REPORTED

IN THE COURT OF SPECIAL APPEALS

OF MARYLAND

No. 670

September Term, 2013

STEVEN L. MCCORMICK, ET UX.

v.

MEDTRONIC, INC., ET AL.

Meredith,
Berger,
Arthur,

JJ.

Opinion by Arthur, J.

Filed: October 6, 2014

This case principally concerns the extent to which federal law expressly or impliedly preempts state common-law and statutory claims for personal injuries that resulted from the so-called "off-label" promotion of a medical device.

Relying on one of the first of what are now numerous federal district court decisions concerning the specific device at issue in this case, the Circuit Court for Montgomery County ruled that federal law preempted all of the plaintiffs' claims, except those for fraud. The court then ruled that the plaintiffs had failed to plead fraud with particularity. Consequently, the court dismissed the claims against the manufacturer with prejudice.

We shall hold that federal law does not expressly or impliedly preempt the plaintiffs' claims concerning misrepresentations or express warranties that the manufacturer may have made in voluntary communications with the public or with members of the medical profession. We shall also hold that the plaintiffs failed to plead common-law fraud with particularity, but that the circuit court, on remand, should allow them an opportunity to replead. We shall affirm the circuit court in all other respects.

QUESTIONS PRESENTED

Appellants present two questions for our review, which we have rephrased as follows:

I. Did the trial court err in holding that all of the appellants' causes of action (except those for fraud) are expressly and impliedly preempted by federal law?

II. Did the trial court err in holding that appellants had failed to plead fraud with particularity?

As stated above, we shall affirm in part and reverse in part on the preemption issues. On the issue of pleading fraud with particularity, we shall affirm, but shall direct the circuit court to afford leave to amend on remand.

FACTUAL AND PROCEDURAL HISTORY

A. Introduction

This is one of numerous cases nationwide concerning the Infuse Bone Graft device, a medical device that is manufactured and marketed by defendant Medtronic, Inc.

In 2007, plaintiff Steven McCormick underwent spinal-fusion surgery, in which his surgeon, defendant Michael K. Rosner, M.D., implanted the Infuse device in an "off-label" manner – *i.e.*, in a manner other than the one "for which it has been approved by the FDA." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Mr. McCormick claims to have suffered serious complications, including excessive bone growth, which allegedly necessitated a second surgery and has left him disabled. He attributes his condition to what he characterizes as Medtronic's "illegal" promotion of off-label uses of the device, including alleged misrepresentations concerning the risks of the off-label uses.

B. The Infuse Device

As approved by the FDA in 2002, the Infuse device consists of three components: a genetically-engineered version of a naturally-occurring protein that stimulates bone growth; a collagen sponge; and a cage or hollow cylinder that holds the vertebrae in place

and directs the development of bone growth.

In surgery employing the device, the genetically-engineered protein is applied to the sponge, which acts as a carrier and scaffold for the protein. The surgeon implants the protein-infused sponge and the cage into the spine, where the protein evidently spurs the bone growth necessary to achieve the fusion. The device thus appears to have been intended to replace or supplant the conventional method of performing spinal-fusion surgery, which involves harvesting bone (either from the patient's hip or from a cadaver) and implanting the harvested bone in the patient's spine.

C. FDA Approval

The McCormicks allege that the majority of spinal-fusion procedures, including those that are used to treat nerve compression, are performed by means of a "posterior approach" through the back. The McCormicks further allege that even before the FDA approved the Infuse device in 2002, Medtronic knew, from clinical trials, that when the surgeons employed a posterior approach, the use of the genetically-engineered protein led to undesired or "heterotopic" bone growth. According to the McCormicks, an FDA advisory panel admonished Medtronic to guard against the use of the device in procedures other than an "anterior approach," by which the surgeon approaches the spine from the front of the body, through an incision in the abdomen. One panel member allegedly observed that because the cage is difficult to implant in a posterior approach, the use of the cage would prevent most surgeons from employing the posterior approach.

When the FDA approved the Infuse device, it required the labeling to warn that the device may be used only via the anterior approach. In addition, the approved labeling warns that the product "must not be used" without the cage.

D. Off-Label Marketing

The McCormicks' complaint is replete with allegations that, after obtaining FDA approval of the Infuse device, Medtronic engaged in an extensive and (they allege) illegal effort to promote the off-label use of the device, apparently by means of a posterior approach without the required cage. The McCormicks specifically allege that Medtronic promoted the off-label use of the Infuse device by giving financial incentives to physicians, by providing physicians with information from consultants and "key opinion leaders" whom Medtronic had targeted and paid, and by placing Medtronic sales representatives in operating rooms when surgeons were performing surgeries in which they employed the off-label, posterior approach.[1]

The McCormicks allege that, as a result of Medtronic's off-label promotion of the Infuse device, sales of the device exceeded $900 million in 2010, of which more than 85

[1] The McCormicks are not alone in making these allegations: "after a 16-month investigation, the Senate Committee on Finance issued a 2,315-page report criticizing Medtronic for its heavy involvement in 'drafting, editing and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic.'" *Schouest v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 1213243, at *2 (S.D. Tex. Mar. 24, 2014) (quoting Staff of Sen. Comm. on Finance, 112th Cong., Staff Report on Medtronic's Influence on Infuse Clinical Studies 6 (Comm. Print 2012)).

percent resulted from off-label procedures.

E. The Spine Journal

The McCormicks' complaint prominently mentions the July 2011 edition of a medical periodical, *The Spine Journal*, which, they say, devoted an entire issue to articles concerning the Infuse device. The complaint alleges that the journal articles discussed Medtronic's failure to accurately report the adverse side-effects that occurred in the clinical trials of the device; Medtronic's failure to disclose that many of the authors who studied and promoted the device had conflicts of interest because of their significant financial ties to Medtronic (having received a median range of payments of between $12 million and $16 million per study); and Medtronic's downplaying of the risks associated with the device (including the stimulation of excessive bone growth) while overemphasizing its advantages over conventional procedures (such as bone grafts).

F. The Disclosure of Increased Risks of Cancer

The McCormicks also allege that a November 2011 study showed that a high-dosage use of the Infuse device, which, they say, occurs in some off-label procedures, can result in a nearly four-fold increased risk of cancer. They go on to allege that, according to the study's lead researcher, the genetically-engineered protein in the Infuse device is a cancer-promoting substance. The McCormicks claim that Medtronic knew of the alleged risks of cancer, but failed to inform the public or the medical community of them.

G. Mr. McCormick's Unsuccessful Surgery

On July 27, 2007, well before the allegations about the Infuse device became public, Mr. McCormick himself underwent spinal-fusion surgery to relieve his complaints of persistent back pain. His surgeon, Dr. Rosner, took a posterior approach (rather than the approved anterior approach), and he used a Medtronic cage that the FDA had not approved for use with an Infuse bone graft. Additionally, the McCormicks appear to allege that the surgeon used an inappropriate amount of the genetically-engineered protein component of the device. According to the McCormicks' complaint, at least one Medtronic sales representative – defendant Vincent Profitt – was present in the operating room during Mr. McCormick's surgery.

The McCormicks allege that the surgery did not succeed in relieving Mr. McCormick's complaints. As a consequence, the McCormicks allege, Mr. McCormick was unable to continue to work and was forced to go on permanent disability in October 2008. They claim that in the spring of 2010 Mr. McCormick's physicians discovered that he suffered from neural foraminal stenosis, or narrowing of the cervical disc space, at the site where the Infuse device had been implanted. Eventually, in September 2010, Mr. McCormick underwent revision surgery to remove the "bony overgrowth" and inflammation that had allegedly resulted from the earlier surgery in 2007. The McCormicks allege that in the revision surgery Mr. McCormick's surgeon was forced to chisel away the excess bone-growth that, they say, the Infuse product had caused.

