruled that Baptist Healthcare had no duty to inform Joyce of the Federal Drug Administration (FDA) regulatory status of a medical device used in her surgery. We agree with the circuit court that the appellants cannot maintain their product liability claims but reverse its conclusion that the medical negligence claim cannot be maintained.

To understand the context in which we write, it is necessary to summarize the federal statutory and regulatory scheme applicable to the introduction of new medical devices into the marketplace. Prior to 1976, "the introduction of new medical devices was left largely to the States to supervise as they saw fit." *Riegel v. Medtronic, Inc*., 552 U.S. 312, 315, 128 S.Ct. 999, 1002, 169 L.Ed.2d 892 (2008). However, with the enactment of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360, *et seq.,* through the FDA, the federal government now has authority to oversee such devices.

[1] As commonly understood and agreed to by the parties, an off-label use is when a medical device is used for a "purpose not approved by the U.S. Food and Drug Administration[.]" *United States v. Caronia*, 703 F.3d 149, 152 (2d Cir. 2012).

Under the MDA, medical devices are regulated by the federal government and divided into three classes. Class III devices, those that present a "potential unreasonable risk of illness or injury," 21 U.S.C. § 360c(a)(1)(C)(ii), undergo a rigorous premarket approval process. *Riegel*, 552 U.S. at 317, 128 S.Ct. at 1004.

In *Riegel*, the Supreme Court provided a summary of the requirements to obtain premarket approval of a Class III device and the contents of the premarket application:

> It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling.

Id. at 318, 128 S.Ct. at 1004 (quoting 21 U.S.C. § 360e(c)(1)). Premarket approval is granted only if "there is a 'reasonable assurance' of the device's 'safety and effectiveness[.]'" *Id*. (quoting 21 U.S.C. §360e(d)).

"Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319, 128 S.Ct. at 1005 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Any change must be submitted to and approved by the FDA

and "evaluated under largely the same criteria as an initial application." *Id.* (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)).

Notably, approval by the FDA of a medical device does not preclude off-label use by health care providers. In fact, the MDA "expressly disclaims any intent to directly regulate the practice of medicine[.]" *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 350-51, 121 S.Ct. 1012, 1018-19, 148 L.Ed.2d 854 (2001) (citing 21 U.S.C. § 396 (1994 Ed. Supp. V)). "Once the FDA has cleared a device for introduction into the stream of commerce, physicians may use the device in any manner they determine to be for the best for the patient, regardless of whether the FDA has approved the device for this usage." *Cooper v. Smith & Nephew, Inc*., 259 F.3d 194, 197 (4th Cir. 2001).

APPROVAL OF THE INFUSE DEVICE

Medtronic is the manufacturer of the Infuse Device which is an implantable device. As a medical system, it consists of BMP, a collagen sponge, (referred together as the BMP/Sponge) and a titanium cage called an LT-Cage. In July 2002, the FDA approved the Infuse Device for use in anterior lumber-inter-body fusion procedures, a lumbar surgery performed through the abdomen and which involves a single level fusion in the L4-S1 region of the lumbar spine. The labeling for the Infuse Device, as approved by the FDA, provides: "These components *must* be used as a system. The Infuse® Bone Graft component *must not* be used without the LT–Cage™ Lumbar Tapered Fusion Device Component." The LT-Cage is designed to prevent excess bone growth.

JOYCE CALES'S SURGERY AND ALLEGED INJURY

On June 24, 2014, Joyce underwent lumbar fusion surgery at Central Baptist Hospital. Dr. Stephen Keifer performed a transforaminal lumbar inter-body fusion at L4-S using a Capstone fusion cage packed with the BMP/Sponge. Unlike the LT-Cage, which is a Class III surgical cage, the Capstone Cage is a Class II cage. Joyce alleges that the Class II cage should have been used only in conjunction with her own bone to generate bone growth and not with the BMP/Sponge.

THE COMPLAINT

The appellants filed a 197-page complaint against Baptist Healthcare and multiple Medtronic entities and individuals. For our purposes, it is only necessary to discuss the allegations against Baptist Healthcare.[2] Only for the purposes of this appeal, we have accepted as true the allegation in the complaint that Dr. Keifer is an agent of Baptist Healthcare.

