FOR PUBLICATION

ATTORNEYS FOR APPELLANTS
JODI McGOOKIN, VICKIE McGOOKIN
And JIM McGOOKIN:

ROBERT J. PALMER
May Oberfell Lorber
Mishawaka, Indiana

ATTORNEY FOR APPELLANT
JULIAN E. SMITH:

JEFFREY P. HINTERMEISTER
O'Koon Hintermeister, PLLC
Indianapolis, Indiana

ATTORNEYS FOR APPELLEE
GUIDANT CORPORATION, et al.:

CARL A. GRECI
Baker & Daniels LLP
South Bend, Indiana

ROBERT T. ADAMS
MATTHEW D. KEENAN
Shook, Hardy & Bacon LLP
Kansas City, Missouri

LYNN E. KALAMAROS
DANE L. TUBERGEN
Hunt Suedhoff Kalamaros LLP
South Bend, Indiana

FILED
Jan 21 2011, 9:49 am
CLERK
of the supreme court, court of appeals and tax court

IN THE
COURT OF APPEALS OF INDIANA

JODI McGOOKIN, as Mother of the Deceased, Samantha Arlene McGookin, VICKY McGOOKIN, JIM McGOOKIN, and JULIAN E. SMITH,	)	
Appellants-Plaintiffs,	)	
vs.	)	No. 71A04-1001-CT-101
GUIDANT CORPORATION, et al.,	)	
Appellee-Defendant.	)	

APPEAL FROM THE ST. JOSEPH SUPERIOR COURT
The Honorable Michael P. Scopelitis, Judge
Cause No. 71D07-0608-CT-192

January 21, 2011

OPINION – FOR PUBLICATION

BAKER, Judge

After their newborn daughter was diagnosed with a heart defect, was given a Guidant pacemaker, and tragically passed away at the age of fourteen months, the appellants filed a state law complaint against Guidant. Among other things, they argue that Guidant should have put specific warnings on the pacemaker labeling related to its implantation into pediatric patients. Because the label had been preapproved by the Food and Drug Administration, however, and Guidant was not required to include the additional warnings, the trial court held that any state law-based failure-to-warn claims were preempted by federal law. Finding that the trial court properly found the claims preempted, we affirm.

Appellants-plaintiffs Jodi McGookin, as mother of the deceased, Samantha Arlene McGookin, Vicky McGookin, Jim McGookin, and Julian E. Smith (collectively, the Appellants) appeal the trial court's order denying their motion to correct error. The Appellants contend that the trial court erred by granting, in part, the motion for summary judgment filed by appellee-defendant Guidant Corporation (Guidant). Among other things, the Appellants argue that the trial court erred by finding a number of their claims

regarding a Guidant pacemaker to be preempted by federal law. Finding no error, we affirm.

FACTS

Samantha's Story

Samantha was born on April 27, 2004, with complete heart block, which is a disorder of the heart's electrical system. Complete heart block occurs in people of all ages, and both children and adults with the condition are treated with pacemakers. Pacemakers are medical devices designed to cause the human heart to beat by providing low-voltage electrical impulses delivered from the device through wires, called "leads," connected to the heart. On April 30, 2004, a Guidant Insignia I Ultra Model 1290 (Insignia 1290) was implanted in Samantha's abdomen and attached to her heart with two unipolar and epicardial leads. Medical records throughout Samantha's life, and testing conducted by Guidant after her death, show that her device provided therapy at all times. On July 9, 2005, Samantha died.

The Insignia 1290

The United States Food and Drug Administration (FDA) must approve all Class III medical devices—such as the Insignia 1290—before they may be commercially distributed. On August 15, 2003, Guidant filed a supplemental application for several devices, including the Insignia 1290. The application contained detailed information regarding the Insignia 1290, including its design, testing, indications for use,

contraindications, warnings and precautions, and its Automatic Capture[1] feature. The application also stated that, consistent with industry practice, pediatric patients had not been included in clinical trials. On November 4, 2003, the FDA approved the Insignia 1290 as a class III medical device, and that approval remains effective today. The FDA's approval included approval of the Insignia 1290 labeling, which is the same today as it was in November 2003.

