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# Commonwealth of Kentucky

# Court of Appeals

NO. 2017-CA-000866-MR
AND
NO. 2018-CA-000195-MR

CLIFFORD RUSSELL, JR. AND
JEANENE RUSSELL — APPELLANTS

v.

APPEALS FROM FAYETTE CIRCUIT COURT
HONORABLE JAMES D. ISHMAEL, JR., JUDGE
ACTION NO. 16-CI-02180

JOHNSON & JOHNSON, INC.; BIOSENSE WEBSTER, INC.; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; JOHNSON & JOHNSON INNOVATION JJDC, INC.; AND BAPTIST HEALTH LEXINGTON ASC OF BAPTIST HEALTHCARE SYSTEM, INC.[1] — APPELLEES

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[1] The medical procedure referenced in this Opinion occurred at Baptist Health Lexington ASC ("Baptist Health"), which was named as a defendant below and as an appellee herein. The two rulings being challenged do not address, resolve or dismiss any claim against Baptist Health and it did not enter an appearance in these appeals. We say nothing more about it as a party.

Biosense Webster, Inc. is part of the Johnson & Johnson Family of Companies. Biosense Webster, Inc. answered the complaint for all defendants—except Baptist Health—admitting it "designed, manufactured, tested and distributed" the heart catheter at the center of this action and reported all adverse effects "in accordance with the applicable Premarket Approval ("PMA") requirements and Food & Drug Administration ("FDA") regulations." Biosense Webster, Inc. argued all other entities under the Johnson & Johnson brand are improper parties; all claims are preempted by federal law; and, three claims—breach of implied and express warranties and the Kentucky Consumer Protection Act ("KCPA")—should be dismissed for lack of privity. We

OPINION
AFFIRMING

** ** ** ** **

BEFORE: JOHNSON, MAZE AND NICKELL, JUDGES.

NICKELL, JUDGE: Clifford Russell, Jr. ("Clifford") and his wife, Jeanene (collectively "Russell"), appeal from two rulings entered by the Fayette Circuit Court in a products liability case stemming from testing of an experimental heart catheter. The first opinion and order, entered May 9, 2017, dismissed all claims with prejudice and granted Biosense judgment on the pleadings under CR[2] 12.03 after finding all claims were preempted by federal law. 21 U.S.C.A. § 360k(a)(1). A second opinion and order, entered January 29, 2018, denied a CR 60.02(b) motion filed by Russell. Deeming the desired evidence—adverse events suffered by other patients and a voluntary recall of specific catheters—to be neither new nor material, and finding no compelling reason to grant extraordinary relief, the trial court declined to set aside the prior judgment, allow Russell to try to amend the complaint to allege a parallel state claim, or conduct discovery. Following a thorough review of the record, briefs and law, we affirm.

refer to Biosense Webster, Inc. and all parties under the Johnson & Johnson brand collectively as "Biosense."

[2] Kentucky Rules of Civil Procedure.

## FACTS AND PROCEDURAL BACKGROUND

On November 5, 2004, Biosense received approval of the THERMOCOOL® catheter via the PMA process. Approval was based in part on reasonable assurance from Biosense to the FDA the catheter was both safe and effective. 21 U.S.C. § 360e(d)(2). On June 2, 2015, the FDA approved use of the THERMOCOOL® SMARTTOUCH® SF Catheter[3] under the Investigational Device Exemption ("IDE")[4] to the Medical Device Amendments of 1976 ("MDA"). Approval under the IDE paved the way for a clinical trial to evaluate this catheter's safety in treating paroxysmal atrial fibrillation ("PAF")—a type of irregular heartbeat.

Suffering from PAF, Clifford was a candidate for cardiac ablation using the Class III[5] IDE. On June 24, 2015, Clifford executed "Consent to Take

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[3] FDA approval of Biosense Webster NaviStar™/Celsius™ ThermoCool® Diagnostic/Ablation Deflectable Tip Catheters was originally granted on November 5, 2004. Catheter Model D-1348-04-SI, Lot number 17177437, was used during Clifford's procedure. Since original approval in 2004, the application for FDA approval has been supplemented and approved more than seventy times, most recently on August 11, 2016, when supplemental PMA was awarded to Model Numbers D-1347-XX-S and D-1348-XX-S.

