

**STATE OF MINNESOTA
IN COURT OF APPEALS**

A14-1149

A14-1150

A14-1151

A14-1152

A14-1153

A14-1154

Paul V. Angeles, et al.,
Appellants (A14-1149),

Charlene Mead, et al.,
Appellants (A14-1150),

Charles Starovasnik, Jr.,
Appellant (A14-1151),

Trudy Marse, et al.,
Appellants (A14-1152),

Rebecca Manuel, et al.,
Appellants (A14-1153),

Claude Davenport, et al.,
Appellants (A14-1154),

vs.

Medtronic, Inc., et al.,
Respondents.

Filed April 20, 2015
Affirmed in part, reversed in part, and remanded
Connolly, Judge

Hennepin County District Court
File Nos. 27-CV-13-1838; 27-CV-13-2611; 27-CV-13-5993;
27-CV-13-8438; 27-CV-13-1952; 27-CV-13-10478

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Minnesota; and

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Andrew E. Tauber (pro hac vice), Mayer Brown LLP, Washington, D.C. (for respondents)

Considered and decided by Peterson, Presiding Judge; Worke, Judge; and Connolly, Judge.

S Y L L A B U S

1. Minnesota state law failure-to-warn patients and physicians claims and design-defect claims impose general requirements that are different from federal device-specific requirements and are therefore preempted by 21 U.S.C. § 360k(a) (2014).
2. Claims based on a failure to warn the FDA of adverse effects impose parallel requirements to federal device-specific requirements and are not preempted by 21 U.S.C. § 360k(a).
3. Minnesota state law express-warranty claims impose parallel requirements to federal device-specific requirements and are not expressly preempted by 21 U.S.C. § 360k(a).

O P I N I O N

CONNOLLY, Judge

In these consolidated appeals, appellants challenge the dismissal of their claims arising out of respondents' advertising and promotion of a medical device that was used and allegedly caused injury to appellants during spinal surgeries. Appellants argue that the district court erred by (1) dismissing as expressly or impliedly preempted by the federal Food, Drug, and Cosmetic Act (FDCA) their claims for negligence, breach of

warranty, unjust enrichment, and violation of state consumer-protection statutes; and (2) dismissing their fraud claims for failure to plead with particularity pursuant to Minn. R. Civ. P. 9.02. We affirm in part, reverse in part, and remand.

FACTS

Respondent Medtronic, Inc., et al. (Medtronic) manufactures and markets the Infuse Bone Graft/LT-CAGE Lumbar Tapered Fusion Device (the Infuse Device), a Class III medical device. The Infuse Device is generally used for patients seeking a vertebral fusion and is composed of three components: (1) a tapered metallic spinal fusion cage (LT-Cage), (2) a recombinant human bone morphogenetic protein (the Infuse Protein), and (3) a carrier/scaffold for the Infuse Protein and resulting bone. Class III medical devices pose the highest level of risk and receive the highest level of regulatory scrutiny before marketing. *See* 21 U.S.C. §§ 360c, 360e (2014). A manufacturer of a Class III device must submit to the Food and Drug Administration (FDA) a premarket approval application before distributing and marketing the device, which must specify the intended use of the product. *Id.* § 360e(c)(2)(A)(iv).

On July 2, 2002, the FDA granted initial premarket approval of the Infuse Device pursuant to the Medical Device Amendment of 1976 (the MDA), finding that it was safe and effective for its intended use. The FDA specified that the premarket approval was limited to the use of the three components together and to uses in surgeries featuring an anterior approach. The FDA label also states: “The safety and effectiveness of the Infuse Bone Graft component with other spinal implants, implanted at locations other than the

lower lumbar spine, or used in surgical techniques other than anterior open or anterior laparoscopic approaches have not been established.”

Appellants in this case are patients who underwent surgeries involving allegedly unapproved, off-label uses of the Infuse Device. Each appellant alleges that he or she was injured after the Infuse Protein was used without the other components of the Infuse Device. Each appellant brought suit against Medtronic for his or her injuries in Hennepin County District Court, where the cases were companioned. Appellants alleged the following 11 causes of action against Medtronic: (1) negligence, (2) strict liability, (3) breach of express and implied warranty, (4) actual fraud, (5) constructive fraud, (6) violation of the Minnesota False Statements in Advertising Act, (7) violation of the Minnesota Deceptive Trade Practices Act, (8) unjust enrichment, (9) violation of Minnesota’s consumer protection statutes, (10) negligence per se, and (11) loss of consortium. Generally, appellants allege that Medtronic compensated doctors who agreed to promote off-label uses of the Infuse Device, and that consequently, the off-label use is now the primary use.

The parties agreed to adjudicate Medtronic’s arguments for dismissal in all the lawsuits in the lawsuit brought by Stephen and Barbara Lawrence. The district court ruled that the Lawrences’ nonfraud claims were expressly or impliedly preempted by the FDCA. *See* 21 U.S.C. §§ 360k(a), 337(a) (2014). The district court dismissed the Lawrences’ fraud claims on the basis of inadequate pleading under Minn. R. Civ. P. 9.02. The Lawrence plaintiffs amended their complaint, survived a subsequent motion to dismiss, and their fraud-based claims are proceeding on the merits.

After the district court issued this ruling, appellants were allowed to amend their fraud pleadings to include allegations that Medtronic misled their respective surgeons into using the Infuse Protein without the other components in their surgeries. The amended complaints alleged that Medtronic promoted the off-label use of the Infuse Protein in the following ways:

M[edtronic] communicated with the medical community about the purported safe and efficacious use of its Infuse® product by playing an active role in authoring and editing medical journal articles published on Infuse®, utilizing Key Opinion Leaders and other paid physicians to actively promote the off-label use of Infuse®, utilizing M[edtronic] sales representatives to actively promote the off-label use of Infuse®, by directly and through its distributors purchasing gifts for physicians, hospitals and clinics, by paying for physician attendance at sponsored medical conferences (both on and off MDT headquarters), and by actively concealing the role played by Defendants in shaping the safety profile of Infuse® through all actions mentioned above.

The district court concluded that these allegations of fraud were insufficiently pleaded under Minn. R. Civ. P. 9.02 and entered final judgments for Medtronic. These appeals followed.

ISSUES

I. Did the district court err by dismissing as expressly or impliedly preempted by the FDCA appellants' claims for negligence, strict liability, breach of warranty, unjust enrichment, and violation of state consumer-protection statutes?

