NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING
MOTION AND, IF FILED, DETERMINED

IN THE DISTRICT COURT OF APPEAL

OF FLORIDA

SECOND DISTRICT

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| LINDA WOLICKI-GABLES and ROBERT GABLES, her husband,<br><br>Appellants,<br><br>v.<br><br>DOCTORS SAME DAY SURGERY CENTER, LTD., d/b/a DOCTORS SAME DAY SURGERY CENTER,<br><br>Appellee. | ) | Case No. 2D15-2495 |

Opinion filed February 15, 2017.

Appeal from the Circuit Court for Sarasota County; Peter A. Dubensky, Judge.

T. Patton Youngblood, Jr. of the Youngblood Law Firm, St. Petersburg, for Appellants.

Joshua P. Welsh of Bush Ross, P.A., Tampa, for Appellee.

LaROSE, Judge.

Linda Wolicki-Gables and her husband, Robert Gables, appeal the trial court's final summary judgment in favor of Doctors Same Day Surgery Center, Ltd. (the Surgery Center). The Gableses brought a third-party spoliation lawsuit against the Surgery Center. They asserted that if the Surgery Center had kept an allegedly defective pain-pump connector removed from Mrs. Wolicki-Gables, the Gableses could

have maintained a civil action against Arrow International, Inc., on one of two grounds: (1) a first-party spoliation suit; or (2) a "parallel claim" for negligent design and/or manufacture under Florida law. We have jurisdiction. See Fla. R. App. P. 9.030(b)(1)(A). Because any potential state law claim for negligent design or manufacture against Arrow is preempted by federal law, and because the Gableses cannot assert a "parallel claim" against Arrow under Florida law, we are compelled to affirm.

## Background

Mrs. Wolicki-Gables suffered from back and neck pain. To alleviate the condition, Dr. James of the Surgery Center implanted a "pain pump system" into Mrs. Wolicki-Gables in the spring of 2002. The system consisted of: (1) an infusion pump to hold and release pain medication; (2) an intrathecal catheter that delivered the medication into Mrs. Wolicki-Gables's spinal canal; and (3) a connector that linked these two components. Arrow manufactured all three components, which are Class III medical devices approved through the Premarket Approval Process (PMA) of the Food and Drug Administration (FDA). See Medical Device Amendments of 1976 (MDA) 5121 U.S.C. § 360e (2012); 21 C.F.R. §§ 814.1-.126.

Unfortunately, Mrs. Wolicki-Gables's pain persisted. In response, Dr. James increased the dosage of the medication being dispensed from the pump in the summer of 2002. Mrs. Wolicki-Gables experienced no relief. About a year later, Dr. James performed a dye injection test to assess whether the pain pump system was operating properly. He concluded that the pain medication was not being directed through the intrathecal catheter into Mrs. Wolicki-Gables's spine; rather, it leaked from

the injection site and dripped down Mrs. Wolicki-Gables's sides. Dr. James scheduled Mrs. Wolicki-Gables for surgery and contacted an Arrow representative, Greg Nelson.

On July 15, 2003, Mrs. Wolicki-Gables arrived at the Surgery Center for the operation. She signed an Informed Consent to Treat and Disclose Information form. She handwrote on the form, "we want old pump." She also noted on the form that she did not want technical support personnel, which would include Mr. Nelson, present during the surgery.

Dr. James proceeded with the surgery, during which Mr. Nelson was present. Dr. James removed the pain pump system and determined that the most likely cause of the malfunction was the connector between the pump and the intrathecal catheter. Dr. James replaced the connector and reinserted the pain pump system into Mrs. Wolicki-Gables's body. Dr. James confirmed that the pain pump system was operating properly.

Following the surgery, Mr. Nelson approached Mr. Gables in the waiting room to explain that the connector had been replaced. Mr. Gables asked for the old connector. Mr. Nelson refused, stating that he had to take it to Arrow for testing. Mrs. Wolicki-Gables claims that she also made a similar request to Dr. James later that same day. He, too, stated that the connector had to go to Arrow.