[4] "The IDE process allows a manufacturer with an experimental device to obtain FDA approval for the device with a less rigorous review process than usual. The purpose of the exemption is to encourage experimentation that would lead to a new development. *See* 21 U.S.C. § 360j(g). In order to obtain an IDE, a manufacturer must provide the FDA with information about, among other things, the device, its manufacture, and the experimental plan for its use." *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1245 (7th Cir. 1997).

[5] Medical devices are divided into three classes depending on level of risk to the public. Class III medical devices support or sustain human life, are useful in preventing impairment of human

Part in a Research Study"[6] of the catheter. That same day, he voluntarily underwent the typically outpatient procedure. Unexpectedly, his heart sustained a tear resulting in the ablation being aborted and emergency surgery to repair the tear. Clifford claims health issues from the aborted procedure persist.

On June 13, 2016, Russell filed suit against Biosense alleging Clifford was seriously injured by use of the catheter they described as "unreasonably dangerous and defective" due to its design, testing, warnings, labeling and instructions. Seeking both compensatory and punitive damages, Russell alleged strict liability, negligence, lack of informed consent, failure to warn, breach of both express and implied warranties, fraud and fraudulent concealment, unjust enrichment, loss of consortium, and violation of the KCPA. Biosense answered the complaint arguing all claims were preempted by 21 U.S.C.A. 360k(a)(1) and seeking dismissal under CR 12.02. In response to the defense motion to dismiss, Russell sought leave under CR 15.03 to amend the complaint to allege state law claims paralleling federal violations and to proceed with discovery.

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health, or pose a "potential unreasonable risk of illness or injury." 21 C.F.R. § 860.3(c)(3). At the time of Clifford's procedure, the catheter used was approved as a Class III medical device granted IDE for a clinical trial. It has since been awarded PMA.

[6] Page five of the consent form Clifford signed states, "the THERMOCOOL® SMARTTOUCH® SF Family of Contact Force Sensing Catheters consists of investigational devices that have not been approved by the FDA for the treatment of PAF."

Relying heavily on *Riegel v. Medtronic, Inc*., 552 U.S. 312, 317, 128 S.Ct. 999, 1003, 169 L.Ed.2d 892 (2008)—the latest pronouncement from the United States Supreme Court on federal preemption of state tort claims against manufacturers of Class III medical devices granted an IDE—the trial court dismissed the complaint with prejudice after finding Russell's alleged claims were preempted by operation of 21 U.S.C.A. § 360k(a)(1). The trial court specifically found Biosense was correct in arguing the catheter used during Clifford's procedure was part of an FDA-approved IDE clinical trial and subject to federally-imposed requirements regarding "the investigational plan, design, manufacturing techniques, clinical protocol, warning or consent form which could potentially affect clinical subjects." The trial court concluded the claims were preempted because the IDE and PMA processes impose device-specific requirements pertaining to safety and effectiveness and the complaint attempted to impose different or additional state law requirements contrary to 21 U.S.C.A. § 360k(a). The trial court denied as "futile" Russell's request to amend the complaint and pursue discovery, noting when asked at oral argument, Russell could identify no violation of federal law and no corresponding parallel state law claim. Russell filed a timely notice of appeal from judgment on the pleadings.

On September 6, 2017, Biosense announced a voluntary recall of various catheters including the *same model* used on Clifford, but *different lot*

*numbers*.[7] Via CR 60.02 motion, Russell asked the trial court to set aside the prior dismissal, allow amendment of the complaint to assert a parallel state claim, and permit discovery. The trial court again found Russell could assert no parallel state claim and the extraordinary relief provided by CR 60.02 was unavailable because the recall did not include the catheter used during Clifford's procedure. Furthermore, the trial court found granting relief based on the voluntary recall—which occurred *after* entry of judgment—would vitiate the concept of finality. *West Vale Homeowners' Ass'n, Inc. v. Small*, 367 S.W.3d 623, 628 (Ky. App. 2012). Finally, the trial court noted, despite adverse event reports and the voluntary recall—all of which were documented on the FDA's public website[8] and available to Russell—the FDA still granted the catheter full PMA on August 11, 2016, ultimately deeming it safe and effective for the treatment of PAF. Russell again filed timely notice of appeal. Pursuant to Russell's unopposed motion, we have consolidated the two appeals for treatment in a single opinion. We affirm both trial court rulings.