According to the McCormicks, Mr. McCormick learned in August 2011 that he had two nodules in his lungs that he must monitor to ensure that they do not become cancerous. The McCormicks contend that Mr. McCormick's exposure to the Infuse product significantly increases the risk that the nodules will become cancerous.

H. The Complaint

On the basis of these essential allegations, Mr. McCormick asserted a series of claims against Medtronic, a Medtronic subsidiary, the Medtronic sales representative who was in the operating room during his surgery (collectively, "Medtronic"), and Dr. Rosner.[2]

As against Medtronic, Mr. McCormick asserted claims for negligence (Count II), strict products liability (Count III), breach of warranty (Count IV), fraud (Count V), negligence per se (Count VI), and violations of the Consumer Protection Act (Count VII). As against the surgeon, Dr. Rosner, McCormick asserted a claim for failure to obtain informed consent (Count VIII). Finally, Mr. McCormick and his wife asserted a joint claim for loss of consortium (Count IX).[3]

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[2] The McCormicks originally filed suit in Minnesota state court, but dismissed their claims before the court could rule on Medtronic's motion to dismiss. They then commenced this suit by filing a nearly-identical complaint in the Circuit Court for Baltimore City. The Baltimore City court transferred the case to Montgomery County because venue was improper in the City.

[3] The complaint contains a Count I, but it consists solely of background allegations and does not contain any request for relief under any specific legal theory.

I. The Proceedings in the Circuit Court

Medtronic moved to dismiss the McCormicks' complaint on several grounds, including federal preemption and the failure to allege fraud with particularity. Dr. Rosner also moved to dismiss the complaint, arguing that the McCormicks had failed to comply with their obligation to submit their claim to the Health Care Alternative Dispute Resolution Office before filing suit. *See* Md. Code (1974, 2013 Repl. Vol.) § 3-2A-04(a)(1)(i) of the Courts and Judicial Proceedings Article. Meanwhile, Mr. McCormick voluntarily dismissed the claim that alleged negligence per se.

After a hearing, the circuit court dismissed the claims against Medtronic, relying exclusively on *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Ok. 2013), one of the first reported cases to consider the extent to which federal law preempts state-law claims concerning the Infuse device. Rather than dismiss the claims against Dr. Rosner, however, the court stayed the proceedings to permit the McCormicks to file the claim in the Health Care Alternative Dispute Resolution Office.

In response, the McCormicks initially asked the court to allow them to appeal the order as to Dr. Rosner under the collateral order doctrine, "a very narrow exception to the final judgment rule." *See, e.g.*, *Nnoli v. Nnoli*, 389 Md. 315, 329 (2011). After the court complied with their request, however, the McCormicks dismissed the claims against Dr. Rosner, without prejudice. Then they took this appeal.

DISCUSSION

I.

Before we discuss the substantive issues in this case, we first must address whether there was a final judgment from which the McCormicks were entitled to appeal.

Although the circuit court granted Medtronic's motion to dismiss, the court did not adjudicate all of the claims against Medtronic's co-defendant, Dr. Rosner. Because the court, therefore, had "adjudicate[d] the rights and liabilities of fewer than all the parties to the action," its ruling was "not a final judgment." Md. Rule 2-602(a)(1). Generally, therefore, the McCormicks would have no right to appeal unless they could establish that the ruling fell within one of the exceptions to the final judgment rule. *See generally Waterkeeper Alliance, Inc. v. Maryland Dep't of Agriculture*, 439 Md. 262, 286-89 (2014); *Falik v. Hornage*, 413 Md. 163, 175-76 (2010); *St. Joseph Med. Ctr., Inc. v. Cardiac Surgery Assocs*., 392 Md. 75, 84 (2006).

The collateral order doctrine, which the McCormicks briefly invoked, would not assist them. Even if the doctrine somehow applied,[4] the court had permitted an appeal only as to Dr. Rosner, not as to Medtronic – the party that the McCormicks most wanted

[4] It did not. An appealable collateral order (1) conclusively determines the disputed issue, (2) resolves an important issue, (3) resolves an issue that is completely separate from the merits of the action, and (4) would be effectively unreviewable if the appeal had to await the entry of a final judgment. *See*, *e.g.*, *Ehrlich v. Grove*, 396 Md. 550, 563 (2007). Among other things, the order as to Dr. Rosner conclusively determined nothing; it merely stayed the proceedings for a time. Nor would the temporary stay have been unreviewable on appeal from a final judgment.

to pursue.

The McCormicks did not solve the problem of Dr. Rosner's continued presence by dismissing all claims against him without prejudice: in *Miller and Smith at Quercus LLC v. Casey PMN, LLC*, 412 Md. 230, 248-53 (2010), the Court of Appeals held that parties cannot transform an otherwise interlocutory ruling into an appealable final judgment through the voluntary dismissal, without prejudice, of the unadjudicated aspects of a case. Thus, in light of *Miller and Smith,* we directed the parties, on our motion, to address whether and how we could exercise appellate jurisdiction.

Having reviewed the parties' submissions, we are convinced that we have the power to decide the appeal under Md. Rule 8-602(e)(1). That rule provides as follows:

> (e) **Entry of judgment not directed under Rule 2-602.** (1) *If* the appellate court determines that the order from which the appeal is taken was not a final judgment when the notice of appeal was filed but that *the lower court had discretion to direct the entry of a final judgment pursuant to Rule 2-602 (b), the appellate court may*, as it finds appropriate, (A) dismiss the appeal, (B) remand the case for the lower court to decide whether to direct the entry of a final judgment, (C) *enter a final judgment on its own initiative* or (D) if a final judgment was entered by the lower court after the notice of appeal was filed, treat the notice of appeal as if filed on the same day as, but after, the entry of the judgment.

(Emphasis added.)

In other words, if this Court confronts an improper, interlocutory appeal in a case where the circuit court could have certified its ruling as final and appealable under Rule 2-602(b), then Rule 8-602(e) authorizes this Court, among other things, to "enter a final judgment on its own initiative." The question thus becomes whether the circuit court

could have certified its ruling as final and appealable under Rule 2-602(b).

Rule 2-602(b) provides as follows:

> (b) **When allowed**. *If the court expressly determines in a written order that there is no just reason for delay, it may direct in the order the entry of a final judgment*:
>
> (1) *as to one or more but fewer than all of the* claims or *parties*; or
>
> (2) pursuant to Rule 2-501(f)(3), for some but less than all of the amount requested in a claim seeking money relief only.

(Emphasis added.)

In dismissing the claims against Medtronic but not against Dr. Rosner, the circuit court disposed of all claims against one or more, but fewer than all, of the parties. If, therefore, the circuit court had expressly determined in a written order that there was no just reason to delay the entry of final judgment as to Medtronic, it would have had some discretion to certify an immediate appeal of that ruling under Rule 2-602(b). *See, e.g.*, *Tharp v. Disabled American Veterans Dep't of Maryland, Inc.*, 121 Md. App. 548, 562-64 (1998); *Allstate Ins. Co. v. Angeletti*, 71 Md. App. 210, 215-17 (1987); *Canterbury Riding Condo. v. Chesapeake Investors, Inc.*, 66 Md. App. 635, 646 (1986)*; see also USA Cartage Leasing, LLC v. Baer*, 202 Md. App. 138, 169-70 (2011), *aff'd*, 429 Md. 199 (2012).