II. Did the district court err by dismissing appellants' fraud claims for failure to plead with particularity pursuant to Minn. R. Civ. P. 9.02?

ANALYSIS

I. Preemption

Appellants argue that the district court erred by dismissing their claims for negligence, breach of warranty, unjust enrichment, and violation of state consumer-protection statutes as preempted by the FDCA. We review de novo the district court's grant of a motion to dismiss under Minn. R. Civ. P. 12.02(e). *Sipe v. STS Mfg., Inc.*, 834 N.W.2d 683, 686 (Minn. 2013). “[W]e review de novo the question of whether federal law preempts state law.” *Angell v. Angell*, 791 N.W.2d 530, 534 (Minn. 2010).

Congress enacted the MDA “to provide for the safety and effectiveness of medical devices intended for human use.” *Medtronic v. Lohr*, 518 U.S. 470, 474, 116 S. Ct. 2240, 2245 (1996) (quotation omitted). As stated above, a Class III device must undergo premarket approval pursuant to the MDA before it may be introduced into the market. *Id.* at 477, 116 S. Ct. at 2246-47. The Infuse Device received premarket approval in 2002.

With respect to federally approved medical devices like the Infuse Device, Congress enacted 21 U.S.C. § 360k(a), which contains the following express preemption provision:

[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). In considering whether appellants' claims are expressly preempted "we must determine whether the Federal Government has established requirements applicable to [the specific device at issue]." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321, 128 S. Ct. 999, 1006 (2008). We then must determine whether the state common-law claim would impose a requirement different from or in addition to the specific federal requirement. *Id.* at 323, 128 S. Ct. at 1007.

Additionally, the implied-preemption provision in 21 U.S.C. § 337(a) requires "all such proceedings for the enforcement, or to restrain violations, [of the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). State law claims that only enforce federal law are impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343, 121 S. Ct. 1012, 1015 (2001).

A. Specific federal requirements applicable to the Infuse Device

Appellants argue that there are no specific federal requirements applicable to the use of Infuse Protein in these cases, because "[t]he FDA has not established federal requirements for the Infuse Protein alone." The district court concluded:

Regarding the first step, the Court finds that the FDA has established requirements for the Infuse device through its premarket approval of the device. [Appellants] sought to convince the Court that the FDA's premarket approval applies only to the Infuse device in its on-label usage. [Appellants] argue that because they have alleged usage of some but not all components of the Infuse device in an off-label procedure, the first *Riegel* step is not satisfied. [Appellants] contend that the individual components of the Infuse device are somehow different from the device including all of those components which received the FDA's premarket approval. The Court disagrees. Section 360k(a) preempts state requirements "with respect to" a particular

device that is subject to federal requirements. [Appellants'] claims relating to the usage of the Infuse device in this case are made "with respect to" a device that is covered by federal requirements.

The Infuse Device containing all three components received premarket approval from the FDA. "[T]he FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323, 128 S. Ct. at 1007 (citing 21 U.S.C. § 360e(d)). And "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Id.* The Supreme Court has decided that premarket approval imposes specific federal requirements that are "specific to individual devices." *Id.*

Appellants argue that the FDA specifically limited its approval of the Infuse Device to the use of all components together to support its argument that there is no specific federal requirement regarding the Infuse Protein. We disagree. The premarket approval states: "These components *must* be used as a system. The InFUSE[] Bone Graft component *must not* be used without the LT-CAGE[] Lumbar Tapered Fusion Device component." Appellants' argument receives support from a few federal district courts that have concluded that premarket approval does not establish federal requirements applicable to the Infuse Protein when it is used without the LT-Cage. *See, e.g., Hornbeck v. Medtronic, Inc.*, No. 13C7816, 2014 WL 2510817, at *3 (N.D. Ill. June 2, 2014) ("[T]he requirement that one use the two components together suggests that the FDA considered the design of the two components together Therefore, the FDCA does

not preempt the Plaintiffs' claims premised on . . . the use of the [Infuse Protein] component alone.'").

In *Hornbeck*, the court considered claims based on facts almost identical to this case. Plaintiff Donna Hornbeck underwent a Transforaminal Lumbar Interbody Fusion procedure, which involved a posterior approach and used the Infuse Protein without the LT-Cage. 2014 WL 2510817, at *2. After experiencing complications from her surgery, she filed claims against Medtronic for (1) fraudulent misrepresentation and fraud in inducement; (2) strict products liability—failure to warn; (3) strict products liability—design defect; (4) strict products liability—negligence; (5) products liability—negligence; (6) breach of express warranty; and (7) breach of implied warranties of merchantability and fitness. *Id.* Medtronic claimed that federal law expressly and impliedly preempted the plaintiff's claims. *Id.* at *1.

In *Hornbeck*, the district court concluded that § 360k of the FDCA does not preempt the plaintiffs' claims by reasoning:

It is true that if the Medtronic Defendants marketed and promoted the InFUSE[®] Bone Graft/LT-CAGE[™] Lumbar Tapered Fusion Device for the use approved by the FDA and in the manner required by the FDA, then the only warnings necessary would be those imposed by the FDA. The gravamen of the Plaintiffs' claims, however, is that the Medtronic Defendants marketed and promoted the InFUSE[®] Bone Graft component in contravention of the FDA's requirements. To the extent that the Medtronic Defendants failed to market and promote their device as required by the FDA, then they have also removed themselves from whatever protection federal oversight of medical devices would have provided.

. . . .

Because the FDA’s approved use requires one to use the InFUSE[®] Bone Graft/LT-CAGE[™] Lumbar Tapered Fusion Device together as a system, it follows that the FDA considers the two safe and effective when used together. In other words, there is no indication that the FDA considered either component as safe and effective when used independent of the other. If anything, the requirement that one use the two components together suggests that use of one without the other is not safe and effective.

Id. at *3-4.