[7] Pursuant to FDA regulation, after Clifford's procedure, the used catheter was returned to Biosense for analysis which showed it to be in good working order and free of defect.

[8] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=158827.

## FEDERAL PREEMPTION

The 1960s and 1970s saw an increase in the marketing of medical devices with mixed results—some devices worked; others—like the Dalkon Shield intrauterine device—failed. *Riegel*, 552 U.S. at 316, 128 S.Ct. at 1003. Regulation of the devices was generally left to the states until 1976, when Congress adopted the MDA to the Federal Food, Drug and Cosmetic Act of 1938. From that point forward, the FDA was authorized to approve and regulate medical devices under 21 U.S.C.A. § 371(a). States were thereafter prohibited from imposing different or additional requirements relating to safety, effectiveness or any other federally-regulated attribute of a medical device. *Riegel*, 552 U.S. at 316, 128 S. Ct. at 1003. 21 U.S.C.A. § 360k(a) recites the general rule:

> 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.

Federal preemption, as explained in *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 516, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (1992), is rooted in our nation's Supremacy Clause.

> Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2. Thus, since our decision in *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427, 4 L.Ed. 579 (1819), it has been settled that state law that conflicts with federal law is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746, 101 S.Ct. 2114, 2128, 68 L.Ed.2d 576 (1981). Consideration of issues arising under the Supremacy Clause "start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947). Accordingly, "'[t]he purpose of Congress is the ultimate touchstone'" of pre-emption analysis. *Malone v. White Motor Corp*., 435 U.S. 497, 504, 98 S.Ct. 1185, 1189, 55 L.Ed.2d 443 (1978) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103, 84 S.Ct. 219, 222, 11 L.Ed.2d 179 (1963)).
>
> Congress' intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co*., 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977). In the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, *see Pacific Gas & Elec. Co. v. State Energy Resources Conservation and Development Comm'n*, 461 U.S. 190, 204, 103 S.Ct. 1713, 1722, 75 L.Ed.2d 752 (1983), or if federal law so thoroughly occupies a legislative field "'as to make reasonable the inference that Congress left no room for the States to supplement

> it.'" *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U.S. 141, 153, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S., at 230, 67 S.Ct., at 1152).

Whether Congressional intent is express or implied, preemption is mandatory when the intention exists and a state regulation conflicts therewith. *State Farm Bank v. Reardon*, 539 F.3d 336, 342 (6th Cir. 2008).

**PRIOR CASELAW**

*Riegel* was a product liability suit filed after a heart catheter ruptured when inflated beyond the pressure recommended by the FDA-approved label. Riegel claimed the catheter was defective under New York state law. The United States Supreme Court held Riegel's claims were expressly preempted by the MDA because New York's common law attempted to impose tougher safety requirements than those imposed by the FDA.

While similar in some respects to the facts we review today, *Riegel* is not a mirror image of our case. The Class III catheter at the heart of *Riegel* received PMA from the FDA *prior* to its challenged use. In contrast, the catheter used during Clifford's procedure was approved for clinical testing as an IDE at the time of use and received full PMA *after* Clifford's procedure.

Russell urges us to discount *Riegel* because the catheter did not have PMA at the time of Clifford's procedure. While Russell has seized upon a distinction between this case and *Riegel*, we follow the lead of some federal

courts—albeit in unpublished decisions—finding the timing of a grant of PMA to a device previously approved for clinical testing under an IDE, to be immaterial. *Dorsey v. Allergan, Inc*., 3:08-0731, 2009 WL 703290, at *5 (M.D. Tenn. Mar. 11, 2009) (whether PMA follows IDE for human testing is "distinction without a difference."). *See also Williams v. Allergan USA, Inc*., CV-09-1160-PHX-GMS, 2009 WL 3294873, at *4 (D. Ariz. Oct. 14, 2009).