While the circuit court's exercise of discretion under Rule 2-602(b) would have been subject to appellate scrutiny to ensure that it did not conflict with Maryland's strong policy against piecemeal appeals (*see, e.g.*, *Tharp*, 121 Md. App. at 562-64), the Court of

Appeals recently approved the exercise of discretion in a similar case, where the circuit court had disposed of all claims against the central defendant, leaving only the claims against a minor defendant who may have been insolvent. *Barclay v. Briscoe*, 427 Md. 270, 278 n.6 (2012). In reaching that decision, the Court of Appeals specifically noted the "financial hardship" that the injured plaintiffs would face were they forced to incur the time and expense of litigating the case to a conclusion before they could appeal. *Id.*; *compare Waterkeeper Alliance*, 439 Md. at 289 (declining to exercise authority under Rule 8-602(e) because there was a significant reason to delay the entry of judgment).

Under *Barclay*, the circuit court could properly have exercised its discretion to certify its ruling as to Medtronic as an appealable final judgment under Rule 2-602(b). Not only is this case almost entirely about Medtronic, but the McCormicks have told us that Dr. Rosner has no liability insurance and that they now regard the Medtronic defendants as the only culpable parties. In fact, after we directed the parties to address the issue of appellate jurisdiction, the McCormicks corroborated their assertions by dismissing their claims against Dr. Rosner with prejudice.

An appellate court "should be reluctant" to enter judgment on its own initiative under Rule 8-602(e) when no party asked the circuit court to exercise its authority under Rule 2-602(b). *Smith v. Lead Indus. Ass'n, Inc.*, 386 Md. 12, 26 (2005). In fact, the appellate court may not exercise that authority at all if the circuit court was asked to certify the judgment under Rule 2-602(b), but exercised its discretion not to do so.

Addison v. Lochearn Nursing Home, LLC, 411 Md. 251, 263 (2009); *Brown & Williamson Tobacco Corp. v. Gress*, 378 Md. 667, 682 (2003).

In this case, however, it seems clear that the circuit court would have exercised its authority under Rule 2-602(b) had the McCormicks asked it to employ that specific tool. After dismissing the claims against the Medtronic defendants, the court and counsel engaged in a discussion about facilitating an appeal. As a result of that discussion, the court signed the order that made its ruling as to Dr. Rosner immediately appealable under the collateral order doctrine. Although that order had no effect on the McCormicks' ability to appeal the decision in favor of Medtronic, it strongly suggests that the court intended to permit an immediate appeal, but used the wrong rule.

In these specific circumstances, it would make little sense not to permit the appeal to proceed. If we were to dismiss the appeal because of a "technical" problem (*Smith*, 386 Md. at 26) resulting from the decision to stay rather than dismiss the claims against Dr. Rosner, we would only prolong the litigation and increase the financial hardship that the plaintiffs face. Thus, because the circuit court could have certified its ruling as final under Rule 2-602(b), we have the power, under Rule 8-602(e)(1)(C), to enter a final judgment on our own initiative, which we hereby do.[5]

[5] Alternatively, because the circuit court's order effectively became final when the McCormicks dismissed their claims against Dr. Rosner with prejudice, we may treat their "notice of appeal as if filed on the same day as, but after, the entry of the judgment." Md. Rule 8-602(e)(1)(D). In either case, the appeal is properly before us.

II.

The McCormicks' claims arise against the backdrop of a highly-detailed scheme of federal regulation. To evaluate the extent to which federal law preempts the McCormicks' claims, we must examine that scheme at some length.

A. The FDCA and the MDA

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et seq.*, which generally required the Food and Drug Administration (the "FDA") to approve the introduction of new drugs onto the market. Until the 1970s, however, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel v. Medtronic, Inc*., 552 U.S. 312, 315 (2008) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76 (1996)).

In the 1970s, in the aftermath of the failure of some complex devices, particularly the Dalkon Shield,[6] several states adopted regulatory measures, including measures requiring premarket approval of new devices. *Id*. In an effort to standardize the regulatory environment, Congress responded by passing the Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360c *et seq*., which "swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel*, 552 U.S. at 316.

The MDA contains an express preemption provision, which provides, in pertinent

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[6] "[T]he Dalkon Shield intrauterine device, introduced in 1970, was linked to serious infections and several deaths[.]" *Riegel*, 552 U.S. at 315.

part, as follows:

> [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.

21 U.S.C. § 360k(a).[7]

The MDA established three levels of oversight of medical devices: Class I, Class II, and Class III. Class I, which includes devices such as elastic bandages and examination gloves, is subject to the lowest level of oversight, consisting of "general controls," such as labeling requirements. *Riegel*, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(A)). "Class II, which includes such devices as powered wheelchairs and surgical drapes, . . . is subject to 'special controls' such as performance standards and postmarket surveillance measures." *Id.* at 316-17 (citing 21 U.S.C. § 360c(a)(1)(B)). Lastly, Class III devices, "which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators," receive "the most federal oversight." *Id.* at 317.

A device is classified as Class III if "it cannot be established that a less stringent

[7] The preemption provision contains an exception that allows the FDA to exempt some requirements from preemption (*see* 21 U.S.C. § 360k(b)), but neither party contends that the exception applies in this case.

classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). Medtronic's Infuse device is a Class III medical device under the MDA.

Unless the FDA deems a new Class III device to be "substantially equivalent" to a device that was on the market in 1976, the device must go through a "rigorous regime of premarket approval." *Riegel*, 552 U.S. at 317. To begin that process, the manufacturer must submit what is typically a multi-volume application, which includes:

> 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 (quoting 21 U.S.C. § 360e(c)(1)).

"Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, . . . and may request additional data from the manufacturer." *Id.* (citing 21 C.F.R. § 814.44(a); 21 U.S.C. § 360e(c)(1)(G)). "The FDA spends an average of 1,200 hours reviewing each application." *Id*. (citing *Lohr*, 518 U.S. at 477).

The FDA "grants premarket approval only if it finds there is a 'reasonable

assurance' of the device's 'safety and effectiveness.'" *Riegel,* 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)). In making that finding, the FDA must "'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Id.* (quoting 21 U.S.C. § 360c(a)(2)(C)). The agency "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.*

"The premarket approval process includes review of the device's proposed labeling." *Id.* "The FDA evaluates safety and effectiveness under the conditions of use set forth on the label . . . and must determine that the proposed labeling is neither false nor misleading." *Id.* (citing 21 U.S.C. § 360c(a)(2)(B); 21 U.S.C. § 360e(d)(1)(A)). Premarket approval "incorporates an FDA finding that a device is safe and effective under the conditions of use included on the label and that the label is not false or misleading." *Cornett v. Johnson & Johnson*, 211 N.J. 362, 381 (2012) (citing 21 U.S.C. § 360e(d)(1)(A), (d)(2)).

After the FDA has granted premarket approval, the MDA imposes further restrictions. For instance, without FDA permission, the manufacturer may not make any "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Furthermore, if the manufacturer wishes to make such a change, "it must submit, and the FDA must approve, an application for supplemental

premarket approval," which is "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)).

B. Express Preemption Under the MDA

As stated above, the MDA expressly preempts certain state-law "requirement[s]" "with respect to" federally-regulated medical devices – specifically, requirements that "relate[] to the safety or effectiveness of the device" and are "different from, or in addition to, any requirement applicable" under the MDA itself. 21 U.S.C. § 360k(a).

In *Riegel*, 552 U.S. at 323-24, the Supreme Court held that common-law causes of action for negligence and strict liability impose "requirements," within the meaning of the MDA's express preemption provision in § 360k(a).[8] In addition, the Court held that the state-law duties underlying negligence, strict liability, and implied-warranty claims impose requirements "with respect to" devices, within the meaning of § 360k(a). *Id.* at 327-30. Thus, because the *Riegel* plaintiffs contended that a Class III medical device (a heart catheter) was defective under state law notwithstanding the manufacturer's full compliance with all of the requirements that the FDA had imposed, the Supreme Court held that the MDA expressly preempted their claims (*id.* at 323-30): the plaintiffs had improperly attempted to impose state-law requirements that were "different from, or in addition to," the requirements for safety and effectiveness that the FDA itself had

[8] A majority of the members of the Court had previously endorsed that conclusion in various concurring and dissenting opinions. *See Lohr*, 518 U.S. at 512 (O'Connor, J., dissenting); *id.* at 503-05 (Breyer, J., concurring in part and concurring in the judgment).

imposed. *See* 21 U.S.C. § 360k(a).