Medtronic counters this reasoning by arguing that “[t]he FDA approves devices, not uses,” and that “the FDA may not interfere with the practice of medicine, and thus approves only devices—their design, manufacture, and labeling—not how devices may be used.” We agree. Section 360k(a) applies if federal requirements are applicable to the *device* rather than a particular *use* of a device. See § 360k(a)(1) (“[N]o State . . . may establish . . . any requirement which is different from, or in addition to, any requirement applicable under this chapter to the device.”). The FDCA’s definition of “device” includes “any component, part, or accessory.” 21 U.S.C. § 321(h). And section 360k(a) broadly preempts state requirements “with respect to” a device, if the state requirement is (1) “different from, or in addition to” any federal requirement “applicable . . . to the device,” and (2) relates to the “safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.” See *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1176 (C.D. Cal. 2013) (*Houston I*). These requirements are device-specific and not use-specific and therefore are applicable to the device in off-label uses. See *Riegel*, 552 U.S. at 318, 320, 322-33, 128 S. Ct. at 1004-08 (holding that Class III premarket approval imposed federal requirements on a device, even though it was used in

an off-label manner); *Perez v. Nidek Co.*, 711 F.3d 1109, 1112, 1118 (9th Cir. 2013) (holding that premarket approval imposed requirements on a device even when used in an off-label manner).

Moreover, the FDA’s “approval process generally contemplates that approved [devices] will be used in off-label ways,” *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012); *see also Caplinger v. Medtronic*, 921 F. Supp. 2d 1206, 1218 n.3 (W.D. Okla. 2013) (noting that off-label use is not illegal or disfavored but an accepted and valuable part of the practice of medicine). Off-label use may even be a recognized standard of care. *Caronia*, 703 F.3d at 153. And congress has prohibited the FDA from “limit[ing] or interfer[ing] with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease.” 21 U.S.C. § 396 (2014). Although the Infuse Device was approved as a system, the statutory definition supports our conclusion that each component is a “device” under the FDA that must follow specific federal requirements. *See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (“It makes no sense—indeed, it would probably be impossible—to pick apart the components of a medical device and apply different preemption analyses to different components.”). Consequently, we conclude that the FDA established specific federal requirements for the Infuse Device, even when the Infuse Protein is used alone.

Alternatively, appellants argue that “the [premarket approval] only established federal requirements for the [Infuse Device] when marketed for use in accordance with its labeling.” We disagree. Appellants acknowledge that the Infuse Device went through

the premarket approval process, but argue that the premarket approval only applies to the Infuse Device that contained all three components and that was used in a specific manner. Thus, appellants argue that the federal requirements were imposed only for that use and that premarket approval does not establish federal requirements applicable to the unapproved uses of the Infuse Protein component by itself.

When a manufacturer submits a premarket approval application for a Class III device, the FDA evaluates the device's safety and efficacy for its "intended use" as set forth in the application. 21 U.S.C. § 360e(d)(1)(B)(iii)(II); 21 U.S.C. § 360e(d)(2)(A) & (B) (secretary shall deny premarket approval if device not shown to be safe and effective under "conditions of use" in proposed labeling). The requirements applicable to the Infuse Device include strict limitations on the ability of Medtronic to change the Infuse Device. See 21 U.S.C. § 360e(d)(6)(A)(i).

Appellants argue that they were injured due to an off-label use of the Infuse Device that resulted from Medtronic's intentional promotion of such uses and request that this court adopt the reasoning set forth in *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013) so that their claims may proceed. In *Ramirez*, the plaintiff had a lumbar fusion operation in which her surgeon used only the Infuse Protein without the LT-Cage. 961 F. Supp. 2d at 983. The plaintiff sued Medtronic under several state tort claims, and Medtronic moved to dismiss. *Id.* The court held that the plaintiff's claims were not expressly preempted under 21 U.S.C. § 360k(a) because:

The fundamental purpose of § 360k's express preemption provision is to avoid having another entity . . . arrive at a determination regarding a device's safety that

conflicts with the conclusion the FDA made after the rigorous PMA process. . . . That concern vanishes when the plaintiff brings a claim against a manufacturer that arises out of a use that has not been reviewed by the FDA but has been promoted by the manufacturer.

. . . .

When the device is not being used in the manner the FDA pre-approved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law designed to provide that protection. It is true that federal requirements are still applicable to the device, including requirements that Medtronic not alter the design or label of the device without FDA consent. But when Medtronic allegedly violated federal law by engaging in off-label promotion that damaged the Plaintiff and thereby misbranded the Infuse device, it departed the realm of federal regulation and returned to the area of traditional state law remedies.

Id. at 991. The court went on to conclude that “[i]n the absence of federal approval of the new use, there is nothing to preempt state law requirements.” *Id.* at 993.

But, *Ramirez* has been rejected by most federal district courts that have reviewed this issue. *See, e.g., Houston v. Medtronic, Inc.*, No. 2:13-cv-01679-SVW-SHx, 2014 WL 1364455, at *5-6 (C.D. Cal. Apr. 2, 2014) (*Houston II*); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1035 (D. Haw. Apr. 10, 2014) (“*Ramirez* has been rejected—for good reason—by numerous courts.”); *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1036 (D. Ariz. July 23, 2014). The court in *Houston II* explained:

[T]he *Ramirez* holding is not consistent with the text of § 360k(a), the scope of federal requirements imposed on Class III devices, or . . . precedent. First, as noted above, § 360k(a) applies when the FDA imposes requirements on a “device.” The scope of the provision is not limited to particular “uses” of a device. *See Riegel*, 552 U.S. at 320-33; *Perez*, 711 F.3d at 1112, 1118. If § 360k(a) does not distinguish between uses of a device, it surely does not

distinguish between whether a particular use of a device was promoted by the manufacturer. *See Gavin v. Medtronic, Inc.*, No. 12-0851, 2013 WL 3791612, at *11 (E.D. La. July 19, 2013) (holding that “nothing in § 360k(a) or *Riegel* suggests that applicability of the preemption analysis depends on how the device is being *promoted* to be used” (emphasis added)); *Hawkins v. Medtronic, Inc.*, No. 13-cv-0499 AWI SKOx, 2014 WL 346622, at *5-6 (E.D. Cal. Jan. 30, 2014) (holding that “premarket approval imposes federal requirements on the Infuse device regardless of off-label *promotion* or use” (emphasis added)); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1218 (W.D. Okla. 2013) (same).

Houston II, 2014 WL 1364455, at *5. Moreover, there are several MDA requirements that apply to devices used in off-label manners promoted by the manufacturer. For example, device manufacturers are required to report to the FDA any information which shows the device “[m]ay have caused or contributed to a death or serious injury,” regardless of whether the device is used in an off-label manner. 21 C.F.R. § 809.50(a). Additionally, off-label promotion equates to misbranding, which is subject to FDA enforcement. *See* 21 U.S.C. § 331(a). Based on this reasoning, we conclude that the FDA imposed specific federal requirements applicable to the Infuse Device.