In another unpublished case, a different federal court found approval of IDE devices to be synonymous with PMA, writing:

> [b]ecause IDE devices are subject to a level of FDA oversight and control that is, for the purpose of a preemption analysis, identical to that governing PMA devices, the body of preemption law governing PMA devices applies equally to the IDE device at issue in this case. *See Martin v. Telectronics Pacing Sys., Inc*., 105 F.3d 1090 (6th Cir.1997) (applying PMA preemption analysis to IDE regulations); *Becker* [*v. Optical Radiation Corp.*, 66 F.3d 18, 21 (2d Cir.1995)] (applying PMA line of cases to optical device subject to regulations effectively identical to IDE regulations); *Berish v. Richards Medical Co*., 928 F.Supp. 185, 190 (N.D. N.Y. 1996) (applying *Becker* to IDE devices). Plaintiff does not contend otherwise.

*Burgos v. Satiety, Inc*., 10-CV-2680 JG, 2010 WL 4907764, at *2 (E.D.N.Y. Nov. 30, 2010).

Russell acknowledges *Riegel's* two-pronged standard of review but argues against its application because the United States Supreme Court has not specifically addressed whether medical devices granted IDE for clinical trials are

subject to federal requirements for preemption purposes. Finding no United States Supreme Court case on all fours, we look to lower courts which have spoken on the topic, specifically *Martin*, 105 F.3d at 1094, and *Slater v. Optical Radiation Corporation*, 961 F.2d 1330 (7th Cir. 1992). Both held state law challenges to devices granted IDE for clinical testing were preempted by federal law.

Seeking to avoid preemption, Russell urges us to rely instead on *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), an opinion rendered by the Supreme Court of Kentucky more than a decade *before Riegel*. Guided by *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), *Niehoff* held state claims for strict liability and negligence were not preempted by the MDA where implantation of an intraocular lens ("IOL") approved by the FDA as an IDE resulted in loss of a patient's eye. *Lohr*, however, on which *Niehoff* is based, did not deal with a device approved as an IDE for a clinical trial; *Lohr* dealt with a pacemaker approved under the § 510k process—a wholly separate expedited means of bringing a product to market without any attempt at PMA approval or even review. Under the § 510k process, a device may be marketed—without any PMA review—simply because it is "substantially equivalent" to a device already in interstate commerce. *Riegel*, 552 U.S. at 317, 128 S.Ct. at 1004; *Lohr*, 518 U.S. at 479, 116 S.Ct. at 2248. *Lohr* is not a perfect fit with our scenario, and neither is *Niehoff*, wherein the manufacturer voluntarily halted clinical investigation of the

IOL before the FDA considered its PMA application and no signed consent form was ever located, giving support to Niehoff's claim she was unaware of the experimental nature of her 1983 surgery.

Stated succinctly, the catheter in this case was approved for a clinical trial as an IDE at the time of use. These facts are undisputed. Clifford signed a lengthy informed consent form stating the catheter was part of a "research study," was "investigational," and, had "not been approved by the FDA for the treatment of PAF." The FDA awarded the catheter PMA approval just over a year after Clifford's procedure. Finally, no violation of any federal regulation has been proved or even alleged. Of the widely varied case law available, *Riegel* offers the greatest similarity.

*Riegel* announced a two-part test for evaluating preemption of state law claims.

> Since the MDA expressly pre-empts only state requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law, § 360k(a)(1), we must determine whether the Federal Government has established requirements applicable to Medtronic's catheter. If so, we must then determine whether the Riegels' common-law claims are based upon New York requirements with respect to the device that are "different from, or in addition to," the federal ones, and that relate to safety and effectiveness. § 360k(a).