The complaint alleges two claims based on product liability against Baptist Healthcare. The first is based on strict liability alleging that Baptist Healthcare purchased only a portion of the Infuse Device—the BMP/Sponge—from Medtronic and, as used in Joyce's surgery, the BMP/Sponge was unreasonably dangerous and defective. The second product liability claim is for "Negligence-Product Liability for Reseller of Medical Products." The complaint alleges Baptist Healthcare had a duty to act as a reasonably prudent hospital in the same or similar

[2] The trial court granted the Medtronic's motion to dismiss in a non-final order. Those defendants are not parties to this appeal.

circumstances in reselling a medical device. It further alleges that in reselling the BMP/Sponge, it knew or should have known that the device would be used off-label.

In addition to the product liability claims, the complaint alleges medical negligence. The appellants allege Baptist Healthcare knew or should have known of the risks of using the BMP/Sponge with the Capstone Cage and that Joyce would not have consented to the off-label use had she been fully informed of the risks by Baptist Healthcare.

Based on the same allegations, Jack claims damages for loss of consortium.

STANDARD FOR MOTION TO DISMISS

The issue before us is whether the circuit court properly dismissed the appellants' product liability claims and claim for medical negligence against Baptist Healthcare. A motion to dismiss based on the failure to state a claim may be granted only if "it appears the pleading party would not be entitled to relief under any set of facts which could be proved in support of his claim." *Pari–Mutuel Clerks' Union of Kentucky, Local 541, SEIU, AFL–CIO v. Kentucky Jockey Club,* 551 S.W.2d 801, 803 (Ky. 1977). "Stated another way, the court must ask if the facts alleged in the complaint can be proved, would the plaintiff be entitled to relief?" *James v. Wilson*, 95 S.W.3d 875, 884 (Ky.App. 2002).

FEDERAL PRE-EMPTION OF THE PRODUCT LIABILITY CLAIMS

Baptist Healthcare argues that after the Infuse Device was approved by FDA, as a healthcare provider, it could then use the device in any manner deemed appropriate including off-label uses. It contends that the product liability claims are covered by the MDA and any law to the contrary is pre-empted.

The pre-emption rule is derived from the Supremacy Clause contained in Article VI cl. 2 of the United States Constitution which establishes that the laws of the United States are "the supreme law of the land" and state laws that conflict with federal laws or regulations are pre-empted. *Malone v. White Motor Corp.,* 435 U.S. 497, 504, 98 S.Ct. 1185, 1190, 55 L.Ed.2d 443 (1978). If Baptist Healthcare is correct, the product liability claims were properly dismissed.

Federal law may pre-empt state law either by express pre-emption language or, "[i]n the absence of express pre-emptive language, Congress' intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." *Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713, 105 S.Ct. 2371, 2375, 85 L.Ed.2d 714 (1985). Therefore, a state law is pre-empted even if not completely displaced by a federal law or regulation, when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz,* 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed. 581 (1941).

In addition to its premarket approval requirements and detailed federal regulatory oversight, the MDA contains an express pre-emption provision which states:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[3]

21 U.S.C. § 360k(a).

As stated in *Worldwide Equip., Inc. v. Mullins*, 11 S.W.3d 50, 55 (Ky. App. 1999) (quoting *Restatement (Second) of Torts* § 402A (1965)): "The strict liability principle of section 402A describes a product as defective for purposes of the application of strict liability as one in a defective condition unreasonably dangerous to the user or consumer or to his property." The question is whether the FDA's approval of the Infuse Device pre-empts a product liability claim based on strict liability for the use of a component of that device.

Express pre-emption under the MDA was addressed in *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) and *Riegel.* In *Lohr,* the plaintiff asserted negligence claims alleging that Medtronic, the manufacturer, failed to warn the "plaintiff or her physicians of the tendency of [a]

[3] The exemption contained in subsection (b) does not apply in this case.

pacemaker to fail, despite knowledge of other earlier failures." *Lohr*, 518 U.S. at 481, 116 S.Ct. at 2248. The Court held "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties *when those duties parallel federal requirements*." *Id.* at 495, 116 S.Ct. at 2255. (Emphasis added). *Lohr* reasoned that the general duty to inform users of potentially dangerous aspects of a product is "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force." *Id.* at 501–02, 116 S.Ct. at 2258.