B. Parallel claims

Appellants argue that, even if there are specific federal requirements applicable to the Infuse Device, their claims still escape express preemption because their state law claims are parallel to and not different from or in addition to the requirements of federal law.

Common-law product-liability claims result in state requirements that are preempted to the extent that they relate to the safety of the device and are different from

or in addition to, the federal requirements established by premarket approval. *Riegel*, 552 U.S. at 322-24, 128 S. Ct. at 1006-08. But section 360k “does not prevent a [s]tate 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, 128 S. Ct. at 1011. “Section 360k does not preclude [s]tates from imposing different or additional *remedies*, but only different or additional *requirements*.” *Lohr*, 518 U.S. at 513, 116 S. Ct. at 2264 (O’Connor, J., concurring).

1. Failure to warn of off-label use

In their complaints, appellants allege that Medtronic failed to warn patients and physicians of the known risk of off-label use of the Infuse Protein.¹ They specifically argue that “the FDA never evaluated the adequacy of the Infuse Protein’s labeling and warnings when it promoted for off-label uses,” and that when the FDA approved the Infuse Device, that approval only pertained to the device when all three components were used together, and that Medtronic changed the intended use of the device when it began promoting the Infuse Protein. The district court dismissed this claim, reasoning that it is “different from or in addition to” the federal requirements imposed on Medtronic by the FDA.

The federal district court for the District of Minnesota considered a similar preemption issue in *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009). Plaintiff Riley was implanted with a stent manufactured by Cordis and subsequently

¹ Appellants’ failure-to-warn claims include claims for negligence, negligence per se, strict liability, Minnesota statutory claims, and unjust enrichment.

suffered a heart attack due to a blood clot that formed at the site of the stent. *Riley*, 625 F. Supp. 2d at 773. “Riley and his wife, Debra Riley, [brought] state-law claims of negligence, strict liability, breach of express and implied warranties, negligent misrepresentation, fraud, and loss of consortium against Cordis.” *Id.* Cordis moved for judgment on the pleadings and the court dismissed the Rileys’ claims as expressly preempted, impliedly preempted, or insufficiently pled. *Id.*

Riley brought a number of claims alleging that Cordis was liable for pre- and post-sale failures to warn about or disclose the defective nature of the stent. *Id.* at 780. His primary claim was that “Cordis should have disclosed the need for long-term use of antiplatelet therapy,” but he generally alleged that “Cordis failed to warn of risks and adverse side [e]ffects associated with the Cypher stent, failed to warn of the need for comprehensive medical screening of potential recipients of the Cypher stent, and failed to warn that Cordis itself had not conducted adequate testing of the stent.” *Id.* at 781.

With respect to the plaintiff’s failure-to-warn claim, the court concluded that it was preempted because “Riley [sought] to impose liability on Cordis for failing to do more than the FDA required.” *Id.* In dictum, the court mentioned one possible exception in which Riley’s claim may escape preemption. *Id.* at 783. The court noted that Riley could plead a narrow failure-to-warn claim that would escape preemption if he pleaded “(1) Cordis affirmatively promoted the off-label use of the Cypher stent in a manner that violated federal law, and (2) that, while promoting the device in violation of federal law, Cordis failed to include adequate warnings and directions about the off-label use that it was promoting.” *Id.* The court reasoned that the first allegation would protect the claim

from being expressly preempted because the manufacturer's conduct of promoting the off-label use of the product violated federal law. *Id.* at 784. It also reasoned that the second claim would not be impliedly preempted because "traditional [Minnesota] state tort law imposes a duty to warn on a supplier of a product if it is reasonably foreseeable that an injury could result from the use of the product—and this duty includes the duty to give adequate instructions for the safe use of the product." *Id.* Although the court concluded that "Riley [could have] succeed[ed] in asserting a claim that is neither expressly nor impliedly preempted," it concluded that he did not adequately plead such a claim. *Id.*

In this case, appellants do not allege that Medtronic failed to provide warnings required by the FDA by violating the labeling requirements set forth by the premarket approval for the Infuse Device. Thus, unlike the claim hypothesized in *Riley*, appellants do not allege that Medtronic promoted the Infuse Device in a manner that violated federal law. Rather, they allege that, while promoting the off-label use of the Infuse Device, Medtronic should have given warnings that were different or additional to those required by the FDA.

Appellants also cite to *Garross v. Medtronic, Inc.*, ___ F. Supp. 3d ___, 2015 WL 264903 (E.D. Wis. Jan. 21, 2015), to argue that their state-law tort claims are neither expressly nor impliedly preempted. The plaintiff in *Garross* brought claims similar to those in this case against Medtronic based on the alleged off-label use of the Infuse Device. *Garross*, 2015 WL 264903, at *1. The court reasoned that "plaintiffs may rely on alleged violations [of Medtronic's duty to investigate adverse events and submit

follow-up reports] as evidence that Medtronic violated state common law duty to warn patients of the risks of off-label use.” *Id.* at *4. The plaintiff did not claim that state law imposed an additional requirement on Medtronic to warn patients directly, but instead argued that a breach of these federal requirements is enough to establish liability under her various common-law claims. *Id.* Without providing much analysis, the court concluded that “none of plaintiff’s state law claims are expressly preempted. . . . Nor are plaintiff’s claims impliedly preempted . . . because none of them arise solely from a violation of federal law.” *Id.* Because the *Garross* court reached its conclusion without providing much guidance as to its legal analysis, we do not find this case persuasive.

Medtronic cites a case from this court, *Lamere v. St. Jude Medical, Inc.*, 827 N.W.2d 782 (Minn. App. 2013), to support its argument that appellants’ failure-to-warn claims are preempted by § 360k(a) because the state law duties and the federal requirements regarding warnings are not substantially identical. In *Lamere*, a patient’s wife brought a wrongful death action against device manufacturer St. Jude Medical Inc. arising out of an alleged product defect in a mechanical heart valve. 827 N.W.2d at 784. Her claims included wrongful death, loss of consortium, strict liability (manufacturing defect), breach of express and implied warranty, negligence, misrepresentation and fraud. *Id.* at 785. The district court granted St. Jude’s motion for summary judgment on preemption grounds. *Id.* The plaintiff subsequently appealed and “argue[d] that the district court erred by concluding that appellant’s manufacturing-defect claim was preempted by the Medical Device Amendments (MDA) of 1976 to the federal Food, Drug and Cosmetic Act.” *Id.* at 784.