When released from the Surgery Center, Mrs. Wolicki-Gables had no apparent complications. At a postoperative follow-up on July 17, 2003, she presented no signs of infection and the pain pump system was working properly. Sadly, twelve days later, Mrs. Wolicki-Gables was rushed to the hospital where she was diagnosed with transverse myelitis—inflammation of the spinal cord. Several days later, the hospital released her. She returned three days later when her incision site became

infected. The hospital again diagnosed Mrs. Wolicki-Gables with transverse myelitis, and added an infected pain pump to her diagnosis. Mrs. Wolick-Gables underwent another surgery where the pain pump system was permanently removed. During her convalescence from this third procedure, Mr. Gables contacted Mr. Nelson to obtain the old connector removed in the second surgery. Mr. Gables learned that Arrow tested the connector, found no defect, and destroyed it in accordance with company policy. The Gableses then sued Arrow in state court.

The Gableses asserted numerous claims against Arrow, including strict liability and negligence claims. Arrow removed the case to federal district court based on diversity jurisdiction. See 28 U.S.C. § 1332 (2011). Ultimately, the federal district court granted summary judgment to Arrow, concluding that their claims were expressly preempted by the Medical Devices Amendment (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA). Wolicki-Gables v. Arrow Int'l, Inc., 641 F. Supp. 2d 1270, 1296 (M.D. Fla. 2009), aff'd, 634 F.3d 1296, 1303 (11th Cir. 2011). The federal district court also granted summary judgment in favor of Mr. Nelson on the Gableses' claims of negligence and loss of consortium. Wolicki-Gables, 641 F. Supp. 2d at 1292-96. The federal district court also concluded that they failed to demonstrate any causal relation between her injuries and the loss of the connector. Id. at 1295. Importantly, experts in the federal case were not impeded from offering meaningful testimony because the connector was unavailable. Id. at 1281.

Undeterred, and convinced that they would have prevailed against Arrow if they had the old connector, the Gableses sued the Surgery Center in state court, asserting a third-party spoliation claim. A third-party spoliation claim arises when "a person or an entity, though not a party to the underlying action causing the plaintiff's

injuries or damages, lost, misplaced, or destroyed evidence critical to that action." Martino v. Wal-Mart Stores, Inc., 908 So. 2d 342, 345 n.2 (Fla. 2005). In such a case, the plaintiff attempts to recover from the third party "the loss of a probable expectancy of recovery against the first-party torfeasor." Id. (citing Humana Worker's Comp. Servs. v. Home Emergency Servs., Inc., 842 So. 2d 778, 781 (Fla. 2003)). The Gableses alleged that but for the Surgery Center allowing Mr. Nelson to take the old connector, they could have proceeded successfully against Arrow on (1) a first-party spoliation claim, or (2) a negligent design/manufacture theory. The trial court granted summary judgment to the Surgery Center. The trial court found that neither a first-party spoliation claim nor a permissible "parallel claim" against Arrow for negligent design/manufacture existed under Florida law. This appeal followed.

## Discussion

The Gableses argue that the trial court erred in concluding that they could not assert a "parallel claim" against Arrow under Florida law for negligent manufacture based on a violation of MDA regulations related to Class III medical devices. We write to explain why the trial court committed no error on this point. As to the first-party spoliation claim, we affirm without further discussion. See Martino, 908 So. 2d at 347.

### a. Express and Implied Preemption Statutes

We begin our "parallel claim" analysis by noting that the MDA bars virtually all state-based claims for allegedly defective Class III medical devices. Two statutes are relevant. 21 U.S.C. § 360k(a) provides that

> [N]o 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.

This section expressly preempts any state requirement or other obligation that is "different from, or in addition to, any requirement applicable [under the MDA] to the device," related to the "safety or effectiveness of the device." Id.

The second statute, 21 U.S.C. § 337(a), provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." Section 337(a) impliedly preempts any action "for the enforcement, or to restrain violations," of the MDA in any name other than that of the United States. Thus, enforcement of MDA requirements, in the first instance, is left to the federal government.