At the heart of the Appellants' case is their claim that the labeling for Samantha's pacemaker was inadequate because it failed to warn of a lack of testing of the Automatic Capture feature with small children, unipolar epicardial leads, and abdominal implantation. In other words, their complaint challenges labeling expressly approved by the FDA.

On August 25, 2006, the McGookins filed a complaint against Guidant for wrongful death, product liability, breach of express and implied warranties, actual fraud, constructive fraud, negligence, violation of the Indiana Deceptive Consumer Sales Act, and intentional and negligent infliction of emotional distress. Julian Smith, Samantha's father, filed similar claims against Guidant, adding a claim for negligence per se.

On April 1, 2009, Guidant moved for summary judgment based on federal preemption, lack of evidence of defect or causation, and certain claim-specific reasons.

[1] The Automatic Capture feature is designed to save battery life by measuring a patient's capture threshold—the minimum amount of voltage required to cause the heart to beat—and then adjusting the output voltage to a set level above that threshold. The label, as approved by the FDA, states that this feature "is designed to work with any ventricular lead." Appellees' App. p. 1117.

On July 22, 2009, the trial court issued an order granting Guidant's motion with respect to the claim for breach of implied warranty. The trial court also held as follows:

> To the extent plaintiffs seek to impose liability on the defendants under substantive legal theories on the basis that the Insignia 1290 . . . should have been subject to requirements and specifications in addition to or different from the device specific requirements imposed by federal law, including specifically the [FDA] regulations, plaintiffs' claims are preempted by the Medical Device Amendments of 1976 ("MDA"). To the extent plaintiffs seek to enforce or restrain violations of federal law including the MDA, their claims are preempted. To the extent plaintiffs seek to impose liability on the defendants under substantive legal theories that seek monetary damages predicated on challenges to conduct of the defendants allowed by and not in violation of any applicable federal requirements including FDA regulations plaintiffs' claims are preempted.

Appellants' App. p. 22. To the extent that the Appellants' claims were premised on a violation of FDA regulations, the trial court held that the claims were not preempted. The trial court went on to find many genuine issues of material fact as to each of the Appellants' claims except for the implied warranty claim, and it merged the claims based on negligence, negligence per se, actual and constructive fraud, intentional and negligent infliction of emotional distress, and the Indiana Deceptive Consumer Sales Act, into a single cause of action under the Indiana Products Liability Act. The trial court then entered the following order:

> 1. Defendants' Motion for Summary Judgment is granted as to Plaintiffs['] claims based on breach of implied warranty. . . .
>
> 2. Defendants['] Motion for Summary Judgment is granted as to any claims of plaintiffs that are not premised upon a violation of an applicable federal requirement except for claims based upon an assumed duty and breach of express warranty resulting from

representations made by defendants to plaintiffs or plaintiffs' physicians that were not true.

3. In all other respects Defendants' Motion for Summary Judgment is denied.

Id. at 27-28. In a subsequent order, the trial court clarified that the claims folded into the single Indiana Products Liability Act cause of action had not been dismissed.

A ten-day jury trial took place between August 25 and September 4, 2009. All of the Appellants' claims aside from implied warranty and manufacturing defect[2] were litigated during the trial. On September 4, 2009, the case was submitted to the jury, with instructions on six substantive claims: product liability based on failure to warn, negligence (based on failure to warn and design defect), negligent and intentional infliction of emotional distress, breach of assumed duty, and breach of express warranty.[3] The jury found in favor of Guidant on all claims on September 8, 2009.

On October 8, 2009, the Appellants filed a motion to correct error, alleging, among other things, that the trial court had erred by finding their claims preempted unless they were based on a violation of federal law. Following a hearing, the trial court denied the motion to correct error on December 21, 2009. The Appellants now appeal.

[2] The Appellants abandoned the manufacturing defect claim before trial.

[3] Before the case was submitted to the jury, the Appellants voluntarily withdrew their claims for actual and constructive fraud, violation of the Indiana Deceptive Consumer Sales Act, and negligence per se.

DISCUSSION AND DECISION

I. Standard of Review

The Appellants are appealing the denial of their motion to correct error, which alleged that the trial court erred in granting a portion of Guidant's motion for summary judgment. We review a trial court's ruling on a motion to correct error for an abuse of discretion. Newland Resources, LLC v. Branham Corp., 918 N.E.2d 763, 772 (Ind. Ct. App. 2009).