On appeal, the plaintiff argued that St. Jude violated federal Good Manufacturing Practices (GMPs) and “therefore her claim parallels federal requirements for the manufacture of the device at issue.” *Id.* at 790. Because the circuit courts were split as to whether federal GMPs may form the basis of a parallel claim, this court discussed federal circuit court cases regarding GMPs before concluding that the plaintiff failed to sufficiently plead a parallel claim without concluding that a GMP may never form the basis of a valid parallel claim. *Id.* at 790-91. Unlike *Lamere*, this case does not concern whether a GMP may form a basis for a valid parallel claim to escape preemption. Furthermore, the court did not decide whether the plaintiff’s GMP claim was preempted because it was not sufficiently pled. *Id.* at 791. Thus, we conclude that *Lamere* is inapposite.

Although *Lamere* is not directly applicable, the majority of federal district courts that have addressed this issue support Medtronic’s position, holding that failure-to-warn claims based on the off-label promotion of the Infuse Protein are expressly preempted. *See, e.g., Beavers-Gabriel*, 15 F. Supp. 3d. at 1039 (failure-to-warn claim based on off-label promotion preempted because it “seeks to impose on Defendants a duty to provide warnings beyond those already outlined by the FDA, which *Riegel* prohibits”); *Houston II*, 2014 WL 1364455, at *6 (“Houston’s claim that Medtronic failed to warn Houston or her physician is expressly preempted”); *Kashani-Matts v. Medtronic, Inc.*, No. SACV-13-01161-CJC(RNBx), 2013 WL 6147032, at *4 (C.D. Cal. Nov. 22, 2013) (holding that failure-to-warn claim based on allegations “that Medtronic failed to warn Plaintiff and her physicians of the risks and dangers involved in the off[-]label use of the Infuse

Device and that the warnings accompanying the Infuse Device did not adequately warn of the dangers of using the Device in cervical fusion surgery” is expressly preempted by the MDA). As explained in *Houston I*:

[F]or Plaintiff to prevail, a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were obligated to issue post-sale warnings about potential adverse effects of using the Infuse Device in an off-label manner. While FDA regulations *permit* Defendants to issue such post-sale warnings, those regulations do not require such warnings.

957 F. Supp. 2d at 1177. Further, appellants’ failure-to-warn claim based on off-label promotion does not parallel state-law claims because there is no state-law duty to abstain from off-label promotion. *Thorn v. Medtronic Sofamor Danek, USA, Inc.*, ___ F. Supp. 3d ___, 2015 WL 328885, at *8 (W.D. Mich. Jan. 23, 2015); *see also Caplinger*, 921 F. Supp. 2d at 1219-20 (“[E]ven the concept of ‘off-label use’ is a creature of the FDCA, is defined by the FDCA, and is not a part of [state] substantive law.”). Requiring a manufacturer to provide directions and warnings for off-label uses in addition to the FDA-required warnings would include requirements in addition to those set forth by the FDA. Consequently, we conclude that the district court did not err by holding that claims based on failure to warn doctors and patients are expressly or impliedly preempted.

Appellants also argue that their failure-to-warn claims based on Medtronic’s failure to warn the FDA runs parallel to Medtronic’s violations of the FDCA’s requirement to submit reports to the FDA of adverse events. After receiving premarket approval, Medtronic has ongoing reporting duties to the FDA. *See* 21 C.F.R. § 803.1-.58

(2014). Manufacturers must report specific adverse consequences, a summary of “[u]npublished reports of data from any clinical investigation or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant,” and a summary of “[r]eports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.” 21 C.F.R. § 814.84(b) (2014). The manufacturer must make an FDA report “no later than 30 calendar days” after it “become[s] aware of information, from any source, that reasonably suggests that a device [it] market[s] . . . has malfunctioned and this device or a similar device that [it] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.” *Id.* § 803.50(a)(2). These self-reporting regulations assist the FDA in protecting “the public health by helping to ensure that devices are . . . safe and effective for their intended use.” *Id.* § 803.1(a).

Appellants rely on *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 2839 (2014), to support their alternative argument that Medtronic failed to warn the FDA of adverse events. “Richard Stengel had a SynchroMed EL Pump and Catheter surgically implanted in his abdomen to deliver pain relief medication directly into his spine,” which subsequently rendered him paralyzed. *Stengel*, 704 F.3d at 1227. When the device at issue in *Stengel* went through premarket approval, Medtronic was not aware of certain risks. *Id.* But, before Stengel became paralyzed, Medtronic knew of the risks but failed to disclose them to the FDA. *Id.* Stengel amended his complaint and alleged,

under federal law, Medtronic had a “continuing duty to monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product’s performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.” It further alleges that Medtronic failed to perform its duty under federal law to warn the FDA. Finally, the complaint alleges that, because Medtronic failed to comply with its duty under federal law, it breached its “duty to use reasonable care” under Arizona negligence law.

Id. at 1232. The Ninth Circuit held that this claim was not preempted insofar as it paralleled a federal-law duty under the FDA and explained:

Plaintiffs’ claim is brought under settled Arizona law that protects the safety and health of Arizona citizens by imposing a general duty of reasonable care on product manufacturers. The whole modern law of negligence, with its many developments, enforces the duty of fellow-citizens to observe in varying circumstances an appropriate measure of prudence to avoid causing harm to one another. Arizona tort law includes a cause of action for failure to warn. Under Arizona law, negligence standards impose a duty to produce products with appropriate warning instructions. A product may be unreasonably dangerous in the absence of adequate warnings. The manufacturer of a product must warn of dangers which he knows or should know are inherent in its use. This duty may be a continuing one applying to dangers the manufacturer discovers after sale.

If a more precise parallel were necessary, the Stengels have alleged it and Arizona law provides it. The Stengels’ new claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA. Arizona law contemplates a warning to a third party such as the FDA. Under Arizona law, a warning to a third party satisfies a manufacturer’s duty if, given the nature of the warning and the relationship of the third party, there is reasonable assurance that the information will reach those whose safety depends on their having it.

Id. at 1233 (quotations and citations omitted).