In tandem, §§ 360k(a) and 337(a) make it exceedingly difficult for a plaintiff to maintain negligence claims for allegedly defective medical devices that entered commerce through the PMA approval process. Often, state law claims, such as claims for negligent manufacture, are broad in scope and are expressly preempted by § 360k(a). This was the conclusion reached by the federal district court in the Gableses' initial lawsuit against Arrow. Wolicki-Gables, 641 F. Supp. 2d at 1288. But, when a plaintiff attempts to assert a claim specifically based on a violation of the MDA, the claim is impliedly preempted by § 337(a), which leaves enforcement of the MDA to the United States.

The PMA approval process does not swallow the entire universe of potential state law claims. Under our federal system, states may enact laws which create a private cause of action for "failure to comply with the federal standards which were established [for a medical device] through the PMA process." Wolicki-Gables, 641

F. Supp. 2d at 1284 (citing Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008)). Unfortunately for the Gableses, Florida has no such law.

**b. Framework for Preemption Analysis**

Three Supreme Court cases provide the primary framework for preemption analysis in the MDA context. The first is Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). There, the Court determined that the MDA did not preempt the Lohrs' negligent manufacture claims against Medtronic for a faulty pacemaker. Id. at 503. The Court noted, however, that Medtronic's pacemaker device did not undergo the PMA process, as had Mrs. Wolicki-Gables' pain pump system. Id. at 480. The Court described the PMA process as a "rigorous" process during which the manufacturer "submit[s] detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." Id. at 477. Without FDA approval, a device which receives premarket approval cannot be modified by the manufacturer in a way which would affect the device's safety or efficacy. 21 U.S.C. § 360e(d)(6).

In contrast, Mr. Lohr's pacemaker had entered the market through the § 510(k) process (as amended, 21 U.S.C. § 360(k) (2012)), which compares a device created after the implementation of the MDA to one that was created before enactment of the MDA. The § 510(k) process determines whether a new device is "substantially equivalent" to one that entered the market before the MDA. Lohr, 518 U.S. at 492-93. As the Court observed, the § 510(k) process involves a truncated, limited review–twenty hours on average. Id. at 478-79. "Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." Id. at 479 (citations omitted). The Court emphasized that the § 510(k) process was based on

equivalency to a pre-MDA device, not on the actual safety of the device that is carried out under the PMA process. Id. at 493. As a result, the Court found that a "substantial equivalence" finding under the § 510(k) process did not preempt the Lohrs' negligent manufacture claims against Medtronic; the § 510(k) process only was meant to "maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. . . . [I]nclud[ing] the possibility that the manufacturer of the device [might] have to defend itself against state-law claims of negligent design." Id. at 494. Because of the approval process involved, Lohr lends little support to Mrs. Wolicki-Gables' claim.

Subsequently, in Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341, 346-47 (2001), the plaintiffs asserted that Buckman defrauded the FDA when it separated its bone screw device, intended for spinal surgery, into component parts—the bone screws themselves and the nested bone plates—in order to obtain a § 510(k) exemption. Apparently, Buckman had been unsuccessful in obtaining such an exemption for the device as a whole. Id. at 346. Allegedly, Buckman knew that the FDA would not approve of Buckman's intended use for the bone screw device components in their totality. As a result of the alleged fraud, plaintiff suffered injuries from Buckman's bone screws. See id. at 346-47 (discussing plaintiffs' claims). Ultimately, the Court determined that the plaintiffs' claims were impliedly preempted, finding that:

> [T]he federal statutory scheme amply empowers the FDA to punish and deter fraud against the [FDA]. . . . [T]his authority is used by the [FDA] to achieve a somewhat delicate balance of statutory objectives. The balance sought by the [FDA] can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id. at 348.

Although Buckman, like Lohr, involved this § 510(k) process, the Court was unwilling to allow a private state law fraud claim to proceed. In reconciling Buckman with Lohr, the Court observed as follows:

> [A]lthough [Lohr] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim. . . . [W]ere plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case.

Buckman, 531 U.S. at 353. Thus, the Court seemed willing to permit state law causes of action based on violations of state law requirements that mirrored federal requirements, but it was unwilling to permit a state law cause of action *based upon a* violation of federal law. Id.