552 U.S. at 321-22, 128 S.Ct. at 1006. Contrary to Russell's suggestion, there is no presumption against preemption. When a

> statute "contains an express pre-emption clause," we do not invoke any presumption against pre-emption but instead "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Chamber of Commerce of United States of America v. Whiting*, 563 U.S. 582, 594, 131 S.Ct. 1968, 179 L.Ed.2d 1031 (2011) (internal quotation marks omitted); *see also Gobeille v. Liberty Mut. Ins. Co*., 577 U.S. ___, ___, 136 S.Ct. 936, 946, 194 L.Ed.2d 20 (2016).

*Puerto Rico v. Franklin California Tax-Free Trust*, ___ U.S. ___, 136 S. Ct. 1938, 1946, 195 L.Ed.2d 298 (2016). Thus, if both *Riegel* prongs are satisfied, state claims are preempted. The Fayette Circuit Court closely followed *Riegel* in finding all claims in this case to be preempted.

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Because the complaint was dismissed after Biosense sought judgment on the pleadings, CR 12.03 is our beginning point. The rule directs:

> [a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings. If, on such motion, matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided for in Rule 56, and all parties shall be given reasonable opportunity to present all materials made pertinent to such a motion by Rule 56.

CR 12.03 permits pretrial disposal of a case containing legally insufficient claims or defenses where "the allegations of the pleadings are admitted and only a question of law is to be decided." *City of Pioneer Village v. Bullitt County ex rel. Bullitt Fiscal Court*, 104 S.W.3d 757, 759 (Ky. 2003). *Fox v. Grayson*, 317 S.W.3d 1, 7 (Ky. 2010), explains how the rule is applied.

> A motion to dismiss for failure to state a claim upon which relief may be granted "admits as true the material facts of the complaint." So a court should not grant such a motion "unless it appears the pleading party would not be entitled to relief under any set of facts which could be proved. . . ." Accordingly, "the pleadings should be liberally construed in the light most favorable to the plaintiff, all allegations being taken as true." This exacting standard of review eliminates any need by the trial court to make findings of fact; "rather, the question is purely a matter of law. Stated another way, the court must ask if the facts alleged in the complaint can be proved, would the plaintiff be entitled to relief?" Since a motion to dismiss for failure to state a claim upon which relief may be granted is a pure question of law, a reviewing court owes no deference to a trial court's determination; instead, an appellate court reviews the issue de novo.

(Footnotes omitted).

Biosense argues each of Russell's allegations was regulated by "device-specific" requirements imposed by the FDA as part of its award of IDE and ultimately PMA. Every step from designing the device to bringing it to market for safe and effective use in a human trial—including labeling of the device, wording of the consent form, post-procedure analysis of the used catheter, and

mandatory reporting and publishing of adverse events and recalls on the FDA's public website—was closely monitored and authorized by the FDA through more than seventy supplemental approvals. Moreover, once the human study was concluded, the FDA awarded PMA to the device, finding it to be safe and effective. As stated in *Riegel*,

> [p]remarket approval, in contrast, imposes "requirements" under the MDA as we interpreted it in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in § 510(k) review are present here. While § 510(k) is "'focused on equivalence, not safety,'" *id*., at 493, 116 S.Ct. 2240 (opinion of the Court), premarket approval is focused on safety, not equivalence. While devices that enter the market through § 510(k) have "never been formally reviewed under the MDA for safety or efficacy," *ibid*., the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness, § 360e(d). And while the FDA does not "'require'" that a device allowed to enter the market as a substantial equivalent "take any particular form for any particular reason," 518 U.S., at 493, 116 S.Ct. 2240, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

552 U.S. at 322-23, 128 S.Ct. at 1007. *Martin* has interpreted *Riegel* to say,

> the regulations governing investigational devices are essentially device specific. There are no specific

> regulations governing pacemakers like the one at issue; however, the application and approval process under the IDE is device specific.

*Martin*, 105 F.3d at 1097. The catheter in this case, having received approval after being subjected to both the IDE and PMA processes, satisfies the first prong of *Riegel*.