Appellants argue that, like the situation in *Stengel*, once Medtronic began to promote the Infuse Protein for intended uses that had not been approved by the FDA, federal law required it to report adverse effects to the FDA and revise its labeling to warn of risks associated with these uses. The court in *Beavers-Gabriel* discussed a similar issue. 15 F. Supp. 3d at 1038-40. In that case, the plaintiff filed an action against Medtronic, asserting state law claims based on injuries she sustained after undergoing spinal surgery in which her surgeon used Medtronic's Infuse Protein in an off-label manner. *Id.* at 1025. Medtronic moved to dismiss the plaintiff's claims as expressly preempted by 21 U.S.C. § 360k(a) and impliedly preempted by the "no private right of action" clause of 21 U.S.C. § 337(a). *Id.*

With respect to the plaintiff's claim that Medtronic unilaterally changed the Infuse Device's intended use by promoting off-label uses and failed to notify the FDA of the intended use, the court granted Medtronic's motion to dismiss. *Id.* at 1039. The court reasoned that, "although Defendants were prohibited from engaging in any off-label promotion of [the Infuse Device] in the first place, they also were prohibited from making changes to the FDA-approved label." *Id.* (quotation omitted). The plaintiff also argued that her failure-to-warn claim "runs parallel to Medtronic's violations of the FDCA's requirements to submit reports of adverse events and include those events in its labeling." *Id.* at 1040. But the *Beavers-Gabriel* court did not address this issue because the plaintiff's complaint alleged that Medtronic failed to provide warnings to patients and physicians and not to the FDA. Thus, the court granted Medtronic's motion to dismiss this count in the complaint with leave for the plaintiff to amend her complaint as to a

failure-to-warn claim based on Medtronic's failure to submit reports of adverse events to the FDA. *Id.*

The court in *Houston II* also addressed this issue. 2014 WL 1364455, at *1. Houston commenced a lawsuit against Medtronic alleging that she suffered adverse side effects after undergoing back surgery in which her surgeon used the Infuse Device in an off-label manner. *Id.* Medtronic moved to dismiss Houston's complaint and the court granted this motion, with leave to amend, and held that some of Houston's claims were expressly preempted, impliedly preempted, or insufficiently pleaded. *Id.*; see *Houston I*, 957 F. Supp. 2d at 1166 (concluding that Houston's claims that Medtronic failed to warn her or her physician were expressly preempted). Houston amended her complaint and alleged that Medtronic failed to warn the FDA of certain adverse effects associated with off-label use of the Infuse Device. 2014 WL 1364455, at *2. In the amended complaint, Houston alleged that Medtronic knew that the off-label use of the Infuse Device had caused death and serious injuries, but failed to report these adverse events to the FDA. *Id.* at *6.

The *Houston II* court noted that the Ninth Circuit held in *Stengel* that such a failure-to-warn claim may escape express preemption under § 360k(a) because MDA regulations require manufacturers to report certain post-sale adverse events to the FDA. *Id.* Thus, the court reasoned that "a state law claim premised on a manufacturer's failure to warn the FDA does not impose state law requirements 'different from, or in addition to' federal requirements." *Id.* But the court noted that this claim must also escape implied preemption under 21 U.S.C. § 337(a), and reasoned that "for a claim premised on

a violation of the MDA to survive implied preemption under § 337(a), the claim must also be moored in traditional state tort law,” and indicated that relevant questions in determining whether this type of claim is impliedly preempted are: (1) is a claim based on failure to warn the FDA also moored in state tort law; and if so, (2) does the plaintiff plead sufficient facts to support such a claim. *Id.* at *6-7.

Thus, to the extent that appellants’ failure-to-warn claim is based on Medtronic’s failure to warn the FDA, we conclude that this claim is not expressly preempted. Appellants’ claim based on a failure to warn the FDA must also escape implied preemption under 21 U.S.C. § 377(a). In order for this type of claim to escape implied preemption under § 337, the claim must be based in traditional state tort law. *Buckman*, 531 U.S. at 343, 121 S. Ct. at 1015. Under Minnesota law, “where the manufacturer or the seller of a product has actual or constructive knowledge of danger to users, the seller or manufacturer has a duty to give warning of such dangers.” *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977).

Because appellants’ claim that Medtronic failed to warn the FDA of adverse events is based in traditional state tort law, we conclude that this claim is not expressly or impliedly preempted by federal law to the extent that appellants allege that Medtronic failed to report adverse events to the FDA. In reaching this conclusion, we do not reach the issue of whether appellants’ claim is sufficiently pleaded, and thus, the district court must decide this issue.² However, in order to sufficiently plead this claim, we do believe

² We do note that the sole reference in appellants’ amended complaint, which totaled approximately 90 pages, to this claim is found in paragraph 68 and simply states,

that appellants must show how Medtronic's alleged failure to warn the FDA about adverse events concerning the Infuse Device contributed to their injuries. *See Martin v. Medtronic, Inc.*, ___ F. Supp. 3d ___, 2014 WL 6633540, at *5 (D. Ariz. Nov. 24, 2014). Appellants must allege factual support for their claims, such as details about adverse events that should have been reported in order to determine if timely reporting would have affected the off-label use of the Infuse Protein in their surgeries. *See id.* Without such detail, it strikes us that it would be difficult if not impossible to determine whether timely reporting would have affected the off-label use of the Infuse Device in appellants' surgeries. Nevertheless, because the claim is not preempted, we reverse the district court's order with regard to appellants' failure-to-warn-the-FDA claims and remand to the district court for further proceedings.

2. *Design defect*

Appellants alleged in their amended complaints that the Infuse Device was defectively designed because it was unsafe when used in the manner promoted by Medtronic. Appellants argue that the district court erred by determining that their design-defect claims were not parallel claims because "the district court's conclusion ignores the fact that the FDA only conducted a risk/benefit analysis of the design of the [Infuse Device] for certain particular anterior spinal procedures."

"Medtronic knew that Infuse Bone Graft was being used in cervical fusion and other off-label lumbar procedures and *failed to warn the FDA*, surgeons, the medical community, and the general public in a timely manner." (Emphasis added.)

The district court concluded that appellants' claims based on the Infuse Device's unreasonably dangerous design, including their claims for negligence, negligence per se, strict liability, and breach of express and implied warranty, were expressly preempted because they "attack[ed] the risk/benefit analysis performed by the FDA in issuing its premarket approval," which is "precisely the kind of claim that is expressly preempted."