In reaching its decision, the Court nonetheless recognized that "[s]tate 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." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)) (emphasis added). "Thus," the Court continued, the express preemption provision in § 360k(a) "does not prevent a State from providing a damages remedy for claims premised on a *violation* of FDA regulations[.]" *Riegel*, 552 U.S. at 330 (emphasis added). "[T]he state duties in such a case," the Court explained, would "'parallel,' rather than add to, federal requirements." *Id.* (citing *Lohr*, 518 U.S. at 495).[9]

Since the *Riegel* decision in 2008, numerous courts have recognized that the MDA expressly preempts state-law claims only when a manufacturer has *complied* with federal law, and not when the manufacturer has in some way *violated* federal law. *See, e.g.*, *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 549-50 (7th Cir. 2010), *cert. denied*, ___ U.S. ___, 132 S. Ct. 498 (2011); *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232-33 (9th Cir. 2013) (en

[9] Indeed, in *Riegel* itself, the district court had held that the MDA did not expressly preempt the plaintiffs' claims that the manufacturer had breached an express warranty and had negligently failed to manufacture the device in compliance with federal standards. *Riegel*, 552 U.S. at 321 n.2. Those claims did not reach the Supreme Court, because the district court disposed of them on summary judgment when the plaintiffs failed to adduce sufficient factual support for them. *See id.*

banc) (holding that the MDA did not expressly preempt a parallel state-law claim based on violations of FDA regulations regarding reporting of adverse events). As the Seventh Circuit stated: "The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive." *Bausch*, 630 F.3d at 549.

C. Implied Preemption Under *Buckman*

Nonetheless, even though a state-law claim may survive express preemption if it is based on a violation of federal law, it may be impliedly preempted if it is based *solely* on a violation of federal law or if the claim would not exist but for federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352-53 (2001). *Buckman* specifically prohibits an attempt to bring a putative state-law claim alleging that a manufacturer defrauded the FDA in obtaining approval for its device. More generally, *Buckman* prohibits the private enforcement of the statutes and regulations that the FDA alone is empowered to enforce.

In *Buckman*, 531 U.S. at 343-46, the device-manufacturer allegedly obtained FDA approval by making fraudulent representations to the FDA about the intended use of the device (bone screws). The manufacturer had unsuccessfully applied for approval for the use of the device in spinal surgery. After the FDA rejected the initial application, the manufacturer revised the application to specify a different use ("long bone surgery"). The FDA approved the revised application for that purpose, but physicians later used the

device for the so-called "off-label" purpose of spinal surgery. The plaintiffs, who were injured because of the off-label use of the device in spinal surgery, claimed that they would not have suffered damages but for the alleged misrepresentations to the FDA. *See id.* at 346-47.[10]

The district court dismissed the case, characterizing it as a claim of "fraud-on-the-FDA." *Id.* at 347. The Supreme Court affirmed, stating that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348.

In reaching its decision, the Court explained that the FDA must achieve a "delicate balance of statutory objectives" (*id.*), and it expressed its concern that the balance could be "skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* In this regard, the Court specifically observed that under federal law the FDA may respond to fraud by instigating both civil and criminal proceedings. *Id.* at 349 (citing 21 U.S.C. § 332; 21 U.S.C. § 333(f)(1)(A); 21 U.S.C. § 334(a)(2)(D); 21 U.S.C. § 333(a)). Indeed,

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[10] The manufacturer had not submitted the device for premarket approval. Rather, because the manufacturer contended that the device was substantially equivalent to a device that had been on the market at the time of the adoption of the MDA in 1976, it was able to take advantage of the less rigorous approval process under 21 U.S.C. § 510(k). The FDA had refused to approve the device on the ground that it was not the substantial equivalent of an earlier device that had been used in spinal surgery. The manufacturer had obtained approval by recharacterizing the device as the substantial equivalent of an earlier device that had been used in long bone surgery. The plaintiffs evidently alleged that, despite the recharacterization of the intended use, the manufacturer had intended all along for the device to be used in spinal surgery. *See Buckman*, 531 U.S. at 346-47.

the FDA alone is authorized to enforce the FDCA or to restrain violations of it. *Id.* at 349 n.4 (citing 21 U.S.C. § 337(a)).

Because *Buckman* involved the off-label use of an FDA-approved device, the Court took pains to remark that off-label usage "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Id.* at 350. The Court worried that fraud-on-the-FDA claims could deter off-label use even though "the FDCA expressly disclaims any intent to directly regulate the practice of medicine, . . . and even though off-label use is generally accepted." *Id.* at 350-51 (citing 21 U.S.C. § 396).

Finally, the Court rejected the plaintiffs' effort to characterize their fraud-on-the-FDA claim as a parallel, state-law claim that would survive express preemption under the MDA. The Court explained that, unlike (for example) a claim concerning the failure to use reasonable care in manufacturing a device, the claims in *Buckman* "exist[ed] solely by virtue of the FDCA disclosure requirements." *Id.* at 352-53. The plaintiffs, thus, were not "relying on traditional state tort law which had predated the federal enactments in question." *Id.* at 353. Accordingly, their claims were impliedly preempted. *See id.*

D. The Scylla and Charybdis of Express and Implied Preemption

In light of *Riegel* and *Buckman*, a plaintiff can survive a preemption challenge to a state-law tort claim concerning an allegedly defective medical device only by steering between the Scylla of express preemption under § 360k(a) and the Charybdis of the

implied *Buckman* preemption of claims that exist solely by virtue of the FDCA. It is a challenge to avoid one obstacle without colliding with the other, because the plaintiffs must show that a manufacturer has violated federal law if they are to defeat express preemption, but the plaintiffs must also show that their legal theories predated the federal enactment or would exist independently of federal law if they are to defeat implied preemption.

In other words, "the conduct on which the plaintiff's claim is premised *must* violate the FDCA if the claim is to escape express preemption," but the conduct must also be "the type of conduct that would traditionally give rise to liability under state law – and that would give rise to liability under state law even if the FDCA had never been enacted." *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (emphasis in original). To put it another way, "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* (emphasis in original).

E. The Legality of Off-Label Promotion

A central feature of the McCormicks' complaint is their repeated allegation that Medtronic has engaged in what they call illegal, off-label promotion of the Infuse device. The legality of off-label promotion is important to this case because the McCormicks can avoid express preemption only if their claims are based on some violation of federal law.

See Riegel, 552 U.S. at 330; *Bausch*, 630 F.3d at 549.[11]

To understand the legality of off-label promotion, it is necessary, first, to distinguish between off-label uses by healthcare practitioners and the promotion of off-label uses by manufacturers. Off-label use by members of the medical profession "is permissible under the terms of the MDA." *Cornett*, 211 N.J. at 380; *see Buckman*, 531 U.S. at 351 n.4. In fact, Congress has specifically denied the FDA any power "to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396; *see Buckman*, 531 U.S. at 350; *Cornett*, 211 N.J. at 382.

Off-label promotion by a manufacturer, however, stands on different footing from off-label use by a healthcare practitioner, because off-label promotion may constitute "misbranding," a criminal violation of the FDCA.