Step two of *Riegel*—whether state law claims impose different or additional requirements relating to safety, effectiveness or any other federally controlled attribute—turns on whether Russell can demonstrate the state claims alleged are "genuinely equivalent" to federal requirements. *Wolicki-Gables v. Arrow Intern., Inc*., 634 F.3d 1296, 1300 (11th Cir. 2011) (citations omitted). Only if a state claim "parallels" a federal requirement does it escape preemption. *Riegel*, 552 U.S. at 330, 128 S.Ct. at 1011 (citations omitted). To proceed, Russell must allege three items: violation of a federal requirement; violation of an identical state violation; and a link between the federal violation and Clifford's injury. Russell has alleged none of them.

> Parallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that "[the] defendant violated a particular federal specification referring to the device at issue." *Ilarraza v. Medtronic, Inc*., 677 F.Supp.2d 582, 589 (E.D. N.Y. 2009). "To properly allege parallel claims, the complaint must set forth facts" pointing to specific PMA requirements that have been violated. *Parker v. Stryker Corp*., 584 F.Supp.2d 1298, 1301 (D. Colo. 2008). The trial court stated in *Parker* that an allegation that "the manufacturing processes for

> the device and certain of their . . . components did not satisfy the Food and Drug Administrations's Pre–Market Approval standards for the devices" is insufficient to satisfy the requisite elements of a parallel claim as set forth in *Riegel* if the complaint fails to "provide any factual detail to substantiate that crucial allegation." *Id.* at 1302.

*Wolicki-Gables*, 634 F.3d at 1301. Review of the thirty-two page complaint is critical to determining whether Russell alleged sufficient foundation for a parallel state claim. Representative of the allegations are: the software module and "other instrumentation was defective and unreasonably dangerous to foreseeable customers"; the catheter "was defectively designed and placed into the stream of commerce . . . in a defective and unreasonably dangerous condition"; Biosense "failed to properly design, manufacture, market, distribute, supply and sell" the catheter, as well as failed to "warn and place adequate warnings and instructions"; Biosense "failed to adequately test"; and, Biosense "failed to provide timely and adequate post-market warnings and instructions" after learning of the risk of injury. Noticeably absent from the complaint is any allegation Biosense violated a federal requirement—a hurdle that must be cleared to assert a parallel state claim and avoid federal preemption. *Id.* Also absent is any factual support for the missing claim of any federal violation. Having failed to identify a federal violation, or even cite a federal regulation that could have been violated or mirror a Kentucky statute, Russell also failed to establish Clifford was injured because of a

federal violation. *Erickson v. Boston Scientific Corp.*, 846 F.Supp.2d 1085, 1092 (C.D. Cal. 2011). Thus, Russell has demonstrated none of the three-part showing required to allege a parallel state claim.

Rather than arguing Biosense violated a specific federal law, Russell attacks the catheter itself, claiming it was "unreasonably dangerous and defective" due to its design, testing, warnings, labeling and instructions—in other words, the FDA should have imposed more stringent requirements—an attack precisely prohibited by the MDA. 21 U.S.C.A. § 360k. We review each of Russell's claims.

**STRICT LIABILITY, NEGLIGENCE and FAILURE TO WARN**

Each of these claims relates to the catheter's safety and effectiveness. None is based on violation of an FDA requirement. These state law claims attempt to impose different or additional requirements than those imposed by the FDA. Therefore, each is preempted. *Martin*, 105 F.3d at 1098-99.

**INFORMED CONSENT**

Russell alleges they were "not fully and adequately informed" of the experimental nature of the catheter and the clinical trial. Russell alleges—with receipt of additional information[9]—Clifford would not have chosen to participate

[9] The consent form Clifford signed contained more than two pages of "General risks of atrial fibrillation ablation," including "surgery in the heart"; "surgical correction"; "cardiac perforation (tear or hole) with bleeding into the pericardium, the membrane which surrounds the heart (known as a "tamponade")"; accumulation of fluid around the heart (effusion); "cardiac arrest";

in the study. The FDA approved the consent form signed by Clifford—a fact undisputed by Russell. The FDA also approved the plan for the clinical trial—another undisputed fact. Russell seeks to impose additional and different requirements than the FDA—in its wisdom and expertise—chose to impose. The claim is preempted.