In *Ramirez*, the court found that a design-defect claim was not preempted because

the fact that Medtronic is alleged to have actively promoted the use of Infuse outside of the prescribed federal approval process has opened up state law claims premised on the new, unapproved use of Infuse. Infuse may indeed be defectively designed for the off-label uses that Medtronic may have actively promoted. Certainly the FDA has not made a finding one way or the other. Because there are no applicable federal regulations that govern the product for this new use, there is no conflict for preemption purposes.

Ramirez, 961 F. Supp. 2d at 999. But most courts have held otherwise. See, e.g., *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK (AJWx), 2014 WL 3056026, at *4 (C.D. Cal. June 25, 2014) (holding that design-defect claim is preempted because for the plaintiffs "[t]o prevail on this claim, a jury would have to make findings that conflict with those of the FDA"); *Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1095 (D. Ariz. 2014) (holding that the plaintiffs' design-defect claim was preempted); *Houston I*, 957 F. Supp. 2d at 1177 (finding a strict liability design-defect claim preempted because it "attack[ed] the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device") (quotation omitted); *Beavers-Gabriel*, 15 F. Supp. 3d at 1040 ("The court joins the majority of courts finding that this claim is expressly preempted—to prevail on this

claim, Plaintiffs would need to establish that the Infuse Device should have been designed in a manner different than that approved by the FDA.”).

The majority of courts reach the more persuasive conclusion. To prevail on their design-defect claims, appellants would need to show that the Infuse Device should have been designed in a way that is different than the FDA-approved design. *See Beavers-Gabriel*, 15 F. Supp. 3d at 1040. Therefore, we conclude that the district court did not err by dismissing these claims as preempted because it imposes a requirement different from or in addition to the specific federal requirement.

3. *Express warranty claims*

Appellants also argue that the district court erred by dismissing their express warranty claims. We agree. Appellants alleged in their complaints that Medtronic made express warranties regarding the safety and efficacy of off-label uses of the Infuse Protein. They allege that, as a result of continuing sales and marketing campaigns concerning the safety of the Infuse Protein while knowing the risk of product failure, Medtronic breached these warranties.

The district court held that appellants’ breach of express warranty claims were preempted based on the reasoning set forth in *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) (*Sprint Fidelis*). In that case, the plaintiffs alleged that Medtronic breached express warranties that Sprint Fidelis Leads were safe, effective, fit and proper for their intended use. *Sprint Fidelis*, 623 F.3d at 1207. The court did not decide whether the plaintiffs’ breach-of-warranty claim was

expressly preempted because it concluded that it was impliedly preempted. The court reasoned:

To succeed on the express warranty claim asserted in this case, Plaintiffs must persuade a jury that Sprint Fidelis Leads were not safe and effective, a finding that would be contrary to the FDA's approval of the PMA Supplement. A state common law claim is preempted if it actually conflicts with the federal requirement—either because compliance with both is impossible, or because the state requirement stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. The MDA in § 360k expressly prohibits States from imposing requirements in addition to federal requirements. The district court correctly concluded that this express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted.

Id. at 1208 (quotations and citation omitted).

But in *Beavers-Gabriel*, the court held that a breach-of-warranty claim “survives both express preemption and implied preemption,” because

[f]ederal law already prohibits false or misleading off-label promotion. Therefore, to the extent that Plaintiff seeks to impose liability on Defendants for voluntarily making misleading warranties outside the label, Plaintiff is not imposing any requirement different from or additional to what federal law already requires. In other words, to avoid state law liability on this claim, Defendants need only to refrain from making misleading warranties, which adds no burden beyond what federal law already imposes.

15 F. Supp. 3d at 1042 (quoting *Houston I*, 957 F. Supp. 2d at 1180-81).

The court in *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 898 (D. Minn. 2006) (*Implantable Defibrillators*) reached a similar conclusion. In that case, the plaintiffs alleged that “Medtronic expressly warranted to the public,

through promotional statements and product literature, that its [products] were safe,” and that “[a]s a result of continuing sales and marketing campaigns which touted the safety of its products while knowing of the possible defect and risk of product failure . . . Medtronic breached these express warranties.” *Implantable Defibrillators*, 465 F. Supp. 2d at 898. The court decided that the plaintiffs’ breach-of-warranty claims survived preemption for two reasons: (1) “to the extent plaintiffs’ breach of express warranty claim is predicated on Medtronic’s failure to adhere to FDA labeling or packaging requirements, the claim is not preempted,” and (2) “while the FDA may approve the devices’ product label, Medtronic is silent on the issue of whether the FDA imposes requirements for its promotional statements.” *Id.* The court further reasoned that express warranties “arise from the representations of the parties,” and “[a]ny requirements imposed by the warranty are created by the warrantor and [are] not imposed by state law.” *Id.* (quotations and citations omitted).

Appellants here seek to impose liability on Medtronic for voluntarily making misleading warranties outside of the Infuse Device label. We are persuaded by the reasoning in *Beavers-Gabriel* and *Implantable Defibrillators*, and conclude that this claim is parallel to federal requirements regarding false or misleading off-label promotion because the requirements allegedly imposed by the warranty were created by Medtronic representatives and not imposed by Minnesota law. Because Medtronic has voluntarily undertaken these requirements, we conclude that the district court erred by holding that appellants’ express-warranty claims are preempted by the FDCA.

We also conclude that these claims are not impliedly preempted. The breach-of-warranty claim is well established under Minnesota law. The elements of a breach-of-warranty claim in Minnesota are (1) the existence of a warranty, (2) breach of the warranty, and (3) causation of damages. *Peterson v. Bendix Home Sys., Inc.*, 318 N.W.2d 50, 52-53 (Minn. 1982). Because this breach of warranty exists independently of FDCA requirements, appellants' claims would exist absent any federal law. Therefore, we conclude that the district court erred by dismissing this claim and remand for further proceedings.

We conclude that the district court properly dismissed appellants' failure-to-warn claims based on Medtronic's failure to warn physicians and patients of risks of off-label use and design-defect claims. But, we conclude that the district court erred by dismissing appellants' failure-to-warn claims based on Medtronic's failure to report adverse events to the FDA and their breach-of-warranty claims. This is not to say that appellants will prevail on these claims. In reaching our conclusion, we do not reach the issue of whether appellants have adequately pleaded their non-preempted claims. Therefore, we reverse and remand for further proceedings.