The third and final case to refine the MDA preemption analysis applicable here is Riegel. In Riegel, a balloon catheter used to dilate the plaintiff's coronary artery ruptured. 552 U.S. at 320. The plaintiff had to undergo emergency coronary bypass surgery. Id. The plaintiff sued Medtronic, alleging various common law claims, including "strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter." Id. He theorized that Medtronic's catheter was "designed, labeled, and manufactured in a manner that violated New York common law." Id.

In Riegel, the Court observed that unlike Lohr, where the device had been approved through the § 510(k) exemption process, the catheter went through the more exacting PMA process. Id. at 322-23. As noted earlier, PMA approval imposes rigorous

requirements under the MDA. Id. The Court observed that PMA approval "is in no sense an exemption from federal safety review—it *is* federal safety review." Id. at 323. With this in mind, the Court determined that the plaintiff's state common law claims for negligence and strict liability imposed requirements preempted by federal requirements specific to the medical device. Id. at 323-24. The Court explained that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties," reasoning that "[s]tate tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved [through the PMA process] disrupts the federal scheme no less than state regulatory law to the same effect." Id. at 324. Thus, the Court stood by its holding in Lohr that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330 (citing Lohr, 518 U.S. at 495). But the Court concluded that Riegel's claims were preempted because they asserted that "Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements." Id. at 330. Seemingly, the Court would not tolerate the pursuit of state law claims that posed the risk of liability, even if the manufacturer complied with all requirements imposed by the PMA.

Taken together, Lohr, Buckman, and Riegel "create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption" under the MDA. Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009). The Court maintained in Riegel that it was, in fact, still possible to bring a parallel claim under state law. Defining a parallel claim, however, remains frustratingly difficult.

**c. Parallel Claims**

The Gableses' spoliation claim against the Surgery Center rises or falls on whether they could have asserted a parallel claim against Arrow. As the Eleventh Circuit noted in the Gableses' federal lawsuit against Arrow:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to the requirements imposed by federal law." Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Wolicki-Gables, 634 F.3d at 1300 (citing Lohr, 518 U.S. at 495) (citations omitted). Thus, the Eleventh Circuit anticipated the existence of a state law that allows a private cause of action for a violation of the MDA and related regulations. Common law damage claims are inadequate to escape federal preemption.

An MDA parallel claim is much like a unicorn—existing in legend, but elusive in reality. "[C]laims alleging a failure to comply with the federal standards which were established through the PMA process are not preempted. Such claims are 'parallel' claims, which do not add to or differ from federal requirements." Wolicki-Gables, 641 F. Supp. 2d at 1284 (citing Riegel, 552 U.S. at 330); accord Lohr, 518 U.S. at 495 ("[section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."). Since Riegel, the "narrow gap" available to allow a parallel claim remains open where the state legislature provides a law that makes available the parallel private remedy for a violation of FDA regulations. Analogous to Goldilocks' porridge, such a statute cannot be overly broad—and thus expressly preempted by § 360k—nor sound like an action to enforce or restrain

violations of the MDA—and thus impliedly preempted by § 337(a). See generally 21 U.S.C. §§ 360k(a), 337(a). The state law must be just right to allow passage through Riegel's narrow gap.