Although "[f]ederal law does not expressly define, or ban, off-label promotion[,] . . . the FDCA prohibits 'the adulteration or *misbranding* of any food, drug, *device*, tobacco product, or cosmetic in interstate commerce.'" *Schouest v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 1213243, at *6 (S.D. Tex. Mar. 24, 2014) (quoting 21 U.S.C. § 331(b)) (emphasis added). "Class III devices may be misbranded if their 'labeling is false or

[11] Of course, the McCormicks may nonetheless be blocked by implied preemption if their claims are based *solely* on a violation of federal law. *See Buckman*, 531 U.S. at 352-53.

misleading in any particular,' 21 U.S.C. § 352(a), or if they use 'false or misleading advertising,' [21 U.S.C.] § 352(q)." *Schouest*, 2014 WL 1213243, at *6. "Devices can also be misbranded if their labeling does not bear 'adequate directions for use,' [21 U.S.C.] § 352(f)," which is "defined by the FDA as 'directions under which the layman can use a device safely and for the purposes for which it is intended.'" *Schouest*, 2014 WL 1213243, at *6 (quoting 21 C.F.R. § 801.5). "A device's intended use is determined by 'the objective intent of the persons legally responsible for the labeling of devices'" – *i.e.*, by the objective intent of the manufacturer. *Id.* (quoting 21 C.F.R. § 801.4). In addition, the intended use "can be demonstrated by 'oral written statements'" by the manufacturer or its representatives. *Id.* (quoting 21 C.F.R. § 801.4).

On the basis of this web of statutes and regulations, the FDA takes the position that off-label promotion can constitute misbranding in violation of the FDCA. *See Schouest*, 2014 WL 1213243, at *6. "Based on this view, the FDA has recovered millions of dollars in settlements from drug manufacturers that have engaged in off-label promotion." *Id.*

The FDA has, however, recognized a safe harbor that allows manufacturers of Class III devices to provide members of the medical profession with peer-reviewed articles or reference publications concerning the safety, effectiveness, or benefit of the off-label uses of the device. *See Riley*, 625 F. Supp. 2d at 781-82; *Cornett*, 211 N.J. at

382 (citing 21 U.S.C. §§ 360aaa, 360aaa-1).[12]

Furthermore, one federal appellate court has held, by a 2-1 margin, that the First Amendment prohibits the United States from prosecuting a person for misbranding if he or she has merely engaged in off-label promotion that does not involve untruthful or misleading statements. *United States v. Caronia*, 703 F.3d 149, 168-69 (2d Cir. 2012) (the FDCA does not prohibit the "truthful off-label promotion of FDA-approved prescription drugs"). In that case, however, the government had not argued "that the promotion in question was false or misleading." *Id.* at 165 n.10. Indeed, the court observed that "off-label promotion that is false or misleading is not entitled to First Amendment protection." *Id.* The court also observed that "[p]hysicians and pharmaceutical manufacturers can be held accountable for off-label drug use through medical malpractice and negligence theories of liability." *Id.* at 168 n.11.

"Out of this muddy statutory and regulatory framework," *Schouest*, 2014 WL 1213243, at *7, a growing number of courts have begun to conclude that "federal law bars off-label promotion when it is false or misleading." *Id.* (citing *Houston v.*

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[12] The safe harbor is based on a statute that expired on September 30, 2006, but the FDA has announced that it continues to take a position consistent with the statute. FDA, *Guidance for Industry – Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), *available at* http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm (last visited Aug. 13, 2014); *see Riley*, 625 F. Supp. 2d at 782 n.7; *Cornett*, 211 N.J. at 382 n.7.

Medtronic., Inc., 957 F. Supp. 2d 1166, 1179 & n.8 (C.D. Cal. 2013); *see also Martin v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 3635292, at *7 (D. Ariz. July 23, 2014) ("The FDCA does prohibit untruthful off-label promotion"); *Beavers-Gabriel v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 1396582, at *9 (D. Haw. Apr. 10, 2014) ("[T]he FDCA prohibits "misbranding" of medical devices, which includes either misleading labeling or misleading advertising of the medical device"); *Brady v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 1377830, at *7 (S.D. Fla. Apr. 8, 2014) (claim based on affirmed misrepresentations in off-label promotion was not preempted); *Riley*, 625 F. Supp. 2d at 783 (failure to warn claim could escape express preemption if plaintiff alleged that manufacturer affirmatively promoted off-label use in a manner that violated federal law); *Cornett*, 211 N.J. at 390-91 (failure to warn claim, based on misrepresentations in off-label promotion outside of safe harbor, was not expressly preempted).

Accordingly, we hold that the MDA does not expressly preempt state-law claims that are based on a violation of the federal prohibition of false or misleading off-label promotion.[13]

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[13] One federal judge has held that the concept of express preemption does not apply at all when a plaintiff's state-law claims arise out of an off-label use "that has not been reviewed by the FDA but has been promoted by the manufacturer." *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 991 (D. Ariz. 2013). *Ramirez* reasoned that federal law imposes no device-specific "requirements" as to an off-label use and, thus, that state law could not impose requirements that were "different from, or in addition to," those

(continued...)

F. Which Claims Are Preempted?

We turn now to the specific allegations of the McCormicks' complaint, to determine which, if any, are expressly or impliedly preempted.

1. The Misrepresentation-Based Claims. The McCormicks' complaint contains a series of counts that are based on misrepresentations, intentional or otherwise: Count V alleges common-law fraud; Count II alleges negligence and includes allegations of negligent misrepresentation; and Count VII alleges violations of the Consumer Protection Act, Md. Code (1975, 2013 Repl. Vol.) § 13-301 of the Commercial Law Article, which prohibits various forms of "unfair or deceptive trade practices," including fraud, false or misleading representations that have the capacity, tendency, or effect of deceiving or misleading consumers, and the failure to state a material fact if the failure deceives or tends to deceive.

These claims are preempted insofar as they attack the accuracy or adequacy of the

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[13] (...continued)
under federal law. *Id.* at 992-93. Although one Maryland circuit court case has followed *Ramirez*, *Ramirez* has been almost universally rejected elsewhere. The courts that have rejected *Ramirez* correctly point out that federal law does impose requirements regarding off-label use and promotion of devices. *See, e.g.*, *Martin*, 2014 WL 3635292, at *6; *Beavers-Gabriel*, 2014 WL 1396582, at *10; *Brady*, 2014 WL 1377830, at *5; *see also Hawkins v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 346622, at *5-6 (E.D. Cal. Jan. 30, 2014); *Gavin v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2013 WL 3791612, at *11 (E.D. La. July 19, 2013); *Houston*, 957 F. Supp. 2d at 1176 ("even though Plaintiff was not implanted with the Infuse Device in an approved manner, her state claims are oriented 'with respect to' the off-label promotion and use of a device that is covered by federal requirements"). We join the many courts that have rejected *Ramirez*'s holding that concepts of express preemption do not apply in a case involving off-label uses.

statements that Medtronic made in the FDA-mandated and FDA-approved labeling. *See, e.g.*, *Hughes*, 631 F.3d at 769; *Martin*, 2014 WL 3635292, at *8; *Beavers-Gabriel*, 2014 WL 1396582, at *10; *Gavin v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2013 WL 3791612, at *12 (E.D. La. July 19, 2013). To fault Medtronic for making the statements that the FDA required it to make, or to impose liability on Medtronic for not making statements that the FDA required it not to make, would be to impose state-law requirements that are "different from, or in addition to," those imposed by the FDCA. *See Martin*, 2014 WL 3635292, at *8; *Beavers-Gabriel*, 2014 WL 1396582, at *10. Section 360k(a) prohibits state courts from entertaining such claims.