Summary judgment is appropriate only if the pleadings and evidence considered by the trial court show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Owens Corning Fiberglass Corp. v. Cobb, 754 N.E.2d 905, 909 (Ind. 2001). If there is any doubt as to what conclusion a jury could reach, then summary judgment is improper. Id.

II. Preemption

The Appellants contend, based on a series of federal and Indiana cases that will be explored below, that the trial court erroneously held that the Appellants' claims were preempted unless the claims were premised on a violation of federal statutes and/or regulations. The substantive crux of their argument is as follows:

> . . . Although Guidant's label complied with the FDA requirements of its premarket approval, other FDA regulations gave Guidant the ability to add to or strengthen those regulations without prior FDA approval. The Indiana Product Liability Act incorporates a "reasonableness" component in determining whether warnings are inadequate. Therefore, it becomes a jury question as to whether Guidant acted reasonably in failing to add to or strengthen its

> warnings pursuant to 21 C.F.R. § 814.39(d). The label, for example, could have informed consumers and physicians that the pacemaker had not been tested in infants or with epicardial leads, or with an abdominal implant. The label could have stated that use with epicardial leads in infants was contraindicated. The trial court therefore erred in granting Guidant's motion for summary judgment and ruling that any attempt to impose liability on Guidant under substantive legal theories . . . predicated on challenges to conduct of Guidant allowed by and not in violation of any applicable federal requirements are preempted.

Appellants' Br. p. 26.

A. Riegel

Before this case went to trial, the United States Supreme Court decided Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). The Riegel Court considered the interplay between the FDA, the MDA,[4] and common law claims challenging the safety or effectiveness of a medical device. Noting that there are various levels of oversight for medical devices, depending on the risks they present, the Court observed that Class III devices receive the most federal oversight. Id. at 316-17. Emphasizing the "rigorous" premarket approval process, id. at 317, the Court highlighted the express preemption provision contained within the MDA:

> Except as provided in subsection (b)[[5]] 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—

[4] 21 U.S.C. § 360c et seq.

[5] The exception contained within subsection (b) permits the FDA to exempt certain state and local requirements from preemption. Riegel, 552 U.S. at 316.

> (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.

21 U.S.C. § 360k(a).

At issue in Riegel was a balloon catheter, a Class III medical device that received premarket approval from the FDA. After the catheter was inserted in Charles Riegel's coronary artery, serious complications ensued, and Riegel and his wife filed a lawsuit alleging that the catheter was designed, labeled, and manufactured in a manner violating New York common law. To determine whether the Riegels' claims were preempted by the MDA, the Court first considered whether the federal government had established requirements applicable to the catheter. Answering in the affirmative, the Court held that premarket approval, synonymous with federal safety review, does impose "requirements" under the MDA. Id. at 322-23.

Next, the Riegel Court turned to a second question:

> whether the Riegels' common-law claims rely upon "any requirement" of New York law applicable to the catheter that is "different from, or in addition to" federal requirements and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device."

Id. at 323 (quoting 21 U.S.C. § 360k(a)). Reasoning that safety and effectiveness were "the very subjects" of the Riegels' claims, the Court focused on whether New York's tort duties constituted requirements under the MDA. Id. at 323. The Riegel Court affirmed

the view that common law causes of action for negligence and strict liability do impose requirements and are preempted by federal requirements specific to a medical device to the extent that they are different from, or in addition to, the requirements imposed by federal law. Id. at 323-24. Finally, the Court emphasized that the MDA does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; such a parallel claim would not be preempted.

B. Wyeth

In 2009—before the parties briefed the preemption issue on summary judgment herein—the United States Supreme Court decided Wyeth v. Levine, 129 S. Ct. 1187, --- U.S. --- (2009), in which a patient filed a state law damages action against a drug manufacturer for failure to warn of the dangers of the administration of nausea medication directly into the patient's vein. Although the drug's labeling had been approved by the FDA, the patient claimed that the manufacturer should have included additional warnings and that the failure to do so violated state common law.

The Wyeth Court held that federal law did not preempt the patient's failure-to-warn claim. Relying heavily on the nature of the Food, Drug, and Cosmetic Act[6] (FDCA), the Court explicitly noted that unlike the MDA, the FDCA does not contain an express preemption provision. 129 S. Ct. at 1196. Additionally, the Wyeth Court noted that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." Id. at 1197-98.