In *Riegel,* the Court dealt directly with the off-label use of an approved medical device. In that case, a catheter was inflated to a higher pressure than recommended on the FDA-approved label. Among their common law claims, the plaintiff's alleged "Medtronic's catheter was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries." *Riegel*, 552 U.S. at 320, 128 S. Ct. at 1005. The Court held the claims were pre-empted by the MDA because the state's common laws imposed more stringent safety requirements than federal law. *Id*. at 330, 128 S.Ct. 1011. In *Beavers-Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021, 1031 (D. Haw. 2014) (citation omitted) the Court summarized the *Riegel* decision:

> *Riegel* outlined that a state-law claim is expressly preempted by the MDA where (1) the FDA has established requirements applicable to the particular

> medical device at issue; and (2) the state common law claims seek to impose requirements that are 'different from, or in addition to' the federal requirements, and that relate to safety and effectiveness. In other words, any claim that a medical device 'violated state tort law notwithstanding compliance with the relevant federal requirements' is expressly preempted.

Infuse-Device related litigation, has been wide-spread across the nation and, claims based on product liability against Medtronic, have been mostly unsuccessful based on federal pre-emption. *See e.g., Houston v. Medtronic,* 957 F.Supp.2d 1166 (C.D. Cal. 2013); *Beavers-Gabriel*, 15 F.Supp.3d at 1040. Those Courts have reasoned that the MDA permits off-label uses and with the FDA's approval of a medical device, conclusively determined that it is not defective and unreasonably dangerous. Any state law or judicial determination to the contrary would impose requirements different from, or inconsistent to those established by the federal government. *Riegel*, 552 U.S. at 321-22, 128 S.Ct. at 1006.

The appellants distinguish these cases on the basis that their claim is against the healthcare provider, not the manufacturer. This distinction is of no avail. [4]

First, the only logical reading of 21 U.S.C. § 360k(a) is that the pre-emption analysis does not depend on how the device is used. It specifically states it pre-empts any requirement applicable "to the device." The Court in *Riley v. Cordis Corp.*, 625 F. Supp.2d 769, 779 (D. Minn. 2009) explained:

[4] We do not resolve the question of whether a hospital is a seller of a product. Resolution of that issue is unnecessary to reach our conclusion that a product liability claim cannot not be maintained under the circumstances.

> [U]nder § 360k(a)(1), the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable "to the *device.*" If there are—and, as *Riegel* makes clear, the [premarketing approval] process unquestionably imposes such requirements—then any state requirements that are different from, or in addition to, those federal requirements are preempted. Nothing in the statute suggests that the preemption analysis somehow depends on how the device is used.

We agree with the circuit court's conclusion that if pre-emption does not depend on how the device is used, it does not depend on who uses the device.

Regarding the product liability claim based on negligence, product liability law precludes the appellants' claim. Kentucky Revised Statutes (KRS) 411.340, part of the Kentucky Product Liability Act commonly referred to as the "middleman statute," provides:

> In any product liability action, if the manufacturer is identified and subject to the jurisdiction of the court, a wholesaler, distributor, or retailer who distributes or sells a product, upon his showing by a preponderance of the evidence that said product was sold by him in its original manufactured condition or package, or in the same condition such product was in when received by said wholesaler, distributor or retailer, shall not be liable to the plaintiff for damages arising solely from the distribution or sale of such product, unless such wholesaler, distributor or retailer, breached an express warranty or knew or should have known at the time of distribution or sale of such product that the product was in a defective condition, unreasonably dangerous to the user or consumer.

"[T]he 'middleman' provisions of the Kentucky Product Liability Act were designed to protect only those distributors, wholesalers, or retailers, who have no

independent responsibility for the design or manufacture of a product[.]" *West v. KKI, LLC*, 300 S.W.3d 184, 192 (Ky.App. 2008).