Section 360k(a) does not, however, preempt claims concerning the misrepresentations that Medtronic allegedly made in voluntary communications with the medical profession or the public, *Houston*, 957 F. Supp. 2d at 1179-80; *Schouest*, 2014 WL 1213243, at *8-10; *Martin*, 2014 WL 3635292, at *9; outside the scope of the safe harbor. *Cornett*, 211 N.J. at 390-91; *Riley*, 625 F. Supp. 2d at 783. Indeed, those claims would survive preemption even under the case on which the circuit court relied. *Caplinger*, 921 F. Supp. 2d at 1220. Insofar as Medtronic's alleged misrepresentations consist of false statements of material fact in the context of off-label promotion, outside the scope of the safe harbor, a state-law misrepresentation claim would parallel the FDCA prohibitions on off-label marketing. To that extent, therefore, a state-law misrepresentation claim would not impose any requirements different from or in addition

to those imposed under federal law. *See, e.g.*, *Beavers-Gabriel*, 2014 WL 1396582, at *9; *Brady*, 2014 WL 1377830, at *7*; Schouest*, 2014 WL 1213243, at *8; *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 884-85 (N.D. Cal. 2013); *Houston*, 957 F. Supp. 2d at 1179-80.

Furthermore, because those misrepresentation claims predate the FDCA and would continue to exist even if the FDCA were repealed, they do not depend on the FDCA for their existence. *See, e.g.*, *Houston*, 957 F. Supp. 2d at 1179 ("fraudulent advertising claims are not impliedly preempted under *Buckman* because they are moored in traditional state common law that exists independently from the FDCA"); *Arthur v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 3894365, at *7 (E.D. Mo. Aug. 11, 2014) (same); *Blankenship v. Medtronic, Inc.*, ___ F. Supp. 2d ___, 2014 WL 1226491, at *10 (E.D. Mo. Mar. 25, 2014); *Schouest*, 2014 WL 1213243, at *9 (fraud is "a venerable common law claim[]"); *Martin*, 2014 WL 3635292, at *8 ("there is a state law duty to refrain from making misrepresentations, and this duty or requirement predates the FDCA"). Therefore, to the extent that the complaint concerns false statements of material fact that Medtronic allegedly made in voluntary communications constituting off-label marketing of the Infuse product, outside the scope of the safe harbor, the McCormicks' claims are neither impliedly preempted under *Buckman* nor expressly preempted under § 360k(a).

Our ruling applies not only to the common-law claims for fraud and negligent

misrepresentation (which is embodied in the generic negligence claim), but also to the separate statutory claim for unfair and deceptive trade practices under the Consumer Protection Act. *See Schouest*, 2014 WL 1213243, at *12 ("a deceptive act in the promotion of the Infuse device would survive a preemption challenge for the same reasons that [the plaintiff]'s fraud and negligent misrepresentations claim [sic] would").[14]

2. Negligence. Count II of the McCormicks' complaint asserts a claim for negligence. As the court in *Riley* said of the complaint in that case, the allegations here are both "prolix and uninformative," *Riley*, 625 F. Supp. 2d at 780 n.5, in that they attack a wide variety of conduct. Some of the allegations are preempted; some are not.

Count II refers to an array of misrepresentations in the context of off-label promotion; the negligent failure to disclose material facts concerning the Infuse device and to "fully disclose" the results of testing on the device; and the failure to "adequately warn" the medical community, the public, and Mr. McCormick concerning the dangers

[14] At least one court has relied on a distinction between claims based on false statements of material fact and claims based on the omission to state material facts. *Schouest*, 2014 WL 1213243, at *5. In the view of that court, omission claims are preempted, but claims based on affirmative misstatements are not. *Id*. The distinction is immaterial in Maryland, because Maryland's common law authorizes a misrepresentation claim for the concealment of material facts only when the defendant has an affirmative disclosure obligation to the plaintiff (as, for example, when the defendant stands in a fiduciary relationship to the plaintiff). *See, e.g.*, *Green v. H&R Block*, 355 Md. 488, 525 (1999). As Medtronic is not alleged to have had any such affirmative disclosure obligation to the McCormicks, it could be liable for fraudulent or negligent misrepresentation under Maryland common law only if it affirmatively made a false statement of material fact or uttered a half-truth (*i.e.*, failed to disclose material facts that were necessary to make its other statements not misleading).

and side-effects of the device. The count also refers to the allegedly negligent failure to disclose Medtronic's employment of consultants, such as Mr. McCormick's surgeon, Dr. Rosner; the negligent failure to inform the public about the identity of the surgeons with whom Medtronic had financial relations; and the negligent failure to act as a "reasonably prudent drug manufacturer, promoter and distributor."

We have already held that federal law neither expressly nor impliedly preempts the allegations of negligent misrepresentations in the context of off-label promotion outside the scope of the safe harbor. For similar reasons, federal law does not preempt the allegations concerning the failure to disclose material facts concerning the device and the failure to "fully disclose" the results of testing on the device, *provided* that those omissions occurred in the context of off-label promotion *and* that the omitted facts were necessary to make Medtronic's other statements not misleading.

Nonetheless, the negligence claim is expressly preempted to the extent that the McCormicks intend to challenge the adequacy of the FDA-approved warnings on the labeling: if such a claim were allowed to proceed, Medtronic would face liability under state law even though it had fully complied with federal law. *See Martin*, 2014 WL 3635292, at *14; *Beavers-Gabriel*, 2014 WL 1396582, at *15; *Hawkins v. Medtronic, Inc*., ___ F. Supp. 2d ___, 2014 WL 346622, at *9 (E.D. Cal. Jan. 30, 2014). *Riegel* prohibits such a result. *See Houston*, 957 F. Supp. 2d at 1180 (a state claim is parallel to federal law, and thus not expressly preempted, only if there is no likelihood that the

defendant could be held liable under state law without also having violated federal law).[15]

Furthermore, to the extent that the McCormicks' allegations solely concern a failure to disclose material facts or test results to the FDA in the premarket approval process, they are impliedly preempted under *Buckman*, because they would amount to allegations of fraud on the FDA, which the FDA alone may pursue. *See Cornett*, 211 N.J. at 389 (to the extent that claim was "based *solely* on a contention that defendants obtained FDA approval for the device only after submitting fraudulent representations to or withholding material information from the FDA, this claim falls squarely within the *Buckman* implied preemption rule") (emphasis in original).

The claims are also impliedly preempted to the extent that they may concern the act of off-label promotion itself, divorced from any misrepresentations that Medtronic may have made in the course of off-label promotion. Such a claim exists solely by virtue of the federal statutes and regulations that concern misbranding, and the claim has no independent existence in Maryland law. *See Houston*, 957 F. Supp. 2d at 1178. "Permitting this claim to proceed would essentially allow a private litigant to attempt to enforce the FDCA," *id.*, which the statute itself expressly prohibits. 21 U.S.C. § 337(a) (providing that, in general, "all such proceedings for the enforcement, or to restrain

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[15] The McCormicks do not appear to allege that the warning labels failed to comply with FDA requirements. If that were the case, a state-law claim for failure to warn would not be expressly preempted, because it would parallel the manufacturer's failure to comply with federal law. *See Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1101 (D. Or. 2013).

violations, of this chapter shall be by and in the name of the United States").

Courts have divided on the question of whether a negligent failure to warn claim is expressly preempted. Some would allow such claims to proceed, at least insofar as they are "founded on" the promotion of off-label uses beyond the safe harbor recognized by the FDA. *Cornett*, 211 N.J. at 391 (citing *Riley*, 625 F. Supp. 2d at 781-82). Other courts, by contrast, hold that the claims are expressly preempted because they would require "warnings beyond those in the FDA-approved label for the Infuse Device." *Houston*, 957 F. Supp. 2d at 1177; *accord Schouest*, 2014 WL 1213243, at *7; *Martin*, 2014 WL 3635292, at *11.