[6] 21 U.S.C. § 301 et seq.

The drug manufacturer contended "that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue." Id. at 1199. The Court rejected this argument, noting that

> Congress enacted the FDCA to bolster consumer protection against harmful products. . . . If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. . . . Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 1199-1200. Having examined the nature of the FDCA and the FDA's traditional position on these issues, the Court concluded that "Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling," and held that Levine's state law claims were not preempted by the FDCA. Id. at 1204.

C. Cook

Following Wyeth, the trial court herein issued its summary judgment order and the jury trial was held. After the conclusion of the trial, but before the motion to correct error was due, a panel of this court issued Cook v. Ford Motor Co., 913 N.E.2d 311 (Ind. Ct. App. 2009), trans. denied. In Cook, the parents of a child who was injured when the front passenger seat airbag deployed filed a failure to warn action against the truck manufacturer under Indiana's products liability statute. The National Traffic and Motor

Vehicle Safety Act[7] (the Safety Act), which was the governing federal statutory scheme at issue in Cook, contains the following preemption clause:

> When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of the State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter.

49 U.S.C. § 30103(b)(1).

Additionally, however, unlike the MDA, the Safety Act contains a state common law savings clause: "[c]ompliance with a motor vehicle safety standard under this chapter does not exempt a person from liability at common law." 49 U.S.C. § 30103(e). In other words, "common law tort actions are not expressly preempted." Cook, 913 N.E.2d at 320. While "[s]tate law tort actions may be preempted if the state standards in question actually conflict with federal objectives," the savings clause "'preserves those actions that seek to establish a greater safety than the minimum safety achieved by a federal regulation intended to provide a floor.'" Id. (quoting Geier v. Am. Honda Motor Co., 529 U.S. 861, 870 (2000)).

Relying heavily on Wyeth, the Cook court found that the state law claims were not preempted by the Safety Act because vehicle manufacturers had "flexibility to tailor the warning language to their vehicles" without agency preapproval. Id. at 325. In other words, the federal regulation at issue set a floor, but not a ceiling, for warnings, and in such a scenario, the state law failure-to-warn claims were not preempted.

[7] 49 U.S.C. § 30101 et seq.

D. Appellants' Claims

The Appellants argue that Cook establishes that the Wyeth rule can be applied to regulatory schemes aside from just the FDCA. While that is true, we cannot agree that Cook necessarily means that Wyeth applies to the MDA and class III medical devices. As noted above, the Wyeth Court explicitly distinguished the FDCA from the MDA, inasmuch as the FDCA has no preemption clause. And as for Cook, we note that while the Safety Act has a preemption clause, it also has an explicit savings clause that "'preserves those actions that seek to establish a greater safety than the minimum safety achieved by a federal regulation intended to provide a floor.'" Cook, 913 N.E.2d at 320 (quoting Geier v. Am. Honda Motor Co., 529 U.S. 861, 870 (2000)). The MDA has no such savings clause; consequently, Cook is inapposite.

The MDA and Riegel could not be clearer that federal law broadly preempts any claim that would allow a jury to impose a standard of care different from or in addition to the FDA's specific federal requirements. Riegel, 128 S. Ct. at 1008. Here, the Appellants seek to do precisely that. Neither Wyeth nor Cook apply to the MDA or in any way circumvent the plain statutory language of the MDA's preemption clause or the United States Supreme Court's interpretation thereof in Riegel. The Appellants herein do not allege that Guidant violated federal requirements. Instead, they contend that Guidant should be liable for its failure to add warnings that are permitted, but not required, by federal law. We cannot imagine a plainer example of an attempt to impose a standard of care in addition to the FDA's specific federal requirements. See McMullen v. Medtronic,

Inc., 421 F.3d 483, 489 (holding, in the context of the MDA and the regulation cited by Appellants herein, that "[w]here a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted"). Consequently, the trial court properly held that the Appellants' claims in this regard are preempted and did not err by denying the Appellants' motion to correct error.[8]

The judgment of the trial court is affirmed.

VAIDIK, J., and BARNES, J., concur.

[8] Because we have ruled in Guidant's favor, we need not address its contingent cross-appeal.