There is no dispute that Medtronic is subject to the jurisdiction of the courts or that the BMP/Sponge was "sold" to Joyce in its original condition. Moreover, the FDA approval pre-empts any contention that the BMP/Sponge was defective or unreasonably dangerous.

Before leaving the product liability issues, we make a closing comment. The problem with the appellants' product liability claims, as we understand the allegations, is that this is simply not a product liability claim. The appellants mistakenly confuse the "use" of a product with its "design." As stated in *Sexton By & Through Sexton v. Bell Helmets, Inc.,* 926 F.2d 331, 335 (4th Cir. 1991), a product liability claim based on a design defect, "whether based on a negligent breach of a duty of care or on strict liability, reduces to the single question of whether the product was defective." In other words, "a defective product is essential" to a strict liability or negligence claim. *Id*. at 336. The BMP/Sponge was not defective either as designed or when delivered to Joyce. The allegations concern its use by Baptist Healthcare. The allegations against Baptist Healthcare are more properly framed as medical negligence claims.

THE APPELLANTS' CLAIMS BASED ON MEDICAL NEGLIGENCE

The appellants allege medical negligence against Baptist Healthcare, including allegations that Baptist Healthcare was negligent in failing to inform

Joyce that the use of the BMP/Sponge with the Capstone Cage had not been approved by the FDA and that Dr. Kiefer's use of the BMP/Sponge was a deviation from the standard of care in light of information Baptist Healthcare knew or should have known at the time of the surgery. Unlike the product liability claims, the medical negligence claims are not pre-empted.

As noted, the MDA expressly provides that Congress did not intend to regulate the practice of medicine. *Buckman Co*., 531 U.S. at 350-51, 121 S.Ct. at 1018-19. Therefore, while a healthcare provider is free to use medical devices off-label and such uses are not inherently unreasonable or dangerous, the physician is held to the common law medical practice standards.

Additionally, KRS 304.40-320, the informed consent statute, provides:

> In any action brought for treating, examining, or operating on a claimant wherein the claimant's informed consent is an element, the claimant's informed consent shall be deemed to have been given where:
>
> (1) The action of the health care provider in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with the accepted standard of medical or dental practice among members of the profession with similar training and experience; and
>
> (2) A reasonable individual, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedure and medically or dentally acceptable alternative procedures or treatments and substantial risks and hazards inherent in the proposed treatment or

> procedures which are recognized among other health care providers who perform similar treatments or procedures;
>
> (3) In an emergency situation where consent of the patient cannot reasonably be obtained before providing health care services, there is no requirement that a health care provider obtain a previous consent.

The failure to obtain informed consent is an actionable form of medical negligence applicable to physicians as well as hospitals. *Keel v. St. Elizabeth Med. Ctr.,* 842 S.W.2d 860, 862 (Ky. 1992).

We disagree with Baptist Healthcare and the circuit court that Baptist Healthcare did not owe a duty to Joyce. First, we have assumed for purposes of reviewing the dismissal of the medical negligence claims, Dr. Keifer was an agent of Baptist Healthcare and acting as its agent. The duty of rendering ordinary professional care applicable to Dr. Keifer would likewise fall upon Baptist Healthcare. Moreover, "[i]nformed consent, or the lack thereof, plainly is an *element* in this medical malpractice action. KRS 304.40–320(1) clearly embodies the general duty we have long recognized in our tort law." *Sargent v. Shaffer*, 467 S.W.3d 198, 207 (Ky. 2015). The issue is not whether there was a duty: Assuredly there was. The issue as we see it is whether the federal government's approval of the Infuse Device establishes the standard of care owed by Baptist Healthcare.

Hyman & Armstrong, PSC v. Gunderson, 279 S.W.3d 93 (Ky. 2008), is instructive. In that case, Dr. Armstrong prescribed a drug conforming to its FDA-approved indicated uses. The plaintiffs' alleged Dr. Armstrong failed to consider

the full risks and benefits of the drug. A jury returned a verdict against Dr. Armstrong and the manufacturer.