We agree that federal law would preempt any effort to impose an amorphous duty to warn that required Medtronic to give warnings "different from, or in addition to," those in the FDA-approved labeling: under federal law, Medtronic cannot deviate from the FDA-prescribed labeling without the FDA's permission. *See Schouest*, 2014 WL 1213243, at *7. However, to the extent that the failure to warn claim simply restates the McCormicks' claim for the failure to disclose material facts that were necessary to make Medtronic's other statements not misleading in the context of off-label promotion, it may proceed for the same reason that the misrepresentation-based claims may proceed.[16]

[16] Some courts have observed that a plaintiff might avoid preemption by alleging a failure-to-warn claim that is based on the manufacturer's failure to comply with the FDCA's requirement that it submit reports of adverse events to the FDA. *Stengel*, 704 F.3d at 1233; *Martin*, 2014 WL at 3635292, at *12; *Eidson v. Medtronic, Inc.*, ___ F. (continued...)

3. Strict Products Liability. Count III of the complaint purports to state a claim for strict products liability, but it is unclear what particular theory the McCormicks intend to pursue. For example, they do not specifically allege that the Infuse product was somehow defective or unreasonably dangerous. Instead, they allege that the off-label *use* of the product in the posterior approach was "defective, unsafe, and ineffective." Elsewhere, they make allegations that sound in fraud or negligent misrepresentation as they reiterate their many complaints about off-label promotion. In addition, they invoke the risk-utility test, claiming that the risk of off-label uses outweighs the benefits. Similarly, they invoke the consumer-expectation test, alleging that the product, when used in an off-label manner, did not perform as a reasonable consumer would expect it to perform.

To the extent that the complaint would impose liability on the basis of the risk-utility or consumer-expectation tests, it is expressly preempted under § 360k(a). The FDA has approved the Infuse product, and the agency neither has prohibited nor can prohibit its off-label use by members of the medical profession. Because Maryland cannot impose different or additional requirements, the risk-utility and consumer-expectation allegations fail to state a claim.

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[16] (...continued)
Supp. 2d ___, 2014 WL 1996024, at *20 (N.D. Cal. May 13, 2014); *Gale v. Smith & Nephew, Inc*., 989 F. Supp. 2d 243, 251 (S.D.N.Y. 2013). No such allegation, however, appears in the McCormicks' complaint.

The complaint also fails to state a claim insofar as it attempts to premise a products liability claim on off-label use: products liability law concerns products, not the uses of products. In any event, to the extent that the McCormicks' products liability claim is a stand-in for a complaint about the off-label use of the Infuse product, it is impliedly preempted under *Buckman*, because the concept of illegal off-label use or promotion of a medical device would not exist but for the FDCA. *See Cornett*, 211 N.J. at 389.

Finally, to the extent that the products liability claim repeats the allegations of misrepresentation and failure to warn, we reiterate our prior conclusions: federal law neither expressly nor impliedly preempts claims of misrepresentation in the context of off-label marketing outside of the safe harbor, but it does expressly preempt any challenge to the adequacy of the warranty or disclosures in the FDA-approved labeling for the Infuse device. Furthermore, federal law impliedly preempts any attempt to recover damages on the basis of a contention that Medtronic obtained FDA approval for the device only after submitting fraudulent representations to or withholding material information from the FDA.[17]

4. Breach of Warranty. Count IV of the McCormicks' complaint

[17] The McCormicks do not appear to have asserted any claim alleging the defective design of the product. Had they done so, however, federal law would have expressly preempted the claim, as the FDA has carried out the only permissible risk-benefit analysis as to the appropriate product design. *See*, *e.g.*, *Houston*, 957 F. Supp. 2d at 1177-78. A state cannot impose design requirements that are "different from, or in addition to," those mandated by the FDA. *Id.*

alleges a claim for breach of warranty. The complaint mentions express warranties to physicians and members of the public, as well as the implied warranties of merchantability and fitness for a particular purpose under the Uniform Commercial Code. *See* Md. Code (1975, 2013 Repl. Vol.) §§ 2-314, 2-315 of the Commercial Law Article.

To the extent that the McCormicks allege the breach of the implied warranties of merchantability or fitness for a particular purpose, their claims are expressly preempted: to impose additional warranties by operation of law would be to impose requirements that are "different from, or in addition to," the specific warranties or representations that the FDA required Medtronic to make in the packaging and labeling that accompanies the product. *See Schouest*, 2014 WL 1213243, at *11. Therefore, the circuit court correctly concluded that the McCormicks failed to state a claim for breach of implied warranty.

Similarly, to the extent that the breach of express warranty claim is based solely on alleged warranties in the FDA-approved labeling, the claim is expressly preempted: to hold otherwise would be to hold that a manufacturer could face liability under state law even though it had done exactly what it is required to do under federal law. *See Riley*, 625 F. Supp. 2d at 787, 788; *see also Cornett*, 211 N.J. at 392. Because a state-law claim is "parallel" (and thus not expressly preempted) only if there is no likelihood that the manufacturer could be held liable under state law unless it had also violated federal law (*Houston*, 957 F. Supp. 2d at 1180), the express warranty claim cannot survive insofar as it is based on the FDA-approved labeling itself.

On the other hand, to the extent that the McCormicks contend that Medtronic breached express warranties that it made in voluntary communications with the medical profession or the public, the FDCA does not expressly preempt those claims. *See*, *e.g.*, *Schouest*, 2014 WL 1213243, at *11; *Houston*, 957 F. Supp. 2d at 1180-81; *Martin*, 2014 WL 3635292, at *15; *Riley*, 625 F. Supp. 2d at 788; *Alton v. Medtronic, Inc*., 970 F. Supp. 2d 1069, 1104 (D. Or. 2013); *Gelber v. Stryker Corp*., 788 F. Supp. 2d 145, 165 (S.D.N.Y. 2011); *Cornett*, 211 N.J. at 392, 393. Because federal law already prohibits false or misleading off-label promotion outside the safe harbor, a state would not impose any requirements that are "different from, or in addition to," those under federal law if it held a manufacturer liable for making misleading warranties outside the label. *Schouest*, 2014 WL 1213243, at *11; *Houston*, 957 F. Supp. 2d at 1180-81; *Martin*, 2014 WL 3635292, at *15; *Beavers-Gabriel*, 2014 WL 1396582, at *16-17; *Riley*, 625 F. Supp. 2d at 788. The manufacturer "need only to refrain from making misleading warranties, which adds no burden beyond what federal law already imposes." *Houston*, 957 F. Supp. 2d at 1181. To that extent, therefore, the express warranty claim survives express preemption.[18]

[18] In *Caplinger*, the case on which the circuit court relied, the federal judge concluded that an express warranty claim would be expressly preempted even if it related to the warranties that the manufacturer made in voluntary communications with the public. *See Caplinger*, 921 F. Supp. 2d at 1222-23. At least one court has criticized the superficial analysis that led the *Caplinger* court to that conclusion. *Alton*, 970 F. Supp. 2d at 1090.

Nor would such a claim be impliedly preempted under *Buckman*. The claim for breach of express warranty has a long and venerable history in Maryland (*see, e.g.*, *Schley v. Zalis*, 172 Md. 336 (1937)), and elsewhere. *Houston*, 957 F. Supp. 2d at 1181; *Martin*, 2014 WL 3635292, at *15. It predated the FDCA, and it would continue to exist if the FDCA were repealed in its entirety. Therefore, to the extent that the breach of warranty claim addresses warranties that Medtronic voluntarily made to the medical profession or the public outside of the context of the FDA-approved and FDA-mandated labeling, the McCormicks have stated a claim.[19]

G. Failure to Plead Fraud With Particularity

As an alternative ground for a part of its decision, the circuit court, like the *Caplinger* court on which it relied, ruled that the plaintiffs had not pleaded fraud with the requisite degree of particularity. We agree.