**BREACH OF EXPRESS AND IMPLIED WARRANTIES**

Russell alleges the catheter did not live up to its marketing, advertising and label as it was expressly warranted to be safe and effective. Russell further alleges the catheter did not satisfy its implied warranty of being "safe, and fit for its intended use." Such claims directly contradict the FDA's conclusion the catheter was safe and effective for use in a human trial as an IDE.

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and "respiratory arrest." Many of these risks came to fruition for Clifford. The form also warned, "You may even die." Under "Benefits of participating," the form states:

> A promise or guarantee of benefit cannot be made. It is likely that you will experience a decrease in the number of symptomatic AF episodes. Your quality of life may improve and you may experience less frequent hospitalization due to PAF.
>
> However, it cannot be guaranteed that this trial will be of benefit to you, although your participation will allow us to gather information on the use of new technologies, which may be beneficial for the treatment of other patients with AF.

The following language appeared on the form under "Alternative treatments:"

> You may choose not to participate in this study and either receive medicine to treat AF or an AF ablation procedure with another commercially available catheter. You may also receive AF ablation procedure with the cleared THERMOCOOL® Navigational Family of catheters outside the study.

A manufacturer may make representations about a device as approved by the FDA. "[T]he representations that can, cannot, and must be made about an investigational device are all determined by the FDA." *Enlow v. St. Jude Medical, Inc*., 210 F. Supp. 2d 853, 862 (W.D. Ky. 2001) (citations omitted). Allowing Russell's state claims to go forward would set up a "direct collision with federal policy." *Chambers*, 109 F.3d at 1248. Both warranty claims are preempted.

**FRAUD and FRAUDULENT CONCEALMENT**

Russell claims Biosense fraudulently failed to disclose material facts about the catheter's "safety and efficacy." These claims mimic the failure to warn and informed consent claims. As stated previously, the FDA approved the warnings, label and informed consent form. Alleging Biosense should have provided different or additional information squarely interferes with the FDA's authority. These claims are preempted.

**UNJUST ENRICHMENT**

Russell claims Biosense wrongly profited from its designing, advertising, marketing, promoting, manufacturing, distributing, supplying and selling the catheter because Clifford did not receive safe and effective medical care from its use. Proving this claim would require showing the catheter was not safe and effective—again, a direct contradiction of the FDA's endorsement of the device as being safe for use in a human trial. This would clearly impose different

and additional requirements in contravention of the MDA. The claim is preempted.

**KCPA**

Relying exclusively on KRS[10] 367.110 *et seq.*, Russell cites no federal statute the KCPA would parallel. Nor has Russell explained how a violation of any federal law injured Clifford. Such a claim was found to be preempted in *Clark v. Medtronic, Inc.*, 572 F.Supp.2d 1090, 1093 (D. Minn. 2008). We follow suit and hold the claim to be preempted.

**LOSS OF CONSORTIUM and PUNITIVE DAMAGES**

Russell's claims for loss of consortium and punitive damages are derivative and/or dependent claims. *Daley v. Reed*, 87 S.W.3d 247, 250 (Ky. 2002). Because all claims were properly dismissed as preempted by federal law, these claims were also properly dismissed.

Finally, we agree with the trial court's finding there was no reason to allow amendment of the complaint. Granting additional time to do so would have been futile and unnecessarily prolonged the case. *See In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 08-1905 RHK/JSM, 2009 WL 1361313, at *1 (D. Minn. May 12, 2009), *aff'd sub nom*. *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010).

[10] Kentucky Revised Statutes.

Russell did not allege a federal violation, nor link Clifford's injury to a federal violation. Additional time would not have transformed Russell's claims into parallel state claims. Discerning no error, we affirm dismissal of the complaint due to federal law preemption.

**No. 2018-CA-000866-MR**

The question posed by this particular appeal is whether a voluntary recall announced by Biosense on September 6, 2017—four months after entry of judgment in its favor on May 9, 2017—constitutes newly discovered evidence justifying setting aside a judgment dismissing all claims due to federal preemption. We hold it does not. Associated questions, which we also answer in the negative, are whether Russell should have been allowed to amend the complaint to assert parallel state claims and to conduct discovery.