II. Fraud pleading requirement

Appellants argue that the district court erred by dismissing their fraud-based claims as inadequately pled under Minn. R. Civ. P. 9.02. We disagree.

“In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” Minn. R. Civ. P. 9.02. “[T]he circumstances required to be pled with particularity under Rule [9.02] are the time, place, and contents

of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.” *Baker v. Best Buy Stores, LP*, 812 N.W.2d 177, 184 (Minn. App. 2012) (quotation omitted), *review denied* (Minn. Apr. 25, 2012). Claims that lack sufficient particularity under rule 9.02 fail as a matter of law and can be dismissed under rule 12.02(e). *Martens v. Minn. Mining & Mfg. Co.*, 616 N.W.2d 732, 747-48 (Minn. 2000).

The elements of a claim of fraud are: (1) there was a false representation by a party of a past or existing material fact susceptible of knowledge; (2) made with knowledge of the falsity of the representation or made as of the party’s own knowledge without knowing whether it was true or false; (3) with the intention to induce another to act in reliance thereon; (4) that the representation caused the other party to act in reliance thereon; and (5) that the party suffer pecuniary damage as a result of the reliance. *Specialized Tours, Inc. v. Hagen*, 392 N.W.2d 520, 532 (Minn. 1986).

The district court, in its August 7, 2013 order in the Lawrences’ case, dismissed the plaintiffs’ claims for fraud and misrepresentation because they failed to plead such claims with the requisite particularity. The district court held:

Plaintiffs do not . . . identify what representations were made to them or their physicians and allegedly relied on by them in deciding to go ahead with the surgical procedure at issue in this case. It is unclear from the Complaint which specific alleged misrepresentations caused Steven Lawrence and his doctors to choose an off-label use of the Infuse device for Mr. Lawrence’s surgery Plaintiffs’ allegations regarding what Mr. Lawrence’s physicians knew and what they relied upon in deciding to recommend an off-label use of the Infuse device in his case are conclusory, at best, and are

stated upon information and belief, signaling that they are not within Plaintiffs' personal knowledge.

. . . Plaintiffs have alleged that Defendants paid consulting fees to various physicians who published favorable studies about their use of the Infuse device, but Plaintiffs have identified no statements in any of those studies that were allegedly false or misleading and that were relied upon by Plaintiffs or their physicians. . . . In order to give rise to a claim of fraud in such a case, the plaintiff must plead facts to show that his or her physician was affirmatively misled in assessing the potential risk by misrepresentations made by the defendant.

(Citation omitted). Subsequently, the district court allowed appellants to amend their complaints with the expectation that they would supply the district court with particulars missing from the original complaints.

As a preliminary matter, appellants argue that in ruling that appellants had not pled their fraud claims with sufficient particularity, the trial court did not apply the standard set forth in *Hardin Cnty. Sav. Bank v. Hous. & Redevelopment Auth. of Brainerd*, 821 N.W.2d 184, 191 (Minn. 2012). Instead, Medtronic argued for, and the trial court adopted, the stricter pleading standard articulated in *Baker v. Best Buy Stores*, 812 N.W.2d 177 (Minn. App. 2012). Appellants claim that the Minnesota Supreme Court declined to adopt the stricter *Baker* standard when it issued *Hardin*. But, this appears to be an overstatement. *Baker* has not received a negative response since it was issued, and the supreme court issued *Hardin* without discussing *Baker*. In fact, since being issued, this court has continually cited *Baker* for the proposition that fraud plaintiffs must plead “the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby,” with particularity in

order to escape dismissal. *See, e.g., Janssen v. Lommen, Abdo, Cole, King & Stageberg, P.A.*, No. A14-0452, 2014 WL 7237121, at *6 (Minn. App. Dec. 22, 2014); *Capital Midwest Fund, LP v. Johnson*, No. A13-2023, 2014 WL 3396580 (Minn. App. July 14, 2014), *review denied* (Minn. Oct. 14, 2014).

Appellants alleged in their amended complaints that the fraud occurred through their treating physicians, who received alleged misrepresentations from Medtronic. Appellants argue that they sufficiently pleaded facts that show that Medtronic made false representations of past or existing material facts and that the amended complaints “contained allegations [that] demonstrated that Medtronic misrepresented the safety and efficacy of [the] Infuse [Device] by . . . actively concealing adverse events, publishing medical literature and deliberately omitting risks associated with unapproved applications of Infuse Protein, and promoting unapproved uses as safer and more effective than they were.” Specifically, the amended complaints allege:

MEDTRONIC communicated with the medical community about the purported safe and efficacious use of its Infuse® product by playing an active role in authoring and editing medical journal articles published on Infuse, utilizing Key Opinion Leaders and other paid physicians to actively promote the off-label use of Infuse, utilizing MEDTRONIC sales representatives to actively promote the off-label use of Infuse®, by directly and through its distributors purchasing gifts for physicians, hospitals and clinics, by paying for physician attendance at sponsored medical conferences (both on and off MDT headquarters), and by actively concealing the role played by Defendants in shaping the safety profile of Infuse[] through all actions mentioned above.

But the allegations in the amended complaints do not identify who made the alleged false representations to the treating physicians, which medical journal articles

were read and relied on by the physicians, or what false statements were contained therein. Appellants also alleged that Medtronic representatives were present in the operating rooms during their surgeries, but they could not identify the representatives, nor did they set forth allegations regarding the role that the representatives played in their physicians' decisions to use the Infuse Protein in an off-label manner. Because appellants did not identify the contents of the false representations or the identity of the person making the misrepresentation, we conclude that the district court did not err when it dismissed appellants' fraud-based claims.

DECISION

State law failure-to-warn and design-defect claims impose general requirements that are different from federal device-specific requirements and are preempted by 21 U.S.C. § 360k(a). But sufficiently pleaded claims based on a failure to warn the FDA of adverse effects or breach of express warranty impose parallel requirements to federal device-specific requirements and are not preempted by 21 U.S.C. § 360k(a). Because appellants' fraud claims do not identify the alleged false representations regarding the role that Medtronic representatives played in their physicians' decisions to use the Infuse Protein in an off-label manner, this claim is not adequately pleaded under Minn. R. Civ. P. 9.02.

Affirmed in part, reversed in part, and remanded.