Although Rule 2-305 generally requires that a complaint contain only "a clear statement of the facts necessary to constitute a cause of action," Maryland courts have long required parties to plead fraud with particularity. *See, e.g.*, *Lloyd v. General Motors Corp.*, 397 Md. 108, 153-54 (2007); *Edison Realty Co. v. Bauernschub*, 191 Md. 451, 461 (1948); *Tucker v. Woolery*, 99 Md. App. 295, 304 (1994), *abrogated on other grounds, D'Aoust v. Diamond*, 424 Md. 549 (2012); *Sims v. Ryland Group, Inc.*, 37 Md.

[19] Because the loss of consortium claim is derivative of Mr. McCormick's claims (*see, e.g.*, *Proctor v. Washington Metro. Area Transit Auth.*, 412 Md. 691, 727-28 (2010)), it survives to the extent that the other claims survive.

App. 470, 473 (1977); *see also Thomas v. Nadel*, 427 Md. 441, 453 (2012) (quoting *Spangler v. Sprosty Bag Co.*, 183 Md. 166, 173 (1944)) ("'It is the settled rule that [one] seeking any relief on the ground of fraud must distinctly state the particular facts and circumstances constituting the fraud and the facts so stated must be sufficient in themselves to show that the conduct complained of was fraudulent'"); *Antigua Condo. Ass'n v. Melba Investors Atl., Inc*., 307 Md. 700, 735 (1986) ("[a] plaintiff must allege facts which indicate fraud or from which fraud is necessarily implied"); *John B. Parsons Home, LLC v. John B. Parsons Found.*, 217 Md. App. 39, 68 (2014) (affirming dismissal of complaint because of failure to plead constructive fraud with particularity). Because the courts have continued to adhere to this principle even after the adoption of the Maryland Rules in 1984, the requirement of particularity must be seen as a kind of judge-made gloss on the general rules of pleading.

The requirement of particularity ordinarily means that a plaintiff must identify who made what false statement, when, and in what manner (*i.e.*, orally, in writing, etc.); why the statement is false; and why a finder of fact would have reason to conclude that the defendant acted with scienter (*i.e.*, that the defendant either knew that the statement was false or acted with reckless disregard for its truth) and with the intention to persuade others to rely on the false statement. *See, e.g.*, *Spaulding v. Wells Fargo Bank, N.A.*, 714 F.3d 769, 781 (4th Cir. 2013) (Davis, J.) (concerning the analogous federal rule).

In this case, the McCormicks' complaint satisfactorily alleges that the Medtronic

defendants knew that the off-label use of the Infuse product could lead to many, serious side-effects, including the side-effects that Mr. McCormick claims to have suffered. Similarly, the complaint satisfactorily alleges that the Medtronic defendants intended to induce physicians, including Mr. McCormick's physician, to rely on the alleged misrepresentations and to use the Infuse product in the allegedly dangerous, off-label procedures. The complaint, however, lacks specificity in alleging when and how the Medtronic defendants made the false statements of material fact (or failed to disclose material facts that were necessary to make other statements not misleading). Instead, the complaint repeatedly makes vague references to Medtronic's failure to accurately report the side-effects from its clinical trials and to its failure to report that many of the authors who studied and promoted the Infuse product had significant financial ties to Medtronic. Because these vague allegations fail to meet the standard of particularity, the circuit court correctly dismissed the fraud claim.

Ordinarily, however, when a circuit court dismisses a complaint for a pleading defect, it should afford the plaintiff an opportunity to amend the complaint and to correct the defect. *See Thomas v. Ford Motor Co.*, 48 Md. App. 617, 631-32 (1981). Perhaps because the circuit court believed that the vast majority of the complaint was preempted, it failed to afford the McCormicks the opportunity to correct the defects in their fraud claim. Thus, because the case must return to the circuit court for consideration of the claims that in our view are not preempted (including the claims based on negligent

misrepresentation and the misrepresentation-based Consumer Protection Act claims), the circuit court, on remand, should allow the McCormicks a reasonable opportunity to amend their complaint and to plead fraud with greater particularity.

H. Failure to Plead Consumer Protection Violations with Particularity

Citing *Lloyd v. General Motors Corp*., 397 Md. 108 (2007), Medtronic argues that the McCormicks' Consumer Protection Act claim is premised on fraud and, thus, must be pleaded with particularity. Medtronic is correct in part and incorrect in part.

Under the Consumer Protection Act, an "unfair and deceptive trade practice" replicates common-law fraud insofar as it includes "[d]eception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with . . . [t]he promotion or sale of any consumer goods . . . ." Md. Code (1975, 2013 Repl. Vol.) § 13-301(9) of the Commercial Law Article. Accordingly, if a party alleges an "unfair or deceptive trade practice" under that specific subsection, he or she must allege fraud with particularity, as the *Lloyd* plaintiffs successfully did. *Lloyd*, 397 Md. at 154.

Under other provisions of the act, however, a party can allege an "unfair and deceptive trade practice" without replicating a claim for common-law fraud. For example, an "unfair or deceptive trade practice" may include a "[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or

misleading consumers" (Md. Code (1975, 2013 Repl. Vol.) § 13-301(1) of the Commercial Law Article), or the "[f]ailure to state a material fact if the failure deceives or tends to deceive." *Id.* § 13-301(3). To prove those violations, it is unnecessary to prove scienter. *Consumer Prot. Div. v. Morgan*, 387 Md. 125, 211 (2005); *Golt v. Phillips*, 308 Md. 1, 10-11 (1986). It is, therefore, unnecessary to allege those violations with particularity.[20]

CONCLUSION

In summary, we reverse the circuit court's conclusion that federal law preempts the claims for fraud, negligent misrepresentation, and violations of the Consumer Protection Act insofar as those claims are based on false statements of material fact that Medtronic may allegedly have made in voluntary communications with the public or members of the medical professions, in the context of off-label promotion of the Infuse device, and outside of the safe-harbor that permits the distribution of peer-reviewed articles or reference publications concerning the safety, effectiveness, or benefit of the off-label uses of the device. We also reverse the circuit court's conclusion that federal

[20] Medtronic makes a number of miscellaneous arguments that the circuit court did not consider. These include arguments that Mr. McCormick has not satisfactorily alleged a demonstrable fear of cancer, that Maryland does not permit strict liability or breach of warranty claims against device manufacturers, and that Medtronic disclaimed all warranties. Although we may consider these arguments in reviewing the grant of a motion to dismiss (*see, e.g.*, *Lizzi v. Washington Metro. Area Transit Auth.*, 156 Md. App. 1, 7, *aff'd*, 384 Md. 199 (2004)), we decline to do so in view of the circuit court's failure to consider them and the lack of emphasis on them in the parties' briefs. Medtronic is free to reassert the arguments on remand.

law preeempts the claims for the breach of any express warranties that Medtronic may have made in voluntary communications with the public or members of the medical professions outside of the context of the FDA-mandated and FDA-approved labeling for the device. We affirm the circuit court in all other respects, including in its conclusion that the McCormicks failed to plead fraud with particularity, but we direct the circuit court to afford them an opportunity to attempt to satisfy that pleading requirement on remand.

JUDGMENTS REVERSED AND REMANDED TO THE CIRCUIT COURT FOR MONTGOMERY COUNTY FOR FURTHER PROCEEDINGS NOT INCONSISTENT WITH THIS OPINION; COSTS TO BE PAID ONE-HALF BY APPELLANT AND ONE-HALF BY APPELLEE.