A handful of post-Riegel cases involve a plaintiff who adequately alleged a parallel claim sufficient to survive a motion to dismiss. See, e.g., Waltenburg v. St. Jude Med., Inc., 33 F. Supp. 3d 818 (W.D. Ky. 2014) (granting defendant's motion to dismiss plaintiff's negligence per se claims premised on violations of federal law, but denying defendant's motion to dismiss plaintiff's claims for negligent manufacture, negligent failure to warn, and strict liability manufacturing defects, finding that they were not expressly or impliedly preempted by the MDA); James v. Diva Int'l, 803 F. Supp. 2d 945 (S.D. Ind. 2011) (denying defendant's motion to dismiss plaintiff's state law claims, finding that the claims were not preempted by the MDA). Many others conclude that plaintiffs' claims are expressly preempted by § 360k(a) for imposing requirements "different from, or in addition to," the MDA, or impliedly preempted by § 337(a) because they attempt to enforce, or restrain violations of, the MDA. See, e.g., Mink v. Smith & Nephew, Inc., 169 F. Supp. 3d 1321 (S.D. Fla. 2016) (granting defendant's motion to dismiss based on preemption under the MDA); Marmol v. St. Jude Med. Ctr., 132 F. Supp. 3d 1359 (M.D. Fla. 2015) (granting defendant's motion to dismiss, and holding that Florida does not recognize private causes of action—such as plaintiff's product liability claim—for violations of FDA regulations); Pearsall v. Medtronics, Inc., 147 F. Supp. 3d 188 (E.D.N.Y. 2015) (dismissing plaintiff's state law claims, including claims for manufacturing defects, as preempted by the MDA); Gross v. Stryker Corp., 858 F. Supp. 2d 466 (W.D. Pa. 2012) (holding that plaintiff's breach of implied warranty claim was expressly preempted because it imposed requirements different than, or in addition

to, applicable federal requirements); In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009) (dismissing a consolidated complaint with prejudice due to preemption under the MDA).

As Judge Kyle noted in In re Medtronic, "nearly all types of claims concerning FDA-approved medical devices are preempted." 592 F. Supp. 2d at 1161. Despite the potential to assert a parallel claim, there appears to be little solid ground remaining on which to construct such a claim for a plaintiff who alleges injury from a PMA-approved medical device.

At the core, the Gableses hoped that with the old connector in hand, they could demonstrate that Arrow did not manufacture the connector in compliance with PMA requirements. Their only basis to proceed is by a parallel claim. Their proposed theory, however, lacks a firm footing under Florida law. "Florida law does not permit a private action to enforce violations of FDA requirements." Marmol, 132 F. Supp. 3d at 1367-68; accord Kaiser v. DePuy Spine, Inc., 944 F. Supp. 2d 1187, 1192 (M.D. Fla. 2013) ("The Court also finds Plaintiff's claims should be dismissed since Florida law does not allow Plaintiff to bring a private cause of action to enforce FDA regulations."); Wheeler v. DePuy Spine, Inc., 706 F. Supp. 2d 1264, 1270 (S.D. Fla. 2010) ("Whether these claims are characterized as negligent design, manufacture, or sale of the product, Florida law does not authorize the only type of 'negligence' claims that might survive the MDA, i.e., a claim based on violation of federal requirements."). Although frequently recited, the holdings in these cases are rarely explained.

Under Florida law, a statutory violation does not give rise to a private cause of action absent a clear legislative intent to do so. Wheeler, 706 F. Supp. 2d at 1268 (citing Murthy v. N. Sinha Corp., 644 So. 2d 983 (Fla. 1994)). Certainly, the MDA

does not reflect a congressional intent to create such a private cause of action. See 21 U.S.C. § 360 (including no specific language to indicate an intent to create a civil cause of action for violation). And the weight of authority in Florida, too, reflects no state legislative effort to create the statutory parallel claim.

The spoliation theory the Gableses assert, if allowed, would permit what the Florida Supreme Court prohibited in Murthy–creation of a private civil cause of action in Florida for violation of a federal statute absent clear legislative intent to do so. See 644 So. 2d at 985–87 (declining to judicially create a civil cause of action based on a statute where the legislature had expressed no clear intent to create such a cause of action).

**Conclusion**

Congress has expressed a clear intent to limit liability for manufacturers of medical devices. Presumably, Congress intended to promote innovation in the medical device field. Florida law provides no parallel claim that would allow the Gableses to pursue Arrow. The Florida Legislature may choose to do so, but it is not within our ken to create a cause of action by judicial fiat. As a result, the spoliation claim must fail. Even if they had the old connector, the Gableses would not have been able to proceed further against Arrow.

Accordingly, we affirm the trial court's entry of summary judgment in favor of the Surgery Center.

Affirmed.

SILBERMAN and BADALAMENTI, JJ., Concur.