Our Supreme Court rejected Dr. Armstrong's contention the FDA-approved labeling was conclusive evidence of his standard of care. In doing so it stated:

> [E]ven though a drug is approved by the FDA for a certain use and may not be contraindicated by the package insert, a reasonably prudent doctor still has to weigh the risks and benefits of the drug relative to a particular patient. [The] testimony [was] consistent with the majority view that while the information about the drug in the package insert and the [Physician's Desk Reference] is relevant and useful information regarding the prescribing physician's standard of care, it is not the sole determinant of the standard of care.

Id. at 114.

Based on similar reasoning, in *Niehoff v. Surgidev Corp*., 950 S.W.2d 816 (Ky. 1997), the Court held that a medical malpractice action could be sustained where there was a failure to obtain informed consent in the context of treating a patient with a medical device, marketed under an Investigational Device Exemption by the FDA. The Court discussed pre-emption by the MDA and, based on *Lohr,* concluded the medical negligence claim was not pre-empted. *Id*. at 822.

Despite Kentucky precedent, the trial court relied on two cases from other jurisdictions to support its conclusion: *Klein v. Biscup*, 673 N.E.2d 225 (Ohio App. 1996) and *Southard v. Temple Univ. Hosp*., 566 Pa. 335, 781 A.2d 101 (2001). Neither case is binding on this Court. To the extent either case holds, as a matter of law, that informed consent does not require that a patient be advised of

the off-label use of a medical device, we simply disagree. The off-label use of a medical device and the need to inform a patient of that use is a question of fact. As indicated by the "reasonable individual" standard in our implied consent statute, the materiality of the off-label use of a medical device or product is to be decided by the jury. The circuit court erroneously dismissed the medical negligence claim under CR 12.02. *James*, 95 S.W.3d at 884.

Baptist Healthcare argues that even if a cause of action for medical negligence can be maintained against it for medical negligence, the appellants' admissions in their complaint required dismissal of the medical malpractice claim. We disagree.

As we noted, the complaint was unusually lengthy with most of the allegations directed at the manufacturer, Medtronic. Baptist Healthcare singles out various allegations in the complaint against Medtronic which it contends precludes any medical negligence claim against it based on information Baptist Healthcare knew or should have known. Specifically, it argues the appellants' allegations that off-label use was common, Medtronic did not inform Dr. Keifer of the risks associated with the use of the BMP/Sponge without the LT-Cage and Medtronic actively misrepresented those risks to health care providers are inconsistent with their medical negligence claims.

Under Kentucky law, a complaint may state alternative causes of action even if inconsistent. CR 8.05(2) provides:

> A party may set forth two or more statements of a claim or defense alternately or hypothetically, either in one count or defense or in separate counts or defenses. When two or more statements are made in the alternative and one of them if made independently would be sufficient, the pleading is not made insufficient by the insufficiency of one or more of the alternative statements. A party may also state as many separate claims or defenses as he has regardless of consistency and whether based on legal or on equitable grounds or on both.

While the appellants' allegations against Medtronic and those against Baptist Healthcare are, in some respects inconsistent, alternative pleading is allowed under our rules. It is not a fatal flaw for appellants to assert Medtronic withheld information from the medical providers and, at the same time, allege Baptist Healthcare knew or should have known of the risks of using the BMP/Sponge with the Capstone Cage or that it should have informed Joyce of those risks.

CONCLUSION

Based on the foregoing, the order of the Fayette Circuit Court is affirmed in regard to the dismissal of the product liability claims. The order is reversed and remanded in regard to the medical negligence claims. The pending motion to strike portions of Baptist Healthcare's brief filed by the appellants is denied as moot.

KRAMER, CHIEF JUDGE, CONCURS.

NICKELL, JUDGE CONCURS AND FILES SEPARATE OPINION.

NICKELL, JUDGE, CONCURRING. I concur with the majority opinion's sound legal analysis. I write to underscore that federal pre-emption is independent of both *how* a device is used and *who* uses the device, and that product liability claims address *design defects* rather than product utilization or application. Regarding the medical negligence claim, I write to underscore that, for purposes of this appeal, we accept the allegation that Dr. Keifer was an agent of the hospital, and to acknowledge hospitals face increased liability exposure by hiring physicians as employees.

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