CR 60.02 was designed "to provide relief where the reasons for the relief are of an extraordinary nature." *Ray v. Commonwealth*, 633 S.W.2d 71, 73 (Ky. App. 1982). A substantial showing is required to justify relief under the rule.

CR 60.02(b) specifically allows a final judgment to be set aside due to "newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial[.]" We review denial of a CR 60.02 motion for abuse of discretion, the test being, "whether the trial judge's decision

was arbitrary, unreasonable, unfair, or unsupported by sound legal principles." *Baze v. Commonwealth*, 276 S.W.3d 761, 765 (Ky. 2008) (citations omitted).

A chief determinant in granting CR 60.02 relief is the moving party's ability to present the claim prior to entry of the order sought to be set aside. *U.S. Bank, NA v. Hasty*, 232 S.W.3d 536, 541-42 (Ky. App. 2007) (citations omitted). Russell claims they could not have discovered the evidence earlier because details of the application for FDA approval were confidential and out of reach. Biosense disagrees, noting much of the application process—including adverse events and recalls on which Russell relies—is documented on a public FDA website. Moreover, Biosense maintains the recall is immaterial because it did not involve the precise catheter used in Clifford's procedure. The trial court denied the motion, a result with which we agree.

First, CR 60.02 does not allow a trial court to reopen a judgment due to facts occurring *after* entry of judgment. *Small*, 367 S.W.3d at 628. Endorsing Russell's interpretation of CR 60.02 would eliminate the concept of finality and potentially subject every judgment to perpetual amendment and reversal. *Id.* Such a result would be wholly inconsistent with the purpose and intention of court rules.

Second, the Biosense recall did not encompass *all* ThermoCool® catheters; it covered only certain models and lot numbers, none of which were used during Clifford's procedure. According to Biosense, the recall had no impact on

Clifford's outcome. It concerned situations wherein a surgeon saw a magnetic distortion of an image, followed by receipt of "Alert 402" indicating the machine should be rebooted to restore the proper image. Operative notes show no alert was received during Clifford's procedure and post-procedure analysis of the device showed no evidence of catheter failure or anomaly.

Third, the subsequent voluntary recall by Biosense negated neither federal preemption nor FDA approval—not of the catheter's status as an IDE for the clinical trial and not of the ultimate grant of PMA. The FDA was aware of the complaints and the recall, details having been posted on its website. Armed with these facts, in its wisdom, experience, and expertise, the FDA—while fully authorized to do so under 21 U.S.C. § 360(e)—did not withdraw approval.

Fourth, a voluntary recall does not create a presumption FDA requirements have been violated. *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 497 (W.D. Pa. 2012); *Erickson*, 846 Supp. 2d at 1093. Nor does it "transform plaintiff's otherwise preempted claim into a parallel cause of action." *Scianneaux v. St. Jude Med. S.C., Inc.*, 961 F.Supp. 2d 808, 813 (E.D. La. 2013).

Finally, from Russell's perspective, the catheter used during Clifford's procedure "was not safe and effective." That position directly contradicts the FDA's conclusion the catheter was safe and effective enough for use in a human trial as an IDE at the time of Clifford's procedure.

> [T]he FDA will not grant an investigational-device exemption unless it believes that the device has sufficient promise of being proved safe and effective to justify the risk of its being used on human beings. Although that belief is different from a certification that the design of the device is safe and effective, it is a certification that the design is sufficiently safe and effective to allow experimental use on human beings.

*Slater*, 961 F.2d at 1333. Just over a year after Clifford's procedure, the FDA granted the catheter PMA pronouncing it "safe and effective" for marketing. As a result of the foregoing, we discern no abuse of discretion in the trial court's denial of the motion to set aside the prior judgment, grant leave to allow amendment of the complaint, and permit discovery to move forward.

There being no grounds for reversal, dismissal of the complaint due to federal preemption and denial of the subsequent motion to set aside judgment due to newly discovered evidence are AFFIRMED.

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